EVALUATION OF THE GUIDE TO ACTION CARE HOME FALL PREVENTION PROGRAMME IN CARE HOMES FOR OLDER PEOPLE: A MULTI-CENTRE, SINGLE BLINDED, CLUSTER RANDOMISED CONTROLLED TRIAL (FINCH)

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HEADLINE

Training care home staff to deliver a systematic falls prevention intervention reduced the rate of falls by 1/3 in residents for up to six months without a negative impact upon residents' functional ability or mobility. Training care home staff to deliver the intervention was relatively inexpensive. The intervention was cost-effective. Implementation issues will include better adaptation of the intervention to individual care homes, maintaining falls prevention awareness over time, and reaching non-research active care homes.

ABSTRACT

Background
Falls in care home residents are common, unpleasant, costly and difficult to prevent.

Trial Design
The objective was to evaluate the clinical and cost effectiveness of the Guide to Action for Falls Prevention Care Homes, GtACH) in which care home staff were trained and supported in the systematic use of a multi-domain decision support tool and identify issues affecting subsequent implementation. A two-arm parallel design, multi-centre, cluster randomised controlled trial of the GtACH programme and usual falls prevention in older care home residents was conducted with embedded process evaluation and economic evaluation.

Method
The study was conducted in care homes from ten UK sites. The primary trial outcome was the rate of falls per resident participant occurring during the 90-day period between 91 days and 180 days post-randomisation. The primary outcome for the cost effectiveness analysis was the cost per fall averted and for the cost utility analysis was the incremental cost per QALY. Secondary outcomes included the rate of falls over days 0-90 and 181-360 post randomisation, activity levels, dependency, and fractures. Care homes were randomised on a 1:1 basis to the GtACH programme or usual care, via a secure web-based randomisation service. Research assistants (RAs), resident participants and staff informants were blind to allocation at recruitment. RAs were blind to allocation at follow up. Data from NHS Digital were extracted blindly. The number of falls per resident was compared between groups using a negative binomial regression model (GEE).

Results
84 care homes were randomised, 39 to GtACH and 45 to usual care. 1657 residents consented and provided baseline measures, mean age 85 years, 32% men. GtACH training was delivered to 1051 staff (71% of eligible staff) over 146 group sessions. Primary RCT outcome data were available for 630 of the GtACH participants and 712 usual care participants. The primary RCT outcome result showed an unadjusted Incidence Rate Ratio (IRR) of 0.57 (95% CI 0.45-0.71, p<0.01) in favour of the GtACH programme. Fall rates were also lower in the GtACH group in the period 0-90 days, but there were no other differences between groups in the secondary outcomes. Care home staff valued the training, the systematic strategies and the specialist peer support, but there was limited incorporation of the GtACH documentation into routine care home practice. No adverse events were recorded. The incremental cost per DEMQoL-based QALY was £20,889.42 and £4,543.69 per EQ-5D based QALY. Mean falls were 1.889 (sd 3.662) in the GtACH arm and 2.747 (sd 7.414)

in the usual care arm. Therefore, 0.858 falls were averted. The base case incremental cost per fall averted was £190.62

Conclusion

The GtACH programme significantly reduced the rate of falls in the study care homes, without restricting residents' activity levels or increasing their dependency and was cost effective at current thresholds in the UK NHS. Widespread implementation of the programme is justified.

Trial registration

Trial registration number: ISRCTN34353836. Protocol V6 14 November 2017

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LIST OF ABBREVIATIONS/GLOSSARY

Abbreviation	Meaning
ADL	Activities of Daily Living
AE	Adverse Event
CEA	Cost Effectiveness Analysis
CEAC	Cost Effectiveness Acceptability Curve
CI	Chief Investigator overall
CIS	Consultee Information Sheet
COMET	Common Outcome Measures in Efficacy Trials
CQC	Care Quality Commission
CRF	Case Report Form
CRN	Clinical Research Network
DEMQOL	Dementia Specific Quality of Life
DEMQOL –U	Dementia Quality of Life Utility Version, self-complete
DEMQOL-P-U	Dementia Quality of Life Utility Version, proxy-complete
DMC	Data Monitoring Committee
EQ-5D-5L	EuroQol Five Dimensions Five Levels, self-complete
EQ-5D-5L-P	EuroQol Five Dimensions Five Levels, proxy-complete
GCP	Good Clinical Practice
GtACH	Guide to Action for fall prevention in Care Homes
HEAP	Health Economic Analysis Plan
HES	Hospital Episode Statistics
HRU	Health Resource Use
HSCIC	Health and Social Care Information Centre

ICER	Incremental Cost Effectiveness Ratio	
ICF	Informed Consent Form	
ICH	International Conference on Harmonisation	
InterRAI	International Resident Assessment Instrument	
IRB	Institutional Review Board	
ITT	Intention to Treat	
MAR	Medication Administration Record	
NCTU	Norwich Clinical Trials Unit	
NHS	National Health Services	
PAM-PC	Physical Activity and Mobility in Residential Care	
PI	Principle Investigator at local Centre	
PIS	Participant Information Sheet	
QA	Quality Assurance	
QC	Quality Control	
QMMP	Quality Management and Monitoring Plan	
QoL	Quality of Life	
R&D	Research and Development Department	
REC	Research Ethics Committee	
RfPB	Research for Patient Benefit	
SAE	Serious Adverse Event	
SAP	Statistical Analysis Plan	
SSA	Site Specific Approval	
TMF	Trial Masterfile	
TMG	Trial Management Group	
TMT	Trial Management Team	
ToR	Terms of Reference	
TSC	Trial Steering Committee	
UEA	University of East Anglia	

TERMINOLOGIES

The following terms are used in this report:

The **Guide to Action for Falls Prevention Care Homes Programme** is the training and support of care home staff in the use of an individualised resident falls risk factor identification checklist and decision support tool for the prevention and management of falls in Care Homes.

The Guide to Action for Falls Prevention Care Homes Programme includes:

1. **Guide to Action for Falls Prevention Care Homes training and support** for care home staff, in the use of the Guide to Action for Falls Prevention in Care Homes Tool

2. **Guide to Action for Falls Prevention Care Homes Tool (GtACH)** which is a paper-based individualised resident falls risk factor identification checklist and decision support tool supported by printed materials (reference manual and poster)

3. **Guide to Action for Falls Prevention Care Homes reference manual** for use during and after the training including copies of slides and the Guide to Action for Falls Prevention in Care Homes Tool, information regarding medications that can increase risk of falls and a case study with a completed GtACH for guidance and reference.

4. **Guide to Action for Falls Prevention Care Homes poster** for display in the care home to promote and maintain fall prevention awareness.

PLAIN ENGLISH SUMMARY

Falls in care home residents are common, unpleasant costly and hard to prevent. We tested whether the Guide to Action to Prevent Falls Care Homes (GtACH) programme was effective in preventing falls. In this programme, care home staff were systematically trained and supported in the assessment of residents' risk of falling and the generation of a falls reduction care plan. We undertook a randomised controlled trial comparing the GtACH programme to usual care, which does not involve this systematic attention to falls prevention. We also undertook a "process evaluation", observing organisational and care processes, and an economic study to evaluate value for money.

Thirty nine care homes were randomly allocated to the GtACH programme and 45 to usual care, involving a total of 1657 residents. The main comparison between the two groups was the rate of falls during months 4-6 after randomisation, when we expected any effects to be at its peak. We also assessed falls rates before and 6 months after this period. We measured activity and dependency levels, as it was important to be sure that any reduction of falls was not achieved by restrictive care practices.

We saw a 43% reduction in the falls rate of GtACH programme participants during months 4-6, without observing any reduction in residents' activity or dependency. Care home staff and relatives were positive about the GtACH programme. The GtACH programme was good value for money, as it was likely to be cost-effective. The effect of the programme waned over months 6-12, which may be because some staff did not embed the GtACH process in their usual practice routines, and awareness levels may have dropped.

The GtACH programme should be implemented widely in UK care homes, with appropriate modification to sustain its effect including measures to increase the adherence to the GtACH processes.

Background

Falls in care home residents are common, unpleasant, costly and difficult to prevent. We evaluated the effect on falls of the implementation of the Guide to Action for Falls Prevention Care Homes (GtACH) programme: an intervention in which care home staff were trained and supported in the systematic use of a multi-domain decision support tool to assess individual residents and generate a falls prevention care plan.

Objective

The objectives were to evaluate the clinical and cost effectiveness of the GtACH programme and identify issues affecting its subsequent implementation and adoption.

Method

Trial Design

A multi-centre cluster parallel 1:1 randomised controlled trial (RCT) to evaluate the GtACH programme compared to usual care (the absence of a systematic and coordinated falls prevention process) in UK care homes for older people. An embedded health economic evaluation and an independent process evaluation were also conducted. The process evaluation used realist evaluation methodology to investigate the context of the GtACH implementation, the mechanisms triggered by the introduction of the GtACH programme. A hub and spoke approach were used to include care home residents, family, care homes staff and the public in the research process.

Eligibility criteria

Care homes were eligible if they:

- Held long-stay with old age and or dementia registration
- Had ten or more potentially eligible residents
- Routinely recorded falls in resident personal records and on incident sheets
- Had written agreement of care home manager to comply with the study protocol

Care homes were excluded if they:

- Had participated in GtACH pilot/feasibility studies
- Primarily provided care for those with learning difficulties or substance dependency
- Had contracts with health or social providers which were under suspension, or were under investigations by the regulator of care homes (the Care Quality Commission, CQC)
- Had a significant proportion of beds taken up by health-service commissioned intermediate-care services

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- Had an existing systematic falls prevention programme

Residents were eligible to take part if they were living as a long-term resident in a recruited home and not in receipt of end of life care.

The process evaluation recruited six of the GtACH intervention homes using purposive sampling and collected data from residents and staff in these homes through interviews and focus groups.

Recruitment

Adult care homes (with and without nursing) in England were studied. Participating care homes were from Nottingham, Nottinghamshire, Derby, Derbyshire, Lincolnshire, Northumbria, Leicester, Stafford, Norfolk, Bradford and Solent. Care homes were identified through examining the CQC website, presenting the study at the ENRICH research network events and liaising with Clinical Research Network research staff. Care home managers were telephoned and/or sent a letter inviting them to participate. If they responded to the letter/invitation, a researcher visited the care home to confirm eligibility and recruit the home. Eligible residents within included homes were identified by care home staff and recruited by research assistants. For eligible residents who did not have the mental capacity to provide consent, a family or care home manager consultee was asked to agree to the resident being recruited.

Intervention – the Guide to Action Care Homes (GtACH) Programme

The Guide to Action in Care Homes (GtACH) programme comprised: a training package delivered by local NHS Falls Leads to care home staff; a GtACH manual to supplement and support the training; the GtACH tool to record the assessment and care plan for individual residents; the appointment of a member of the care staff as Falls Champion to maintain falls awareness on the home, and a GtACH awareness raising poster to be displayed in the care home. The GtACH tool comprised 33 falls risk factors under four domains: falls history, medical history, movement/environment, and personal needs, 30 corresponding suggested actions were included alongside the relevant risk factors to prompt action to be taken to reduce, reverse, modify or manage the risk of falls from that risk factor. The GtACH programme was co designed by University of Nottingham researchers in conjunction with care home and NHS staff, and its content was based on National Institute for Clinical Excellence (NICE) clinical guidelines for fall prevention.

Control - Usual care

Care homes allocated to the usual care did not receive any training in falls prevention, were not given the manual or the GtACH poster. All routine clinical care continued as usual.

Outcomes

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The primary outcome for the RCT was the rate of falls per resident participant occurring in the 90-day period between 91 days and 180 days (a three month period, months 4-6) post-randomisation. Falls data were obtained from care home records and incident forms.

The secondary outcomes were
- Falls recorded, in care home records and incident forms, during the 90-day periods between 1-90 days (months 1-3) post randomisation, 181-270-days post randomisation (months 7-9) and 271-360 days (months 10-12) post-randomisation
- Physical activity (measured using physical activity and mobility in residential care questionnaire (PAM-RC) and completed by care home staff)
- Activities of daily living (measured using Barthel Index and completed by care home staff)
- Quality of life (DEMQOL-U-5D and EQ-5D-5L) for participant completed where the participant had capacity
- Quality of life (DEMQOL-P-4D and EQ-5D-5L) proxy completed by a member of care home staff with a good knowledge of the participant for all participants. This was necessary in case a resident lost the capacity to self-complete during the study. Medication as taken (as recorded on care home Medication Administration Record sheets)
- Frequency and type of fractures as reported by NHS Digital
- Days in hospital as reported by NHS Digital
- Deaths as reported by NHS Digital

Sample size

The original sample size was based on the primary outcome of falls rate over the 90-day period between 91 days and 180 days post-randomisation. Assuming a falls rate of 2.5 falls per year (0.625 falls in 3 months) in the control group, 80% power and a two-sided significance level of 5%, 189 residents per group were required in order to detect a 33% reduction in falls rate in the intervention group. The adjustment for clustering assumed an average cluster size of 20 residents and an intra-cluster coefficient (ICC) of 0.1, and gave a sample size of 549 residents per group. Incorporating a further 16% to the sample size to account for potential attrition, the original aim was to recruit a total of 1308 residents (654 to intervention group and 654 to control group). The power calculation was updated in a substantial protocol amendment, for two reasons. First, the average number of individuals per care home was 18.9, less that the cluster target of 20. Second, there was considerable variation in the number of individuals from each care home being recruited, the largest being 65 and the smallest eight. The previous assumptions from the original calculation remained unchanged: the average number of individuals recruited per care home was approximately 19 and the standard deviation was 9.5, hence the design effect was 3.275. The revised sample size calculation increased the target to 78 care homes and 1482 resident participants.

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Randomisation

Care homes were randomised on a 1:1 basis to one of two parallel arms: the GtACH programme or usual care, using 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. Care homes were submitted for randomisation service by site trial research assistants once all participants within that home were recruited and baseline assessments had been completed. The sequence of treatment allocations was concealed from the study statistician until the main analyses were complete.

Blinding

It was not possible to blind resident or care home staff participants to treatment arm because the nature of the intervention required them to be aware of and engage with it. Researchers were blind to allocation when they collected follow-up data. The Trial Management Group (TMG) and the Data Monitoring Committee (DMC) were un-blinded to the intervention.

Analysis

The primary analysis was intention to treat based on the group to which participants were randomised. The primary outcome, rate of falls per participating resident during the 90-day period between 91 days and 180 days post-randomisation, was expressed as the number of falls per 1,000 participating resident days for each group. The number of falls per resident was compared between groups using a negative binomial regression model (GEE).

The cost effectiveness analysis took a health and personal social service provider perspective. The Cost utility analysis was calculated based on EQ-5D-5L. The primary analysis was a cost-utility analysis and presents proxy-reported outcomes as quality-adjusted life years (QALYs). Cost-effectiveness analysis based on cost per falls averted was also conducted. For our base case, we conducted intention-to-treat analysis using complete case data.

The process evaluation used realist methodology to collect data from six purposively selected care homes who had received the GtACH intervention programme. Data were collected using a combination of interviews, focus groups, fidelity observations, documentary review and falls-rate review. Data were primarily collected during a three-month period following the introduction of the GtACH programme, with an additional home visit made six-months after the introduction of the GtACH programme. GtACH training was observed in each care home using a checklist to assess fidelity with the training protocol. Data were analysed qualitatively using framework analysis and discussed in relationship to the falls rates.

Results

Recruitment opened on November 1st, 2016 and closed 31st January 2018. 84 care homes were randomised, 39 to the GtACH programme and 45 to usual care. 1657 residents consented and provided baseline measures, mean age 85 years, 32% men. GtACH training was delivered to 1051 staff in 146 group sessions, representing 71% of eligible care home staff.

Primary RCT outcome data were available for 630 GtACH and 712 usual care participants. The primary RCT outcome result showed an unadjusted Incidence Rate Ratio (IRR) of 0.57 (95% CI 0.45-0.71, p<0.01) in favour of the GtACH programme. The fall rates over this period were 6/1000 residents in the GtACH group and 10.4/1000 residents in the usual care group. This translates to a falls rate per participant per year of 2.2 for the intervention group and 3.8 for the control group.

The secondary RCT results saw a significantly lower falls rates in the GtACH programme participants for the month 1-3 period, but not in the months 7-9 or 10-12 periods. There were no differences between groups in any of the other secondary outcomes.

In the base case analysis the mean cost per resident was £3955 in the GtACH arm and £3935 in the usual care arm, giving a mean (adjusted) difference in cost of £108 (95% CI -271.06, 487.58). In the base case, the DEMQoL-based QALYS were 0.578 in the GtACH arm and 0.581 in the usual care arm, with (adjusted) incremental QALYs of 0.005 (95% CI -0.019, 0.03). The respective numbers for EQ-5D-based QALYs was 0.266 and 0.232, with adjusted incremental QALYs of 0.024 (95% CI 0.004, 0.044). The incremental cost per DEMQoL-based QALY was £20,889 and £4,544 per EQ-5D based QALY. The base case incremental cost per fall averted was £191.

The process evaluation identified that care home staff valued the GtACH programme training, the systematic strategies aligned to specific risks and the specialist peer support from the NHS, but did not complete the GtACH paper assessment and action tool on every participant and it was not routinely embedded in existing care recording processes.

The Patient and Public Involvement study found that a hub and spoke approach to including hard to reach public members of the team was very successful and allowed perspectives from a number of locations to be considered. PPI members were also able to effectively contribute to data analysis, dissemination of results and writing reports.

Conclusion

Implementing the Guide to Action Fall Prevention in Care Homes programme reduced falls rates by 43% in this large multi-centre UK study in care homes for older people. This benefit was achieved without any restriction in activity or independence. Given current willingness

to pay thresholds in the UK, it was likely to be cost effective, although the differing results found using different methods to assess health related quality of life in care home residents showed that the economic evaluation is challenging in this group of people.

Preparation for widespread implementation of this programme is warranted focusing upon the adaptation of the programme to local care home documentation practice, and maintaining falls awareness.

Trial registration
Trial registration number: ISRCTN34353836. Protocol V6 14 November 2017

Funding

1 INTRODUCTION: WHY THIS STUDY WAS NEEDED

1.1 Why are falls Important?

A fall can have a devastating impact on a person, their family, carers and can place demand on health and social care resources. Falls are common, with a third of those over 65, and half of those over 80, falling at least once a year (Public Health England, 2018a). Ageing societies pose challenges for health and social care systems. The UK has an ageing population – there are nearly 12 million people aged 65 or over, of which 5.4 million people are aged 75+, 1.6 million are aged 85+, over 500,000 people are 90+ and 14,430 are centenarians (Age UK, 2019). Falls are the most common cause of emergency hospital admissions for older people (NHS, 2018). In 2017/18 there were around 218,000 emergency hospital admissions related to falls among patients aged 65+, with around 149,000 (68%) of these patients aged 80+ (Public Health England, 2018b).

1.2 Consequences of a fall

Falling can cause injury, distress, pain, reduced mobility, loss of confidence or independence, and a fear of falling leading to reduced levels of activity in daily life and increased mortality (Public Health England, 2018a). In 2017, 5,048 people aged 65+ died from having a fall, equating to 14 people every day (NHS, 2018). Hip fracture is the most common serious injury following a fall and it is estimated around a quarter of people who are aged over 65 and fracture their hip will consequently require long term care in a care home. Hip fractures are the leading cause of accidental death (Royal College of Physicians, 2018). Older adults with frailty are less able to cope and recover from accidents, physical illness or other stressful events, including falls. People living in care homes are more frail than community-based populations and their care needs merit specific attention (Gordon, 2015). Delivering comprehensive, consistent and structured enhanced support to them will ensure that their needs continue to be identified and met proactively (NHS England).

1.3 Prevention and management of falls

The National Falls Prevention Coordination Group's 'Falls and fracture consensus statement' advocates a whole system approach to prevention of falls which includes: risk factor reduction across the life-course; case finding and risk assessment; strength and balance exercise programmes; healthy homes; high-risk care environments; fracture liaison services; and collaborative care for severe injury (Public Health England, 2017). Identification of those at risk of falls, assessment of contributory risk factors for falling, and interventions to reverse, reduce or modify those risk factors are recommended by the National Institute for Health and Care Excellence (NICE, 2013). However, these recommendations are based on

people living in their own homes and who have capacity to listen and react to health professional's advice. They were not written for care home staff or care home residents.

1.4 Falls in Care Homes

Approximately 421,000 older people were living in UK care homes in 2016/2017 (Laing, 2017). Two levels of care accommodation are available depending on the level of care required. These are personal care and 24-hour support (provided by care homes without nursing, sometimes called residential homes), and on-site nursing in addition to this (provided by care homes with nursing, sometimes called nursing homes). Some homes provide both levels of care (dual-registered homes). Care homes both with and without nursing match the international consensus definition of a nursing home (Sanford et al., 2015). Around 5,500 different providers in the UK operate 11,300 care homes for the elderly with 95% of beds provided by the independent sector (both for-profit and charitable providers) (Competition & Markets Authority, 2017).

The majority of older people living in care homes are aged over 85, live with cognitive impairment, multi-morbidity, limited mobility and take multiple medications (Gordon et al., 2013). The rate and risk of falls for residents of care homes is high, with falls three times more common in care home residents than in older people living in their own homes, and those falling in care homes ten times more likely to suffer a serious injury (Department of Health, 2009). One in five people will die within a year of suffering an injurious fall. Falls may often occur as a symptom of underlying frailty and illness (Gillespie et al., 2012). Falls may engender feelings of anxiety in care home staff, and fear of litigation and complaints which may impact on care staff's willingness to encourage residents to be physically active (Robertson K MacDonald A, 2015).

Multiple and diverse factors can contribute to the increased risk of falls in care home residents including frailty, the presence of long-term conditions, physical inactivity, taking multiple medications and the unfamiliarity of the surroundings. The interaction of factors that contribute to an individual's risk of falling is unique to them and therefore interventions to reduce falls risk must be individualised and meaningful for individuals. Protocols used to perform risk assessments for falls in care homes vary in quality, do not necessarily trigger individually tailored interventions to reduce risk factors and some only seek to stratify risk (Robertson K et al., 2010)

A number of interventions have been applied to reduce falls in care homes including multifactorial approaches. However, a Cochrane review found the evidence to be of low quality and inconclusive regarding effective strategies to reduce both falls rates and falls risk (Cameron et al., 2018).

1.5   Implementing Healthcare Interventions in Care Homes

Improving the lives and health of older people living in care homes is a major UK government priority. NICE falls guidelines and quality standards do not explicitly provide guidance for care home residents. Instead, relying on care home staff and clinicians to apply research evidence from hospital in-patient and community falls trials. Interventions are often difficult to implement within a care home and it is unclear whether interventions can lead to cultural change that becomes embedded in care home practices, so that effects are sustained or even increase after the intervention (Livingston et al., 2019).

Improving the lives and health of older people living in care homes is a major UK government priority and is embedded in the NHS Long term plan (NHS, 2019). The NIHR Enabling Research in Care Homes (EnRICH) initiative brings together care home staff, residents, and researchers to facilitate the design and delivery of research in care homes. Increasingly research has looked at providing care home staff with training from experts in an aspect of care with the aim of increasing carer's knowledge and expertise in caring for older people with frailty. A recurrent observation has been the need to adapt existing approaches to improvement and implementation to take account of, and empower, care home staff and organisations (Marshall, 2017). In addition, there is evidence that a number of care home specific issues affect how ready care homes are to engage with external organisations around change (Bunn, 2020). Where care home staff and NHS professionals are required to work together, there is evidence that outcomes will be better if specific activities which encourage shared working between care home staff and visiting healthcare professionals are integrated into care delivery (Goodman et al., 2016).

Falls are often a consequence of undiagnosed and untreated underlying health conditions, frailty, and environmental factors including the way that care is structured. Approaches to falls prevention are therefore likely to be multi-agency collaborations between care home staff and external healthcare providers. Taking account of the lessons learned hitherto about effective partnership working and implementation science adoption of early co-design and strong stakeholder involvement in the planning and design of the intervention and study was essential to make a fall prevention programme pragmatic and suitable to subsequent adoption but also maximising the external validity of the study. The Medical Research Councils Framework for Developing and Evaluating Complex interventions (Craig et al., 2008) provided a framework for the development of our fall prevention programme, feasibility study and multi-centre trial. The framework highlights the need to understand the "context" for delivery of complex intervention which is even more relevant in care homes which pose a distinct challenge for the introduction of complex interventions: they vary in size, funding, workforce and culture, and house vulnerable individuals with far-reaching health and social care needs.

The feasibility study – Falls in Care Homes (FiCH) – which laid the foundation for the current FinCH study found that an effective falls prevention programme would have to: use

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language which care home staff could understand and identify with; explain the rationale for falls prevention in ways that aligned with care home organisational priorities; and be conducted in a way that allowed for care home schedules and care regimes (Walker et al., 2016).

1.6   The Guide to Action to Prevent Falls in Care Homes programme

Our intervention, the Guide to Action for Falls Prevention Care Homes (GtACH) programme (Walker et al., 2016, Robertson K et al., 2012b) was developed 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. Care home staff are trained by an NHS Falls Lead over one hour in small groups to implement the programme in their home. The NHS Falls Lead is a nurse, physiotherapist or occupational therapist who has specialist training, skills and knowledge in falls prevention and bone health. The homes are asked to identify a Falls Champion to help maintain implementation. When the GtACH programme is implemented, homes are given a copy of the GtACH manual, and a supply of the GtACH tool forms. The latter is a paper form, comprising an assessment component (a checklist of falls risk factors) and care planning section supported by suggested actions linked to each fall risk factor. After training, it takes on average 20 minutes to complete the GtACH tool for each resident (Robertson K et al., 2012a). Initial proof of concept work (Robertson et al., 2010) and a subsequent feasibility randomised controlled trial (RCT), FiCH, showed that the GtACH programme was implementable and changed staff behaviour in line with gold standard practice (Walker et al., 2016).

1.7   Limitations of Previous Studies

A Cochrane Review published in 2018 (Cameron et al., 2018) looking at the effectiveness of interventions designed to reduce falls in older people in care facilities and hospitals found the majority of trials were at high risk of bias in one or more domains, mostly relating to lack of blinding. With few exceptions, the quality of evidence for individual interventions in either setting was generally rated as low or very low. Risk of fracture and adverse events were generally poorly reported and, where reported, the evidence was very low-quality. The authors concluded that there was a need for further research and in particular large randomised controlled trials in care facilities to inform practice in falls prevention.

1.8. Justification for current trial

The Cochrane Review in 2018 (Cameron et al., 2018) concluded that further research to strengthen the evidence for multifactorial interventions to reduce falls in care homes was required as there were some individual trials that showed potentially important reductions in the rate of falls. The authors noted that a key feature of these multifactorial interventions was the individualised nature of the interventions delivered. The review stated "this implies that further research with emphasis on an individualised, standardised approach to delivery of interventions with consistent description and application within further trials is warranted, including as a clear description of existing falls prevention practices in the control arm of any trials and the interaction of the intervention arm of the trial with usual care. A mixed methods approach may be necessary to achieve this".

1.9   Research aims

1. The aim of the trial was to determine the clinical and cost effectiveness of the GtACH for fall prevention in care homes programme compared to usual care
2. Complete a process evaluation to provide complementary insight into the implementation of the GtACH programme and to contextualise trial findings

2 TRIAL DESIGN, INCLUDING INTERVENTIONS

This chapter describes the trial as originally designed and the interventions. It is a summary of the full protocol (Logan, 2019) with the methods of analysis for the economic evaluation and results in chapter 4. The methods and analysis for the process evaluation are in chapter 5.

2.1 Trial Design

The FinCH trial was a pragmatic, multi-centre cluster parallel 1:1 randomised controlled trial to evaluate the GtACH falls prevention programme compared to usual care (an absence of a systematic and coordinated falls prevention process) in UK care homes for older people. The allocation was at the level of the care home.

Care homes and residents took part in the study. The primary RCT health outcome was fall rates in the 90-day period between 91 days and 180 days post-randomisation. Secondary outcomes were collected at baseline and at three, six, nine and twelve months.

Identify research sites in UK

Identify eligible settings

(Care Homes for older adults; without systematic falls prevention programmes;

Recruit target population

(Residents of care homes)

Baseline data collection

(Falls in last 3 months; Functional ability; Physical activity; Medication use; Equipment and healthcare resource use**;** Quality of life)

Randomisation of care homes

Allocated to intervention

GtACH training for care home staff**; s**mall group training**,** poster**,** on-going support

Allocated to usual care

Embedded process evaluation

Multi-method process evaluation informed by the principles of realist evaluation to generate detailed insight about the delivery of the GtACH programme in selected care homes

3 month follow up

(Falls in last 3 months; Functional ability; Physical activity; Medication use; Equipment and healthcare resource use**;** Quality of life)

3 month follow up

(Falls in last 3 months; Functional ability; Physical activity; Medication use; Equipment and healthcare resource use**;** Quality of life)

6 month follow up

(Falls in last 3 months; Functional ability; Physical activity; Medication use; Equipment and healthcare resource use**;** Quality of life)

6 month follow up

(Falls in last 3 months; Functional ability; Physical activity; Medication use; Equipment and healthcare resource use**;** Quality of life)

9 month follow up

(Falls in last 3 months; Functional ability; Physical activity; Medication use; Equipment and healthcare resource use**;** Quality of life)

9 month follow up

(Falls in last 3 months; Functional ability; Physical activity; Medication use; Equipment and healthcare resource use**;** Quality of life)

12 month follow up

(Falls in last 3 months; Functional ability; Physical activity; Medication use; Equipment and healthcare resource use**;** Quality of life)

12 month follow up

Falls in last 3 months; Functional ability; Physical activity; Medication use; Equipment and healthcare resource use**;** Quality of life)

Within trial economic evaluation
Cost-utility analysis and proxy-reported outcomes as quality-adjusted life years (QALYs).

2.2 Trial Population

Care Homes (with and without nursing) registered with the care home regulator (the Care Quality Commission) in England.

2.2.1 Eligibility criteria – Care Homes

Inclusion criteria:
- Long-stay with old age and or dementia registration
- Ten or more potentially eligible residents
- Falls routinely recorded in resident personal records and on incident sheets
- Written agreement of care home manager to comply with the protocol and identify a care home falls champion if allocated to the intervention group

Exclusion criteria:
- Participated in GtACH pilot/feasibility studies
- Exclusively provided care for those with learning difficulties or substance dependency
- Contracts with health or social providers were under suspension, or were under investigations by the regulator of care homes (the Care Quality Commission, CQC) or special measures at time of recruitment
- A significant proportion of beds taken up by health-service commissioned intermediate-care services
- Existing systematic falls prevention programme

2.2.2 Eligibility criteria – Resident

Inclusion criteria:
- All long-term care home residents

Exclusion criteria
- Residents in receipt of end of life care

2.2.3 Identification of care homes and consent of care home managers

Sites identified care homes through examining the CQC website, presenting the study at the ENRICH research network events and liaising with CRN research staff who had experience of conducting research in care homes. Care home managers were telephoned and/or sent a letter inviting them to participate. If they responded to the letter/invitation, the researcher posted details of the study to the care home and an appointment was made to visit the

home. A researcher then visited the care home to confirm eligibility at least 24 hours later, to provide adequate time for the manager to digest the written study information. Questions and an opportunity to clarify their involvement were encouraged on the visit, and if willing, informed consent from the care home manager was obtained.

2.2.4 Screening, recruitment and identification of participants

Once the care home manager agreed to the study, care home staff distributed (within the care home) or posted study invitation letters and Participant or Consultee Information Sheets to residents, relatives and/or personal consultees. After a two-week window, details of those who confirmed that they were happy to take part were provided to the researcher who then arranged 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 took place prior to randomisation of the care home.

2.2.5 Resident participant recruitment & consent procedures

All residents were consented to participate, or a consultee agreed to their participation. For residents who were unable to give consent, the research used a short 'picture' version of the Participant Information Sheet (PIS) to explain the study to the resident, in the presence of their consultee.

Change to protocol: A recommendation by the TSC to change the definition of 'fall' on the PIS, in order that the control group and intervention group were given the same definition, was implemented.

The researcher confirmed eligibility, assessed capacity and fully explained the study to the resident, relative and/or personal consultee. Before being enrolled in the study, informed written consent was obtained in accordance with Research Ethics Committee (REC) guidance and Good Clinical Practice (GCP). Where a consultee was required, the consultee signed a declaration if they believed that the participant would have wished to take part in the study had they had the mental capacity to state their preference. Residents who did not have capacity, and whose relatives did not respond to the invitation letter within two weeks, were also able to be enrolled onto the study. The care home manager acted as consultee in this instance. Baseline data was collected by the researcher after consent or consultee agreement was given.

<u>Change to protocol:</u> The process of contacting personal consultees (PCs), for residents who did not have capacity, was identified as the main barrier to recruitment. An amendment to the Research Ethics Committee was sought with PPI input, for a cover letter to be sent to residents' personal consultees, summarising the research, and indicating that if a response from the consultee was not received within two weeks of receipt of the letter, a care home manager would act as nominated consultee on the resident's behalf. The amendment was approved by ethics in June 2017 and implemented in July 2017.

2.3 Interventions

2.3.1 The Guide to Action to Prevent Falls in care homes intervention

The GtACH Fall Prevention Programme is summarised using the template for intervention description and replication (TIDieR) checklist (Hoffmann et al., 2014).

Rationale

- The relatively untrained nature of care home staff, the complex nature of falls risk factors in care residents and the need for multiple interventions to address multiple risk factors requires a systematic home-wide programme including staff education and support, in the use of risk assessment and decision support tools.

Materials

- GtACH training slides – these were used by the NHS Falls Lead to train each intervention home
- The GtACH manual – given to care home staff to support implementation of the GtACH paper screening and assessment tool. It included a master copy of the paper tool, information about the study, a copy of the training session slides, falls information (including definition of a fall, why falls are important and causes of falls), instructions on how to complete the GtACH paper screening and assessment tool, a Falls Incident Analysis template, a Medication and Falls Chart and information on how to obtain further expert advice or support from the local falls expert.
- The GtACH screening and assessment tool comprised 33 items related to falls risk factors grouped into four domains: falls history, medical history, movement/environment and personal needs. The presence of risk factors prompts up to 30 individual staff actions.
- Attendance certificate – given to care home staff at the end of training
- A4 sized poster – given to care homes for display in the home to act as a reminder to implement the GtACH programme in the home.

Procedures

- Care home staff training provided by the local NHS Falls Lead, lasted one hour per session and included: purpose of the study, purpose of the training, prevalence of falls in care homes, GtACH history, and how to complete and where to file completed forms. It emphasised consistent delivery, referenced the materials listed above especially the GtACH manual. Case studies and role play were used. The NHS Falls Lead was a registered nurse, physiotherapist or occupational therapist who was trained and specialised in falls prevention and bone health. As it was not feasible for all care home staff to attend a single training session, repeated training sessions were offered according to care home staff availability.
- A care home Falls Champion, with roles for awareness raising and liaison between staff and the NHS Falls Lead, was identified in each care home.
- Trained staff were taught to complete the GtACH screening and assessment tool with every resident, within two weeks after training, in private, and discussed with family, friends and other care home staff. Completed GtACH documentation was to be placed in the resident's care records and expected to contribute to the care plan for each resident. Re-assessment was expected if the resident developed a new health condition, or fall, or every three-six months.

Change to protocol: The training period for care homes was extended from two weeks to four weeks (post randomisation) to enable fall leads time to train very large homes (+50 staff members).

2.3.2   Control Intervention

The intervention in the homes randomised to the control was usual care. The materials and procedures described in the intervention were not used, and no systematic falls prevention approach was applied.

2.3.3   Strategies to reduce contamination

Healthcare trials of complex interventions are at risk of contamination bias as the interventions often involves multiple components, multiple stakeholders and a range of organisations that interact with the context in which they are delivered. FinCH was a complex rehabilitation trial where the intervention and trial procedures involved interactions between clinicians, care homes, residents, researchers, and wider stakeholders (for example, commissioners and private organisations). These interactions could lead to a

change in behaviour and potentially a change in usual care, even in control settings where exposure to the intervention is intended to be prohibited. In the design and conduct of FinCH the following strategies were used to reduce the potential for contamination.

1. Research staff at the set-up meetings explained importance of continuing with usual care for the control group to act as a comparator.
2. NHS Falls Leads in the sites were asked to sign a confidentiality agreement to state that they would not share the training manual
3. Data on the number of care home staff leaving and starting at each home was collected.
4. The intervention manual was not published prior to the study completion.
5. The content of the intervention was not described in detail when the study team were invited to present the on-going trial information at conferences and high-profile impact events.
6. The study team spoke to commissioners to explain the trial timelines and confirm that all usual care homes would be offered the intervention at the end of the trial.
7. All usual care homes were offered the intervention at the end of the trial.
8. Therapists and nurses in the sites were given training in randomised controlled trial design and ethical considerations to help them understand the issues.

2.3.4   Strategies to reduce bias

We aimed to minimise the risk of falls recording and ascertainment bias by care home staff by our criterion that eligible homes were required to have a falls recording process in place to routinely record falls in resident personal records and on incident sheets. The GtACH programme did not include a fall recording system.

We aimed to reduce bias arising from research staff collecting outcome data by ensuring that they were not involved in, and independent of, care delivery in any of the study care homes.

Further steps were:

1. All research assistants collecting outcome data were blind to allocation of the homes
2. Where un-blinding has occurred, we asked the RAs to report this on an un-blinding form, localised by site and collated by Norwich CTU. Where site staff were available, RAs/CRN staff did not continue data collection at care homes in which they had been un-blinded.
3. Collecting data from care home records using a standardised data collection form, data checked by a second researcher if concerns over content of handwritten notes.
4. Using CRN staff where possible to collect data, better trained and less emotive about the results

5. Data inputted onto the research trial database (RedCap) by data entry technicians unrelated to the study where site capacity allowed Norwich CTU monitored data quality throughout the trial, reporting to sites on a weekly basis so more chance that researchers could find the source data in the care homes to check.

2.4 Baseline and Outcome Measures and Assessment

2.4.1 Baseline data collected
The following characteristics of care homes were collected:
- Number of staff in caring role
- Number of beds in care home
- Number of residents
- Falls monitoring processes

2.4.2   Primary outcome
The primary RCT outcome was the rate of falls per participant in the 90-day period between 91 days and 180 days post-randomisation with data collected from care home records and incident forms. The primary outcome for the economic analysis was the cost per fall prevented (cost-effectiveness) and the incremental cost per QALY (cost utility).

2.4.3   Secondary outcomes
The secondary outcomes were assessed at 90 days, 180 days, 270 days and 360 days from randomisation.

- Falls were assessed by a researcher examining residents' care home records for routinely collected data at each time period. Incident report forms were also examined. The date, time and source of the information for each fall was recorded on the participant Case Report Form (CRF).

- Fall injuries were assessed by a researcher, using residents care home records, and liaison with care home staff to source the data. A yes/no response to 'sustaining an injury' question was recorded at the same time period, by the researcher on the CRF. Any details of medical assistance and source of the information was collected and added to the CRF.

- Medication administration record (consent was sought to allow clarification of medication data from GP records where necessary).
- Days in hospital were obtained from NHS Digital data.
- Fractures per participant were collected using NHS Digital data.
- Personal Activities of Daily Living (ADL) was assessed using the Barthel ADL Index completed by care home staff and collected by the researcher.

- Resident knowledge, skills and confidence (activation) was assessed using the residential care version of the Physical Activity Measure –Residential Care Homes PAM-RC completed by care home staff and collected by a researcher.

- Quality of Life was assessed using validated questionnaires Dementia Quality of Life measure (DEMQOL-U_5D) and (EQ-5D-5) completed by the resident, and proxy completion (DEMQOL-U-4D) and (EQ-5D-5L-P). Participants were offered help to complete by the researcher, if necessary. Dual recording of this data was undertaken to ensure baseline data was captured in the event of a resident losing mental capacity.

- Death was recorded using care home records.

2.4.4   Economic data were:

- Secondary care resource use was identified from electronic records held by NHS Digital.
- Provision of equipment to an individual resident and the item, date purchased, and description of item obtained, was identified from resident's care home records and care home staff knowledge.
- Medications administration record (consent was sought to allow clarification of medication data from GP records where necessary).
- Community health care provision identified from care home records
- Resources used to deliver the intervention (training, staff time and materials) by recording the number of training sessions delivered, the number and names of staff at each training session, and the cost of the manual and printed materials.
- Secondary care resource obtained from NHS Digital data

2.5 Ethics and Regulatory Issues

The trial was not initiated before the protocol, informed consent forms and participant information sheets received approval / favourable opinion from the Research Ethics Committee (REC), and the National Health Service (NHS) Research & Development (R&D) department. Approval was 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).

The Norwich Clinical Trials Unit governed the trial, monitored data collection, and completed data checking and data cleaning.

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

The trial was registered: ISRCTN34353836. Protocol V6 14 November 2017

2.6 Sample Size

The sample size was based on the primary RCT outcome of falls rate during the 90-day period between 91 days and 180 days 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 (Gillespie et al., 2012) and therefore deemed clinically significant. The sample size calculation was based on information obtained from a previous care home study which had a falls rate of 15 falls per year (Robertson K et al., 2012b) but only recruited residents who had fallen recently. The adjustment for clustering assumed an average cluster size of 20 residents (Dyer CA et al., 2004) and an intra-cluster coefficient (ICC) of 0.1 (Dyer CA et al., 2004), giving a sample size of 549 residents per group. Incorporating a further 16% to the sample size to account for potential attrition (Gordon et al., 2014a) 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 was anticipated that the rate of recruitment of care homes and residents was five or six care homes each with 18-19 residents.

2.7 Randomisation and Blinding

Care homes were randomised on a 1:1 basis to one of two parallel arms: the GtACH Fall Prevention Programme or control (usual care). Participants, care home staff, site Falls Lead and RA's undertaking the process evaluation at the care homes were not blinded to allocation.

Randomisation of homes to allocation occurred after all participants had given consent and all baseline data had been collected. The research assistant who gathered the baseline

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information confirmed to the local site NHS Falls Lead that the care home was ready to be randomised. The Falls Lead used a remote, internet-based randomisation system to obtain the allocation for each home and informed the falls champion within the care home of the allocated intervention arm.

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

The sequence of treatment allocations was concealed from the study statistician until all interventions had been assigned and recruitment, data collection, and all other study-related assessments were complete.

The trial management group and the data monitoring committee were un-blinded to the intervention. The chief and principal investigators had direct contact with the randomised care homes, although not with the participants.

The RA's at the sites, resident participants and staff informants were blind to allocation at recruitment and for baseline data collection because resident participants were recruited prior to care home randomisation. RA's collecting outcome data were not informed of allocation (occasions of un-blinding were recorded). NHS digital data were extracted blind to allocation.

Interim analyses required to populate recruitment and data monitoring for harm reports for the data monitoring committee were conducted on un-blinded data by the Norwich CTU.

2.8 Assessment of Compliance

Care home records for all care homes randomised to the intervention were reviewed by the Falls Lead during the first three months post randomisation GtACH training and implementation period to consider broad compliance with GtACH. Evidence that the GtACH manual was accessible; that the GtACH poster was displayed; and that GtACH paperwork was attached to care records, were sought as part of this evaluation. The number of care home staff who attended the GtACH programme training, as a proportion of the total available staff was recorded. Compliance with the intervention was also evaluated as part of the process evaluation. We did not collect the number of GtACH forms completed in the homes.

2.9 Withdrawal of Participants

Residents were able to withdraw from the trial either at their own request, consultee request, or at the discretion of the investigator. The participants were assured that

withdrawal would not affect their future care. Participants and consultee where appropriate, were made aware (via the information sheet and consent form) that should they withdraw, the data collected up to the date of withdrawal could not be erased and may still be used in the final analysis. Care home managers were able to withdraw support for the trial at their own request or at the discretion of the investigator (residents were also withdrawn following care home manager withdrawal of consent).

2.10 Adverse Event Reporting

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

This was a low risk intervention. No specific risks, untoward incidents or adverse events were reported during feasibility work. The GtACH screening and assessment 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 became distressed during the GtACH assessment or in actions, the process was halted, the event recorded and closely monitored until resolution, stabilisation, or until it was shown that the study intervention was not the cause. The participant had the right to decline any intervention at any time.

Gentle exercises were one of the 30 activities included in the action checklist. If gentle exercises were recommended after the assessment, staff in the care home were advised to refer the resident to a physiotherapist in order that a programme of exercise could be put in place. It was possible that participants may have suffered an injury that they would not have if they had not taken part in the exercise. These were recorded and monitored by the Falls Champion in the care home. If there was any concern, the Falls Champion referred to the NHS Falls Lead for advice. If needed the exercises were stopped.

Fall rates were monitored for harm and reported to the IDMC and TSC every three months after they have been collected. The IDMC and TSC had ability to recommend changes to the study protocol if fall rates were substantially higher than expected. The IDMC reviewed un-blinded safety data including reported falls frequencies at least yearly. This were provided by the NCTU via secure email.

As the GtACH programme is copyrighted by Nottingham, Nottingham were responsible for any issues which arose due to the design of the intervention, training given to care homes staff or any issues with the programme itself. However, in respect of the use of this in care homes, the care home would be responsible if the programme as a whole was incorrectly used. Care home managers were requested to confirm that they have indemnity for this and, if the indemnity did not include research, they were requested to seek indemnity from their insurance providers, making clear that all individual components of GtACH were currently being used in routine care but in a consistent or structured manner.

GtACH assessments and or actions were stopped if the participant showed evidence of distress. This was documented, but the participant was not withdrawn from the study.

2.10 Data handling and Record Keeping

All trial staff and investigators endeavoured to protect the rights of the trial's participants to privacy and informed consent, and adhered to the Data Protection Act, 1998. The CRF only collected the minimum required information for the purposes of the trial. CRFs were held securely, in a locked room, or locked cupboard or cabinet. Access to the information was limited to the trial staff and investigators, and relevant regulatory authorities. Computer held data, including the trial database was held securely and password protected. All data was stored on a secure dedicated web server. Access was restricted by user identifiers and passwords (encrypted using a one-way encryption method). Information about the trial in the participant's care home records was treated confidentially in the same way as all other confidential medical information. Electronic data was backed up every 24 hours to both local and remote media in encrypted format.

2.11 Statistical Analysis

Analyses were undertaken on an intention-to-treat basis in which care homes were analysed in the group to which they were allocated regardless of their compliance with the intervention. The progress of care homes and residents through the phases of trial from the screening and enrolment of care homes through to the analysis of the outcome data, has been summarised in the CONSORT flow diagram. Those who died between care home randomisation and the three-month follow-up data collection were regarded as having been exposed to the intervention (GtACH/control) and recorded as lost to follow-up at the time of death.

Data were analysed according to a pre-specified statistical analysis plan which was finalised prior to the start of the analysis. Full details of all analyses are provided in the Statistical Analysis Plan (Appendix A). Analyses were based on available case data. Two-sided tests were used to test statistical significance at the 5% level. The analysis was carried out using standard statistical software, either Stata, SAS or R.

Baseline characteristics of care homes and residents, and outcome measures at baseline and each follow up time point were summarized by treatment arm using descriptive statistics. The baseline fall rate was expressed as the number of falls per 1,000 resident days for each group.

The primary outcome, rate of falls per participating resident during the 90-day period between 91 days and 180 days post-randomisation, was expressed as the number of falls

per 1,000 participating 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 secondary outcomes, rate of falls occurring during the 90-day period between 181- and 270-days post-randomisation, and the 90 day period between 271 and 360 days post-randomisation were calculated and reported in the same way as for the primary outcome.

The number of falls per resident was compared between groups using a random effects/hierarchical two-level Poisson model with resident at level one and care home at level two, with length of residence in care home as an offset. The primary analysis adjusted for type of care home (residential, nursing, dual registration) and site.

Two additional models were fitted in order to assess the robustness of the model. In addition to adjusting for care home type and site, we adjusted for i) baseline fall rate during the three months before the baseline assessment; ii) baseline fall rate and other variables that were thought to be associated with falling.

The falls rates during the three-month periods prior to nine, and twelve-month follow-up were analysed and presented in the same way as for the primary outcome variable. For other secondary outcomes, groups were compared using multi-level regression analysis for continuous outcomes and multi-level logistic regression for binary outcomes. Regression coefficients and 95% confidence intervals were presented.

Compliance with the intervention was calculated as the percentage of care giving staff in each care home trained to use the GtACH screening and assessment tool. We calculated this as:

$$\% \text{ compliance} = \frac{\text{number of care giving GtACH trained staff at care home}}{\text{number of care giving staff at care home}} * 100\%$$

The percentage compliance was calculated and presented for each home in the intervention arm. The average compliance for all intervention care homes has also been presented.

2.11 Site Support

RA's supported the recruitment, data collection, data entry and data cleaning within each site. Delivery models included a combination of NIHR Clinical Research Network delivery staff, NHS research staff, NHS research therapists and academics employed by higher education institutions. RA's received training in trial processes by the Clinical Trials Unit. A research assistant network to support RA's across the 10 sites who were geographically dispersed was developed, led by a RA based in the same site as the Chief Investigator.

Monthly teleconferences were held to discuss challenges and share good practice with any on-going issues raised at the monthly trial management meetings. The format, content and evolution of the network was directed by the RA's. The peer support of the group allowed open discussion of challenges in a supportive environment. The primary focus of discussions were clarification of recruitment and data collection processes, identification of common barriers to recruitment through personal consultee's and sharing of methods to engage and sustain relationships with care homes. Face-to-face investigator meetings for all FinCH team members, this included the RA's, PPI and teams delivering the interventions. Two meetings were held throughout the trial:

- May 2017 (16 RA's, 4 PPI, 10 therapists attended) which included training in the recruitment of older adults lacking capacity, open discussions on good practice and the opportunity to feedback challenges and solutions to the senior research team.

- July 2018 (23 RAs attended) which included training in abstract and poster design, data quality and awards for sites related to recruitment outcomes.

3   RANDOMISED CONTROLLED TRIAL RESULTS

3.1 Recruitment

Recruitment to the FinCH trial opened on November 1st, 2016. The first care home was recruited on 16th November 2016, and the first resident was consented on 23rd November 2016. In total ten sites were opened to the FinCH trial (Table 1). The last care home was recruited on 29th December 2017 and the last resident was recruited 31st January 2018; all care homes were randomised by 31st January 2018.

Table 1 Care home recruitment by site

Sites	Date Recruitment Started	Total care homes recruited
Nottingham City	16/11/2016	12
Nottinghamshire	21/11/2016	12
Bradford	02/02/2017	12
Norfolk	01/03/2017	15
Derby	07/03/2017	11
Leicester	24/04/2017	6
Lincolnshire	07/06/2017	7
Stafford	24/07/2017	6
Northumbria	02/08/2017	3
Solent	03/10/2017	3
Total		87

In total 87 care homes were recruited, of these 84 were randomised to either the GtACH programme or usual care (Figure 2). Over recruitment was permitted to allow care homes that were actively engaged in recruitment of residents by the 29th December 2017 to continue through to randomisation by the 31st January 2018.

Figure 2 – Recruitment of care homes

Care Homes Recruited

..... Projected original (66,5.5 per mth) —— Actual recruitment
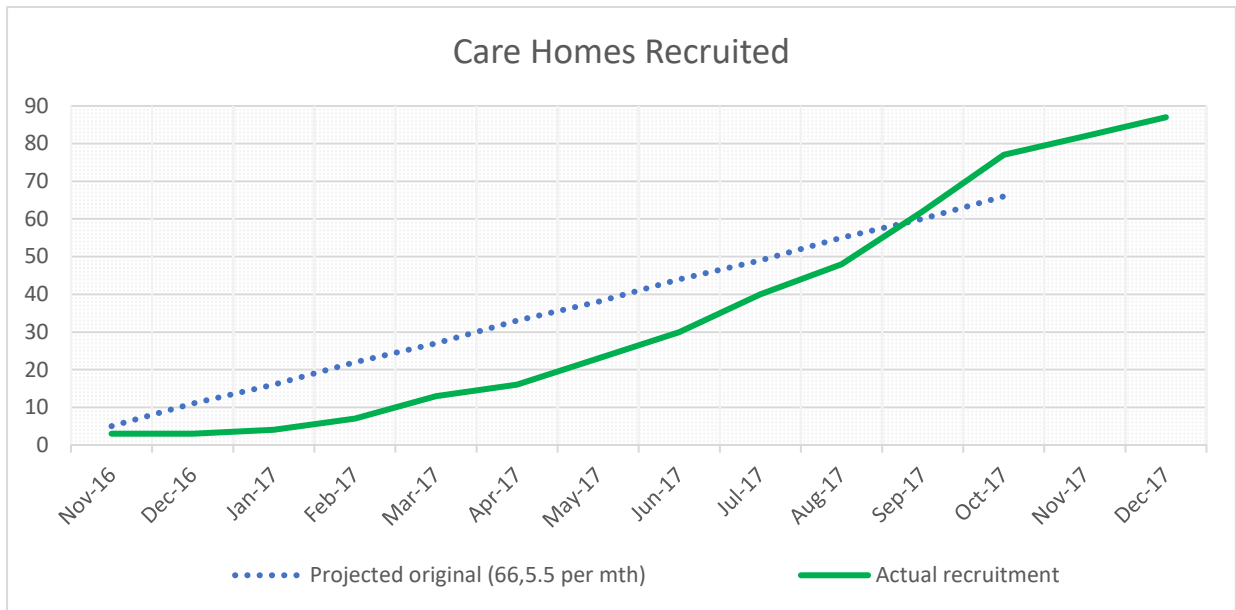
Within the same time period, a total 1,698 residents were recruited, again this was larger than the adjusted target of 1482 individuals (Figure 3).

Figure 3 Recruitment of Residents

Resident Recruitment

..... Projected original (1308 residents) —— Actual recruitment
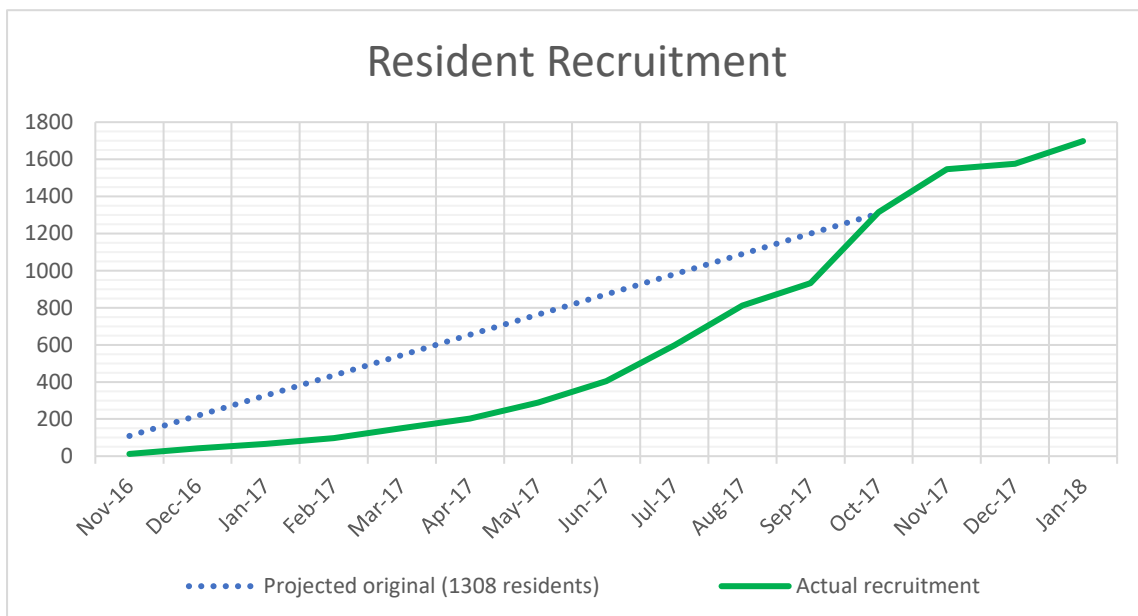
Figure 4 shows care home recruitment and resident recruitment by site. An average 50% of residents from the consented care homes were consented, and there was an average of

19.5 participants per care home. There was an average of 45 days between care home consent and randomisation.

Figure 4 Care home recruitment by site
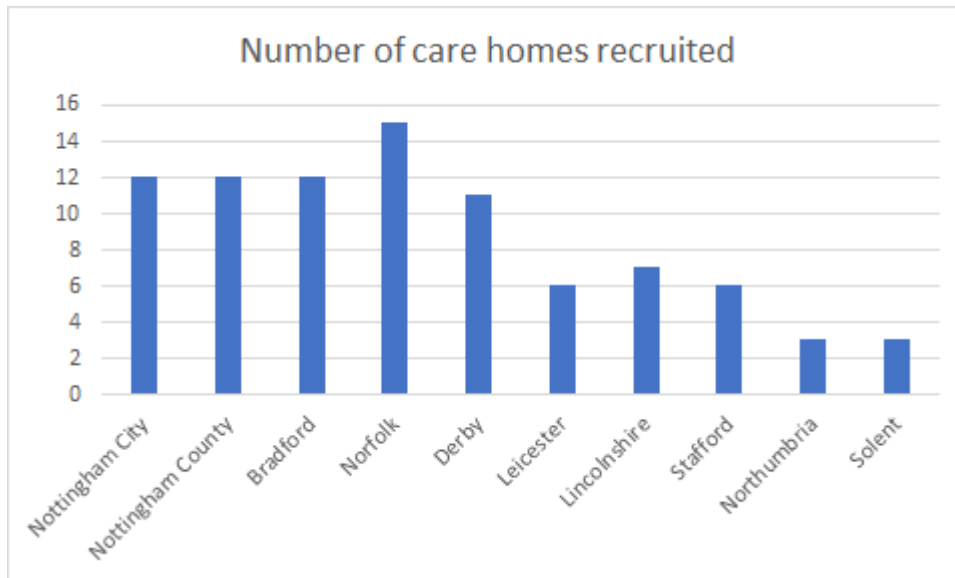
Figure 5 Care home residents recruitment by site

The consort diagram (Figure 6) shows trial screening and recruitment to completion, as well as follow-up loss and completion. Over the duration of the study, there were 490 deaths, of which 459 occurred following care home randomisation. Sixty-three participants moved out of the study care home, 60 of these following randomisations. Twenty-four participants

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were resident in a care home which withdrew from the trial, and a further 8 participants were resident in a care home which was closed following a CQC inspection. Primary outcome data (falls occurring between 90 days and 180 days after randomisation of the care home) were available for 1342 residents.

Figure 6. Consort diagram giving the flow through the trial

Care Homes Assessed for Eligibility (n=186) → **CH Excluded (n=99):**
Did not meet inclusion criteria[1] (n=55)
Recruitment Closed before consent (n=25)
Other Reasons[2] (n=19)

Care Homes Recruited (n= 87)

Residents Recruited & Baseline (n=1698)

CH withdrawn prior to randomisation (n=3)
Did not facilitate resident recruitment (n=1)
Inappropriately consented [language barrier] (n=1)
Care home changed mind [staffing issues] (n=1)

Residents withdrawn (n=41)
Consented in error (n=1)
Died (n=31)
Moved (n=3)
Lost due: CH withdrawal [language] (n=2)
No capacity to collect data from (n=4)

Care Homes Randomised (n=84)
GtACH (n=39) | **Usual Care (n=45)**

Residents (n=775) | **Residents (n=882)**

Dropped out
Participant died (28)
Moved home (2)

Dropped out
Participant died (31)
Moved home (6)

Care Home lost to follow up (n=1)

90 days

GtACH (n=745)
No data available: (n=48)
  Died n=43
  Moved care home n=3
  Other n=2
Time data available: (n=697)

Falls data unavailable with reason: n=56
  Unwilling (n=2)
  Care home withdrawn (n=24)
  Participant died (n=26)
  Moved care home (n=4)
  No reason (n=11)
Falls data available (n=630)

Usual Care (n=845)
No data available: (n=52)
  Died n=45
  Moved care home n=6
  Other n=1
Time data available: (n=793)

Falls data unavailable with reason: n=56
  Unwilling (n=2)
  Participant died (n=51)
  Moved care home (n=2)
  Other (n=1)
  No reason (n=25)
Falls data available (n=712)

180 days

GTACH (n=641)
No data available: (n=40)
  Died: n=38
  moved care home: n=2
Time data available: (n=601)

Falls data unavailable with reason: n=43
  Unwilling: n=1
  participant died: n=27
  moved care home: n=7
  care home closed following CQC inspection: n=8
  no reason: n=11
Falls data available: n=547

Usual Care (n=737)
No data available: (n=53)
  Died: n=44
  moved care home: n=6
  other: n=3
Time data available: (n=684)

Falls data unavailable with reason: n=37
  participant died: n=30
  moved care home: n=6
  other n=1
  no reason: n=16
Falls data available: n=631

270 days

GTACH (n=558)	Usual Care (n=647)
No data available: (n=27)	No data available: (n=28)
Died: n=23	Died: n=24
moved care home: n=4	moved care home: n=2
Time data available: (n=531)	other: n=2
	Time data available: (n=619)
Falls data unavailable with reason: n=26	
participant died: n=22	Falls data unavailable with reason: n=35
moved care home: n=4	participant died: n=27
no reason: n=3	moved care home: n=6
Falls data available: n=502	other n=2
	no reason: n=11
	Falls data available: n=573

360 days

[1]Would not provide a falls champions (n=24), had falls prevention in place (n=13), had participated in FinCH Feasibility (n=4), home exclusively to Learning Disability/Substance misuse (n=3), in special measures, n=1), did not wish to participate, no reason given (n=10)

[2]Wished to participate but did not have time (n=1), initially indicated willingness but then stopped communicating with researcher (n=8), initially indicated willingness
[1]Would not provide a falls champions (n=24), had falls prevention in place (n=13), had participated in FinCH Feasibility (n=4), home exclusively to Learning Disability/Substance misuse (n=3), in special measures, n=1), did not wish to participate, no reason given (n=10)

[2]Wished to participate but did not have time (n=1), initially indicated willingness but then stopped communicating with researcher (n=8), initially indicated willingness but prior to consent adopted a local falls intervention (n=3), wished to participate, but were not recruited, no reason given (n=7)

3.2 Intervention adherence

Intervention adherence was defined as the percentage of care-giving staff trained to use GtACH. Table 2 shows intervention adherence for each care home randomised to GtACH. Average adherence to the training per care home was 71% (70% per site), minimum 17%, maximum 130%. Fourteen (36%) of care homes achieved adherence of 80% or more.

Table 2 Intervention adherence

	Number of care giving staff at time of care home recruitment	Number (%) of care giving staff trained to use GTACH
Lincolnshire	**123**	**105 (85.3%)**
01/01	75	67 (89.3%)
01/07	48	38 (79.2%)
Derby	**171**	**121 (70.8%)**
02/01	40	26 (65.0%)
02/03	16	16 (100.0%)
02/07	41	29 (70.7%)
02/08	32	20 (62.5%)
02/09	18	11 (61.1%)
02/11	24	19 (79.2%)
Northumbria	**60**	**65 (108.3%)**
03/02	27	22 (81.5%)
03/03	33	43 (130.3%) *
Leicester	**91**	**60 (65.9%)**
04/01	37	18 (48.6%)
04/02	54	42 (77.8%)
Stafford	**141**	**45 (31.9%)**
05/02	16	9 (56.3%)
05/03	59	25 (42.4%)
05/06	66	11 (16.7%)
Norwich	**238**	**182 (76.5%)**
06/02	55	40 (72.7%)
06/05	30	24 (80.0%)
06/07	36	30 (83.3%)
06/09	39	30 (76.9%)
06/12	38	30 (78.9%)
06/13	22	18 (81.8%)
06/15	18	10 (55.6%)
Nottingham City	**185**	**127 (68.6%)**

07/01	25	22 (88.0%)
07/03	39	24 (61.5%)
07/04	45	30 (66.7%)
07/05	48	22 (45.8%)
07/08	16	19 (118.8%) *
07/11	12	10 (83.3%)
Nottinghamshire	**220**	**169 (76.8%)**
08/03	59	47 (79.7%)
08/04	67	51 (76.1%)
08/06	23	22 (95.7%)
08/10	22	12 (54.5%)
08/11	49	37 (75.5%)
Bradford	**262**	**177 (67.6%)**
09/01	26	10 (38.5%)
09/06[+]	38	17 (44.7%)
09/08	53	43 (81.1%)
09/09	50	40 (80.0%)
09/10	33	29 (87.9%)
09/11	62	38 (61.3%)
Solent	No care homes allocated to intervention	

* adherence in excess of 100% due to homes having a higher number of care-giving staff at the point of training, than reported at the time of care home recruitment.

[+] Withdrew between randomisation and 180-day data collection.

 Total trained = 1051 increase of 28 trained personnel

3.3 Baseline Characteristics

3.3.1 Baseline characteristics of care homes

Characteristics of the 84 randomised care homes are given in Table 3. Overall, just under half the homes had dual registration (nursing and residential), 96% were reported, by the care homeowner, to be privately owned, and the average number of staff per care home was 43. Homes were fairly well balanced between the two arms, on size and registration, although homes in the usual care arm reported a higher number of care giving staff.

Table 3 Baseline characteristics of randomised care homes

	Overall n=84	GTACH n=39	Usual care n=45
Number of care homes by site			
Lincolnshire	7 (8%)	2 (5%)	5 (11%)
Derby	10 (12%)	6 (15%)	4 (9%)
Northumbria	3 (4%)	2 (5%)	1 (2%)
Leicester	5 (6%)	2 (5%)	3 (7%)
Stafford	5 (6%)	3 (8%)	2 (4%)
Norwich	15 (18%)	7 (18%)	8 (18%)
Nottingham City	12 (14%)	6 (15%)	6 (13%)
Nottinghamshire	12 (14%)	5 (13%)	7 (16%)
Bradford	12 (14%)	6 (15%)	6 (13%)
Solent	3 (4%)	0 (0%)	3 (7%)
Number of care homes by type			
Nursing	11 (13%)	5 (13%)	6 (13%)
Residential	34 (40%)	16 (41%)	18 (40%)
Dual Registration	39 (46%)	18 (46%)	21 (47%)
Number of care homes by ownership			
Charity	3 (4%)	2 (5%)	1 (2%)
Private	81 (96%)	37 (95%)	44 (98%)
Total number of care giving staff	3609	1491	2118
Mean (SD) care giving staff per home	42.9 (41.0)	38.2 (16.4)	47.1 (53.8)
Total number of beds	4112	1912	2200
Mean (SD) beds per home	49.0 (25.1)	49.0 (21.3)	48.9 (28.2)
Total number of residents	3561	1672	1889
Mean (SD) residents per home	42.4 (21.9)	42.9 (19.4)	42.0 (24.1)

3.3.2 Baseline characteristics of participants

Table 4 shows the characteristics of the 1657 trial participants. Overall average age was 85 years, with the majority female. Median time spent in the care home at baseline was just under 19 months. Just under a third of residents experienced one or more falls in the 3 months prior to randomisation (baseline period). Resident characteristics were reasonably well balanced between arms.

Table 4 Baseline characteristics of trial participants

	Overall n=1657	GTACH n=775	Usual Care n=882
Age at consent to FinCH (years): mean (SD)	85.04 (9.28)	86.03 (8.64)	84.16 (9.74)
Male: N (%)	532 (32.1%)	231 (29.8%)	301 (34.1%)
Consent: Resident	387 (23.4%)	186 (24.0%)	201 (22.8%)
Consultee	1270 (76.6%)	589 (76.0%)	681 (77.2%)
Time in care home (months): median (IQR)	18.6 (8.3 – 36.4)	18.8 (8.1 – 36.5)	18.1 (8.6 – 35.8)
Recorded diagnosis: Dementia N (%)	1109 (67.0%)	506 (65.4%)	603 (68.4%)
Diabetes	320 (19.3%)	150 (19.4%)	170 (19.3%)
Stroke	262 (15.8%)	118 (15.2%)	144 (16.3%)
CHD	234 (14.1%)	100 (12.9%)	134 (15.2%)
Number of falls during period 3 months prior to baseline data collection:			
none	1138 (68.8%)	546 (70.6%)	592 (67.1%)
1	299 (18.1%)	134 (17.3%)	165 (18.7%)
2	92 (5.6%)	42 (5.4%)	50 (5.7%)
3	55 (3.3%)	26 (3.4%)	29 (3.3%)
4	25 (1.5%)	10 (1.3%)	15 (1.7%)
5	6 (0.4%)	2 (0.3%)	4 (0.5%)
6	8 (0.5%)	2 (0.3%)	6 (0.7%)
7	5 (0.3%)	3 (0.4%)	2 (0.2%)
8	5 (0.3%)	1 (0.1%)	4 (0.5%)
9	9 (0.5%)	2 (0.3%)	7 (0.8%)
10	2 (0.1%)	0 (0.0%)	2 (0.2%)
11	3 (0.2%)	2 (0.3%)	1 (0.1%)
12	2 (0.1%)	1 (0.1%)	1 (0.1%)
13	2 (0.1%)	0 (0.0%)	2 (0.2%)
15	1 (0.1%)	1 (0.1%)	0 (0.0%)

16	1 (0.1%)	0 (0.0%)	1 (0.1%)
20	1 (0.1%)	1 (0.1%)	0 (0.0%)
31	1 (0.1%)	0 (0.0%)	1 (0.1%)
Number of falls per person during period 3 months prior to baseline data collection			
none	1138 (68.8%)	546 (70.6%)	592 (67.1%)
1 to 5 falls	477 (28.8%)	214 (27.7%)	263 (29.8%)
6 to 10 falls	29 (1.8%)	8 (1.0%)	21 (2.4%)
11 to 15 falls	8 (0.5%)	4 (0.5%)	4 (0.5%)
16 or more falls	3 (0.2%)	1 (0.1%)	2 (0.2%)
Mean (SD) number of falls per person during period 3 months prior to baseline data collection	0.71 (1.82)	0.61 (1.57)	0.79 (2.02)
Number of medications in period 3 months prior to baseline data collection			
none	0	0	0
One to three	56 (3.4%)	26 (3.4%)	30 (3.4%)
Four or more	1601 (96.6%)	749 (96.6%)	852 (96.6%)
Physical activity (PAM-RC) score at baseline: mean (SD)	8.61 (6.09)	8.57 (5.95)	8.66 (6.21)
Activities of Daily Living (Barthel) score at baseline: mean (SD)	8.57 (6.05)	8.86 (6.12)	8.30 (5.99)
DEMQOL self-completion at baseline	0.82 (0.16)	0.83 (0.16)	0.81 (0.16)
DEMQOL proxy at baseline	0.74 (0.12)	0.74 (0.12)	0.74 (0.12)
EQ-5D-5L self-completion at baseline	0.49 (0.36)	0.52 (0.36)	0.46 (0.35)
EQ-5D-5L proxy at baseline	0.35 (0.37)	0.36 (0.37)	0.34 0.36)

3.3.3 Un-blinding rates

The RAs responsible for recruiting care homes, consenting patients and carers and collecting care home and patient level outcome data was to remain blinded to the home allocation. In some instances, the RAs became un-blinded, typically by the care home manager.

Un-blinding occurred in 24 of the 84 participating care homes when the RA entered the home 3 months after randomisation to collect the primary outcome measure and the 3-month data. Of these 22 homes, 12 were GtACH and 10 were usual care homes.

3.4 Primary Outcome – Falls Between 90 days and 180 days

A negative binomial regression model (GEE) showed that the fall rate in the GtACH group was reduced compared to that in the usual care group in both unadjusted and adjusted analyses. Over the period of the primary outcome assessment (90 days, occurring between 91 days and 180 days after randomisation), the fall rate was 6/1000 residents in the GtACH group and 10.4/1000 residents in the usual care group (Table 5). Results of other approaches to the analysis of the primary outcome may be seen in Appendix B.

Table 5 - Negative Binomial regression model – GEE

	GtACH			Usual Care			Unadjusted		Adjusted for baseline falls	
	N at risk	N falls	Fall rate	N at risk	N falls	Fall rate	IRR (95% CI)	p-value	IRR (95% CI)	p-value
pre-randomis ation*	773	0.61 (1.57)	6.97 (17.67)	882	0.79 (2.02)	9.48 (24.14)				
0 – 90 days	708	0.55 (1.36)	6.93 (20.56)	826	0.88 (2.37)	10.24 (27.26)	0.6 (0.49,0.73)	<0.001	0.74 (0.60,0.92)	0.006
91 – 180 days	630	0.49 (1.13)	6.04 (14.02)	712	0.89 (2.60)	10.38 (29.52)	0.57 (0.45,0.71)	<0.001	0.63 (0.52,0.78)	<0.00 1
181 – 270 days	547	0.60 (1.29)	7.28 (16.67)	633	0.73 (1.85)	9.21 (28.77)	0.85 (0.69,1.05)	0.128	0.91 (0.74,1.12)	0.369
271 – 360 days	502	0.55 (1.14)	6.22 (12.88)	573	0.79 (2.37)	9.22 (27.36)	0.79 (0.60,1.03)	0.078	0.93 (0.71,1.22)	0.614

* Pre-randomisation covers period between randomisation and up to 90 days prior to randomisation

3.5 Secondary outcome analysis

3.5.1 Fall rates and fallers over other periods of time

There was a significant reduction in falls rates in the GtACH group in the period 0-90 (Table 5) but no significant difference between the groups' fall rates for either of the further two three months follow up periods between 6 and 9 months or 9 and 12 months (Table 5).

There was no difference in the proportion of residents who fell on one or more occasion "fallers", during any of the outcome time periods (Table 6).

Table 6: Number of fallers compared between groups

	GtACH	Usual Care	Unadjusted	Adjusted for baseline

	N at risk	N fell (%)	N at risk	N fell (%)	OR (95% CI)	p-value	OR (95% CI)	p-value
pre-randomisation*	773	227 (29.4%)	882	290 (32.9%)				
0 – 90 days	708	194 (27.4%)	826	266 (32.2%)	0.7 (0.50,1.00)	0.048	0.75 (0.53,1.05)	0.09
91 – 180 days	630	167 (26.5%)	712	216 (30.3%)	0.76 (0.56,1.03)	0.078	0.81 (0.60,1.10)	0.179
181 – 270 days	547	165 (30.2%)	633	187 (29.5%)	1.00 (0.73,1.37)	0.986	1.06 (0.78,1.45)	0.697
271 – 360 days	502	147 (29.3%)	573	175 (30.5%)	0.88 (0.60,1.29)	0.516	0.94 (0.65,1.37)	0.752

* Covers the 90 days prior to randomisation up the day before randomisation.

3.5.2 Activities of Daily Living - Barthel Index

There was no difference in 20-point Barthel (activities of daily living) scores between groups at any of the time points considered (Table 7)

Table 7: Barthel Index score compared between groups

	GtACH		Usual Care		Unadjusted		Adjusted for baseline	
	N	Mean (SD)	N	Mean (SD)	Mean difference (95% CI)	p-value	Mean difference (95% CI)	p-value
pre-randomisation*	768	8.86 (6.12)	854	8.30 (5.99)				
0 – 90 days	643	8.24 (6.12)	726	7.87 (5.94)	0.08 (-0.96,1.13)	0.874	-0.03 (-0.69,0.64)	0.937
91 – 180 days	584	8.12 (6.05)	648	7.54 (5.86)	0.16 (-0.89,1.20)	0.766	-0.02 (-0.48,0.43)	0.924
181 – 270 days	514	8.52 (6.17)	576	7.18 (5.98)	0.90 (-0.29,2.10)	0.138	0.46 (-0.10,1.01)	0.11
271 – 360 days	447	8.11 (6.20)	519	6.86 (5.92)	0.82 (-0.32,1.96)	0.159	0.44 (-0.26,1.15)	0.214

3.5.3 Physical activity and Mobility - PAM-RC

There was no difference in PAM-RC (physical activity and mobility) scores between groups at any of the time points considered (Table 8).

Table 8: PAM-RC compared between groups

	GtACH		Usual Care		Unadjusted		Adjusted for baseline	
	N	Mean (SD)	N	Mean (SD)	Mean difference (95% CI)	p-value	Mean difference (95% CI)	p-value
pre-randomisation*	773	8.57 (5.95)	878	8.66 (6.21)				
0 – 90 days	652	7.99 (6.01)	736	8.16 (5.98)	-0.41 (-1.51,0.69)	0.468	-0.1 (-0.55,0.35)	0.662
91 – 180 days	578	8.11 (6.05)	633	7.74 (6.08)	0.07 (-1.04,1.17)	0.908	0.23 (-0.28,0.75)	0.376
181 – 270 days	491	8.13 (5.98)	576	7.59 (6.12)	0.32 (-0.90,1.54)	0.61	0.43 (-0.24,1.10)	0.209
271 – 360 days	439	7.96 (5.63)	520	7.19 (6.03)	0.45 (-0.57,1.47)	0.39	0.49 (-0.16,1.14)	0.141

* Covers the 90 days prior to randomisation up the day before randomisation.

3.5.4 Inpatient days in hospital

There was no difference in inpatient hospital days between groups, either at baseline to six months post-randomisation, or at six months to twelve months post-randomisation, using a GEE approach (Table 9). A Poisson regression of these data (Appendix C) yielded similar results.

Table 9: Inpatient days in hospital compared between groups

	GtACH		Usual Care		Unadjusted		Adjusted for baseline	
	N	Mean (SD)	N	Mean (SD)	Mean difference (95% CI)	p-value	Mean difference (95% CI)	p-value
pre-randomisation*	773	0.46 (2.62)	877	0.60 (2.69)				
0 – 180 days	697	1.54 (5.36)	793	1.61 (4.85)	0.91 (0.64,1.28)	0.588	0.94 (0.67,1.32)	0.725
181 - 360 days	532	1.08 (4.04)	620	1.58 (6.03)	0.66 (0.40,1.08)	0.101	0.63 (0.38,1.06)	0.081

* Covers the 90 days prior to randomisation up the day before randomisation.

3.5.5 Quality of Life

EQ-5D

There was no difference in EQ-5D scores between groups at any of the time points considered (Table 10)

Table 10: EQ-5D compared between groups

	GtACH		Usual Care		Unadjusted		Adjusted for baseline	
	N	Mean (SD)	N	Mean (SD)	Mean difference (95% CI)	p-value	Mean difference (95% CI)	p-value
pre-randomisation*	766	0.36 (0.37)	878	0.34 (0.36)				
0 – 90 days	728	0.30 (0.38)	802	0.30 (0.36)	-0.01 (-0.08,0.06)	0.851	0 (-0.05,0.04)	0.854
91 – 180 days	717	0.26 (0.36)	817	0.22 (0.34)	0.02 (-0.05,0.08)	0.588	0.02 (-0.03,0.07)	0.483
181 – 270 days	693	0.25 (0.36)	823	0.20 (0.33)	0.03 (-0.03,0.10)	0.288	0.04 (-0.01,0.08)	0.083
271 – 360 days	674	0.21 (0.32)	809	0.16 (0.31)	0.04 (-0.01,0.08)	0.105	0.03 (0.00,0.07)	0.083

* Covers the 90 days prior to randomisation up the day before randomisation.

DEMQOL

There was no difference in DEMQOL scores between groups at any of the time points considered (Table 11)

Table 11: DEMQOL

	GtACH		Usual Care		Unadjusted		Adjusted for baseline	
	N	Mean (SD)	N	Mean (SD)	Mean Difference (95% CI)	p-value	Mean Difference (95% CI)	p-value
pre-randomisation*	764	0.74 (0.12)	877	0.74 (0.12)				
0 – 90 days	716	0.66 (0.25)	807	0.67 (0.23)	-0.02 (-0.05,0.02)	0.355	-0.02 (-0.05,0.02)	0.315
91 – 180 days	698	0.59 (0.31)	805	0.57 (0.31)	0.02 (-0.04,0.08)	0.511	0.02 (-0.04,0.07)	0.565
181 – 270 days	694	0.52 (0.34)	807	0.52 (0.35)	0.00 (-0.07,0.07)	0.977	-0.01 (-0.07,0.05)	0.85
271 – 360 days	673	0.48 (0.36)	809	0.47 (0.36)	-0.01 (-0.07,0.06)	0.868	-0.01 (-0.07,0.05)	0.779

* Covers the 90 days prior to randomisation up the day before randomisation.

3.5.6 Deaths

There was no difference in deaths occurring at any time during the trial (Table 12)

Table 12: Deaths compared between groups

	GtACH		Usual Care		Unadjusted	
	N	Deaths	N	Deaths	OR (95% CI)	p-value
Overall deaths	775	233 (30.1%)	882	281 (31.9%)	0.93 (0.73, 1.20)	0.576

3.5.7 Fractures

There was no difference between groups in hip fractures, wrist fractures or any fractures occurring between baseline and six months. There was a significantly lower rate of fractures between six months and twelve months, (Table 13) – noting that the actual numbers were small and that there was no corresponding reduction in fall rates over this period. A list of fractures included in these analyses is provided in Appendix D.

Table 13: Fractures compared between groups

	Fracture type	Number of fractures	GtACH Number (%)	Usual Care Number (%)	OR (95%)	p-value
Baseline to 180 days	Hip	0	758 (97.8%)	867 (98.3%)		
		1	12 (1.5%)	8 (0.9%)	1.4 (0.67,2.96)	0.371
		2	5 (0.6%)	7 (0.8%)		
	Wrist	0	772 (99.6%)	880 (99.8%)		
		1	3 (0.4%)	2 (0.2%)	1.63 (0.26,10.2)	0.603
	Any	0	742 (95.7%)	850 (96.4%)		
		1	22 (2.8%)	17 (1.9%)	1.19 (0.70,2.01)	0.527
		2	10 (1.3%)	12 (1.4%)		
		3	1 (0.1%)	2 (0.2%)		
		4	0 (0.0%)	1 (0.1%)		
181 – 360 days	Hip	0	591 (98.5%)	662 (96.6%)		
		1	9 (1.5%)	23 (3.4%)	0.38 (0.17,0.85)	0.019
	Wrist	0	600 (100.0%)	685 (100.0%)	NA	NA
	Any	0	591 (98.5%)	659 (96.2%)		
		1	7 (1.2%)	11 (1.6%)	0.34 (0.15,0.75)	0.007
		2	2 (0.3%)	15 (2.2%)		

3.6 Changes to the analysis plan during the trial

Although we had specified that multiple imputation would be used to account for missing data, this has not been done as the primary reason for missing data was that the patient had died. However, we did collect and analyse the falls data until the date of death. We have

presented median and inter-quartile range for time spent in the care home, rather than mean and standard deviation, due to the skewed distribution of these data.

4: ECONOMIC EVALUATION

4.1 Overview

The aim of this chapter is to report the within-trial economic evaluation undertaken to estimate the cost effectiveness of delivering the GtACH programme in care homes from an NHS and Personal Social Services (PSS) perspective. The primary analysis was a cost-utility analysis and presents proxy-reported outcomes as quality-adjusted life years (QALYs). Cost-effectiveness analysis based on cost per falls averted was also conducted in order that the GtACH programme can be directly compared with other interventions aimed at reducing falls.

4.2 Methods

4.2.1 Measuring resource use and estimating costs

In line with National Institute for Health and Care Excellence guidelines (NICE, 2013), we estimated costs from a health and personal social services (PSS) perspective. This included the cost of implementing the GtACH programme, any health resource use (primary care, secondary care, medications and activities of daily living [ADL] equipment) and social services received as part of routine care.

GtACH programme resource use and costs

The specific technology under investigation was the Guide to Action for Falls Prevention Care Home (GtACH) programme, delivered to care home residents by care home staff who had been trained and were supported (Walker et al., 2016) (Robertson K et al., 2012b, Robertson K et al., 2010)). GtACH is a systematic falls risk assessment and action process, co-designed by care home and NHS staff, based on NICE clinical guidelines.

The GtACH programme was delivered by care home staff, having received training from Falls Leads healthcare professionals (generally occupational therapists or physiotherapists) who were recruited in each location to provide on-site training for care home staff.

GtACH programme costs included the senior trial team training Falls Leads, Falls Leads then delivering GtACH training sessions to care home staff, care home staff delivering the GtACH process with residents, and support provided by the falls prevention leads in the first three months of delivery. Specific training details were recorded by the Falls Lead at each care home. Additional costs of the delivery and receipt of GtACH training included travel time and consumables, but we excluded the cost of developing the tool itself as this had been developed previously and was considered a sunk cost (Walker et al., 2016).

We assumed, in the base case, every resident was assessed using the GtACH tool once, as this was reflective of what the Process Evaluation team observed. The estimated amount of

time required for the GtACH process was 30 minutes, based on observations from Process Evaluation and discussion with the senior trial team.

The per-protocol delivery of GtACH would be for the checklist to be repeated after any fall. We surmised that given staffing pressures, the maximum number of repeat GtACH's each care home could provide would be one per month. Therefore, in sensitivity analysis, we included the cost of up to 11 extra intervention sessions (after the initial session in month 1) which would take place for an individual experiencing any falls in the previous 30 days, continuing to trial end.

In order to calculate the total cost of staff time, an hourly wage was estimated for a typical falls lead and care home staff based on Agenda for Change wage rates {Curtis, 2018 #647} (Appendix E). The training costs and cost of delivering the GtACH programme were calculated for each care home, and then divided among the residents recruited in that home to arrive at an estimated cost per resident.

Usual care resource use and costs

The comparator to the intervention was usual care, where usual care was defined as the absence of a systematic and coordinated falls prevention process. The usual care homes had the option to receive the GtACH training at the end of the trial but the cost of this has not been included as this occurred after the trial follow-up period.

Health and social services resource use

To estimate the cost of primary care, community health, and social services visits, data on resource use incurred during the previous 3-months was extracted from care home residents care plans by study RA's at 3, 6, 9, and 12 months. Baseline resource use (90 days pre-randomisation) was also collected in order to control for prior health resource use in analyses since past use may predict future costs. A copy of the Health Resource Use questionnaires used as part of the case report form are provided in Appendix F. For secondary care (inpatient stays, A&E and outpatient attendances) we requested linked data from NHS digital, receiving one single data transfer covering the entire trial period after the trial had closed.

Unit costs, in UK pounds sterling for 2017-18 (the most recent year available at time of analysis), were applied based on annually published national sources including National Schedule of Reference Costs (NHS improvement 2018) and the PSSRU's Unit Costs of Health and Social Care {Curtis, 2018 #647}.

Medication Costs

Researchers collected data on all medications recorded in care home records ongoing at baseline, or having occurred in the previous 90 days. At each subsequent quarterly data collection point, researchers reported whether the medications stopped or new medications were started. Medications were mapped to the Prescription Cost Analysis (Health and Social Care Information Centre 2018, price year 2017/18) to apply unit costs for each individual preparation used, assuming one item was prescribed per month during the period a resident was recorded as using the medication.

Equipment Costs

Residents' use of any equipment to help them cope with a health problem was recorded. Items deemed to be shared among other residents (for instance, stair lift or hoists) were not costed. For larger Activities of Daily Living (ADL) equipment (for instance, wheelchairs or profile beds), costs were annuitised to reflect the expected lifespan of the piece of equipment (assuming an expected lifespan of five years {Drummond, 2015 #649}. Unit costs were derived from NRS Health care where possible (https://www.nrshealthcare.co.uk/, see Appendix E)

Secondary Care Costs

Hospital Episodes Statistics (HES) data were requested from NHS Digital for all inpatient stays, outpatient attendances and A&E attendances for all residents for the period they were in the trial. Costs were applied by mapping the HES-provided HRG code to the NHS National Tariff, using 2017-18 prices regardless of activity date. Further detail on costing HES data is reported in Appendix G, and unit costs and sources are reported in Appendix E: Unit Costs.

The mean cost per resident in the intervention group and the mean cost per resident in the usual care group was estimated by summing intervention costs and wider NHS and PSS costs before dividing by the number of residents in the respective trial group.

4.2.2 Outcomes

The main outcome measure in the economic evaluation was Quality-adjusted life years (QALYs) accrued for the resident over the 12 month follow-up period as valued using the DEMQOL-P-U and EQ-5D-5L. For both instruments, responses were obtained from proxies (care home staff) at baseline and three-monthly intervals. Responses were converted into a utility using published UK tariff values, the DEMQOL-P-U using the valuation set published by Mulhern et al 2013 and Rowen et al 2012, and those for the EQ-5D-5L-P in line with current recommendations (NICE, 2017) to use the 'cross-walk' valuation set published by

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van Hout et al 2012. These utilities represent residents' overall health-related quality of life at single points in time. These utilities were employed to generate QALYs using linear interpolation and area under the curve analysis with baseline adjustment, adjusted for age at randomisation and gender (Manca et al, 2005). If residents died, their utility value (and costs) were assumed to be zero from the subsequent assessment point, and their data were retained in the analyses.

If residents had sufficient mental capacity they were also asked to self-complete the EQ-5D-5L and DEMQOL-U (whilst also having these measures captured by proxy respondents). This secondary analysis was important due to uncertainties about how best to capture health utilities in this population (Rowen et al. 2012, Mulhern et al 2013, Herdman et al 2011).

4.2.3 Economics Analysis

The primary economic analysis was a within-trial cost-utility analysis comparing the GtACH intervention to usual care without a systematic and coordinated falls prevention process in place, with outcomes expressed in QALYs. As the clinical analyses used falls rates as the primary endpoint, a secondary cost-effectiveness analysis based on difference in fall rate over 12-months was also conducted. Analysis was undertaken based on the intention to treat principle, including all randomised residents with data available. As follow-up did not continue past 12-months, discounting of costs or outcomes was not undertaken.

Mean cost and outcomes data were combined to calculate an incremental cost-effectiveness ratio (ICER) from the NHS/PSS perspective. Since randomisation was clustered by care home, analysis should reflect the increased uncertainty of randomising clusters rather than individuals. Several approaches have been proposed for taking this into account, with each method found to generate similar findings (Gomes et al 2012b, Gomes et al 2012a). The use of regression analysis is advocated to account for potential baseline differences and/or confounders when comparing costs and outcomes between treatment arms, and is essential to formally take account of the cluster-randomised design. We chose the generalised estimating equations (GEE) regression model to analyse cost and outcomes, adjusting for age, sex, site and baseline measures for costs/outcomes respectively. In order to account for correlation between cost and outcomes measures, standard errors were estimated by repeatedly re-estimating the equations on non-parametric bootstrap replications of the data, retaining the coefficient on treatment arm for each measure from each bootstrap replicate. Mean (sd) cost, QALYS and falls per resident per randomised group were estimated. The mean (95% CI) difference in costs, QALYs and falls between groups were estimated with adjusted and unadjusted results reported. The bootstrapped estimates were used to generate a graphical representation of the sampling uncertainty, presented as a scatterplot of incremental cost-outcome pairs and the cost-effectiveness acceptability curve (CEAC).

4.2.4 Sensitivity Analyses

Sensitivity analyses were undertaken to explore uncertainties surrounding key parameters in the economic evaluation, in order to investigate the robustness of findings. The following sensitivity analyses were undertaken:

1.   In the base case the cost of a single GtACH assessment being undertaken per resident was included in the cost. The per-protocol delivery of the GtACH process would have required the GtACH tool to be applied again, refreshed, for each resident after each fall. To test the impact of this on the cost of the GtACH programme, the cost of refresher GtACHs (assuming that if a participant fell at least once in a month they would receive a GtACH refresh in that month such that participants could receive up to 11 refresher GtACHs) were included in sensitivity analyses.

2.   The base case analysis did not include the costs of final hospital stays where a resident left the study following the stay (for instance, where the resident transferred to another care home). A sensitivity analysis was undertaken including these costs.

3.   The base case was adjusted for baseline variables. In sensitivity analyses we present both raw, unadjusted results and an adjusted analysis with missing data imputed using multiple imputation (MI). The MI model included predictors of secondary and non-secondary care costs (baseline and full follow-up); EQ5D-5L and DEMQoL-P based QALYs; treatment group, care home, age and sex. The imputation generated values for missing data at each follow-up using OLS, generating fifty data sets. The GEE models were then run on each of these and the outputs pooled using Rubin's rules (Little&Rubin 2019, Roysten 2004). This estimated paired incremental cost and outcome data for the entire study population.

All regression analysis was conducted in STATA MP 16 (Stata Corp), with some figures and determination of the appropriate number of bootstrap replications performed in R. Code is available on request from the corresponding author.

4.3 Results

4.3.1 Participants and data completeness

The final dataset for the economic analysis was n=1603 (732 GtACH; 871 Usual care). Completion rates for data were very high, with no more than 283/1603 (17.7%) items missing from any individual variable (DemQoL-based QALYs) and complete datasets available for 1260/1603 (78.6%) of participants. Six of 1603 (0.4%) were missing cost data, 13 and 15 of 1603 (0.8% and 0.9%) were missing baseline EQ5D and DemQol utility data and 262 and 283 of 1603 (16.3% and 17.7%) missing EQ5D and DemQol-based QALYs respectively.

During development of the multiple imputation model (sensitivity analysis 3), visual inspection confirmed the imputed means and SDs of most parameters with missing data achieved stability within 10 or 20 chained cycles. However, the exception was the estimates of total cost, which failed to achieve stability even after 1000 cycles and use of various estimation methods (including predictive mean matching). This is most likely due to the skewed nature of costs, where outliers can severely influence the mean and SD cost. Given that there were only 6 observations with missing cost data (0.4% of the dataset), these were dropped from the dataset for the MI analysis, leaving a sample size of 1597 observations for this sensitivity analysis.

While completion rates for the proxy measures (as completed by care home staff on behalf of the resident) were high, for self-reported measures, completion rates were much lower (only 12% with full data at each assessment point to calculate QALYs). The number completing the measures decreased gradually over the 12 months follow-up (see Appendix G). Due to this the self-reported measures are not discussed further in this chapter.

4.3.2 GtACH intervention Costs

Total costs of delivering the GtACH programme are outlined in Table 14. In total, 1,211 care home staff members were given GtACH training by NHS Falls Leads over 146 group sessions. The cost per intervention resident to each receive one GtACH tool assessment without any refreshers was estimated as £87.57 per resident. This increased to a mean cost of £108.91 per resident when the refresher sessions, if they fell in a month, were added. Costs varied depending on how many times Falls Leads visited the care home, and how many residents were recruited per care home, with the range of costs per resident varying between £54 - £208 (or £357 when costs of refresher GtACH's were included). Given the large number of homes in the study we believe the training costs estimated in this study would be generalizable were the intervention to be rolled out using the methods employed in the current study. It may be possible to change the format of training and by implication costs of the training and achieve the same outcomes but this was not tested within this study.

Table 14: GtACH intervention costs

GtACH Intervention costing	Costing Details/assumptions	Total	Mean	Min	Max	Component cost per GtACH resident
# staff trained per CH	Taken from GtACH training log: attendees recorded job title & attendance/DNA.	1211	31.05	10	70	1.53
# residents recruited per CH	Taken from baseline eCRF	790	20.26	10	65	1.00
Max # FL Sessions in CH	Falls lead travel costs incurred for each session	146	3.74	1	13	0.18
Cost components						
Train the Trainer day costs	1 day Nottingham; 4 on-site. Includes trial staff time; falls lead time and travel reimbursement	£11,295	£289.62	flat fee per CH		£14.30
Training Care Home staff costs	Each session costed according to number of staff attending & their roles.	£31,701	£812.85	283	2,025	£40.13
Falls lead delivering training to care homes	Band 6, 60min training + 30min prep	£9,636	£247.08	66	858	£12.20
Falls lead travel to care homes	Assume 5 miles, 40p/mile, 30min travel	£3,504	£89.85	24	312	£4.44
Cost of consumables	2 manuals per care home; 2 Checklists per resident; Attendance certificate per staff member	£2,381	£61.04			£3.01
Undertaking GtACH - CH Staff time	Assume undertaken by care home worker (£27/hr) - 30min per participant (NB higher than per protocol - evidence from process evaluation)	£10,665	£273.46	135	877.5	£13.50

Residents who fall: Refreshing GtACH – sensitivity analysis	Assume if the resident fell, the 30min checklist process (£13.50) would be repeated. Realistic number of refresher sessions – 1 per month – maximum 11 extra sessions (max £14	£16,861	£21.34	0 (no falls)	148.5 (11 extra sessions)	£21.34
GtACH cost per Care home (Intervention arm only)		£69,182	£1,773.88	858.62	4530.62	
GtACH cost per intervention arm resident			**£87.57**	53.75	208.46	
GtACH cost per resident + refresher			**£108.91**	53.75	356.96	

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4.3.3 Health and Social care resource use and costs (excluding intervention)

Resource use and costs were broadly similar in the GtACH programme and usual care homes. Table 15 and 16 provides estimates of mean resource use per resident pre-baseline and during follow-up, respectively. The provision of the GtACH programme to care homes was not associated with changes in the level of wider health-care use received by residents, and the cost of the intervention was not offset by lower costs in wider health care use (for instance, GP visits, inpatient stays or contact with other therapists). Participants had frequent visits from GPs, district nurses and podiatrists, whereas visits to A&E, outpatient appointments and inpatient stays were relatively infrequent. Despite their relative infrequency, hospital stays were an important cost driver due to their high cost (see Appendix E), as were medication costs.

During the trial, costs were higher in the GtACH group (including intervention costs) but the difference was very small with wide confidence intervals (see Table 16).

Medication costs were estimated for items reported in the GtACH group. Pre-intervention GtACH residents had slightly lower medication costs than usual care residents (mean £332.70 per GtACH resident versus mean £363.41 per usual care resident) and this difference widened by 12 months post-intervention (£1,330.79 versus £1,453.66). The mean number of prescription items over the 12 month trial period was 10.28 (sd 21.72) and 10.23 (sd 1.65) in the usual care arm, giving a 0.04 difference (95% -0.12 to 0.21). Equipment costs were similar between study groups both pre and post intervention. Mean number of equipment items during the 12 month trial period was 3.02 (sd 2.31) in the GtACH group and 3.01 (sd 2.27) in the usual care group, difference 0.01 (95% CI -0.21 to 0.24).

Secondary care resource use and costs was similar between study groups pre- and post-intervention. There were 1296 unique inpatient stays within the 12 month trial period, the cost of these can be seen in Table 16.

Table 15: Health and social care costs per resident by intervention group pre-intervention

	GtACH (n=732) Mean (SD) [no. missing]	Usual Care (n=871) Mean (SD) [no. missing]	Mean Difference (95% CI) (GtACH – Usual)
Secondary Care	**462.60 (1681.93)**	**509.50 (1599.67)**	**-46.90 (-208.24 to 114.45)**
Inpatient	399.44 (1625.17)	431.26 (1524.84)	-31.82

			(-186.64 to 122.99)
A&E	29.91 (77.66)	35.03 (88.13)	-5.13 (-13.35 to 3.10)
Outpatient	33.26 (87.91)	43.20 (109.88)	-9.948 (-19.84 to - 0.06)
Primary and Community Care	**216.83 (263.64)**	**187.79 (200.49)**	**29.04 (6.23 to 51.85)**
Equipment	**77.19 (108.70)**	**81.34 (113.07)**	-4.15 (-15.09 to 6.80)
Medications	**332.70 (300.34)**	**363.41 (307.53)**	**-30.72 (-60.69 to -0.75)**
Total costs	**1089.32 (1780.41)**	**1142.04 (1694.86)**	**-52.72 (-223.59 to 118.15)**

Table 16: Health and social care costs per resident by intervention group over follow-up period

	GtACH (n=732) Mean (SD) [no. missing]	Usual Care (n=871) Mean (SD) [no. missing]	Mean Difference (95% CI) (GtACH – Usual)
Intervention cost without refresher GtACHs	88.55 (26.87)	0.00 (0.00)	88.55 (86.76 to 90.34)
Intervention cost with refresher GtACHs	111.46 (47.44)	0.00 (0.00)	111.46 (108.29 to 114.62)
Secondary Care without mortality costs	1790.20 (3436.28)	1814.74 (3336.26)	-24.54 (-357.74 to 308.65)
Secondary Care including mortality costs	1938.87 (3634.96)	1927.09 (3459.34)	11.78 (-337.02 to 360.58)

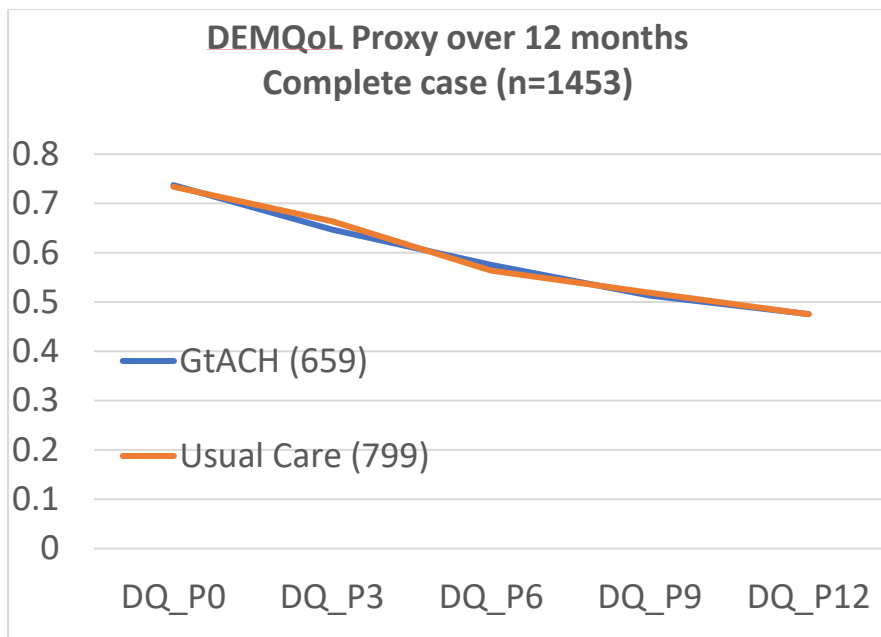|			
Inpatient without mortality costs	1567.763 (3249.07)	1581.07 (3148.96)	-13.30 (-328.06 to 301.45)
Inpatient including mortality costs	1716.43 (3447.82)	1693.42 (3269.41)	23.02 (-307.21 to 353.25)
A&E	119.67 (207.99)	126.25 (210.89)	-6.58 (-27.22 to 14.07)
Outpatient	102.76 (255.68)	107.42 (212.46)	-4.66 (-27.64 to 18.32)
Primary and Community Care	728.46 (795.49)	646.80 (734.36)	81.66 (6.50 to 156.81)
Equipment	17.30 (53.34)	20.34 (51.21)	-3.036941 - 8.17865 2.104767
Medications	1330.79 (1201.37)	1453.66 (1230.13)	-122.87 -(242.76 to -2.99)
Total Cost – Base case	3955.29 (3949.38)	3935.54 (3879.9)	19.76 (-365.88 to 405.39)
Total Cost - With refresher GtACH	3978.2 (3955.87)	3935.54 (3879.9)	42.66 (-343.32 to 28.64)
Total Cost - Including extra mortality costs	4103.96 (4121.02)	4047.89 (3989.66)	56.08 (-343.7 to 455.85)
Total Cost - Including refresher GtACH and extra mortality costs	4126.87 (4127.1)	4047.89 (3989.66)	78.98 (-321.12 to 479.09)

4.3.3 Outcomes

Table 17 shows the mean (sd) utility estimates at each time point for both intervention groups using the Proxy versions of the DEMQol-Proxy-U and EQ-5D-5L-Proxy in addition to the estimated QALYs and mean difference (95% CI) of each.

DEMQoL – Proxy

Mean proxy-completed DEMQoL utilities decline in both groups over time at a virtually identical rate. Thus, accumulated QALYs over time are virtually identical (Figure 7 and Table 17).

Figure 7: DEMQOL-U proxy over the trial period

Figure: DEMQoL Proxy over 12 months Complete case (n=1453). Lines for GtACH (659) and Usual Care (799) across DQ_P0, DQ_P3, DQ_P6, DQ_P9, DQ_P12.

EQ-5D-5L – Proxy

EQ5D-based utilities were consistently higher in the GtACH group than the usual care group (See Figure 8 and Table 17). This leads to higher observed mean QALYs. These raw, unadjusted, comparisons describing the data illustrate the importance of adjusting for baseline utility.
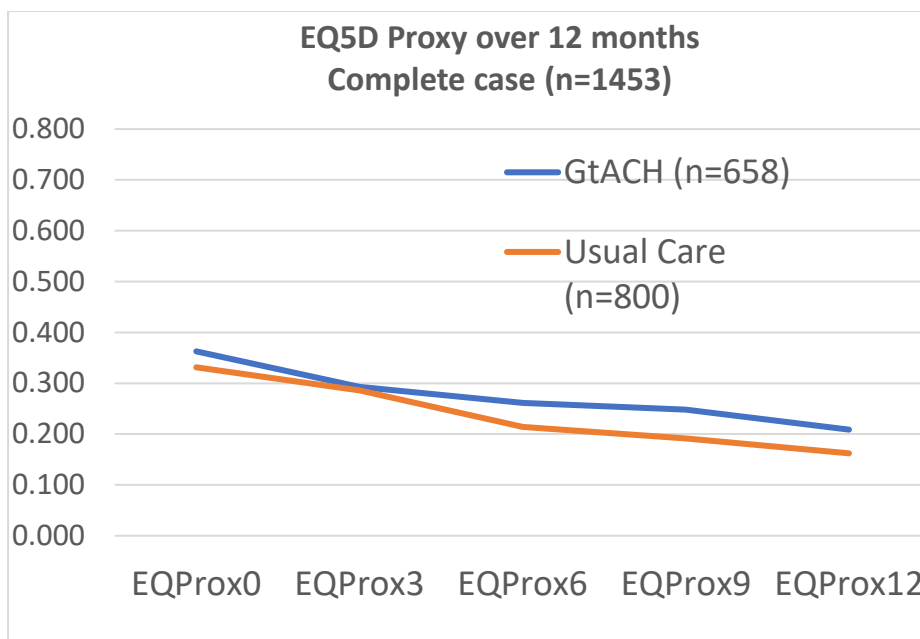
Figure 8: EQ-5d-5L proxy over the trial period

EQ5D Proxy over 12 months
Complete case (n=1453)

Table 17: Proxy Utility and QALYs

	GtACH Intervention			Usual Care			
	N (max=732)	Mean	Std dev	N (max=871)	Mean	Std dev	Mean difference
Proxy Completed							
DEMQOL-P-U baseline	722	0.740	0.123	866	0.737	0.124	0.003 (-0.009 to 0.015)
DEMQOL-P-U 3 months	699	0.655	0.248	799	0.669	0.230	-0.001 (-0.013 to 0.012)
DEMQOL-P-U 6 months	683	0.585	0.306	798	0.573	0.312	0.012 (-0.010 to 0.016)
DEMQOL-P-U 9 months	687	0.523	0.336	801	0.524	0.346	-0.001 (-0.006 to 0.010)
DEMQOL-P-U 12 months	666	0.477	0.357	804	0.476	0.358	0.001 (-0.036 to 0.038)
QALYs (DEMQOL-P-	**611**	**0.578**	**0.240**	**708**	**0.581**	**0.235**	-0.003 (-0.028 to 0.023)

U) at 12 months							
EQ-5D-5L-P baseline	723	0.367	0.369	867	0.344	0.360	0.021 (-0.015 to 0.057)
EQ-5D-5L-P 3 months	711	0.301	0.379	794	0.300	0.364	-0.001 (-0.038 to 0.037)
EQ-5D-5L-P 6 months	702	0.260	0.361	810	0.223	0.343	0.036 (0.000 to 0.072)
EQ-5D-5L-P 9 months	686	0.250	0.358	817	0.198	0.328	0.051 (0.016 to 0.085)
EQ-5D-5L-P 12 months	667	0.210	0.321	803	0.162	0.313	0.047 (0.014 to 0.079)
QALYs (EQ-5D-5L-P) at 12 months	**622**	**0.266**	**0.317**	**718**	**0.232**	**0.291**	**0.033 (0.000 to 0.065)**

Falls

The primary outcome for the trial was based on falls in months 3-6, analysis of the primary outcome showed a substantial difference between arms with more falls in the usual care group. The economic evaluation measures falls over the full 12 month period, and as Figure 9 shows the difference between groups became smaller in the latter half of the trial. Reflecting the RCT results, the intervention appeared to be more effective in the first six months compared to the final six months.

There was a mean of 1.89 (sd 3.66) falls recorded per resident in the intervention arm and a mean of 2.77 (sd. 7.44) falls per usual care resident, mean difference -0.877 (95% CI -1.469 to -0.285).

Figure 9: Mean number of falls per quarter over the trial period
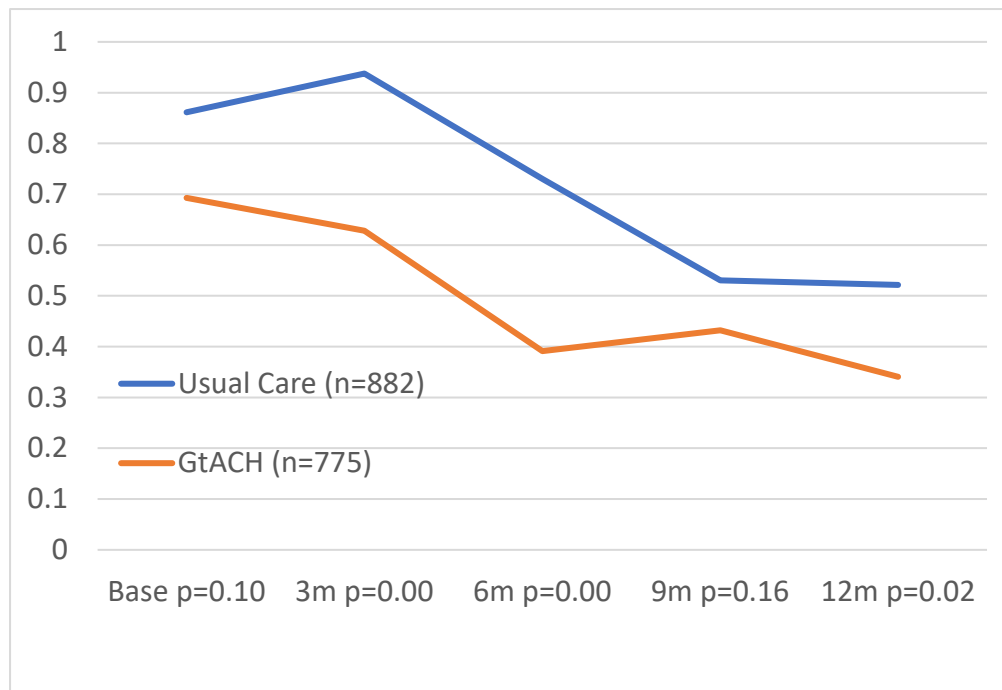
Cost-effectiveness

Results of the cost effectiveness analyses are shown in Table 18. The raw incremental cost between groups was £19.76. However, this figure is unadjusted for baseline imbalances in cost and potential influences on cost other than the intervention. Adjusting for these yields and incremental cost of £108.26 with a 95%CI of -£271 to £488 ('adj, bs' analysis). Adding in the cost of additional refresher sessions (sensitivity analysis 1, row 2 of Table 6) increases the incremental cost to £131.81 (-£248 to +£511). Further adding in the cost of mortality (sensitivity analysis 2, row 4 of Table 6) increases the incremental cost to £148.52 (-£245 to +£542). The MI sensitivity analysis yields an identical mean cost, but narrower confidence intervals (final column "MI, adj, bs", rows 1-4 of Table 6).

Point estimate unadjusted DemQol-based QALYs are -0.003 per care home resident. However, adjusting for baseline values and other predictors of QALYs yields an estimate of +0.005 attributable to the intervention (95%CI -0.019 to +0.030). The (adjusted) incremental gain in EQ5D-based QALYs was larger at +0.024, with the 95%CI excluding zero (0.004 to 0.044). Likewise, the incremental gain in falls was -0.568 per person over the 12 month period (-0.970 to -0.166). Note a negative indicates fewer falls in the intervention arm. As per the cost estimates, imputing missing values does not materially affect the results.

Depending on the costs included (ie extra mortality and refresher sessions), point estimate ICERs range between £20,889 and £28,658 per DEMQol-based QALY gained, with a 53% to 57% probability that the ICER is below £20,000, and £4544 and £6234 per EQ5D-based

QALY gained, with an 88.8% to 91.6% of being below £20,000 per QALY (Figures 10 and 11). The incremental cost per fall prevented is between £190 and £262, with a 98.6% probability of being cost-effective as long as the willingness to pay to avoid a fall is above £2000 (Figure 12).

Table 18: Cost-effectiveness results

		Intervention		Control		Increment mean (95%CI)		
	Parameter	n	mean (SD)	n	mean (SD)	raw	adj, bs (primary analysis)	MI, adj, bs
Cost								
1	Basecase	732	3955.29 (3949.38)	865	3935.54 (3879.9)	19.76 (-365.88, 405.39)	108.26 (-271.06, 487.58)	108.26 (-232.89, 449.41)
2	With refresher GtACH	732	3978.2 (3955.87)	865	3935.54 (3879.9)	42.66 (-343.32, 428.64)	131.81 (-247.77, 511.4)	131.81 (-209.28, 472.9)
3	Including extra mortality costs	732	4103.96 (4121.02)	865	4047.89 (3989.66)	56.08 (-343.7, 455.85)	124.98 (-268.68, 518.64)	124.98 (-230.84, 480.8)
4	Including refresher GtACH and extra mortality costs	732	4126.87 (4127.1)	865	4047.89 (3989.66)	78.98 (-321.12, 479.09)	148.52 (-245.4, 542.45)	148.52 (-207.33, 504.38)
Outcomes								
5	DEMQoL-P-U based QALYS	611	0.578 (0.24)	708	0.581 (0.235)	-0.003 (-0.028, 0.023)	0.005 (-0.019, 0.03)	0.005 (-0.018, 0.029)
6	EQ-5D-5L-P based QALYs	622	0.266 (0.317)	718	0.232 (0.291)	0.034 (0.002, 0.067)	0.024 (0.004, 0.044)	0.023 (0.003, 0.043)
7	falls	732	1.889 (3.662)	871	2.747 (7.414)	-0.858 (-1.417, -0.299)	-0.568 (-0.97, -0.166)	-0.574 (-0.961, -0.186)
ICERs	**Analysis**							
1/5	Base case, Incremental cost per DEMQol-P-U based QALY					-£7,226.47	£20,889.42	£20,557.80
2/5	With refresher GtACH, Incremental cost per DEMQol-P-U based QALY					-£15,605.59	£25,433.80	£25,030.04

3/5	With extra mortality cost, Incremental cost per DEMQol-P-U based QALY	-£20,513.22	£24,115.39	£23,732.56
4/5	With extra GtACH and mortality cost, Incremental cost per DEMQol-P-U based QALY	-£28,892.34	£28,658.26	£28,203.32
1/6	Base case, Incremental cost per EQ-5D-5L-P based QALY	£575.01	£4,543.69	£4,651.63
2/6	With refresher GtACH, Incremental cost per EQ-5D-5L-P based QALY	£1,241.73	£5,532.14	£5,663.56
3/6	With extra mortality cost, Incremental cost per EQ-5D-5L-P based QALY	£1,632.22	£5,245.37	£5,369.98
4/6	With extra GtACH and mortality cost, Incremental cost per EQ-5D-5L-P based QALY	£2,298.94	£6,233.50	£6,381.58
1/7	Base case, Incremental cost per fall averted*	£23.02	£190.62	£188.72
2/7	With refresher GtACH, Incremental cost per fall averted*	£49.72	£232.09	£229.77
3/7	With extra mortality cost, Incremental cost per fall averted*	£65.35	£220.06	£217.86
4/7	With extra GtACH and mortality cost, Incremental cost per fall averted*	£92.05	£261.52	£258.91

Rows numbered 1 to 4 show the sample size, mean and SD of cost in each arm, followed by three estimates of the incremental cost, each shown with 95% confidence intervals. The 'raw' increment is the arithmetic difference in the means. The 'adj, bs' increment is the incremental cost adjusted for baseline covariates using GEE, repeated with 10,000 bootstrapped resamples of the raw data, and as such is the primary analysis. The 'MI, adj, bs' increment is the incremental cost where missing data are imputed 50 times, with GEE run on each set and the results combined using Rubin's rules. This entire process was repeated 200 times with bootstrapped resamples of the raw data (scenario 3 analysis). The four estimates of cost represent the base case and three scenario analyses around cost, the first adding in estimates of the cost of refresher GtACH as per the protocol (but which was not observed in the trial). The second adds in extra cost of mortality. The third adds in both the refresher and mortality costs. Rows numbered 5-7 show the same data for the three outcomes: DEMQOL-P-U based QALYs, EQ-5D-5L-P based QALYs and number of falls. The ICERs for each analysis are as described, with the first column showing which rows are divided by which.

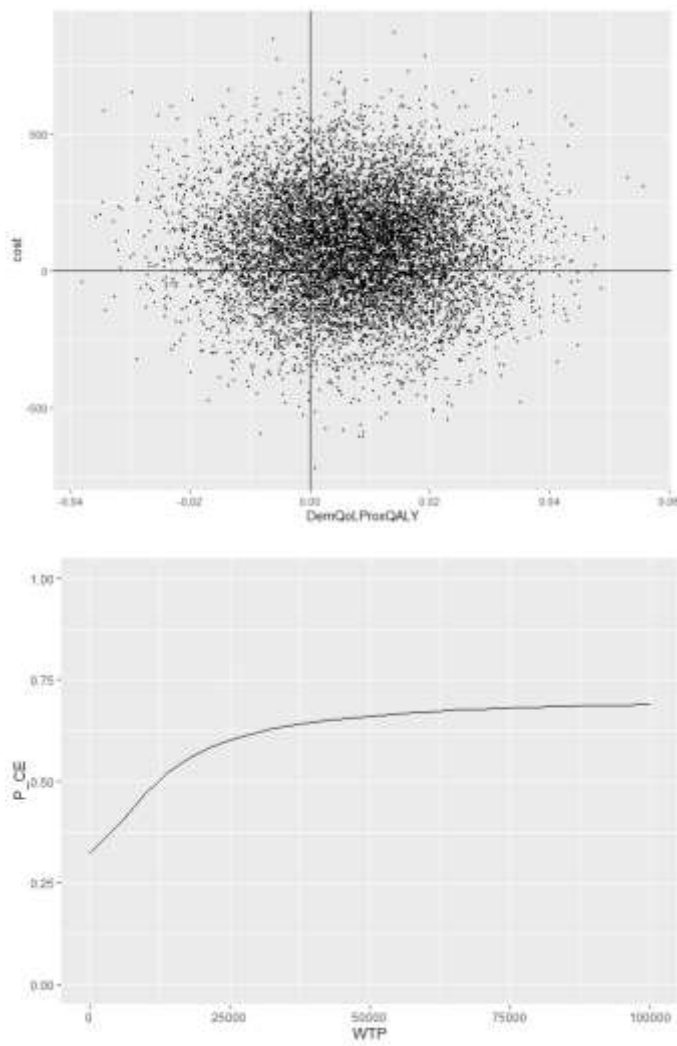Figure 10a, b: Scatter plot and CEAC, DemQol-P-U based QALYs, Base case costs

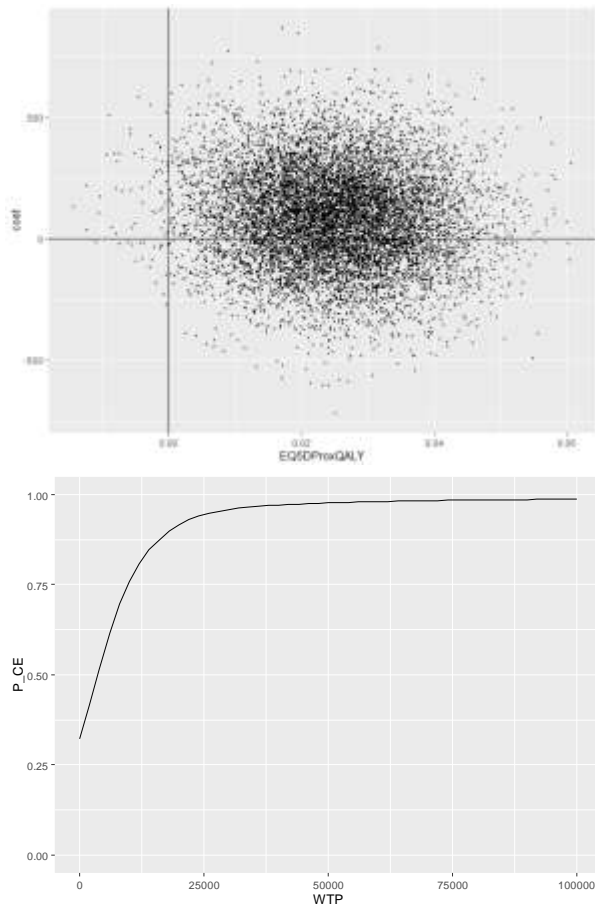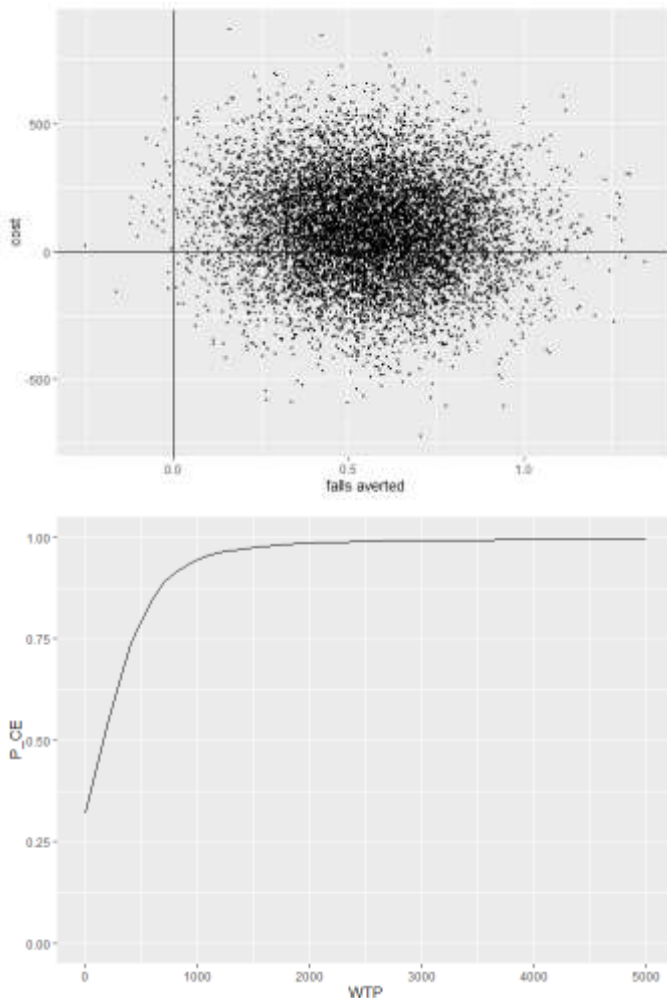Figure 11a,b: Scatter plot and CEAC, EQ-5D-5L-P based QALYs, Base case costs

Figure 12 a,b: Scatterplot and CEAC, falls, base case costs (note negative falls = intervention prevents falls)

4.4 DISCUSSION

4.4.1   Interpretation of results

Overall, the GtACH programme showed a benefit in terms of EQ-5D-5L-P based QALYs and falls. However, DemQOL-P-U based QALYs yielded almost identical results; point estimates were marginally worse in the GtACH arm, but this disappeared after adjustment for baseline parameters. There was very little difference in health service costs between the arms. There was no evidence of an increase in ADL costs associated with the intervention: this is consistent with care homes already being well fitted out with relevant equipment.

When measuring QALYs with the DEMQoL-P-U, the GtACH intervention was of borderline cost-effectiveness compared to the willingness to pay for a QALY of £20,000 to £30,000 commonly employed in England (NICE 2013): the ICER was between approximately £20,900 and £28,700, depending on choice of cost scenario, with around 53% to 57% probability of being below the lower threshold of £20,000. When measuring QALYs based on EQ-5D-5L-P, point estimate ICERs were well within the range normally considered cost-effective in

England, at between £4500 and £6200 per QALY gained, and approximately 89% to 92% probability of being below £20,000. The cost to prevent one extra fall with GtACH was approximately £190 to £260.

In designing this economic evaluation there was always an uncertainty about which preference-based measure to use to elicit quality of life amongst care home residents. This uncertainty reflects a number of issues involved in measuring health related quality of life in this population (most notably who should rate it (Rowan et al 2015) and which instrument should be used (Ratcliffe et al 2017)) and whilst the number of studies looking at these issues has increased substantially in the last year or two it is still a question researchers would face in designing a similar study from scratch today (Easton et al 2018). We included both the generic EQ-5D-5L, and a dementia-specific outcome measure, the DEMQOL-U (Mulhern 2013, Rowen et al., 2012). The relative merits of each is discussed below (see strengths and weaknesses). Ultimately it is for the decision maker to decide whether DemQoL-P-U or EQ-5D-5L-P based QALYs are more appropriate, and to interpret the results accordingly: if the former, the GtACH programme was of borderline cost-effectiveness. If the latter, it was solidly within conventionally accepted limits.

Finally, the incremental cost per fall prevented is of note, and may appear subjectively 'reasonable', at £190 to £260. The willingness to pay for preventing a fall is less clearly established, and furthermore does not take into account the varying severity of falls. This is a major advantage of the QALY which (theoretically) captures the health consequences of events, so this may be considered a more useful metric in this regard.

4.4.2 Strengths and limitations of the economic evaluation

A major strength of this study is the quality and completeness of data collected. Data were collected at quarterly follow-up points. These relatively frequent collections were needed as discussion with care home managers revealed that care records tend to be archived very quickly following deaths and as such less frequent collection would have had the potential to lose data on of falls, resource use and outcomes from residents who died or transferred homes between assessment points. The final dataset for the economic analysis was n=1603 (732 GtACH; 871 Usual care), with no missing data on falls and only 6 missing observations for cost data. Completion rates for DEMQoL-P-U and EQ-5D-5L-P at each time point were such that QALYs were calculable on at least 82.3% for these.

A major limitation was uncertainty as to which health related quality of life measure to use. Neither the EQ-5D-5L nor the DEMQOL-U are perfect: the utility value sets for the DEMQOL-U and DEMQOL-P-U are fairly recently published so have not been extensively used or validated as yet in funded trials. In contrast, there were concerns about the valuation of the EQ-5D-5L so whilst the EQ-5D is the preferred instrument of the National Institute for Health and Care Excellence (NICE) (NICE, 2013), the position statement published by NICE in 2017 raised concerns about use of the 5L variant (NICE, 2017). Against this concern there was

some evidence to support the use of proxy scores instead of self-report scores on the EQ-5D for care home residents {Devine, 2014 #648}.

A decision was made to use the DEMQOL-P-U in the base case analysis at the time the health economic analysis plan (HEAP) (see Appendix G) was signed off, however, there was not a strong conviction for this choice. As such this chapter presented the cost utility analysis based on the DEMQOL-P-U first followed by the cost utility analysis based on the EQ-5D-5L-P and finally the cost effectiveness analysis based on falls outcomes. In interpreting these results, it is necessary to acknowledge the growing evidence that the choice to use the DEMQOL in the base case may not have been the most appropriate choice. Since the HEAP was signed off, concerns over its use in care home populations may be inappropriate led to it being adapted for use in this population (Hughes et al 2019). At the same time, several economic evaluations in care home populations have been published which show the EQ-5D can be used in this population (Livingston et al 2019, Meads et al 2020) and may be more responsive than the DEMQOL-P-U (Martin et al 2019). Recently, however, a qualitative study comparing (in terms of face and content validity) six preference based measures in the context of dementia found no single instrument was favoured (Engel et al 2020), such that choice of preference based measure remains on the research agenda.

A further limitation was that whilst we recorded how many staff in each care home received training, it was not feasible to record whether each resident actually received a completed GtACH. However, even if the GtACH was not delivered per resident as planned, educating staff on falls risks would be expected to have had an impact. To explore this uncertainty, in the base case we assumed each resident had one session, with the cost of refresher sessions if the resident experienced a fall added in sensitivity analysis. Even with the refresher, the GtACH intervention was low cost compared to other care home interventions. At the base case this was £88, rising to £109 in sensitivity analysis, although this does increase the the DEMQol-based ICER by approximately £4,600 and the EQ5D-based ICER by £1000.

4.4.3 Future research

In the analysis reported, utility is derived from the proxy versions of the DEMQoL-P-U and EQ-5D-5L-P. Both instruments have self-complete and proxy versions available. A previous study (Devine et al 2014) found that the proxy version of the EQ-5D was an acceptable source of data for utility index scores. Given the anticipated difficulties collecting self-report data for quality of life, due to cognitive difficulties, the trial collected proxy estimates for all residents from their main carer in the care home. Those with capacity were additionally asked to self-report quality of life, however, completion rates were much lower for the self-reported versions (Appendix G) for data completion figures for the DEMQOL-U and EQ-5D-5L self-report). Future work should be undertaken to compare the proxy and self-report data collected for those residents with both available.

4.5   CONCLUSION

Depending on choice of health related quality of life measure, the GtACH programme was either of borderline cost-effectiveness or well within conventional thresholds of cost-effectiveness. Implementation of the GtACH programme was associated with a reduction in falls in care homes and improvements in EQ5D-based QALYs. Future research should explore the relative validity and appropriateness of different health related quality of life measures in care home residents.

5 PROCESS EVALUATION

5.1 Introduction

5.1.1 Context – A Realist Process Evaluation

Process evaluation promises insight about fidelity and quality of implementation; about causal mechanisms and contextual factors; and, supports understanding why an intervention fails or has unexpected consequences (Craig et al., 2008). More recent development of the MRC guidelines have stressed the importance of theory in this (Moore et al., 2015).

Realist evaluation is one such theoretical approach (Moore et al., 2014). Based on the work of Pawson and Tilley (Pawson and Tilley, 1997, Pawson, 2013, Emmel et al., 2018, Pawson, 2006) realist evaluation demonstrates a concern for causality and change mechanisms postulating the "contextually contingent nature of these" and challenging how "hypothesised causal chains play out in the implementation of a complex interventions" (Moore et al., 2015). Put more simply, a realist approach considers the GtACH programme to be a resource which enables change to happen. GtACH in itself does not reduce falls but rather provokes a response, or creates mechanisms, for change to happen. Change may come (for example) in individual knowledge, awareness, confidence or organisational structures and it is these changes which lead to difference in falls outcome.

That different mechanisms will be triggered in different contexts is a key tenet of realist evaluation. GtACH may not work in all places, and if it does work it may work in different ways depending upon which mechanisms (organisational structure, individual knowledge, self-confidence, etc.) are triggered. Understanding the contextual circumstances of GtACH delivery and identifying those mechanisms which are triggered in different settings, is key to understanding how GtACH might be implemented in the future.

5.1.2   Aims and Objectives

The aim of this realist evaluation was to generate detailed insight about the delivery of the GtACH programme in order to: i) identify those contexts where GtACH is easily adopted; and ii) recognise those mechanisms which lead to positive outcomes.

The evaluation considered consistency of GtACH use within and across care home settings and illustrated the views and opinions of key stakeholders about the adoption of GtACH. Specifically, it assessed:

- fidelity in GtACH training
- fidelity in the use of the GtACH screening and assessment paper tool
- acceptability of the GtACH programme (training and tool)
- impact of GtACH upon falls rate

5.2 Background

Care homes pose a distinct challenge for the introduction of complex interventions: they vary in size, funding, workforce and culture, and house vulnerable individuals with far-reaching health and social care needs. This heterogeneity of organisational context and uncertainty of individual need is an inherent (and unavoidable) barrier to effective innovation (Gordon et al., 2018, Devi et al., 2018, Rycroft-Malone et al., 2018, Goodman et al., 2017, Robbins et al., 2013, Goodman et al., 2016) . So whilst delivery of programmes such as GtACH are intended to be consistent, with only justifiable variation, it may be that the needs of local residents and the preference of local staff create situated and specific variations in how programmes are delivered.

Our starting point in this (as with all realist evaluation) was to consider how the GtACH programme was intended to work. In the realist tenet, programmes are not simply treatments or interventions, but rather "Programmes are 'theories incarnate'. Every programme has a theoretical underpinning, whether it is made explicit or not."(Pawson, 2006). A programme such as GtACH rests upon some theorised causal relationship which has broader reach and application than its specific components; previous realist research illuminate the type of programme theories which might underpin initiatives in care homes.

In a recent realist review, three broad programme theories were recognised in the delivery of healthcare to care home residents (Goodman et al., 2016). Incentives, targets and sanctions might motivate general practitioners to engage more routinely; greater involvement of experts in elderly healthcare might make for more appropriate healthcare provision; and, health outcomes might be improved by better relational working which spans care home staff and external health professionals.

More recent research by the same authors (Gordon et al., 2018) identified similar programme theories. Improved relational working might underpin better outcomes in healthcare delivery; dedicated (financial) investment can trigger more appropriate provision; and, wrap around care, manifest in referral networks for external services, can support care home staff in accessing appropriate specialist care. The benefit of dementia-specialist services is a final focus for improved care home healthcare.

The PEACH programme (Devi et al., 2018) looked to programme theories derived from the quality improvement collaborative (QIC) literature to examine the implementation of comprehensive geriatric assessment (CGA) in care homes.

The FIRE evaluation (Rycroft-Malone et al., 2018) speculated that the implementation of incontinence recommendations is mediated by organisational context, the theory of action inherent in the recommendation and staff support for change.

GtACH had its own programme theories (see section 5.2.1), but these examples demonstrate how broader theories and causal relationships might underpin the specific components of an intervention. They highlight that it is not (simply) the adequacy of the

incontinence recommendations, the appropriateness of CGA approach, or the healthcare delivered but rather that it might be incentives, better relational working (Gordon et al., 2018, Goodman et al., 2016), sharing best practice (Devi et al., 2018), or fit with organisational context (Rycroft-Malone et al., 2018) which govern the impact that an intervention has.

5.2.1 Initial Programme Theories

In accordance with this approach, this evaluation looked beyond the individual elements of the GtACH programme in order to identify initial programme theories which could be tested in the evaluation. These programme theories were derived from previous published work relating to the creation of the GtACH (Robertson K et al., 2010, Robertson K et al., 2012b) and its early testing (Walker et al., 2016), and were verified by the FinCH Trial Management Group (February 2017).

Programme theory I – Connecting Falls Risk to Remedial Actions

In care homes, falls are a constant risk due to a complex mix of individual, organisational and environmental factors; this complexity and variety has made falls management difficult.

Prior approaches to falls management have stressed the interrelationship of different risk factors and have sought to quantify individual risk of falling.

Prior strategies have often focused upon generating combined risk scores for individual care home residents, with less concern for the measures which might be taken to limit falls risk.

The GtACH screening and assessment paper tool isolates and disaggregates individual risk factors and connects them with specific actions to reduce risk.

GtACH programme is premised upon the value of considering each category of falls risk independently, and in the importance of generating solutions as well as understanding risks.

Programme theory II – Supporting All Staff in Falls Risk Management

Care home staff are heterogeneous in expertise, experience, training, and skills; they will be more or less aware of falls risk and those measures which might reduce it.

Consequently, care home staff may be more or less able and prepared to utilise the GtACH paper tool, which has implications for the effective delivery of GtACH programme.

Specialist staff (local falls champions and regional falls leads) are intended to support implementation by offering direct support to individual staff and by providing greater knowledge and expertise about falls risk management. Specialist staff are intended to ensure consistent and appropriate delivery of GtACH.

5.3 Methods

5.3.1 Study Design

This was a multi-method process evaluation run concurrently with (but independently of) the main trial. It was informed by the principles of realist evaluation (Pawson and Tilley, 1997, Pawson, 2006, Pawson, 2013, Emmel et al., 2018) and was characterised by a concern for testing the programme theories described above.

The evaluation incorporated a number of distinct but interrelated stages: i) the formulation of initial programme theories (as above); ii) theoretical sampling to identify the most appropriate environments to test these theories; iii) the adaptation of these theories or creation of new programme theories; iv) recognising patterns in these revisions; and v) identifying a mid-range theory which explains these patterns.

Review and revision of the initial programme theory takes the form of Context-Mechanism-Outcome (CMO) configurations which are the mainstay of the realist approach (Pawson and Tilley, 1997, Pawson, 2006, Pawson, 2013). To be explicit, context here relates to those individual or organisational features which pre-date the introduction of the GtACH programme; these included (amongst a multitude of specific detail) the size and ownership of the care home, the nature of its provision (residential and/or nursing), and will also include characteristics of both staff and residents. Outcome describes that which results from the introduction of the GtACH; this included a concern for fidelity and acceptability as well as any measurable change in the frequency or consequence of resident falls.

Mechanism is perhaps the most complex element of this equation (Emmel et al., 2018) and is seen here as a mediating factor which illuminates the causal relationship between the introduction of a programme into a specific context and the precise outcomes which result therein. Mechanisms are more than the resources introduced they also encapsulate the individual or organisational reaction to, or reasoning about, the resources invested (Pawson and Tilley, 1997). As this suggests a realist approach acknowledges that mechanism might equally be a subjective response to the GtACH just as it might be an objective change to practice.

Multiple CMO configurations are the likely output of any realist evaluation and it is evidence of recurrent patterns across these C-M-Os which is suggestive of more certain causal relationships (Pawson, 2010). Whilst such demi-regularities do not represent undeniable causality, they do offer a layer of explanatory power which aids understanding the outcomes achieved. Reflecting upon these demi-regularities completes the evaluation cycle and it is in these recurrent patterns that the strengths and shortcomings of the initial programme theories are made explicit. Further explanatory power might be achieved in the application of some more general mid-range theory to unpick these patterns.

5.3.2 Participants

Only care homes randomised to the GtACH programme were included in this process evaluation, and the evaluation was consented independently of the main trial.

Homes were selected purposively (Lavrakas, 2008) from those that expressed a willingness to participate; selection was driven by the realist agenda of testing programme theories with home size, ownership, and the presence of nursing staff initially considered pertinent contextual features which might impact upon the delivery of the GtACH programme. Subsequent sampling used other contextual features in order to test revised or evolving programme theories.

Where the care home manager consented, all pertinent staff were approached and those willing were consented to the process evaluation. Residents who were identified as able were also approached and consented where they were willing.

Homes were recruited in different geographic areas, so as to capture any variation in local practice/policy, and regional falls leads (who delivered GtACH training) were also involved in the process evaluation.

Finally, for each care home involved, falls-rate data was also included. This necessarily includes falls data for those residents not able (or unwilling) to consent to the process evaluation, but this was collected as part of the main trial and was not specifically collected for the process evaluation.

5.3.3   Data collection

Data were collected using a combination of interviews, focus groups, fidelity observations, documentary review and falls-rate review. Data were primarily collected during a three-month period following the introduction of the GtACH programme, with an additional care home visit made six-months after the introduction of GtACH.

GtACH training was observed in each care home using a checklist to assess fidelity with the training protocol (the fidelity checklist is included in Appendix H). The primary training session was observed by two researchers, with additional sessions observed by at least one.

The implementation of the GtACH paper tool was observed in each care home using a checklist to assess fidelity with the GtACH protocol (the fidelity checklist is included in Appendix H). In each care home multiple researchers would record this process with a number of different residents. Evidence of GtACH tool use was also sought in a review of care home records.

A staff focus group was held immediately post GtACH training – this considered their experience of training and their expectations of the GtACH. At the six months visit a second focus group was organised – this reflected upon staff experiences and their thoughts about future use (focus group guides are included in Appendix I).

During the evaluation a number of key stakeholders were interviewed. This included care home staff, the care home manager, the care home Falls Champion and the regional Falls Lead, where possible care home residents were also interviewed. Interviews focussed upon

the local experience of the GtACH (interview topic guides are included in Appendix I). All interviews were recorded using digital, audio equipment.

Falls data for homes included in the process evaluation were sought to inform the Outcome element of our CMO configurations. Practicalities of trial management (to maintain blinding, etc) meant that this was provided as a single dataset after all other process evaluation data had been collected, and it did not include adjustments informed by HES data about resident hospitalisation.

5.3.4 Data Analysis

All interview and focus group data were transcribed in full, anonymised and handled using the NVivo software package. All data were coded by at least two researchers and organising themes and the structure of the coding book was agreed by the process evaluation team. Initial Coding was also verified by the FinCH PPI group. Fidelity checklists were reviewed by at least two researchers.

The focus of analysis in this realist evaluation was in the iterative development of those programme theories which aid understanding of the implementation and impact of the GtACH programme; it is focused through the lens of three conceptual tools – Context, Mechanism and Outcome.

Thematic analysis (Braun and Clarke, 2006) of interview and focus group data added specific detail to the context by exposing existing practice, process and priorities. Baseline falls data also supplemented our understanding of the context.

Thematic analysis (Braun and Clarke, 2006) exposed those mechanisms triggered by the introduction of the GtACH programme which are manifest in stakeholders' descriptions of its delivery.

Descriptive statistics for each process evaluation care home, for all intervention care homes and for all control arm care homes were produced to illuminate the outcome of GtACH. These findings were mapped to the main trial baseline and primary data outcome time points. Thematic analysis and fidelity check also aided our understanding of outcome, illuminating stakeholder assessment of acceptability and demonstrating fidelity of use.

Data were synthesised in the form of multiple, specific C-M-O configurations for each care home. In each configuration context and outcome were considered fixed, with the mechanism ascribed the causal power to explain why/how specific outcomes emerged in a context. C-M-O configurations were reviewed by the process evaluation team and recurrent patterns across multiple care homes (demi-regularities) were identified.

5.4 Results

5.4.1 Care Home Characteristics

Six care homes were recruited to the process evaluation from different parts of the country (to reflect different local practice), they ranged in size, included both residential and nursing homes, and demonstrated different models of ownership and management (Table 19).

Table 19 – Care Homes and participants in Process Evaluation.

Home	Registration	Size (no residents recruited to trial)	Home ownership	Number of Focus groups	Number of Staff interviews
A	Residential	71 beds (18)	Part of large national corporate chain	4	7
B	Dual Registered	48 beds (16)	Part of small local corporate chain	2	1
C	Residential	46 beds (29)	Part of small local charitable chain	2	10
D	Residential	40 beds (10)	Part of large national corporate chain	1	10
E	Residential	17 beds (12)	Independent (business with one home)	0	8
F	Residential	53 beds (42)	Part of small local corporate chain	2	8

Across these settings 88 participants consented to take part in the evaluation; 44 stakeholders were interviewed, and 11 focus groups took place. Seven managers, 4 deputy managers, 1 nurse, 3 Falls Champions, 1 floor manager, 22 senior caring staff, 38 caring staff, 6 residents and 6 Falls Leads took part in the evaluation

One hundred and ninety-four independent codes were identified in the data. These were organised within a simple thematic structure (consisting of 14 broad themes) which reflect a pragmatic concern for delivering GtACH. Themes include: the GtACH tool, the Falls Champion, GtACH training, GtACH implementation, etc. The complete code book is presented as Appendix J.

5.4.2 Falls Rate Data

Data presented in Chapter 3 suggests that the GtACH programme (training and tool) offered benefit to those homes where it was introduced. The Process Evaluation was completed in six of the intervention care homes with the falls rates for these homes shown in Table 20 alongside the average from all the homes.

Counts of the number of falls in each setting (unadjusted for the size of the care home or the nature of care offered) suggests a distinct trend which we describe here to allow the data from the Process Evaluation to be seen compared to the whole sample. At baseline (90 days prior to randomisation) the number of falls recorded in participants from all homes ranged from 0 falls to a maximum of 25 falls (0-25). For the period 91-180 days post randomisation the number of falls ranged from 1 to 116 in control settings (1-116) and 0 to 28 in those homes where GtACH was introduced (0-28). No care home that received the GtACH intervention recorded more than 30 falls in a 90-day period (at either baseline or post randomisation); in the control arm three recorded more than 50 falls in the period 91-180 days post randomisation. An unadjusted count of falls in all care homes is presented as Appendix K. In the control arm the rate of falls increased by 4.53 more falls per 1,000 resident days at 91-180 days post randomisation (Table 20); in the intervention arm the increase was less pronounced with only 1.32 more falls per 1,000 resident days.

Table 20 – Summary of falls and falls rate data for PE.

	CONTROL (All - average)	GtACH (All - average)	Care Home A	Care Home B	Care Home C	Care Home D	Care Home E	Care Home F
no. of falls: baseline period	8.09	7.13	12	6	14	8	9	12
primary end point	14.13	7.97	19	4	20	16	3	20
change	+6.04	+0.85	+7.0	-2.0	+6.0	+8.0	-6.0	+8.0
falls rate: baseline period	4.76	4.17	7.41	4.21	5.42	8.97	8.33	3.19
primary end point	9.29	5.49	12.44	3.53	8.85	18.29	3.03	6.93
change	+4.53	+1.32	+5.03	-0.68	+3.43	+9.32	-5.3	+3.74

In those care homes included in the process evaluation: the falls rate decreased in care homes B and E; in care homes C and F the rate of falls increased at a slower rate than the control group; and, in care homes A and D the rate of falls increased at a greater rate.

5.4.3   Care Home Experiences

Results for each home are now described with a full list of CMO configurations for all care homes presented as Appendix L and summarised in Table 21.

Care Home A (0803)

Context - This was a 71 bedded home providing residential dementia care. The home was corporately owned and was part of a large national chain.

Outcome - GtACH training was delivered in accordance with the training guidelines but implementation of the GtACH screening and assessment paper tool was poor (only 6 GtACH's tools were completed for the 18 recruited participants). Only senior staff used the GTACH tool correctly as per the training and intervention manual, carers rarely used it independently (only when observed by a researcher) and did not complete it in full. The GtACH tool was not being used at the end of the 6-month period.

Both the number of falls and falls rate increased during the observation period, from 12 in the baseline period to 19 in the primary outcome period, and the falls rate from 7.41 (falls per 1,000 resident days) to 12.44 (falls per 1,000 resident days).

Commentary - The staff reported that falls prevention provision was well established before the study started, and staff felt knowledgeable about falls and confident in their management. Staff were reluctant to adopt new ways of working alongside (in addition to) the home's existing systems. Managerial changes during the study had a negative impact upon the implementation of the GtACH programme, and change was neither driven by senior managers nor by care home staff. The home did not actively instigate the Falls Champion role.

Care Home B (0703)

Context – This was a 48 bedded dual registered nursing-led home providing residential, dementia and nursing care. The home was corporately owned by a small chain.

Outcome - The GtACH training was delivered in accordance with the training guidelines. Implementation fidelity was poor. A number of GtACH assessments were completed by a single member of nursing staff – but only in anticipation of a process evaluation interview. Otherwise the tool was not used during, or after, the process evaluation observation period.

Both the number of falls and falls rate decreased during the observation period. From 6 falls (baseline) to 4 falls (primary outcome period), and from 4.21 (falls per 1,000 resident days) to 3.53 (falls per 1,000 resident days).

Commentary - A change of manager at the outset of the study was marked by a reluctance to introduce new systems at a time of change. The new manager would not sanction additional paperwork alongside existing home system and processes. In contrast the GtACH training was well received and valued by staff and management alike. Staff described feeling more aware of falls risk and more confident in addressing them; management described changes to staff behaviour with staff becoming more pro-active in falls management.

Care Home C (0402)

Context - This was a 46 bedded residential home, part of a small local chain run by a charity that specialised in supporting people with sight loss and/or dementia.

Outcome – The GtACH training was delivered in accordance with the training guidelines. Twenty-four GtACH screening and assessment paper tools were completed during the observation period – although most of these (n=14) were completed when researchers were present. Few of those observed were actually completed correctly. It was considered unlikely that the GtACH would be continued post study.

Falls and falls rate increased during the observation period. From 14 falls (baseline) to 20 falls (primary outcome period), and from 5.42 (falls per 1,000 resident days) to 8.85 (falls per 1,000 resident days).

Commentary - An enthusiastic Falls Champion involved all grades of staff in the GtACH completion, and staff reported that it was more in-depth than the home's own documentation. Despite (because of?) this, care staff in this setting were uncomfortable and lacked confidence when faced with the GtACH. Some of whom did not consider 'paperwork' to be part of their job and some who were anxious about their ability to complete the tool correctly. Longer term it was felt unlikely that the GtACH would be used as any change in paperwork had to be adopted by all homes in the chain.

Care Home D (0302)

Context - This was a 40 bedded residential home with a high number of residents with dementia. Only residents with dementia were recruited into the trial.

Outcome - Training was delivered in accordance with the GtACH training guidelines. Implementation fidelity was poor. Only one observation was completed due to cancelled visits and fidelity was assessed via filed tools – in all cases this was judged to be poor. The GtACH was not continued post study period.

Both the number of falls and falls rate increased during the observation period. From 8 falls (baseline) to 16 falls (primary outcome period), and from 8.97 (falls per 1,000 resident days) to 18.29 (falls per 1,000 resident days).

Commentary - This home was part of a very large national chain. The manager had previously worked as the Falls Awareness Trainer for the chain and had trained the staff in falls prevention. Staff felt knowledgeable and confident in falls management. It was reported that most falls occurred in the evenings and that this may be attributed to increased confusion as a result of dementia. The staff perceived the GtACH as a useful prompt but felt that it could not be used as a standalone tool without the entire chain changing practice and procedures.

Care Home E (0209)

Context - This was a small independent residential home with 17 beds and 19 staff.

Outcome - Training was delivered in accordance with the GtACH training guidelines. Implementation fidelity was poor - 3 tools completed during observation period, none of the completed GtACH's were judged to have met fidelity. It was reported that it would be unlikely that the GtACH tools would be continued post study.

Both the number of falls and falls rate decreased during the observation period. From 9 falls (baseline) to 3 falls (primary outcome period), and from 8.33 (falls per 1,000 resident days) to 3.03 (falls per 1,000 resident days).

Commentary - In contrast to the other homes residents here were more physically able and independent in their day-to-day lives, some residents were observed leaving the home to walk around a local park. This home was not registered for dementia care. Few of the residents were considered to be at high risk of falling.

This independent care home had only previously received in-house falls prevention training, and the external training provided as part of FinCH was received with enthusiasm. In contrast, perhaps because residents were more mobile and independent, the GtACH tools was not considered appropriate for the residents' needs.

Care Home F (0107)

Context - This is a 53 bedded residential home which is part of a small family operated chain providing care across five homes.

Outcome - Training was not observed in this setting so it is not possible to comment on the fidelity of the training. Some negative feedback about the training was received, and it should be noted that the Falls Lead did not participate in the in-depth training but was introduced to GtACH at the site initiation visit. The GtACH tool was not inserted into

residents' notes until the latter end of the process evaluation period and consequently the implementation of the GtACH tools could not be observed.

Both the number of falls and falls rate increased during the observation period. From 12 falls (baseline) to 20 falls (primary outcome period), and from 3.19 (falls per 1,000 resident days) to 6.93 (falls per 1,000 resident days).

Commentary - There was a change of management in this home, with the new (temporary) management having little knowledge of the FiNCH study. This meant that the Falls Champion role was not adopted and the implementation of GtACH was delayed. Previous training in this home had been largely limited to in-house training. Staff were reported to be keen to attend falls awareness training. There was however a lack of staff confidence around completing the GtACH.

Table 21: CMO's for six care homes

Care home A (0803)		
Contexts	**Mechanism**	**Outcome**
Knowledgeable staff	Little motivation for change	Persistence of existing practice
Effective falls systems in place	Inertia (inhibits innovation)	Persistence of existing practice
Demarcation of staff roles in falls management – not all staff manage falls	Inflexibility in job roles	Persistence of existing practice – falls champion role not adopted
Existing administrative/paperwork burden	Little appetite for more paperwork	Persistence of existing practice - GtACH tool not adopted
Internal and external management systems	Change processes not owned locally	Persistence of existing practice – change requires corporate approval
A high proportion of residents with dementia, and a consequent greater than average risk of falls	Staff believing that residents with dementia will fall, and so not motivated to introduce change for these residents	Persistence of existing practice with residents with dementia– falls rate does not decrease
Care home B (0703)		
Contexts	**Mechanism**	**Outcome**
Existing administrative/paperwork burden	Reluctance to introduce additional burden	Persistence of existing practice – GtACH tool explicitly not adopted

Nursing staff as part of the care home team	Nurses take ownership and lead falls awareness initiative	Changes to existing practice –all staff encouraged/supported to take part in falls risk management
Demarcation of staff roles in falls management – not all staff manage falls	Cascade of falls risk information (from training) to all staff	Changes to existing practice – broader range of staff engaged in falls management activities
Demarcation of staff roles in falls management – not all staff manage falls	Cascade of falls risk information (from training) to all staff	Changes to existing practice – broader range of staff confident about falls management
Demarcation of staff roles in falls management – not all staff manage falls	Shared responsibility for falls recognised across a broader group of staff	Changes to existing practice – staff more proactive in identifying and responding to falls risks

Care home C (0402)

Contexts	Mechanism	Outcome
Falls systems in place – staff working at capacity	No appetite for practice change	Persistence of existing practice - GtACH tool not adopted
Existing administrative/paperwork burden – staff working at capacity	No appetite for more paperwork	Persistence of existing practice - GtACH tool not adopted
Demarcation of staff roles in falls management – not all staff manage falls	Staff reluctant about taking on new responsibilities	Persistence of existing practice - GtACH tool not adopted
Demarcation of staff roles in falls management – not all staff manage falls	Staff anxious about completing paperwork	Persistence of existing practice - GtACH tool not adopted
External management systems	Change process not owned locally	Long-term adoption of GtACH unlikely
A high proportion of residents with a greater than average risk of falls (residents who are visually impaired and/or with dementia)	Staff believing that residents will fall irrespective of what they do, and so not motivated to introduce change	Persistence of existing practice – falls rate does not decrease

Care home D (0302)		
Contexts	**Mechanism**	**Outcome**
Falls systems in place – staff working at capacity	No appetite for practice change	Persistence of existing practice - GtACH tool not adopted
External management systems	Change process not owned locally	Long-term adoption of GtACH unlikely
Demarcation of staff roles in falls management – not all staff manage falls	Staff reluctant about taking on new responsibilities	Persistence of existing practice - GtACH tool not adopted
Demarcation of staff roles in falls management – not all staff manage falls	Staff anxious about completing paperwork	Persistence of existing practice- GtACH tool not adopted
Knowledgeable staff who had received internal training on falls prevention	No motivation to change paperwork or systems	Persistence of existing practice- GtACH tool not adopted
A high proportion of residents with dementia, and a consequent greater than average risk of falls	Staff believing that residents with dementia will fall, and so not motivated to introduce change for these residents	Persistence of existing practice with residents with dementia– falls rate does not decrease
Care home E (0209)		
Contexts	**Mechanism**	**Outcome**
Independent residents. Few with dementia	Lack of perceived need for change	Persistence of existing practice - GtACH tool not adopted
Independent residents. Few with dementia	GtACH tool considered inappropriate	Persistence of existing practice - GtACH tool not adopted
Demarcation of staff roles in falls management – not all staff manage falls	Staff anxious about completing paperwork	Persistence of existing practice - GtACH tool not adopted
Staff know the residents well	Lack of motivation to adopt a tool which duplicates, rather than adds information, about residents	Persistence of existing practice - GtACH tool not adopted
A staff group who have received limited prior training in falls risk management	GtACH training brings improved knowledge about falls risks	Staff more engaged in falls management activities

A staff group who have received limited prior training in falls risk management	GtACH training brings improved confidence in dealing with falls risk	Staff more engaged in falls management activities

Care home F (0107)

Contexts	Mechanism	Outcome
Frequent changes in management impacting on working practices in the home	Lack of staff ownership with documentation	Persistence of existing practice - GtACH will only be adopted if there is management ownership
Demarcation of staff roles in falls management – not all staff manage falls	Staff anxious about completing paperwork	Persistence of existing practice - GtACH tool not adopted
Demarcation of staff roles in falls management – not all staff manage falls	Staff reluctant about taking on new responsibilities	Persistence of existing practice - GtACH tool not adopted
The Falls Lead was not trained alongside the other Falls Leads, and weaknesses were identified with the training	Lack of confidence to use the GtACH following training	Persistence of existing practice - GtACH tool not adopted
A staff group who have received limited prior training in falls risk management	GtACH training brings improved knowledge about falls risks	Staff more engaged in falls management activities
A high proportion of residents with dementia, and a consequent greater than average risk of falls	Staff believing that residents with dementia will fall, and so not motivated to introduce change for these residents	Persistence of existing practice with residents with dementia– falls rate does not decrease

5.4.4   Recurring Patterns (Demi-regularities)

The effectiveness of the GtACH programme is predicated on two notions: i) that falls risks are better managed when they are identified and specifically rectified (rather than simply quantified); and, ii) that care home staff may benefit from training and peer support in managing falls. Here we introduce five recurring patterns which illuminate the extent to which these notions are fulfilled in the data generated here.

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5.4.5   The Relevance of Prior Practice

All settings included in this evaluation demonstrated the existence of falls management systems prior to the introduction of the GtACH, and no setting totally adopted the GtACH tool and removed their own process. The tool was more often used for the evaluation team rather than being adopted into routine practice. Care home staff indicated satisfaction and familiarity with their existing systems which meant that they were not motivated to adapt their practice and incorporate a new tool:

"I don't think I'd feel any better or, I don't feel I'd do my job any better filling this in every time. The form we've got is adequate" Senior Carer 0209 417

Staff pointed to capacity issues (and to the duplication of effort) associated with the implementation of the GtACH tool:

"It'd be the time element, we wouldn't be able to fill one out three times because it'd be three times for the same thing. We wouldn't have the time to do that because we've already got the action tools to fill out, then we've got the twenty four hour obs to fill out. Erm, so realistically, you know, we wouldn't be filling that out." Carer 0803 502

"Because our paperwork, as it is, takes a lot of our day up, especially when it comes to a fall, you know…to then have to fill out more paperwork, and to duplicate it however many times it happens, it can be time consuming to us, and it takes us away from doing the rest of our work, you know, that's the concern for me." Senior Carer 0302 413

(In accordance with programme theory 1) staff did recognise the value of identifying and specifically rectifying falls risks but felt that their existing systems already achieved this without the need for new tools to complete.

5.4.6   The Relevance of Training

The benefits of the GtACH training were recognised across all settings, with a clear recognition amongst more experienced staff that its benefits reach beyond, and are distinct from, using the GtACH tool:

"…. I liked the training. It was a refresher for myself and the other qualified [staff] …I think, again, it made us look a bit beyond what, why, you know, what medication are they on, have they got an infection? I think we pretty much do that anyway. But there was factors on there that I perhaps didn't think of myself. You know, because it does tell you through the list of other things to look for. I think, we have struggled filling the paperwork in but the knowledge has stayed in our head. I don't know if that's the right or wrong thing to say but the knowledge is certainly there and we do talk and look at why people are falling, but I think some of the care staff struggled with the paperwork." Falls Champion 0703

Training was considered especially beneficial in those settings where prior training had been lacking (or had been internally delivered) (such as Care Homes B, E & F) and in those settings where parts of the staff group had not previously managed falls (such as Care Home B). In

these settings training generated greater knowledge and confidence about falls management, and more acceptance of shared responsibility for managing residents' falls.

Comments in Care Home F expressed a disappointment that more had not been covered in the training:

"Thought it was very good, really. I thought it was going to be a bit more about falls in general, rather than just the form (tool), it seemed to just cover the form (tool), and I thought it was, well, it was just kinda sold to us wrong as staff." Deputy Manager 0107 203

It is manifest in other aspects of the evaluation that the GtACH training did not sufficiently encourage a broad use of the GtACH tool (as perhaps was intended). However, what it did do was act as a refresher for experienced staff and provided new knowledge for the less experienced; training encouraged engagement with falls management, if not with the GtACH tool itself.

5.4.7   Staff Roles

Where "not all staff manage falls" GtACH potentially brings changes to staff roles and responsibilities – no longer are falls the domain of nursing staff or senior staff alone but they become a concern for all. Training might encourage carers to engage in falls management, but this process is more effectively cemented where local staff take ownership of GtACH and support its use. In Care Home B, where the falls rate decreased, it was nursing staff who acted as advocates for GtACH; in Care Home C the Falls Champion sought to engage all staff in its use.

"…because the carers care for the people, and they know them more than what we probably do, and what their daily living is, that's why we're getting involved with the carers with this as well…"Falls Champion 0402 0602

Where (less experienced) staff indicate that they might become engaged with falls they often made a distinction between providing care and completing paperwork:

"…we want to provide practical care and support etcetera, and unfortunately, it's like in the hospitals, there's more and more going in, on to, you know, the computer, on to paper, and it's time consuming, it does take you away from looking after the ladies and gentlemen" Carer 533 0107

Anxiety about completing paperwork was communicated in all Care Homes; and many carers felt that completing formal records was beyond their level of qualification and experience:

"I think is better for someone who is more … higher from me. I am not confident with fill this everything. I think is better job for them, and I think, because, exactly, they have better contact with GP, doctors, everything. They know more better about like, some forms, documents, I mean" Carer Focus Group 0803

The introduction of the GtACH programme challenges care home staff to review their roles and responsibilities with regard to residents' falls. With the provision of training and the support of peers (programme theory 2) such changes seem acceptable to care staff; however, this acceptance does not extend to the incorporation of completing paperwork into their roles.

5.4.8   The Significance of Residents with Dementia.

The presence (or absence) of residents with dementia would seem significant in the implementation of the GtACH programme: it is care homes A (with a high proportion of residents with dementia) and D (where only residents with dementia were recruited) which demonstrate the greatest increase in falls rate; and, it is care home E (where no residents were registered with dementia) which shows the greatest reduction in falls rate. The GtACH tool was not adopted in any of these settings, but for quite different reasons.

In homes A, D and C (with residents who have dementia and/or are visually impaired) falls were considered an inevitable consequence of residents' health. Implementing the GtACH with residents with dementia could not change this underlying factor and was thus considered to be of little value with these residents.

"… *it's silly questions to me, because I know the gentleman has got, probably, the end journey of dementia, he's not going to be able to tell us, you know. He knows, if he gets up, he's not aware of what's around him, you know, and you're asking me these questions where I'm thinking, Oh my God, you know, you lot, you know, people, whatever, you know, I know him that well, he doesn't acknowledge what time of day it is, what's around him or anything, you're asking me these quest- it just doesn't help*". Carer 0402 518

This directly challenges the notion that falls risks can be mitigated and managed by appropriate actions as proposed by programme theory 1. In contrast the circumstances in home E led staff to make a similar assessment, but in this case because no resident displayed a constant and significant risk of falling.

"… *even though we're relatively small as care homes go, we do have quite a lot of able bodied residents, at least half or so, with capacity, so they make their own decisions around their own risks. And it's something that we're very keen on here, that we don't restrain anybody with moving around the home with freedom. So we do have quite a lot of falls, we have periods where we'll have, you know, one or two people that, for whatever reason, do have a number of falls in a short space of time…*" Care Home Manager 0209 104

Although residents fell in this home, the more independent and self-caring nature of the residents meant that risks were perceived differently:

"[*Residents] take their own risks, and it's something that, that we train the staff to, to support residents to explain what the risks are, but actually then make them, allow them to make that decision*". Care Home manager 0209 104

Both the presence and absence of residents with dementia undermine the perceived utility of the GtACH tool – in one setting residents are beyond assistance, in the other they do not require assistance.

5.4.9   Care Home Ownership and Operation

All bar one of the care homes were part of broader organisations - Care Homes A and D part of large national care home groups, Homes B and F part of smaller regional groups and Care Home C operated by a national charity; only Care Home E was independently operated. External management potentially inhibit the freedom with which a home might adapt its local practice, and/or might place restrictions on what might be changed so as to maintain consistency across a number of care settings:

"*As an organisation, across the four homes, because there's four homes, if we want to change anything or do anything, we have to do it as an organisation. So it would not be sort of, if you like, correct for us to suddenly stop using what we already use, and to take on board a different tool, unless we could get that tool approved for the rest of the organisation, particularly around falls and falls prevention.*" Care Home Manager 0402

Of more immediate impact within this study was the requirement for homes to continue using systems and paperwork; GtACH might be used alongside, but not instead of, existing systems and processes. With internal processes a requirement for all staff their motivation to utilise GtACH was somewhat diminished by the sense that it would duplicate their efforts and double their workload:

"*I feel like, well, first of all, we have to fill out the accident form, the legal one. Then we've got our own that we have to fill out. Then we have to go on to the system, and update all the care plans due to the accident, we have to write all what, everything that I've wrote on this, I put on the system, anyway, so I just feel like I'm duplicating myself all the time*" 0402 Senior carer

"*I know that the seniors think that it's a lot, it's a lot of, sort of, it's, if they were doing one or the other, if they were doing, I think they wouldn't mind doing it, but because they're having to fill two lots of documentation in at the moment, they sort of do pull a face and say Oh, I've got another one to fill in, another, more document, paperwork*" Manager 0302

The implementation of GtACH is premised on programme theories which make sense in relation to individual care settings (PT1- identify and act on falls risks, PT 2 - support staff in this), but which might be inhibited by the organisation of broader management systems.

5.5 Discussion

5.5.2   Key Points

Several general points might be made about care home experiences of GtACH intervention:

The impact of GtACH intervention might vary in different settings: in our evaluation the falls rate decreased in two homes, stayed stable in two and increased in two.

It is pertinent to reflect that (1) awareness of the intervention, (2) taking part in training, (3) completing the tool, and (4) taking action to reduce falls might be distinct activities that are not mutually dependent. A commitment to falls management and fidelity in training might impact positively on falls rate without the GtACH tool being widely used in a care home as was evident in some settings here.

Different aspects of the programme sparked different mechanisms: training was viewed as a refresher by some, empowering others and broadening engagement with falls management; the tool was viewed with indifference, considered a duplication of local systems, and was a source of anxiety for some; in some homes local champions encouraged innovation in practice, in others external management inhibited local ownership of change and were a barrier to long-term integration.

Despite these variations the initial programme theories still have broad application.

Falls would seem best managed when specific systematic strategies are aligned to specified risks. However, there was a strong feeling that in people who have dementia falls are viewed as unavoidable and efforts to manage them considered pointless.

The evaluation also demonstrates the value of specialist and peer support to care home staff - although this may not take the form of a formal falls champion but might be more informally managed.

5.5.3   Interpreting the Results

The final element in our realist evaluation is to utilise Normalisation Process Theory (May and Finch, 2009, May, 2013) to reflect upon our findings. NPT is a mid-range, sociological theory which supports understanding how innovation in practice becomes normalised in everyday routines. For the GtACH intervention to become part of everyday practice it needs to be understood by stakeholders (Coherence) and valued by them (Cognitive participation); individuals should be able to enact the work associated with GtACH (Collective action) and the outcome of GtACH should be manifest and observable (Reflexive monitoring). A failure to achieve any of these building blocks is a barrier to GtACH becoming part of normal practice.

Coherence

A recurrent observation was that staff (and some managers) found it difficult to differentiate the GtACH programme from already existing falls management initiatives (evident in demi-regularities 5.4.5 and 5.4.6). GtACH training was identified as a refresher for previously undertaken training; or was viewed as disappointing, too limited in its focus

upon GtACH (rather than upon falls generically). The GtACH tool was viewed in some places as an unwelcome duplication of existing paperwork. It is important to recognise this in the future implementation of the GtACH intervention. It is notable that in Care Home E, where no previous external training had been received, GtACH training was recognised as novel and as improving local understanding – this setting witnessed the largest improvement in falls-rate of those homes included. In Care Home C the GtACH tool was identified as more detailed than local documentation; here, despite a population at high risk of falling, the increase in falls-rate was more marginal and better than in the control arm of the study. Communicating the value and distinctiveness of the GtACH approach is perhaps an important element of any future implementation; distinguishing it from more routine falls assessment will help stakeholders to more readily accept it into local practice. Communicating that GtACH is a more appropriate form of provision might also support adoption and mirrors strategies identified in the management of healthcare in care homes (Goodman et al., 2016).

Cognitive participation

We have noted above that dementia is an important contextual feature which might challenge the underlying legitimacy of the GtACH programme (see also demi-regularity 5.4.8). This is most explicit in Care Home D where (evening) falls were directly attributed to dementia and Care Home C where carers questioned the value of using GtACH tool with residents who have dementia. In Care Home E it was the absence of dementia which brought challenges about the value of the GtACH approach.

The pertinence of dementia-specialist services has been identified in other realist care home research (Gordon et al., 2018) and positioning GtACH in this regard might aid stakeholders in recognising its appropriateness for all care home residents.

A second area where the legitimacy of the GtACH tools has been commonly challenged is by those staff who consider forms to be a distraction from the act of caring for residents, or who view forms to be outside of their job role (demi-regularity 5.3.4.3). To this we might add those staff who lack confidence in completing paperwork. This was manifest across all homes and perhaps suggests that a simpler form of paperwork is required for the future implementation of the GtACH programme, or that different types of GtACH tool are required for different levels of care staff

Collective action

The persistence of local, organisational falls management systems after the introduction of the GtACH programme was perhaps the single most significant barrier to it becoming normalised in those homes. Introducing it alongside existing systems and paperwork (demi-regularity 5.4.9) undermined the contextual integration of the GtACH tool into the actual

work done by care home staff. Staff faced the unenviable dilemma of either duplicating their efforts (for ostensibly the same ends) or ignoring one system or other.

We have noted above that the distinctiveness of GtACH should be stressed to help it to become established; but better still in future implementation GtACH should be adopted as a single, coherent system to the exclusion of other approaches. GtACH needs to be recognised as the most appropriate form of provision (Goodman et al., 2016).

Whilst the GtACH tool did not integrate well into the work done by staff this does not mean that the knowledge gained, and increased awareness of falls made no practical difference. Such differences were most clearly manifest in Care Home B (where falls rate decreased) and Care Home C, in both these locations local individuals championed the GtACH approach and encouraged all staff to change their practice (demi-regularity 5.4.7). The role of the Falls Champion, and other informal advocates of GtACH, should be stressed in future implementation, these individuals have a critical role translating the GtACH approach into workable local practice and in supporting other staff to adapt to new ways of working (Goodman et al., 2016).

Reflexive monitoring

Changes in management in Care Homes A, B and F undermined the coherence of the implementation of the GtACH programme in part (a reluctance to use the tool) or in total (not wishing to introduce new things at a time of managerial uncertainty). Without the commitment and (importantly) monitoring of senior management the delivery and impact of GtACH is uncertain; changes to practice are not rewarded, benefits of new approaches are not recorded. Without locally observed evidence of GtACH making a positive contribution to residents' well-being it is difficult for it to become established - the success of the future implementation of GtACH rests not only in integrating new ways of working but in effective monitoring of impact.

Of more general concern is the role of external management systems in governing local practice (demi-regularity 5.4.9). With the exception of Care Home E (where most improvement was manifest) all other homes had some form of external management system which might impose their own incentives, targets and sanctions (Goodman et al., 2016). For GtACH to become normalised it needs to sit within these wider systems and demonstrate value to the broader corporate group. Future implementation needs to consider how GtACH maps to broader organisational priorities and stress how it serves these metrics.

5.5.4 Process Evaluation Reflections – strengths and limitations

This process evaluation offers detailed, contextualised understanding of how GtACH was delivered and illuminates the experiences and opinions of those stakeholders involved.

Using different methods, it complements the clinical and economic data reported previously and provides a framework for others to interpret these findings. It offers more textured results than the overarching RCT and provides insight about how best to implement GtACH in the future – supporting stakeholders in considering which elements of GtACH might work best in their setting, what adaptations might be required, and which elements might be ignored. In this way it demonstrates the value of a process evaluation aligned with a randomised controlled trial in the trajectory of developing and evaluating complex interventions (Craig et al., 2008).

In line with more recent recommendations (Moore et al., 2015, Moore et al., 2014) a theorised approach to evaluation is taken here with initial programme theories a focus for testing and sampling decisions. The adoption of a realist approach provides a distinctive flavour in this: highlighting contextual variation in how GtACH might work and recognising that subjective responses can be as important as objective change in the delivery of GtACH. This evaluation demonstrates a pragmatic application of the different stages of a realist evaluation: from initial programme theories, sampling to test theories, revised theories (and emergent mechanisms), recurrent patterns in C-M-O configurations, and mid-range theory to explore these patterns.

The evaluation was delivered by a multidisciplinary team and managed independently of the main study – to ensure that care home allocation was not revealed to other parts of the FinCH study (Robinson et al., 2020a), and to ensure that insight did not lead to early adaptation of GtACH whilst still in the trial (Leighton et al., 2019). Each home was visited by multiple researchers on multiple occasions and all data was reviewed by at least two members of the team. Researchers were flexible and responsive to the needs of the care home, accepting that caring responsibilities were more important than our research. Other practical challenges might be taken as limitations: few homes had private space where interviews or focus groups could take place; in some homes staff could only participate when on their break or off-shift; in some, management governed which staff participated; and, research visits and research activities were sometimes cancelled or curtailed at short-notice because of staffing and/or resident issues in the home (Allen et al., nd (under review)).

We should also acknowledge some limitations with the realist method as applied here (Leighton et al., 2019). Resources allowed us to evaluate in one care home at a time recruiting sequentially, this impacted upon our purposive sampling strategy. Rather than being able to recruit from a broad population (the 39 care homes randomised to GtACH) at any one point in time a more restricted choice was possible – recently recruited to the trial, randomised to GtACH but not yet received training and willingness to participate in the process evaluation. The time window of recruitment to GtACH training made local investigation of (for example) prior falls history or staff knowledge (which might have productively directed our purposive sampling) not possible. Consequently, our sampling

used simpler and more restricted characteristics (size, ownership, nursing provision, etc.) to govern where we tested the programme theories.

Difficulties accessing outcome data also impacted upon the realist evaluation. Seeking data for specific homes risked identifying them as receiving GtACH to the trial team; consequently, hard outcome data was not used in the C-M-O configurations, rather these incorporated softer, process concerns for fidelity, acceptability and evidence of use. Also, primary outcome data (falls rate adjusted in accordance with Hospital Episode Statistics) was not available until all trial data collection had been completed; consequently the process evaluation pragmatically used unadjusted data in reviewing care home outcomes. Both these barriers impact upon the completeness of data available to the process evaluation when finalising C-M-O configurations, prioritising mechanisms, and in sampling care homes for inclusion.

Despite these issues this evaluation demonstrates the potential of a realist approach and contributes to recent debates about the integration of realist evaluation within RCTs (Belle et al., 2016, Fletcher et al., 2016, Rycroft-Malone et al., 2018, Bonell et al., 2012). To be explicit, to sit within the FinCH RCT some methodological compromises were necessary, most notably (although not exclusively) in sampling and access to outcome data, but these compromises do not undermine the insight generated here (Leighton et al., 2019). A realist approach has uncovered those contexts where the GtACH intervention had most impact and has identified those reasons and responses to GtACH which make it successful; a realist approach has extended our understanding beyond that which would have been possible with a trial alone.

# 6 PATIENT AND PUBLIC INVOLVEMENT (PPI)

6.1 Introduction

Public and Patient Involvement (PPI) was embedded in the FinCH study to enhance the design, conduct, dissemination of the trial and future implementation findings. The PPI team were instrumental in securing funding, influencing the trial set up and advocating for care home residents throughout the trial. An adaptation of the research cycle (Appendix M) was examined to plan for PPI involvement at each stage of the study, as advocated by INVOLVE (Involve, 2019). The aim was to ensure the trial had relevance to care home residents and care home interested parties, and public. The GRIPP2 short form (Staniszewska et al., 2017) framework was used to ensure consistency. This approach captures the unique perspective of patients and public experience at each stage of the research cycle. This co-designed model with people skilled and willing to enhance the FinCH trial, had a PPI budget of £21,252.00. This chapter first describes and then explores the acceptability and appropriateness of the model.

6.2 Methods

6.2.1 Description of the Hub and Spoke model

A hub and spoke organisational approach, (Elrod and Fortenberry, 2017) where there is a central anchor [Hub] and spokes located at trial sites, was used (Figure 13). Success of this approach is evidenced in healthcare practice and services (Millar, 2014, Huddleston and Zimmermann, 2014).

Figure 13: Hub and Spoke Model
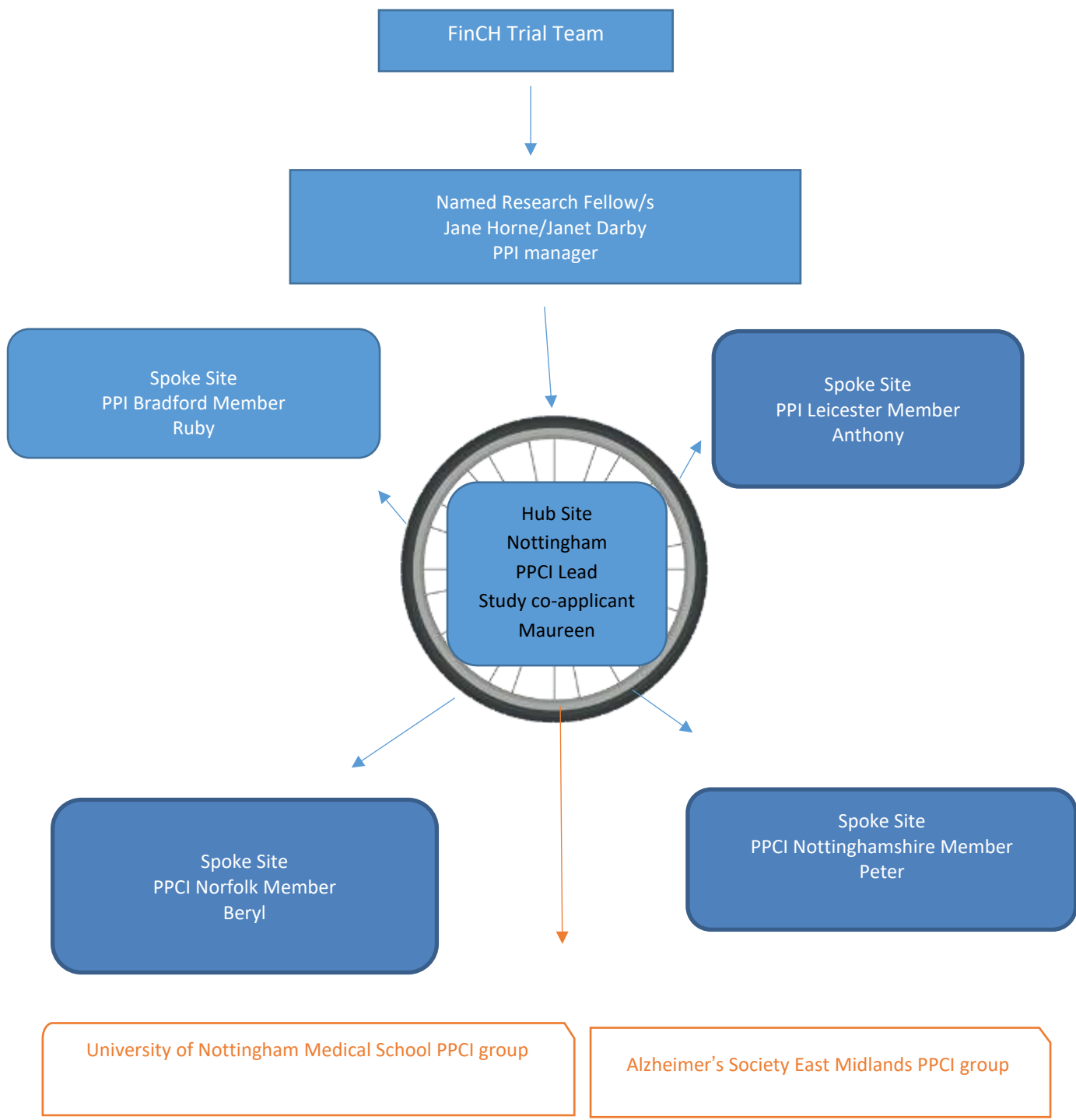
Hub Role in FinCH

A job description focusing on this leadership role, was produced and research networks approached to find interested people with appropriate skills and training. A PPI member who had previous experience of being a carer for a care home resident, and experience on a

range of research projects including RCTs, expressed an interest in the hub role. She was appropriately trained, with leadership experience. She contributed to the monthly trial management group meetings, to oversee the study conduct from a PPI perspective and represent the broader PPI team. This role was supported and managed by a named PPI researcher. Specific support for the role included communication throughout the duration of the trial, via email, telephone, one-one meetings (formal and informal), and open-door access to the wider trial team, including the Chief Investigator to foster professional relationships, and a trial administrator providing administrative support, including the processing of expenses.

Spoke Role in FinCH

The research team recruited 'spoke' members. The PPI researcher asked FinCH networks and Principal Investigators to identify willing individuals to give a minimum of one hour, bi-monthly, to contribute their local trial perspectives. The PPI Lead worked with the PPI researcher to recruit four spoke members with a range of experience. The majority had worked assessing grant proposals and leading PPI roles on research committees. A retired care home manager and nurse (female); a retired medic who had been in a caring role (male); a carer who had previous experience of caring for a partner who had dementia (male); a patient research ambassador (female), who was a lay chair for NIHR joined the FinCH team. The PPI researcher completed a telephone interview with the person and appropriate training was provided in line with the national standards for public involvement (Staniszewska et al., 2018).

PPI attendance at FinCH meetings

In addition, annual investigators meetings were organised as a communication mechanism to engage all trial team members, including the PPI team, to provide an opportunity to interact and connect with the national trial research team, keynote speakers and invited guests. These events included research methods training on topics such as gaining consent and writing an abstract.

Monitoring the GtACH programme delivery

Two members of the PPI team observed the GtACH intervention training in care homes and feedback their perspectives to the process evaluation team via written and vocal reports and to the trial team via the TMG.

Undertaking data analysis for the Process Evaluation

The PPI team participated in the qualitative data analysis, with the trial process evaluation team. PPI members were asked for their perspectives on emerging themes to broaden data

validation. These perspectives were then embedded in the process evaluation findings. The lead PPI member received training organised at the University of Nottingham. Spoke members received training material via email/post and support from a qualitative research expert (JD) via the telephone and email. All five members contributed to the data analysis.

<u>PPI contribution to dissemination of results</u>

The PPI team attended the investigators meeting to reflect on the results and celebrate successful completion and supported workshops on dissemination and ways to add impact. The PPI team contributed to the resources to ensure plain accessible language was used when the key findings were relayed to forums, such as, ENRICH, a research ready care home network. The lay summary for the final report for the funders NIHR was written by the hub lead and this PPI chapter was co-written.

6.2.2   <u>Evaluation of the Hub and Spoke Approach</u>

We evaluated the Hub and Spoke Approach to understand the PPI members' everyday experiences of participating in the trial, making sense of any surprising experiences that arose during the conduct of the main trial and process evaluation component.

<u>Data Collection</u>

Participants took part in a one-hour focus group in August 2019. A prompt sheet was devised to explore the barriers and facilitators of the 'hub and spoke' model. Those that were unable to dial in were offered a one-one telephone interview or written responses using the same prompt sheet. Responses were recorded digitally and transcribed verbatim. Postal responses were collated and filed with the transcription data, prior to analysis.

<u>Data Analysis</u>

Data analysis, was conducted using a framework analysis method (Gale et al., 2013).
The focus group (n=2), one-one interview data (n=1) and postal (n=2) data was examined by two experienced qualitative researchers. A process of familiarization occurred, notes on the transcripts and a simple indexing method was independently conducted.   A thematic framework was constructed, and two researchers met to discuss these initial findings. The next stage resulted in indexing and amalgamating the researcher's frameworks, ideas and differences into one agreed index, and data from the transcripts was applied. This ensured that patterns in the data could be easily identified and any differences and gaps were noted. The data was summarised using the language of the PPI members. Mapping and interpretations were initially undertaken by the qualitative researchers. These were then sent out to participants for comment, views, perceptions and interpretations of the final themes. All five PPI team members participated in the evaluation.

6.3 Findings and emergent themes

Initially twelve themes and 50 sub themes were generated from the data. Final mapping and interpreting the data resulted in identifying five principle themes:

1   Team cohesion, communication and engagement
2   Confidence and personal development
3   Support and training
4   Motivation, commitment and responsibility
5   Identified needs

Theme one: Team cohesion, communication and engagement

Participants referred to the process of forming and developing the PPI team. Initial anxieties revealed uncertainties about whether the hub and spoke approach could work given members were in different locations.

"*I value the diversity and depth of experience from my peer lay members. Embedding their experience at every stage of the study is strengthened by their practical commitment and involvement*" (P1)
I was looked after, but I was definitely on my own. Geographically I was away
from the action and unable to connect to the wider research team. (P4)

However, the benefit of telephone conferences, regular communication via group email, individual email, and postal lay summaries of the trial monthly management minutes appeared to facilitate team cohesion and facilitated performance as a group. The descriptive data suggests that regardless of some initial anxieties' participants perceived the teleconferences mechanism for communication, was effective. One idea that emerged from the data, was to rotate the teleconference around the sites. Making sites feel more included, and potentially, enhancing the 'spoke' member role by chairing teleconferences.

..it has felt very rewarding. And it feels like a new model we are trying, and there is always something nice about trying something new, isn't there? (P1)
Specific tasks that stimulated me and made me feel even more involved, was the process evaluation [data analysis]. I particularly liked that because I think as a team we also contributed. So that gave me a sense of team membership. (P2)

One spoke member chose not to engage in the telephone conferences, as the telephone was not her preferred method of communication. This was established early in the trial and alternatives, such as, posting an accessible agenda for comments, prior to the telephone

conference and posting minutes after the conference for information and comment facilitated inclusion.

Even though based in a different part of the country, felt involved, informed via email and the telephone conference provided a connection to the team (P5)
..your university can get PPI members not just in Nottingham or where you are, you can get PPI members from all over the country or all around the world and we can do this and it works. (P5)

Theme two: Confidence and Personal Development
Participants described the positive reinforcement from the hub lead, their peers and the research team, feeling heard and being listened to, had improved their confidence as PPI members.

'..and in the telephone conference (pause) because I may not have got the right end of the stick about something. But there is a kindly tolerance and indulgence of someone not quite comprehending (laughs) what was written or said. But there was an openness which allowed me to make a contribution.'(P2)

There was acknowledgement that members had differing levels of confidence dependent upon which role they took. The data indicated a strong self-belief in their expertise when contributing to areas they felt they had previous experience.

'I feel valued because I could contribute from a hands on perspective. My strengths were 'I have been there and done that' (P4)

Although all PPI members offered to analyse the process evaluation data they needed training which then helped with improving confidence and led to further personal development.

'It [training] was two days and I think what was so useful about it was that I just like to learn from other people and feel more confident when I am looking at a piece of work, you know? I was able to undertake valuable qualitative research training and have used these skills in FinCH and other studies that I am now working on'. (P1)

Theme three: Support and training

The data highlighted that effective leadership and support from the PPI researcher was crucial to work of the PPI team.

'Throughout I felt valued and supported by everyone in the study' (P1)
'*So what I am really saying is there is a place for people to be involved who have minimal or limited experience. There was appropriate training.' (P2).*

PPI members identified that they would have liked more background information to the topic and one participant felt the training was not adequate enough to let them confidently complete the qualitative data analysis, but the telephone support filled the gap.

It wasn't the training for me (that was most helpful), it could have been for other people. If you wanted more PPI's to be involved that have not done it before (analysed qualitative data) than someone like myself who has, where you could have done with a bit more support. For me personally, the benefit that I had, was to speak to the team (qualitative researcher in the team who delivered the telephone training). (P5)

Theme four: Motivation, Commitment and Responsibility

The PPI team felt that their past experiences were crucial to the role. However, whilst there was merit in experience the data suggests PPI members without such experience could be equally committed and valuable to a study.

'It is quite important to involve people who do not have a great deal of direct understanding, so you achieve two things. You get a better mix of public and patient involvement, and you have people who will ask what seem to be naïve questions, but they are the kind of questions that the engrossed researcher may not have thought to ask.' (P2)

The opportunity to conduct data analysis and to observe the care home training appeared to key activities that were particularly meaningful and motivational to PPI members. These activities enhanced their roles and developed their research knowledge. Enabling these skills to be used in other studies.

'Because we weren't just talking or sat on the outside of the project. Doing that [data analysis] was very useful. Because we were able to understand it better and get involved in the data side and give the input that could help'. (P5)

When participants did not engage in these activities, they expressed regret and said that they had more to give, particularly around the care home training, and described how they were keen to get involved with future studies. Members described observing the care home training as hugely motivational for them. Whilst all members volunteered to engage in this activity, timing was described as an issue. Expanding the observation role to include observation of the intervention, in addition to the training, was a common suggestion from PPI members.

'I was disappointed only to do one care home visit' (P4)
'If this project came up or an extension of this project I would be definitely wanting to put myself forward. Without hesitation I would get involved'. (p5)

'I could have added more value there for you [by visiting a care home] probably missed out because I couldn't get there. ….I think [name of geographical area] has an interesting diversity, so it would have been an interesting insight into staff, staff members who were new to English, you know, a different angle to it, which I feel was missed out'. (P5).

'Observation in the care homes to see the implementation of the tool might be one omission but ethically the participant's privacy must be respected. '(P1)

Theme 5: Identified needs

Leadership and direction as the trial progressed was considered key in terms of keeping the PPI team informed and engaged. A clear understanding of the PPI roles and responsibilities, throughout the research cycle was one area the PPI team felt could have been improved. Although they recognized this is difficult they felt that the stages of the research cycle used by the main trial could have been reinforced in the PPI team.

'I think you have followed that cycle… it would be nice if we (the PPI team) touched base with that cycle as well. It would have been really good, because you could go back over we're on this part, we're here on the cycle in our telephone conferences as well, a bit more… (P5)

The need to be flexible throughout the trial was voiced. Ensuring that members had time to plan their research activity around their often busy lives. The idea that PPI was becoming increasing complex was also expressed within the data. The need for improved induction training or pack was evident in the data. Especially, when members joined the team after the study had started.

'Increasingly as I get involved in the studies they become more and more complex. The role that is asked of PPI is expanding, the process analysis [data analysis] is an example. But I really feel strongly, if you are out of your depth it's best to actually say you are out of your depth. (P1)

Although finance and budgets were not explicitly highlighted in the data, there were a few covert references such as, an acknowledgement of the issue of limited funding generally for PPI. Emerging from the data was an understanding that intensive training (qualitative analysis) was costly and there was an acceptance from lay representatives that such funds were limited.

6.3.2 Impact and influences on the trial

Effective two-way communication was established, ensuring five PPI members contributed diverse knowledge by attending and contributing to 10 telephone conferences. The outcome resulted in 20 written lay statements of the monthly trial management meetings,

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being distributed to improve accessibility of information. There was independent representation at an international PPI conference, and presentation of a poster at a scientific conference.

The participant facing materials were improved with the PPI team's suggestion of pictures and accessible wording. The PPI team were instrumental in helping the research team secure additional funding, with our funding monitoring committee and adapting our recruitment methods, suggesting care home managers were best placed to understand their resident's wishes in terms of participating in this research. This resulted in a 3% increase in recruitment per care home.

Independent perspectives when observing the intervention in four care homes, in addition to analysing the qualitative data, was undertaken by four out of the five PPI members and enriched the qualitative findings.

6.4 Discussion
6.4.1 Main findings
In the evaluation the PPI members described a positive experience of the hub and spoke approach. The data suggested this was an acceptable and workable approach to employ, in future trials. There is evidence that hub and spoke models have been used successfully in other areas of healthcare service and delivery research.

The enhanced role offered to PPI members to view the development of thematic data in the qualitative analysis and offer their perspective was not only valued but embraced by all PPI members. The volition to participate and enthusiasm of all PPI members to undertake this role was a surprise finding for the research team, having assumed not all PPI members would want to participate. It was reported that the quality of PPI member's comments added a valued perspective. There is substantial evidence to suggest how PPI impacts on improving retention and recruitment in trials but limited reporting on the impact in the later stages, with few studies involving older people in data collection and analysis (Fudge et al., 2007).

Contributing to the data analysis and observing the intervention training resulted in issues being identified, pertinent to care home staff and residents that were not thought about by the trial team, which is the purpose of PPI. These contributions have the potential to add to the impact of the trial, in addition to adding value to the PPI role.

Although training was given to PPI members, not all attended face to face training as there was a limited budget for this purpose. It is recommended that future trials include such training into the PPI budget at the proposal stage, to build knowledge, skill and confidence.

Participants also valued the opportunity for enhanced roles and willingly volunteered for roles that required them to observe the intervention in a care home, for example. Finding suitable dates, often at short notice, proved challenging in some sites. In one case the
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observation did not happen, regardless of trying very hard to facilitate a date that worked for the trainer, the care home manager/staff and the PPI member. Future trials should ensure planning research activities well in advance may enable wider participation.

The research cycle was used throughout the trial and guided the trial team to ensure the co-production was evident at each stage of the trial. This resulted in the voice of care home residents and their families being represented throughout the conduct of the trial. Our approach enabled an integration of PPI views and ideas throughout the study that challenged thinking and therefore raised ethical standards (Boivin et al., 2018).

Job descriptions were used to establish role expectation. This process appeared formal when recruiting experts who were volunteering their time willingly. However, the process helped to establish clear expectations, as it is argued that PPI works well when goals are clear (Bagley et al., 2016). In addition, it also gave both the hub and spoke members a baseline to work with, which ensured clarity from the outset. However, the trial was not able to recruit a PPI member in every site. This questions whether there is a pool of adequately skilled personal with lived experiences willing to undertake this role. There is evidence in the literature to suggest this process is challenging (Dudley et al., 2015) and it may not be an easily accessible resource.

The regular PPI telephone conferences provided a means of supporting both experienced and less experienced members and appeared to be the mechanism that ensured team cohesion, coupled with the opportunity to meet face to face. Telephone conferences were evaluated as being cost effective, generating good relationships and provided an opportunity for regular member engagement. The forming and storming stages of establishing a group were evident in the initial few telephone conferences prior to entering the norm and perform stages of Tuckman's small group development model. Tuckman describes these 'necessary stages' as a group matures (Tuckman and Jensen, 1977). An induction pack and being sensitive to people's potential anxiety at the start of a project, could guide PPI members through these initial stages of group formation.

Cost was a factor in our decision to implement a hub and spoke approach. By operating a network approach, linking in members from various sites to the hub via telephone conferences and email, ensured that travel costs to attend training and FinCH meetings were kept to a minimal. Members reported they felt they had sufficient information to keep them involved and active without high travel costs and cost to the environment.

Once the telephone conferences were established there was commitment and buy-in from PPI members. When time enabled them to participate, they dialled in, contributed to the agenda items, followed up with ideas, and demonstrated a respect and humour evident in the content of the calls. They described having a voice, to be able to talk and be heard. They appeared to value the respect, evidenced by feeling their suggestions were discussed and actioned by the research team.

6.4.2 Critical reflection

Using the UK standards for public Involvement in Research as a framework (Involve, 2019) we present: What we did, what we might do differently and what other researchers might learn from our experience.

Inclusive opportunities

We involved key PPI members from the very early stages of the project's development and design and the lead PPI member was a co-applicant on the grant. Some PPI members were recruited later. These members were provided with information and a job description; an induction pack may have helped with clarity of the role and relieve any initial anxieties about their role on the study.

Working together

The investigators' annual meetings included targeted PPI sessions and quality external training. A planned budget enabled transport to be provided and PPI members were encouraged to attend. Resulting in members feeling they were a cohesive group, valued, and listened to. We would increase our efforts to encourage every member to attend as it facilitated integrated working.

Support and learning

We sought PPI perspectives on emerging themes in the qualitative data, after analysis had been conducted in the first three homes. Face to face data analysis training was not provided for all, due to limited budgets. We would aim to provide this training in future trials to enhance the PPI role in undertaking data analysis. There was an appetite to engage in this activity. Training would be essential.

Communication

The regular telephone conferences ensured all members were included and communicated with at each stage of the trial. A two-way open communication mechanism was a useful engagement tool. Members, not comfortable with technology, alternatives, such as, post and paper were used. This ensured they were not excluded. Future trials might include similar mechanisms or other digital platforms, such as, zoom or MS teams for this purpose.

Impact

 A collaborative poster (research team/PPI) illustrating the hub and spoke approach and how this worked in an RCT, won the best AHP prize at the 2016 BGS spring conference.

Governance

The lead hub member attended the ethics committee at the beginning of the project. Demonstrating both lay and academic perspectives were being presented. The lead hub PPI member contributed to the funders oversight and monitoring meetings. We would recommend adopting this approach as it demonstrates leadership, accountability, and shared responsibility.

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7   DISCUSSION

7.1 What this trial shows

Care homes where the Guide to Action for Falls Prevention programme was implemented experienced significantly lower falls rates than homes where the programme was not used. The primary RCT outcome result showed an unadjusted Incidence Rate Ratio (IRR) of 0.57 (95% CI 0.45-0.71, p<0.01) in favour of the GtACH programme. The fall rates over this period were 6/1000 residents in the GtACH group and 10.4/1000 residents in the usual care group. This translates to a falls rate per participant per year of 2.2 for the intervention group and 3.8 for the control group. The secondary RCT results saw a significantly lower falls rates in the GtACH programme participants for the month 1-3 period, but not in the months 7-9 or 10-12 periods. There were no differences between groups in any of the other secondary outcomes. In the base case analysis the mean cost per resident was £3955 in the GtACH arm and £3935 in the usual care arm, with an adjusted mean difference in cost of £108 (95% CI -271.06, 487.58) representing the mean additional cost per resident in the GtACH arm. In the base case, the DEMQoL-based QALYS were 0.578 in the GtACH arm and 0.581 in the usual care arm, with incremental QALYs of 0.005 (95% CI -0.019, 0.03). The respective numbers for EQ-5D-based QALYs was 0.266 and 0.232, with incremental QALYs of 0.024 (95% CI 0.004, 0.044). The incremental cost per DEMQoL-based QALY was £20,889 and £4,544 per EQ-5D based QALY. The base case incremental cost per fall averted was £191.

The intervention programme was feasible: 69% of care homes achieved acceptable levels of staff training, with 80% of staff working in a caring role trained. It was also likely to be affordable: the mean cost per resident of the GtACH programme was £88. The process study showed that the GtACH programme was widely accepted by stakeholders. Care home staff valued the way in which the GtACH programme helped them address specific falls risks directly, and the emphasis on training and peer support. They valued that different elements of the GtACH programme might work independently of each other and be of benefit to the care home residents. Improved knowledge acquired through training or an increased awareness of falls through taking part in the GtACH programme, did not always trigger completion of the GtACH tool. However, action was taken to limit falls risks, which is the likely mechanism for the reduction into falls rates.

7.2 Comparison with other studies

Prior to the FinCH trial there was an indication, from the Cochrane care home and falls prevention reviews, that multifactorial interventions could prevent falls but the evidence for effectiveness in care homes was limited and of low quality. FinCH was the largest care home RCT completed to date to evaluate a multi-factorial falls prevention intervention and it has added a large amount of data to the evidence base (increasing it by over 50%).

The Cochrane review (Cameron et al., 2018) recommended further research into falls in care homes, with emphasis on evaluating an individualised, standardised approach to delivery of interventions that are adequately described and therefore easily replicated or implemented and using a mixed methods approach. The FinCH study met these recommendations by using a published and standardised falls prevention programme, successfully replicated delivery across 87 care homes (control homes were given the training at the end of the study) and measuring effectiveness through a randomised controlled trial that followed CONSORT guidelines, a process evaluation, an economic evaluation and resident, care home staff and public collaboration.

In closer comparison to the existing evidence, the Cochrane review identified 13 studies where multifactorial interventions in care homes were trialled. These included studies ranging from 31 to 682 participants. The FinCH study was considerably larger with 1657 recruited participants. The FinCH study reported the rate of falls in the same way as the Cochrane review, by measuring the total number of falls per unit of person time. Studies report a range of 1.7 falls per person per year (Rubenstein, 2006) to 2.51 fall per person per year (Kennedy, 2015). This FinCH study found slightly higher rates, with the intervention group having a rate of 2.2 falls per year and the control group a rate of 3.8 falls per participant per year. These were similar to those seen in the Falls in care Homes feasibility study (Walker et al., 2016), and could indicate that residents in care homes are falling more than in previous years, that care home residents in the UK are more likely to fall than in Canada or the US (where the Kennedy and Rubenstein studies were conducted) or that some intrinsic selection factors recruited those residents at greater risk of falls.

In order to be able to compare the results of FinCH to other studies it is useful to compare the populations on a range of outcomes. Hospital admission rates usually indicate a person is unwell and although a blunt measure, it can be objectively measured and is needed in health economic evaluations. The mean number of hospital inpatient days for participants in the FinCH study was 1.8 days per year, which is lower compared to the study by Gordon (Gordon et al., 2014b) who found in a cohort of 227 participants they had a mean of 2.2 days in hospital. This could indicate that the FinCH participants were more stable than those recruited by Gordon et al, or that interventions undertaken across the UK to reduce admission of care home residents to hospital (Wolters et al., 2019) may be working to reduce admissions.

The Barthel Index was used in the FinCH trial to measure activities of daily living ability and although there was no difference between groups, the mean score of 8 points out of 20 indicates that most of the population could walk around the home with the use of aids, feed themselves and were continent. Another large care home study of a rehabilitation intervention, the Occupational Therapy in Care Homes Trial (OTCH) (Sackley CM et al., 2009) which recruited 1042 residents with stroke from 227 care homes, found that 70% of the participants recruited were classified as severely limited on the Barthel Index, at baseline, with 50% in the very severe (0-4) category. OTCH, however, was focussed primarily on stroke related disability, most of whom are immobile and dependent, since less impaired

patients with stroke are discharged to home. FinCH, meanwhile, focussed on residents at risk of falls, and by definition ambulant, with this being the likely explanation for the difference between the cohorts recruited for these two large studies.

7.3 Strengths and limitations

This is the largest randomised controlled trial of a falls prevention intervention in care homes in the UK to date. The study was well powered to detect meaningful differences in falls rates, even allowing for our inflation for the power calculation and adjustment of recruitment targets during the study. Clinically plausible outcome measures, likely to be impacted by the GtACH, were used. We adhered to best practice for resident and public involvement, randomisation, allocation, outcome assessment and analysis. We took overt steps to reduce contamination bias (Robinson et al., 2020b). Research assistants collecting outcome data were blinded and less than a third of residents (29%) were accidentally un-blinded as the study progressed.

A potential limitation was that the care home staff and participants were not blind to allocation, due to the nature of the intervention. In common with all falls trials, a limitation is the possibility of falls ascertainment bias: care home staff might have been sensitised to falls and more likely to record them in the intervention arm due to the awareness raising aspect of the GtACH programme. We believe we minimised this risk by only recruiting care homes in which there was a well-established falls recording system in place before randomisation. It is not clear if such bias occurred, or if it did what effect it might have had on our results. We assume that if there was an effect it would have increased fall reporting in the homes allocated to the GtACH programme and thereby attenuated our observed effect size. For this reason, we believe our positive primary study finding is unlikely to be due to bias.

The care homes we recruited were generally representative of UK care homes and hence our findings are likely to be generalizable within the UK and settings with similarly sized and run care homes: 10 sites in England took part, spread across urban, suburban and rural locations, and 87/186 home we approached took part. However, we acknowledge that the impact of the GtACH programme may differ in other countries and settings, such as some nursing homes where medical and therapy staff are on site and regularly contribute to care. In such settings, the GtACH programme may contribute little, but it is likely that some kind of structured and evidence-based approach to falls management will be associated with a reduction in falls incidence. Although the GtACH programme was implemented across all residents in an allocated care home, we were not able to recruit all residents in all homes. Residents lacking mental capacity to give consent and where no suitable consultee was available were a particularly under-recruited group in common with other care home studies(Luff R, 2015). However, we have no reason to think that the programme would be more or less effective in residents we were not able to recruit.

Another strength of this study is that we conducted a process evaluation undertaken by a research team independent of the RCT trial team. This not only helped to illuminate the mechanisms by which the intervention led to the improved outcomes but also identified where its implementation could be improved. The findings of the process evaluation will be of value in optimising the subsequent adoption of this intervention beyond this trial setting.

We recognise that the measurement of quality of life in care home residents sufficient for economic analyses is challenging, largely because of the high prevalence of cognitive impairment in this population which makes it difficult for them to complete assessment schedules asking questions about abstract concepts such as quality of life. For this reason, we chose two approaches to measuring QALYs, the widely used EQ-5D-5L and the more recently developed DemQol. Our estimates of cost utility differed between these two approaches – using the EQ-5D-5L the GtACH programme was conventionally cost effective but using the DemQol it was only of borderline cost effectiveness. At the time we finalised our analysis plan we chose the DemQol over the EQ5D, although this decision was finely balanced. Since then, limitations to DemQol has led to the development of a care home specific version, DEMQOL-CH. Although there are limitations using the EQ-5D-5L in this setting it has consistently evaluated better than other Quality of Life measures in care homes (Hughes LJ, 2019). Given the uncertainty of the methods available to assess cost utility in care home residents, whilst we cannot conclude that the GtACH programme was unequivocally cost effective, we have presented evidence that it is soundly cost effective when using the EQ-5D, but of borderline cost effectiveness when using the (original) DemQol. We would argue that decision makers should not rely solely upon one effectiveness or economic statistic to make funding decisions, and that the overall evidence presented here supports a decision to implement the GtACH programme more widely.

7.4 Adoption and implementation

Given our findings, we believe that further trials of falls prevention interventions against usual care in care homes are no longer required or justified, although this and any other trials recently and yet to be completed should be added to existing meta-analyses. We believe that it is important now to put these findings into practice as widely and swiftly as possible so that the GtACH programme, or other programmes derived from it, become part of usual care in care homes. The GtACH programme was extensively developed and delivered before being evaluated in this trial and hence is inherently designed to be suitable for implementation. Our process evaluation sheds light on how it could be implemented even more effectively, for example by greater engagement with care home provider organisations to encourage the adaptation of the GtACH programme and documentation to the systems and processes of different care homes.

There are very few published papers of care home research and implementation.   A recent rapid review and consensus study around implementation in care homes (Bunn, 2020) recommended consistent and regular, fluid conversations across diverse care home settings with close attention to understanding when care homes are ready for change and what

measures have to be taken to enable them to be so. An increasing body of evidence suggests that implementation and improvement in care homes must be led by care home staff, with NHS colleagues playing a facilitatory role, with the aim being to support the development of improvement capacity in care homes in parallel with implementation (Chadborn NH, 2020;) .

Stacey (Stacey, 2019) looked to determine the use of patient decision aids in clinical practice following RCTs. Only 44% of trial authors indicated some level of subsequent use following the trials. Douglas in 2019 explored the difficulty behind translating evidence-based healthcare innovations into clinical practice settings (skilled nursing facilities) and examined barriers and facilitators for implementation and found that engagement of managers was crucial, and time for investment was needed.

A key issue for implementation of the GtACH programme is whether the short term effect could be extended to a longer term effect, or whether the short term effect of a relatively inexpensive intervention is enough to persuade people to implement the GtACH programme. It is an important consideration that reduction in falls rates was not maintained beyond 6 months after randomisation. The process evaluation findings suggested that the training was beneficial, increasing staff knowledge and awareness of falls risks and providing skills to reduce the risks, but it also indicated that one component (the paper assessment) of the programme was not completed as regularly as expected. This appeared to be due to a number of barriers including care staff not allowed to write in care records and lack of on-going support and training from the GtACH trainers. By not reinforcing the learning through physically completing the paper assessment the longer-term implementation of the GtACH programme may have been lost. Working out how to better embed learning into longer-term practice will be an important component of follow-on work.

The study identified a number of contextual features which are pertinent to how the GtACH programme is received and used. Existing falls management processes, prior staff training in falls, strongly demarcated staff roles, external management systems, and a high proportion of residents with dementia might all impact upon how GtACH is implemented. Subsequent long term implementation of the GtACH programme will need to address these issues, but not through a series of external interventions by NHS staff. Rather, in keeping with care home implementation research, they can only be addressed if care home staff see value in doing so. Dissemination materials must look at packaging the important learning from FinCH in such a way that it is accessible, and immediately useable by care home staff, and in such a way that the work can be seen to align with their organisation and personal priorities, and achieve immediate recognisable results. Normalisation process theory(Murray, 2010) suggests that minimising additional work is essential for implementation. How to do this is dependent upon leadership by the care home sector, since it is care home staff who understand their own organisational processes and routines.

Essentially if the GtACH programme is to be implemented the following actions should be taken into consideration:

- The care home community needs to be supported to lead the implementation process and any implementation research. Where the GtACH programme was championed by local staff (formally or informally) it had greater impact.
- Information aimed at care home owners, managers, staff and residents should be aimed to highlight the ways in which the benefits of the GtACH programme align with individual and organisational priorities.
- The context of the care home will need to be assessed in a sensitive way to understand any barriers to training or use of the GtACH programme. For example in care homes that were willing to be recruited into the study the care home staff indicated a willingness to take part in the research, attend training, explore quality improvement concepts and assist with data collection. It maybe that these homes had a different context to homes who did not offer to be in the research study. Plus, in the context where no prior training had been received, or where training had been solely managed internally, care home staff were keener to adopt the GtACH programme. In the context where not all care home staff were allowed to write in care records the GtACH paper assessments were not completed as regularly as in other homes. But, again, the emphasis should be on enabling care home managers and staff to assess, and respond to their own organisational contexts.
- The role for NHS staff in this will be championship, an approach long established to work in care homes. NHS Falls Leads may be well placed to do so, but will be particularly enabled where care home work is recognised and protected within their job plans.
- The GtACH programme consists of awareness, training, a tool and action and although we acknowledge that its elements might be independently important but it is the combination of the components which makes it a programme. The only justifiable conclusion based upon the FinCH study is that the GtACH programme should be delivered as a whole to gain similar results.
- The strongest impact of the GtACH programme followed its introduction, whilst it remained a novelty and is a focus for attention. Beyond this period, existing systems may re-emerge as the normal way of working. For future implementation, this means that the distinctiveness and benefit of the GtACH programme (beyond standard falls management) need to be better communicated to encourage stronger engagement.

There are some important areas for further research to be conducted in tandem with implementation. The GtACH training increased knowledge and awareness in the short term, however, to maintain knowledge we know whether learning is better established when it is enacted on a regular basis, and how to reinforce such activities. The GtACH programme

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content may need to be in different formats, as some homes only use electronic records and some only use paper. Online/electronic/ smart phone digital platforms that host the components of the GtACH programme may need to be developed. For future implementation the role of the GtACH programmes' associated paper resources should be considered – it may be that GtACH can make a difference without all staff completing dedicated paperwork. Or it could be that revised or simplified versions of the GtACH programme are created for less experienced staff to complete. Given the above points about minimizing effort to support implementation, minimising the labour associated with the GtACH will be an important consideration. In some homes with a high number of residents with dementia, falls were considered inevitable, and initiatives such as the GtACH programme considered ineffectual and not worth implementing, therefore future implementation rests in appropriate adaptation of the GtACH programme for residents with dementia; or in clearer communication of the pertinence/application of the GtACH programme to residents with dementia. Targeted co-design work with care home staff would be a powerful means by which to achieve this.

7.4.1   Lessons learnt

Care homes are keen to take part in research studies, residents could be recruited, and reliable data could be collected. Processes for claiming costs to deliver interventions under evaluation and costs for staff to attend training and help with data collection for care homes to take part in research projects may have discouraged some homes from taking part. Few of the care home staff had any research experience. Care home staff learn about research by doing, and this is central to capacity development. Life expectancy in care homes is short so studies need relevant primary outcomes to be measured in a timely manner. Data from NHS digital was difficult to obtain, meaning many of the participants had died before the results could be analysed.

7.4.2   Conclusions

The intervention showed a significant reduction in falls. This was achieved without a reduction in residents' activity levels or an increase in dependency. The GtACH programme was likely to be cost effective at current thresholds used in the UK, and was accepted by care home staff and residents. The programme should be implemented widely, through a programme designed to empower care home staff to lead its implementation. There are a number of important   implementation research questions that require to be addressed in parallel with this process.

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Contribution of authors:

Pip Logan (Professor of Rehabilitation) was the chief investigator, from the concept of the study, through to lead authorship of the final report.

Jane Horne (Senior Research Fellow and Occupational Therapist) was the intervention trial manager, providing clinical advice and support to the falls leads delivering the intervention. Co-trained the falls leads (therapists). Managed PPI members, co-authored PPI chapter. Contributed important intellectual content to the report.

Sarah Armstrong (Professor of Medical Statistics) oversaw the statistical analysis of the trial. Jointly prepared statistical results for publication, contributed to the development of the trial application and trial protocol and contributed important intellectual content to the report.

Allan Clark (Senior Statistician) jointly prepared the statistical plan, analysis and results for publication. Advised the oversight committees on statistical procedures and analysis. Contributed important intellectual content to the report.

Simon Conroy (Professor of Geriatric Medicine, Geriatrician) contributed to the grant application and protocol and contributed important intellectual content to the report.

Janet Darby (Research Fellow) jointly conducted the qualitative interviews and analysis for the process evaluation. Jointly prepared the qualitative results for publication. Contributed to the grant application, trial protocol and contributed intellectual content to the report.

Chris Fox (Professor of Clinical Psychiatry) contributed to study design, interpretation of data, and intellectual content to the final report.

John Gladman (Professor of the Medicine of Older People), contributed to the grant application, protocol and contributed important intellectual content to the report.

Maureen Godfrey (Patient and Public Representative) contributed to the grant application and protocol, observed the intervention, contributed to the qualitative data analysis, co-authored the PPI chapter and wrote the lay summary for the final report.

Adam Gordon (Professor of the Care of Older People) contributed to the study protocol, and contributed important intellectual content to the report.

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Karen McCartney (Research Fellow) prepared the protocol for publication and contributed to the preparation of the final report.

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Data sharing statement:

All data should be submitted to the corresponding author for consideration. Access to anonymous data may be granted following review

REFERENCES

AGE UK 2019. Later Life in the United Kingdom 2019.

ALLEN, F., COOK, M., DARBY, J., EVLEY, R., GODFREY, M., HORNE, J., LEIGHTON, P. & LOGAN, P. nd (under review). Learning gleaned from a successful Process Evaluation in care homes. *AGe and Ageing* under review.

BAGLEY, H. J., SHORT, H., HARMAN, N. L., HICKEY, H. R., GAMBLE, C. L., WOOLFALL, K., YOUNG, B. & WILLIAMSON, P. R. 2016. A patient and public involvement (PPI) toolkit for meaningful and flexible involvement in clinical trials–a work in progress. *Research involvement and engagement,* 2**,** 15.

BELLE, S. V., WONG, G., WESTHORP, G., PEARSON, M., EMMEL, N., MANZANO, A. & MARCHAL, B. 2016. Can "realist" randomised controlled trials be genuinely realist? *Trials,* 17.

BOIVIN, A., RICHARDS, T., FORSYTHE, L., GRÉGOIRE, A., L'ESPÉRANCE, A., ABELSON, J. & CARMAN, K. L. 2018. Evaluating patient and public involvement in research. British Medical Journal Publishing Group.

BONELL, C., FLETCHER, A., MORTON, M., LORENC, T. & MOORE, L. 2012. Realist randomised controlled trials: A new approach to evaluating complex public health interventions. *Social Science & Medicine,* 75**,** 2299-2306.

BRAUN, V. & CLARKE, V. 2006. Using thematic analysis in psychology. *Qualitative research in psychology,* 3**,** 77-101.

BUNN, E. A. 2020. 'Setting Priorities to Inform Assessment of Care Homes' Readiness to Participate in Healthcare Innovation: A Systematic Mapping Review and Consensus'. *International Journal of Environmental Research and Public Health,* 17(3)**,** 987.

CAMERON, I. D., DYER, S. M., PANAGODA, C. E., MURRAY, G. R., HILL, K. D., CUMMING, R. G. & KERSE, N. 2018. Interventions for preventing falls in older people in care facilities and hospitals. *Cochrane database of systematic reviews*.

CHADBORN NH, D. R., HINSLIFF-SMITH K, ET AL 2020;. Quality improvement in long-term care settings: a scoping review of effective strategies used in care homes *Eur Geriatr Med* doi:10.1007/s41999-020-00389-w.

COMPETITION & MARKETS AUTHORITY 2017. Care homes market study: Final report.

CRAIG, P., DIEPPE, P., SALLY MACINTYRE, MICHIE, S., NAZARETH, I. & PETTICREW, M. 2008. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ,* 337**,** a1655.

DEPARTMENT OF HEALTH. 2009. *Falls and Fractures: effective interventions in health and social care.* [Online]. Available: http://www.laterlifetraining.co.uk/wp-content/uploads/2011/12/FF_Effective-Interventions-in-health-and-social-care.pdf [Accessed].

DEVI, R., MEYER, J., BANERJEE, J., GOODMAN, C., GLADMAN, J. R. F., DENING, T., CHADBORN, N., HINSLIFF-SMITH, K., LONG, A., USMAN, A., HOUSLEY, G., BOWMAN, C., MARTIN, F., LOGAN, P., LEWIS, S. & GORDON, A. L. 2018. Quality improvement collaborative aiming for Proactive HEAlthcare of Older People in Care Homes (PEACH): a realist evaluation protocol. *BMJ Open,* 8**,** e023287.

DUDLEY, L., GAMBLE, C., ALLAM, A., BELL, P., BUCK, D., GOODARE, H., HANLEY, B., PRESTON, J., WALKER, A. & WILLIAMSON, P. 2015. A little more conversation please? Qualitative study of researchers' and patients' interview accounts of training for patient and public involvement in clinical trials. *Trials,* 16**,** 190.

DYER CA, TAYLOR GJ, REED, M., ROBERTSON DR & R, H. 2004. Falls Prevention in Residential Care Homes: A randomised controlled trial.

ELROD, J. K. & FORTENBERRY, J. L. 2017. The hub-and-spoke organization design: an avenue for serving patients well. *BMC health services research,* 17**,** 25-33.

EMMEL, N., GREENHALGH, J., MANZANO, A., MONAGHAN, M. & DALKIN, S. 2018. *Doing Realist Research,* London, Sage.

FLETCHER, A., JAMAL, F., GRAHAM, M., EVANS, R., MURPHY, S. & BONELL, C. 2016. Realist complex intervention science: Applying realist principles across all phases of the Medical Research Council framework for developing and evaluating complex interventions. *Evaluation,* 22**,** 286-303.

FUDGE, N., WOLFE, C. & MCKEVITT, C. 2007. Involving older people in health research. Age and Aging: Oxford University Press.

GALE, N. K., HEATH, G., CAMERON, E., RASHID, S. & REDWOOD, S. 2013. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC medical research methodology,* 13**,** 117.

GILLESPIE, L. D., ROBERTSON, M. C., GILLESPIE, W. J., SHERRINGTON, C., GATES, S., CLEMSON, L. M. & LAMB, S. E. 2012. Interventions for preventing falls in older people living in the community. *Cochrane database of systematic reviews*.

GOODMAN, C., DAVIES, S. L., GORDON, A. L., DENING, T., GAGE, H., MEYER, J., SCHNEIDER, J., BELL, B., JORDAN, J., MARTIN, F., ILIFFE, S., BOWMAN, C., GLADMAN, J. R. F., VICTOR, C., MAYRHOFER, A., HANDLEY, M. & ZUBAIR, M. 2017. Optimal NHS service delivery to care homes: a realist evaluation of the features and mechanisms that support effective working for the continuing care of older people in residential settings. *Health Services and Delivery Research,* 5.

GOODMAN, C., DENING, T., GORDON, A. L., DAVIES, S. L., MEYER, J., MARTIN, F. C., GLADMAN, J. R., BOWMAN, C., VICTOR, C. & HANDLEY, M. 2016. Effective health care for older people living and dying in care homes: a realist review. *BMC health services research,* 16**,** 269.

GORDON, A. 2015. What is the case for care home medicine? The geriatrician's perspective. *Royal College of Physicians of Edinburgh*.

GORDON, A., GOODMAN, C., DENING, T., DAVIES, S., GLADMAN, J. & BELL, B. 2014a. The Optimal Study: Describing the key components of optimal health care delivery to UK care home residents: A research protocol. Journal of the American Medical Directors Association.

GORDON, A. L., FRANKLIN, M., BRADSHAW, L., LOGAN, P., ELLIOTT, R. & GLADMAN, J. R. 2013. Health status of UK care home residents: a cohort study. *Age and ageing,* 43**,** 97-103.

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

GORDON, A. L., GOODMAN, C., DAVIES, S. L., DENING, T., GAGE, H., MEYER, J., SCHNEIDER, J., BELL, B., JORDAN, J., MARTIN, F. C., ILIFFE, S., BOWMAN, C., GLADMAN, J. R. F., VICTOR, C., MAYRHOFER, A., HANDLEY, M. & ZUBAIR, M. 2018. Optimal healthcare delivery to care homes in the UK: a realist evaluation of what supports effective working to improve healthcare outcomes. *Age and Ageing,* 47**,** 595-603.

HOFFMANN, T. C., GLASZIOU, P. P., BOUTRON, I., MILNE, R., PERERA, R., MOHER, D., ALTMAN, D. G., BARBOUR, V., MACDONALD, H. & JOHNSTON, M. 2014. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *Bmj,* 348**,** g1687.

HUDDLESTON, P. & ZIMMERMANN, M. B. 2014. Stroke care using a hub and spoke model with telemedicine. *Critical Care Nursing Clinics,* 26**,** 469-475.

HUGHES LJ, F. N., PAGE TE, ET AL 2019. Adaptation of the DEMQOL-Proxy for routine use in care homes: A cross-sectional study of the reliability and validity of DEMQOL-CH. *BMJ Open* doi:10.1136/bmjopen-2018-028045.

INVOLVE. 2019. *The UK standards for public involvement in research.* [Online]. Available: https://sites.google.com/nihr.ac.uk/pi-standards/home [Accessed Date accessed 08/April 2020 2020].

L, C. & A, B. 2018. Personal Social Services Research Unit *Unit Costs of Health and Social Care,* Available: https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2018/ Accessed: 05 03 2020.

LAING, W. 2017. *Care homes for Older People market analysis and projections* [Online]. Available: www.laingbuissonevents.com/wp-content/uploads/2017/05/William-COP.pdf [Accessed].

LAVRAKAS, P. J. 2008. Encyclopedia of survey research methods (Vols. 1-0).

LEIGHTON, P., DARBY, J., ALLEN, F., EVLEY, R. & LOGAN, P. 2019. PS9D-03 What worked for us in which circumstances, and what didn't; reflections upon incorporating a realist evaluation within a clinical trial of a complex intervention. *TRIALS,* 20.

LIVINGSTON, G., BARBER, J., MARSTON, L., STRINGER, A., PANCA, M., HUNTER, R., COOPER, C., LAYBOURNE, A., LA FRENAIS, F. & REEVES, S. 2019. Clinical and cost-effectiveness of the Managing Agitation and Raising Quality of Life (MARQUE) intervention for agitation in people with dementia in care homes: a single-blind, cluster-randomised controlled trial. *The Lancet Psychiatry*. 2019 Apr 1;6(4):293-304.

LOGAN, E. A. 2019. Evaluation of the Guide to Action Care Home fall prevention progamme in care homes for older people: protocol for a multi-centre, single blinded, cluster randomised controlled trial (FinCH). www.nottingham.ac.uk/emran: The University of Nottingham.

LUFF R, L. A., FERREIRA Z, ET AL 2015. A guide to research with care homes. *Qual Ageing Older Adults* 16**,** 186–94.

MARSHALL, M. E. A. 2017. What we know about designing an effective improvement intervention (but too often fail to put into practice). *BMJ quality & safety*, 578-582.

MAY, C. 2013. Towards a general theory of implementation. *Implementation Science,* 8.

MAY, C. & FINCH, T. 2009. Implementing, Embedding, and Integrating Practices: An Outline of Normalization Process Theory. *Sociology,* 43**,** 535-554.

MILLAR, L. 2014. Use of Hub and Spoke model in nursing students' practice learning. *Nursing Standard,* 28.

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

MOORE, G. F., AUDREY, S., BARKER, M., BOND, L., BONELL, C., HARDEMAN, W., MOORE, L., O'CATHAIN, A., TINATI, T., WIGHT, D. & BAIRD, J. 2015. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ : British Medical Journal,* 350.

MURRAY, E. 2010. N ormalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC Medicine*.

NHS. 2018. *Injuries due to falls in people aged 65 and over*

 [Online]. Available: https://www.nhs.uk/Scorecard/Pages/IndicatorFacts.aspx?MetricId=8135 [Accessed].

NHS 2019. The NHS Long Term Plan.

NHS ENGLAND. *Ageing well and supporting people living with frailty* [Online]. Available: https://www.england.nhs.uk/ourwork/clinical-policy/older-people/frailty/ [Accessed].

NICE. 2013. *Falls in older people: assessing risk and prevention* [Online]. Available: https://www.nice.org.uk/guidance/cg161/resources/falls-in-older-people-assessing-risk-and-prevention-pdf-35109686728645 [Accessed].

PAWSON, R. 2006. *Evidence Based Policy: a realist perspective,* London, Sage.

PAWSON, R. 2010. Middle Range Theory and Programme Theory Evaluation: From Provenance to Practice *In:* VAESSEN, J. & LEEUW, F. (eds.) *Mind the Gap: Evaluation and the Disciplines.* Abingdon: Routledge.

PAWSON, R. 2013. *The Science of Evaluation - a realist manifesto,* London, Sage.

PAWSON, R. & TILLEY, N. 1997. *Realistic Evaluation,* London, Sage.

PUBLIC HEALTH ENGLAND 2017. Falls and Fracture Consensus Statement. Supporting Commissioning for Prevention.

PUBLIC HEALTH ENGLAND. 2018a. *Falls: Applying All Our Health* [Online]. Available: https://www.gov.uk/government/publications/falls-applying-all-our-health/falls-applying-all-our-health [Accessed].

PUBLIC HEALTH ENGLAND. 2018b. *Hip fractures in people aged 65 and over* [Online]. Available: https://fingertips.phe.org.uk/search/hip%20fractures#page/3/gid/1/pat/6/par/E12000004/ati/102/are/E06000015/iid/41401/age/27/sex/4 [Accessed].

RAMSEY, S., WILLKE, R., BRIGGS, A., BROWN, R., BUXTON, M., CHAWLA, A., COOK, J., GLICK, H., LILJAS, B. & PETITTI, D. 2005. Good research practices for cost‐effectiveness analysis alongside clinical trials: the ISPOR RCT‐CEA task force report. *Value in health,* 8**,** 521-533.

ROBBINS, I., GORDON, A., DYAS, J., LOGAN, P. & GLADMAN, J. 2013. Explaining the barriers to and tensions in delivering effective healthcare in UK care homes: a qualitative study. *BMJ open,* 3**,** e003178.

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

ROBERTSON K, LOGAN P, WARD M, POLLARD J, GORDON A, WILLIAMS W & J., W. 2012b. Thinking falls-taking action: a falls prevention tool for care homes. *Br J Community Nurs. ,* 17**,** 206-209.

ROBERTSON K, LOGAN PA, CONROY S, DODS V, GORDON A, CHALLANDS L, SMITH S, HUMPAGE S & A., B. 2010. Thinking falls - taking action: a guide to action for falls prevention. *Br J Community Nurs.,* 15**,** 406-410.

ROBERTSON, K., LOGAN, P., CONROY, S., DODS, V., GORDON, A., CHALLANDS, L., SMITH, S., HUMPAGE, S. & BURN, A. 2010. Thinking Falls- Taking Action: development of a Guide to Action for Falls Prevention *British Journal of Community Nursing,* 15**,** 406 - 410.

ROBERTSON K MACDONALD A. 2015. *Preventing falls in care homes.* [Online]. Available: https://www.gmjournal.co.uk/preventing-falls-in-care-homes [Accessed].

ROBINSON, K., ALLEN, F., DARBY, J., FOX, C., GORDON, A., HORNE, J., LEIGHTON, P., SIMS, E. & LOGAN, P. 2020a. Contamination in complex healthcare trials: the falls in care homes (FinCH) study experience. *BMC Med Res Methodol,* 20.

ROBINSON, K., ALLEN, F., DARBY, J., FOX, C., GORDON, A. L., HORNE, J. C., LEIGHTON, P., SIMS, E. & LOGAN, P. A. 2020b. Contamination in complex healthcare trials: the falls in care homes (FinCH) study experience. *BMC Medical Research Methodology* 20.

ROYAL COLLEGE OF PHYSICIANS. 2018. *National Hip Fracture Database (NHFD) annual report 2018* [Online]. Available: https://www.rcplondon.ac.uk/projects/outputs/national-hip-fracture-database-nhfd-annual-report-2018 [Accessed].

RYCROFT-MALONE, J., SEERS, K., ELDH, A. C., COX, K., CRICHTON, N., HARVEY, G., HAWKES, C., KITSON, A., MCCORMACK, B., MCMULLAN, C., MOCKFORD, C., NIESSEN, T., SLATER, P., TITCHEN, A., VAN DER ZIJPP, T. & WALLIN, L. 2018. A realist process evaluation within the Facilitating Implementation of Research Evidence (FIRE) cluster randomised controlled international trial: an exemplar. *Implementation Science,* 13**,** 138.

SACKLEY CM, VAN DEN BERG ME, LETT K, PATEL S, HOLLANDS K, WRIGHT CC & HOPPITT TJ 2009. Effects of a physiotherapy and occupational therapy intervention on mobility and activity in care home residents: a cluster randomised controlled trial. *BMJ,* 339:.

SANFORD, A. M., ORRELL, M., TOLSON, D., ABBATECOLA, A. M., ARAI, H., BAUER, J. M., CRUZ-JENTOFT, A. J., DONG, B., GA, H. & GOEL, A. 2015. An international definition for "nursing home". *Journal of the American Medical Directors Association,* 16**,** 181-184.

STACEY, D. E. A. 2019 Are patient decision aids used in clinical practice after rigorous evaluation? A survey of trial authors *Medical Decision Making,* 39 805-815

STANISZEWSKA, S., BRETT, J., SIMERA, I., SEERS, K., MOCKFORD, C., GOODLAD, S., ALTMAN, D., MOHER, D., BARBER, R. & DENEGRI, S. 2017. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. *Research involvement and engagement,* 3**,** 13.

STANISZEWSKA, S., DENEGRI, S., MATTHEWS, R. & MINOGUE, V. 2018. Reviewing progress in public involvement in NIHR research: developing and implementing a new vision for the future. *BMJ open,* 8**,** e017124.

TUCKMAN, B. W. & JENSEN, M. A. C. 1977. Stages of small-group development revisited. *Group & Organization Studies,* 2**,** 419-427.

WALKER, G. M., ARMSTRONG, S., GORDON, A. L., GLADMAN, J., ROBERTSON, K., WARD, M., CONROY, S., ARNOLD, G., DARBY, J., FROWD, N., WILLIAMS, W., KNOWLES, S. & LOGAN, P. A. 2016. The Falls In Care Home study: a feasibility randomized controlled trial of the use of a risk assessment and decision support tool to prevent falls in care homes. *Clinical Rehabilitation,* 30**,** 972-983.

WOLTERS, A., SANTOS, F., LLOYD, T., LILBURNE, C. & STEVENTON, A. 2019. Emergency admissions to hospital from care homes: how often and what for? *The Health Foundation,* May.

Appendix A - Statistical Analysis Plan – SAP

FinCH

Falls in Care Homes

EUDRACT: 2015-003410-25
ISCRN: ISRCTN34353836
Version of SAP: 1.0
Version of Protocol: 6.0 14 November 2017

Author	Title	Signature	Date
Reviewer	Title	Signature	Date
Approver	Title	Signature	Date

Section 2: Introduction

Background and rationale:

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

Community fall prevention interventions reduce falls by about 30%, but literature to date has found no conclusive reduction in falls in care homes (Gillespie 2012, Cameron 2012). To decrease fall rates it has been suggested that interventions need to be targeted at high risk groups such as elderly care home populations and include specific components (Close, 2005). They need to be delivered by the whole team (Bouwen 2008, Jensen 2004) to the whole environment.

The GtACH intervention aims to reduce fall rates in care homes by facilitating change in practice of care home staff. It was co-produced by a group of care home staff, clinicians, researchers, public, voluntary and social care organisations and includes care home staff training, support and documentation.

Objectives

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

Secondary objectives listed in the protocol are as follows::

  i.   Comparison of fall rates between the two groups during the 3-month period comprising 7, 8 and 9 months post randomisation.
 ii.   Comparison of fall rates between the two groups during the 3-month period comprising 10, 11 and 12 months post randomisation.
iii.   Comparison of frequency of falls injuries between the two groups for falls occurring between baseline and 6 months, and between 7 and 12 months post randomisation.
 iv.   Comparison, between the two groups, of frequency and type of fractures occurring between baseline and 6 months, and between 7 and 12 months post randomisation.
  v.   Comparison, between the two groups, of physical activity , measured using PAM-RC, at 6 months, and 12 months post randomisation.
 vi.   Comparison, between the two groups of functional ability, measured using Barthel index, at 6 months, and 12 months post randomisation.

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vii.   Comparison, between the two groups, of quality of life, measured using DEMQOL and EQ5-D at 6 months, and 12 months post randomisation.

viii.   Comparison, between the two groups, of medication use between baseline and 6 months, and between 7 and 12 months post randomisation.

ix.   Comparison, between the two groups, of number of days in hospital between baseline and 6 months, and between 7 and 12 months post randomisation.

x.   Comparison, between the two groups, of percentage of deaths

Changes from the protocol

The following objective has been added, on the recommendation of the DMC

i   Comparison, between the two groups, of percentage of residents falling, between 3 and 6 months post-randomisation, and between 7 and 12 months post-randomisation

Changes to original secondary objectives

i   original objective viii (Comparison, between the two groups, of medication use between baseline and 6 months, and between 7 and 12 months post randomisation) has been amended to Comparison, of risk of falling, among those on 4 or more medications at baseline

Full details of the trial are given in the protocol.

Section 3: Study Methods

Trial Design

FinCH is a cluster randomised controlled, 2 arm, parallel group trial comparing the GtACH fall prevention intervention against usual care for people living in care homes in England (with and without nursing). Care home is the unit of randomisation.

Randomisation

Care homes are randomised on a 1:1 basis to one of two parallel arms: intervention (GtACH fall prevention programme) or control (usual care).

Randomisation is based on a bespoke computer generated pseudo-random code using variable block randomisation (block sizes 2 and 4) within strata (site [Lincolnshire, Derby, Northumbria, Leicester, Stafford, Norwich, Nottingham City, Nottinghamshire, Bradford and Solent] and care home type [nursing/residential/dual registration]) provided by the Norwich CTU via a secure web based randomisation service.

Sample size

The most recent sample size calculation was based on a falls rate of 2.5 falls per person per year (0.625 falls in 3 months) with 80% power and a two-sided significance level of 5%. Based on an average cluster size of 19 (SD 9.5) residents per cluster, a coefficient of variation (CV) of 0.5 and allowing for 16% attrition, the sample size target was 78 care homes - 1482 residents in total. Full details of this sample size calculation, and the original calculation, may be found in sections 9.1.1, 9.1.2 and 9.1.3 of the FinCH protocol.

Framework

The FinCH trial is to determine whether fall rates are reduced following the implementation of the GtACH intervention and therefore is testing for superiority. Secondary outcomes will also be tested for superiority.

Statistical interim analyses and stopping guidance

There are no interim analyses planned for FinCH.

Timing of final analysis

All analyses will take place at one time point once all data are cleaned and locked.

Timing of outcome assessments

Data on falls, medication use, time in hospital and use of primary care and community services for the previous 3 months ("baseline") are collected at the time of resident recruitment, then at 3 months following randomisation, and at 3 monthly intervals thereafter, with the final collection of these items taking place at approximately 12 months post-randomisation. Data on Physical activity (PAM-RC), Activities of Daily Living (Barthel), Health related Quality of Life in Dementia (DEMQOL-U-5D / DEMQOL-P-4D, EQ-5D-5L/EQ-5D-5L proxy) will be collected from participating residents at the same 3 month intervals.

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Frequency and type of fractures occurring during the period of baseline and outcome data collection will obtained from Hospital Episode Statistics at the end of the 12 month follow-up. Full details of timing of collection of outcome measures are included in the FinCH trial protocol.

Section 4: Statistical Principles

Confidence intervals and p-values

All statistical tests will be 2-sided and performed using a 5% significance level. All confidence intervals presented will be 95% and 2-sided. No adjustment for multiplicity is planned.

Adherence and protocol deviation

Compliance with the intervention is based on the percentage of care giving staff in each care home trained to use the GtACH tool. It is calculated as follows:

$$\% \text{ compliance} = \frac{number\ of\ care\ giving\ GtACH\ trained\ staff\ at\ care\ home}{number\ of\ care\ giving\ staff\ at\ care\ home} * 100\%$$

Percentage compliance will be calculated and presented for each home in the intervention arm; average compliance for all intervention care homes will also be presented.

Analysis populations:

Analyses will be undertaken on an Intention to Treat basis in which care homes (and corresponding participating residents) will be analysed in the group to which they were allocated regardless of their compliance with the intervention). Those who died between care home randomisation and the three month follow-up data collection will be regarded as having been exposed to the intervention (GtACH/control), recorded as lost to follow-up at the time of death, and included in the consort diagram. The consort diagram will include the number of people who were randomised in error – eg those who were randomised but did not fulfil all the eligibility criteria.

Section 5: Trial Population

Screening data

The following summaries will be presented for all screened care homes, both overall and by study site:

Number of screened care homes

The number of care homes not recruited for the following reasons: would not benefit the care home; have not got the time; not interested in research; other

Eligibility

Care homes: the number of ineligible care homes will be reported, along with reason(s) for ineligibility

Residents: the number of eligible and ineligible residents will be reported, along with reason(s) for ineligibility

A list of inclusion and exclusion criteria for care homes and residents is provided in section 7.5.2 of the protocol.

Recruitment

The Consort diagram will be used to summarise the following information:

Number of Care homes assessed for eligibility
- Number of care homes eligible at screening
- Number of care homes ineligible at screening

Number of care homes recruited

Number of residents recruited

Number of care homes randomised to each trial arm

Number of care homes lost to follow-up

Number of participating residents lost follow-up

Number of care homes discontinuing the intervention

Number of residents included in the primary analysis

Withdrawal/follow up

Reason for, and level and timing of, withdrawal of consent of care homes and participating residents will be indicated in the Consort diagram

Baseline characteristics

Baseline characteristics of randomised care homes and participating residents will be presented according to Table 1 and Table 2 respectively, both overall and by randomised group. No formal hypothesis tests will be undertaken. Categorical data will be summarised by numbers and percentages; continuous data will be summarised by mean, SD and range if data are normal, and median, IQR and range if data are skewed.

Table 1: Baseline characteristics of randomised care homes

Baseline characteristics of randomised homes by allocated group	Overall (n=)	Group A (n=)	Group B (n=)

Number of care homes by site			
- Lincolnshire			
- Derby			
- Northumbria			
- Leicester			
- Stafford			
- Norwich			
- Nottingham City			
- Nottinghamshire			
- Bradford			
- Solent			
Number of care homes by type			
- Nursing			
- Residential			
- Dual Registration			
Number of care homes by ownership			
- charity			
- private			
Total number of care giving staff Mean (SD) care giving staff per home			
Total number of beds Mean (SD) beds per home			
Total number of residents Mean (SD) residents per home			
Percentage of residents recruited out of those eligible			
Percentage of residents recruited out of those resident			

Table 2: Baseline characteristics of participating residents

Baseline characteristics of participating residents by allocated group of care home	Overall	Group A	Group B
Age at consent to FinCH (years): mean (SD)			
Male: N (%)			
Consent: N(%)			
- Resident			
- Consultee			
Time in care home (months): mean (SD)			
Active medical diagnoses: N(%)			
- Dementia			
- Diabetes			
- Stroke			
- CHD			

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Number of falls during period 3 months prior to baseline data collection			
Number of Medications in period 3 months prior to baseline data collection - None - One to three medications - Four or more medications			
Physical activity (PAM-RC) score at baseline: mean(SD)			
Activities of Daily Living (Barthel) score at baseline: mean(SD)			
DEMQOL-U-5D at baseline			
DEMQOL-P-4D at baseline			
EQ-5D-5L at baseline			
EQ-5D-5L proxy at baseline			

Section 6: Analysis
Outcome definitions

i) Falls rates:
Primary outcome

The primary outcome is the rate of falls per participating resident during the 3 month period comprising months 4, 5 and 6 post-randomisation. For the purpose of the analyses, a month will be taken to consist of 30 days. Baseline, or time zero, for each care home will be the date of randomisation of that care home. For participating residents at each care home, month 4 will therefore start 91 days after randomisation, and month 6 will finish 180 days after randomisation. Therefore for each participating resident the numerator of the falls rate will be the number of falls occurring in the care home between 91 and 180 days. The denominator will be 90 days, for those participating residents who have lived at the care home for the entire 90 day period; for those participating residents who have spent time in hospital or elsewhere during the 90 day period, the denominator will be the number of days during that 90 day period spent as resident in the care home. The falls rate will be expressed as the number of falls per 1000 participating resident days for each group. For individuals who stopped participating in the trial before 180 days, data will be included up until the date of withdrawal.

Secondary outcomes

Rate of falls occurring during the 3 month period comprising months 7, 8 and 9 post-randomisation, and the 3 month period comprising months 10, 11 and 12 post-randomisation. As above, a month will be assumed to consist of 30 days. The 3 month period comprising months 7, 8 and 9 will therefore commence on day 181 and end on day

270. Likewise the 3 month period comprising months 10, 11 and 12 will commence on day 271 and end on day 360. Falls rates will be calculated as described for the primary outcome, and expressed as the number of falls per 1000 participating resident days for each group.

ii) Other secondary outcomes:

The number and percentage of residents having one or more falls, between 3 and 6 months post-randomisation, and between 7 and 12 months post-randomisation.

The number and percentage of residents having no medications at baseline, who have one or more falls, between 3 and 6 months post-randomisation, and between 7 and 12 months post-randomisation.

The number and percentage of residents having 4 or more medications at baseline, who have one or more falls, between 3 and 6 months post-randomisation, and between 7 and 12 months post-randomisation.

Fractures (from HSCIC data) occurring between baseline and 6 months and between 7 months and 12 months:

- Number of fractures of any type, per resident
- Number of residents having one or more fractures of any type
- Number of hip fractures, per resident
- Number of residents having one or more hip fracture
- Number of wrist fractures, per resident
- Number of residents having one or more wrist fracture

Physical activity (measured by the PAM-RC questionnaire) at 3, 6, 9 and 12 months following randomisation. The PAM-RC questionnaire comprises 5 questions addressing ability (mobility and balance), and activity (walking frequency, wandering and outdoor mobility). Each question has graded responses, scored between 0-3 and 0-6. The total PAM-RC will be calculated by summing the scores for each question, giving a range of scores between 0 and 21, with 0 indicating no activity, and 21 indicating that the resident is fully mobile in all aspects of the questionnaire.

Activities of daily assessment (measured by the Barthel Index) are recorded at baseline, 3, 6, 9 and 12 months following randomisation. The Barthel Index of Activities of Daily Living comprises ten questions concerning resident's ability to self-care. Each item is scored between 0 and 1, 2 or 3, with minimum possible score 0 and maximum possible score 20; lower values indicating less independence with respect to Activities of Daily Living. Total ADL scores will be treated as continuous data.

Quality of life in dementia, measured using DEMQOL-U for residents with capacity and DEMQOL-Proxy for residents lacking capacity, is recorded at baseline, and at 3, 6, 9 and 12

months following randomisation. DEMQOL comprises 28 questions and DEMQOL-Proxy 31 questions, each scored between 1 and 4. Scores are summed to give total DEMQOL and DEMQOL-Proxy scores with possible ranges 28 to 112 and 31 to 124 respectively; higher scores imply better Quality of Life. DEMQOL and DEMQOL-Proxy also each include a single global health question – this is not included in the total DEMQOL or DEMQOL-Proxy score. Total DEMQOL and DEMQOL-Proxy scores will be analysed as continuous data.

Health status measured using EQ-5D-5L (where the participating resident has capacity), and EQ-5D-5L proxy (where the participating resident does not have capacity), is recorded at baseline and at 3, 6, 9 and 12 months post-randomisation. At each timepoint responses to the 5 component questions of the EQ-5D_5L/EQ5D-5L proxy will be converted to a weight. The values of weights range from -0.285 to 0.950, with higher weights indicating more favourable health states. A further question asks residents / proxy respondents to score how well or poorly they rate their health on that particular, on a scale ranging from 0 (worst imaginable health state) to 100 (best imaginable health state).

The number of days spent by residents in hospital (from HSCIC data) between baseline and 6 months, and between 7 months and 12 months post-randomisation

The number of residents who die (from HSCIC data)

Analysis methods

Primary outcome
The average number of falls occurring during the 3 month period comprising months 4,5 and 6 post randomisation (ie between 91 and 180 days post-randomisation) per participating resident, and the average rate of falls, occurring during the 3 month period comprising months 4, 5 and 6 post randomisation (again number of days spent as resident in the care home between 91 and 180 days post-randomisation, excluding any days spent in hospital during this period), per participating resident, will be presented by treatment group. Falls rates will be expressed as the number of falls per 1000 participating resident days. The primary effect estimate will be Incidence Rate Ratio, reported with 95% confidence interval.

The number of falls per resident will be compared between groups using a random effects/hierarchical two-level Poisson model with resident at level one and care home at level two, with length of residence in care home as an offset. The primary analysis will adjust for type of care home (residential, nursing, dual registration) and site.

Adjustment for covariates

Two further models will adjust for i) baseline fall rate; ii) baseline fall rate and other variables that are associated with falling, in addition to adjusting for care home type and site. Baseline fall rate will comprise information collected on falls in the care home for the 90 days prior to the date of baseline data collection. In the case of participants resident in the care home for fewer than 90 days prior to the baseline data collection, the fall rate will be calculated for the period in which data are available. For residents not fulfilling a minimum period of four weeks of baseline data collection in the care home, missing data will be imputed.

Methods used for assumptions to be checked for statistical methods

A negative binomial model will also be fitted, and goodness of fit will be compared between the two models, and the best-fitting model will be reported.

Details of alternative methods to be used if distributional assumptions do not hold

If neither Poisson nor negative binomial models are appropriate then alternative models will be explored, or two-stage bootstrap will be used. Alternatively cluster level analyses could be performed.

Secondary outcomes

Falls rates for the three month period comprising 7,8 and 9 months post randomisation and for the 3 month period comprising 10, 11 and 12 months post-randomisation will be analysed in a similar way to the primary outcome. Frequency and type of fractures and days in hospital between baseline and 6 months (180 days), and for the period between 6 months (181) and 12 months (360 days).

For other secondary outcomes, groups will be compared using multi-level regression analysis for continuous outcomes (DEMQOL, EQ-5D-5L, medication use, Barthel ADL and PAM-RC) and multi-level logistic regression for binary outcomes (death, at least one fall or not).

28 Missing data

A multiple imputation using iteratively chained equations [1] will be used to account for incomplete data and missing data in other outcomes. A random effect will be used to account for the clustering by care-home. The total number of imputations will be approximately the same as the percentage of cases that are incomplete, up to a maximum of 20 imputations. The estimates from imputation will be combined using Rubin's equations. The imputation model used will include all outcome measures and any baseline covariates which are associated with loss-to-follow-up and treatment group.

If any of the variables have a skewed distribution, then transformations will be attempted, however if none are found then predictive mean matching will be used for these variables.

The imputation model may be adapted during the analysis if

a) Perfect prediction is observed. This occurs when the variance-covariance matrix is singular. If this occurs then 'augmenting' will be attempted, but if this does not resolve the issue then variables may be removed from the imputation model.
b) If the imputation procedure does not converge then it will be necessary to remove variables from the imputation model.
c) If the imputation model includes too many variables then instability in the imputation may occur. In this case it may be required to remove variables from the imputation model.

In order to avoid potential issues in model mis-specification, the imputation may not be attempted for outcomes with more than 50% missing data. Multiple imputation will only be used for the intention-to-treat analysis.

Details of any additional statistical analyses required
No other analyses are planned at this time

Safety Analyses
No additional analyses will be conducted other than those specified

Statistical software
The analysis will be carried out using standard statistical software, either Stata, SAS or R.

References[1] White, Ian R., Patrick Royston and Angela M. Wood (2011) "Multiple imputation using chained equations: Issues and guidance for practice." *Statistics in Medicine* 30: 377-399

Appendix B - Primary outcome analysis – Poisson regression, negative Binomial regression model

1.1.1	1.1.2	**1.1.3** GTACH	1
1.1.7	1.1.8	1.1.9 <u>N at risk</u> 1.1.10 <u>N falls</u> 1.1.11 <u>Fall rate</u>	1
1.1.21 <u>pre-randomisation*</u>	1.1.22	1.1.23 <u>773</u> 1.1.24 <u>0.61</u> (1.57) 1.1.25 <u>6.97</u> (17.67)	1
1.1.33 <u>0 – 90 days</u>	1.1.34	1.1.35 <u>708</u> 1.1.36 <u>0.55</u> (1.36) 1.1.37 <u>6.93</u> (20.56)	1
1.1.45 <u>91 – 180 days</u>	1.1.46	1.1.47 <u>630</u> 1.1.48 <u>0.49</u> (1.13) 1.1.49 <u>6.04</u> (14.02)	1
1.1.57 <u>181 – 270 days</u>	1.1.58	1.1.59 <u>547</u> 1.1.60 <u>0.60</u> (1.29) 1.1.61 <u>7.28</u> (16.67)	1
1.1.69 <u>271 – 360 days</u>	1.1.70	1.1.71 <u>502</u> 1.1.72 <u>0.55</u> (1.14) 1.1.73 <u>6.22</u> (12.88)	1

Primary Outcome Analysis - Poisson GEE

	1.1.83 <u>Usual Care</u>			**1.1.84** <u>Unadjusted</u>	
1.1.89 <u>Fall rate</u>	1.1.90 <u>N at risk</u>	1.1.91 <u>N falls</u>	1.1.92 <u>Fall rate</u>	1.1.93 <u>IRR</u> 1.1.94 <u>(95% CI)</u>	1.1.95
<u>0.61</u> 1.1.102 <u>6.97</u> (17.67)	1.1.103 <u>882</u>	1.1.104 <u>0.79</u> (2.02)	1.1.105 <u>9.48</u> (24.14)	1.1.106	1.1.107
<u>0.55</u> 1.1.113 <u>6.93</u> (20.56)	1.1.114 <u>826</u>	1.1.115 <u>0.88</u> (2.37)	1.1.116 <u>10.24</u> (27.26)	1.1.117 <u>0.61</u> (0.52,0.71)	1.1.118
<u>0.49</u> 1.1.124 <u>6.04</u> (14.02)	1.1.125 <u>712</u>	1.1.126 <u>0.89</u> (2.60)	1.1.127 <u>10.38</u> (29.52)	1.1.128 <u>0.55</u> (0.46,0.65)	1.1.129
<u>0.60</u> 1.1.135 <u>7.28</u> (16.67)	1.1.136 <u>633</u>	1.1.137 <u>0.73</u> (1.85)	1.1.138 <u>9.21</u> (28.77)	1.1.139 <u>0.81</u> (0.69,0.96)	1.1.140
<u>0.55</u> 1.1.146 <u>6.22</u> (12.88)	1.1.147 <u>573</u>	1.1.148 <u>0.79</u> (2.37)	1.1.149 <u>9.22</u> (27.36)	1.1.150 <u>0.71</u> (0.58,0.87)	1.1.151

Primary outcome – Negative binomial regression model

1.1.154	**1.1.155** GTACH			**1.1.156** <u>Usual Care</u>	
1.1.159	1.1.160 <u>N at risk</u>	1.1.161 <u>N falls</u>	1.1.162 <u>Fall rate</u>	1.1.163 <u>N at risk</u>	1.1.164 f
1.1.172 <u>pre-randomisation*</u>	1.1.173 <u>773</u>	1.1.174 <u>0.61</u> (1.57)	1.1.175 <u>6.97</u> (17.67)	1.1.176 <u>882</u>	1.1.177 (

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1.1.183	0 – 90 days	1.1.184	708	1.1.185	0.55 (1.36)	1.1.186	6.93 (20.56)	1.1.187	826	1.1.188 (
1.1.194	91 – 180 days	1.1.195	630	1.1.196	0.49 (1.13)	1.1.197	6.04 (14.02)	1.1.198	712	1.1.199 (
1.1.205	181 – 270 days	1.1.206	547	1.1.207	0.60 (1.29)	1.1.208	7.28 (16.67)	1.1.209	633	1.1.210 (
1.1.216	271 – 360 days	1.1.217	502	1.1.218	0.55 (1.14)	1.1.219	6.22 (12.88)	1.1.220	573	1.1.221 (

In Stata, the results for the negative binomial model (table above) were very different from those obtained in the negative binomial GEE and the Poisson models. However, using R (results not shown) rather than Stata yielded similar results to the Poisson regression model.

Primary outcome – sensitivity analysis
Ordinal regression

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Ordinal logistic regression model

1.1.227		1.1.228		1.1.229	
1.1.230 -		1.1.231 Ordinal OR (95% CI)	1.1.232 p-value	1.1.233 Ordinal OR (95% CI)	1.1.234 p-value
1.1.235 pre-randomisation*		1.1.236 -	1.1.237 -	1.1.238 -	1.1.239 -
1.1.240 0 – 90 days		1.1.241 0.67 (0.47,0.94)	1.1.242 0.023	1.1.243 0.68 (0.49,0.95)	1.1.244 0.02
1.1.245 91 – 180 days		1.1.246 0.69 (0.51,0.94)	1.1.247 0.02	1.1.248 0.76 (0.58,1)	1.1.249 0.04
1.1.250 181 – 270 days		1.1.251 0.98 (0.71,1.35)	1.1.252 0.899	1.1.253 1.06 (0.79,1.41)	1.1.254 0.71
1.1.255 271 – 360 days		1.1.256 0.89 (0.6,1.32)	1.1.257 0.556	1.1.258 0.98 (0.67,1.44)	1.1.259 0.91

The ordinal logistic regression model, looking at 0 falls, 1, 2, or 3 or more, gave evidence of a difference between groups, for falls occurring between baseline and 3 months, and between 3 and 6 months

Primary outcome –sensitivity analysis

Cluster summary approach, A cluster summary analysis also gave evidence of a difference in falls occurring between three and six months.

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	TACH		Usual Care		Unadjusted		Adjusted for baseline	
	Mean (SD)		Mean (SD)		Mean difference (95% CI)		Mean difference (95% CI)	p-value
re-randomisation*		.55 (6.30)		.94 (7.09)				-
– 90 days		.74 (6.50)		.84 (9.04)	.64 (0.43,0.97)		.85 (0.61,1.17)	0.314
1 – 180 days		.99 (4.9)		0.39 (10.63)	.59 (0.41,0.85)		.69 (0.49,0.97)	0.033

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1.1.301	1.1	1.1.303	1.1	1.1.305	1.1.306	1.1.30	1.1.308	1.1.309	
81 − 270 days		1) .93 (4.25)		.99 (8.09)	.08 (0.74,1.58)		.17 (0.83,1.64)	0.357	
1.1.310	1.1	1.1.312	1.1	1.1.314	1.1.315	1.1.31	1.1.317	1.1.318	0.
71 − 360 days		.10 (5.51)		.08 (9.51)	.83 (0.53,1.31)		.95 (0.62,1.45)	0.796	

Appendix C - Poisson regression analysis of hospital admissions

Poisson results

	GTACH		Usual Care		Unadjusted		Adjusted for baseline	
	N	Mean (SD)	N	Mean (SD)	Mean difference (95% CI)	p-value	Mean difference (95% CI)	p-value
pre-randomisation*	773	0.46 (2.62)	877	0.60 (2.69)				
0 – 180 days	697	1.54 (5.36)	793	1.61 (4.85)	0.94 (0.64,1.38)	0.75	0.98 (0.67,1.43)	0.919
181 - 360 days	532	1.08 (4.04)	620	1.58 (6.03)	0.81 (0.49,1.33)	0.403	0.81 (0.49,1.32)	0.394

Appendix D - Fractures

Hip fractures

S72.0 Fracture of neck of femur
S72.00 Fracture of unspecified part of neck of femur
S72.1 Pertrochanteric fracture
S72.10 Unspecified trochanteric fracture of femur
S72.2 Subtrochanteric fracture
S72.20 Not found in ICD10, but occurs 7 times in dataset

Wrist fractures

S52.5 - fracture of lower end of radius
S52.50 - Unspecified fracture of the lower end of radius
S52.6 - fracture of lower end of both ulna and radius
S52.60 - Unspecified fracture of lower end of ulna
S62.0 - fracture of navicular(scaphoid) bone of hand
S62.1 - fracture of other carpal bone
S62.4 - multiple fractures of carpal bones
S62.40 - Not found in ICD10, but occurs once in dataset
S62.8 - fracture of other and unspecified parts of wrist and hand

S62.80 - Not found in ICD10, but occurs twice in dataset

Any fracture

S02.0 - fracture of vault of skull
S02.00 Not found in ICD10 but occurs twice in dataset
S02.1 Fracture of base of skull
S02.10 Unspecified fracture of base of skull
S02.2 fracture of nasal bones
S02.20 Not found in ICD10 but occurs twice in dataset
S02.4 Fracture of malar and maxillary bones
S02.40 Fracture of malar, maxillary and zygoma bones, unspecified
S02.5 Fracture of tooth (traumatic)
S02.50 Not found in ICD10 but occurs once in dataset
S02.6 fracture of mandible
S02.7 Multiple fracture involving skull and facial bones
S02.8 Fractures of other skull and facial bones
S02.9 Fracture of skull and facial bones, part unspecified
S22.0 Fracture of thoracic vertebra
S22.00 Fracture of unspecified thoracic vertebra
S22.1 is multiple fractures of thoracic spine
S22.10 Not found in ICD10 but occurs once in dataset
S22.2 Fracture of sternum
S22.3 fracture of one rib
S22.30 Not found in ICD10 but occurs 11 times in dataset
S22.4 is multiple fractures of ribs
S22.40 Not found in ICD10 but occurs 13 times in dataset
S22.5 Flail chest
S22.8 Fracture of other parts of bony thorax
S22.9 Fracture of bony thorax, part unspecified
S32 Fracture of lumbar spine and pelvis
S32.0 Fracture of lumbar vertebrae
S32.00 Fracture of unspecified lumbar vertebra
S32.1 Fracture of sacrum
S32.2 Fracture of coccyx
S32.3 Fracture of ilium
S32.30 Unspecified fracture of ilium
S32.4 fracture of acetabulum
S32.40 Unspecified fracture of acetabulum
S32.5 fracture of pubis
S32.5- Not in ICD10 but occurs 5 times in dataset
S32.50 Unspecified fracture of pubis
S32.7 Multiple fractures of lumbar spine and pelvis
S32.8 Fracture of other & unspecified parts of lumbar spine & pelvis
S42.0 fracture of clavicle
S42.00 Fracture of unspecified part of clavicle
S42.1 fracture of scapula
S42.2 Fracture of upper end of humerus
S42.20 Unspecified fracture of upper end of humerus
S42.3 Fracture of shaft of humerus
S42.30 Unspecified fracture of shaft of humerus
S42.30~ Not in ICD10,occurs 3 times in dataset
S42.4 Fracture of lower end of humerus
S42.7 Multiple fractures of clavicle, scapula and humerus
S42.8 Fracture of other parts of shoulder and upper arm
S42.9 Fracture of shoulder girdle, part unspecified
S42.90 Fracture of unspecified shoulder girdle, part unspecified
S52.0 fracture if upper end of ulna
S52.1 Fracture of upper end of radius
S52.2 Fracture of shaft of ulna
S52.3 Fracture of shaft of radius
S52.4 Fracture of shafts of both ulna and radius

S52.5 Fracture of lower end of radius

S52.6 Fracture of lower end of both ulna and radius

S52.7 Multiple fractures of forearm

S52.8 Fracture of other parts of forearm

S52.9 Fracture of forearm, part unspecified

S62.0 Fracture of navicular[scaphoid] bone of hand

S62.1 Fracture of other carpal bones

S62.2 Fracture of first metacarpal bone

S62.3 Fracture of other metacarpal bone

S62.30 Unspecified fracture of other metacarpal bone

S62.4 Multiple fractures of carpal bones

S62.40 Not found in ICD10 but occurs once in dataset

S62.5 Fracture of thumb

S62.50 Fracture of unspecified phalanx of thumb

S62.6 Fracture of other finger

S62.60 Fracture of unspecified phalanx of finger

S62.61 Displaced fracture of proximal phalanx of finger

S62.7 Multiple fracture of fingers

S62.8 Fracture of other and unspecified parts of wrist and hand

S62.80 Not in ICD10, occurs twice in dataset

S72.0 Fracture of neck of femur

S72.00 Fracture of unspecified part of neck of femur

S72.1 Pertrochanteric fracture

S72.10 Unspecified Pertrochanteric fracture

S72.2 Subtrochanteric fracture

S72.20 Not found in ICD10 but occurs 7 times in dataset

S72.3 Fracture of shaft of femur

S72.4 Fracture of lower end of femur

S72.40 Unspecified fracture of lower end of femur

S72.7 Multiple fractures of femur

S72.8 Fractures of other parts of femur

S72.9 Fracture of femur, part unspecified

S82.0 Fracture of patella

S82.00 Unspecified fracture of patella

S82.1 Fracture of upper end of tibia

S82.10 Unspecified fracture of upper end of tibia

S82.2 Fracture of shaft of tibia

S82.20 Unspecified fracture of shaft of tibia

S82.3 Fracture of lower end of tibia

S82.31 Torus fracture of lower end of tibia

S82.4 Fracture of fibula alone

S82.40 Unspecified fracture of shaft of fibula

S82.5 Fracture of medial malleolus

S82.6 Fracture of lateral malleolus

S82.7 Multiple fracture of lower leg

S82.8 Fractures of other parts of lower leg

S82.9 Fracture of lower leg, part unspecified

Appendix E - Unit Costs for Staff and Equipment

Unit Costs for Staff

Description	Unit cost UK£ 2017/18	Source of Unit cost
Ambulance hear & treat or refer	37	Reference costs 2017-8
Ambulance see and treat or refer	192	Reference costs 2017-8
Advanced clinical practitioner, ANP	66	Assume AfC Band 8a
Community Mental health team (inc CPN & DOT)	160	Ref Costs 2017-8, Other Mental Health Specialist Teams, Adult and Elderly
Dentist	164	Reference costs 2017-8
Dietician	86	Curtis and Burns, PSSRU, 2018
District Nurse (Community matron)	38	Reference costs 2017-8
Falls lead	44	Assume AfC Band 6
FINCH research staff "Train the Trainer"	63	Assume AfC band 8a
Any Nurse (phone only)	19	Reference costs 2017-8
GP	34	Curtis and Burns, PSSRU, 2018
GP (phone only)	15.1	Curtis and Burns, PSSRU, 2018
GP (OOH service)	34	Curtis and Burns, PSSRU, 2018
Hearing test	63	Audiology
Home care manager	40	Curtis and Burns, PSSRU, 2018
Home care worker	27	Curtis and Burns, PSSRU, 2018
Optician	55	Assume AfC Band 7
OT	78	Curtis and Burns, PSSRU, 2018
Pharmacist	55	Assume AfC Band 7
Phlebotomist	32	Assume AfC Band 4
Physio & falls team	54	Curtis and Burns, PSSRU, 2018
Podiatrist	41	Reference costs 2017-8
Practice nurse	10.5	Curtis and Burns, PSSRU, 2018
SALT	97	Curtis and Burns, PSSRU, 2018
Social worker (adult services)	84	Curtis and Burns, PSSRU, 2018
Specialist nurse	79	Reference costs 2017-8
GP surgery admin	8	Assume AfC Band 4
Social services	84	Curtis and Burns, PSSRU, 2018
Support and outreach Worker	23	Curtis and Burns, PSSRU, 2018
Funding assessment	84	Assume social worker
Equipment (Various, see equipment table below)	6.79 to 3,500*	NRS or CCS

  * 1 to 421 at Equivalent Annual Cost

Equipment Cost

Item	Numbers recorded in CRF	Unit cost £	Source	Annualised costs?	Personal or shared?

Hoists etc

Hoist	555	639.95		not costed	shared
Slide sheet	239	16.94	NRS	no	personal
Sling	199	99.69	NRS	yes	personal
Stand aid	91	785.00		not costed	shared
Rotunda	79	359.95		not costed	shared
Handling belt	9	49.63	NRS	yes	personal
Arjo sara stedy	4	1,209.00		not costed	shared

large CH equip - all shared

stair climber	13	1,900.00		not costed	shared
hand rail	11	6.79		not costed	shared
stair lift	9	1,900.00		not costed	shared
brackets	2	73.35		not costed	shared
ramp	2	47.19		not costed	shared

mobility

Basic wheelchair	728	114.45	NRS	yes	personal
walking frame	571	23.33	NRS	yes	personal
rollator frame	179	41.95	NRS	yes	personal
walking stick	166	9.39	NRS	yes	personal
Electric wheelchair	30	1,235.00	CCS	yes	personal
mobility scooter	12	649.00	CCS	yes	personal

sensor/alarms

sensor mat	269	27.05	NRS	yes	personal
crash mat	103	27.05	NRS	yes	personal
pendant alarm	57	31.45	NRS	yes	personal
PIR sensor	24	12.55	NRS	yes	personal
call bell	22	42.95	NRS	yes	personal
motion sensor	12	12.55	NRS	yes	personal
chair sensor	4	103.65	NRS	yes	personal

sitting

cushion	312	24.95	NRS	no	personal
recliner chair	43	652.15	NRS	yes	personal
pro-pad cushion	36	52.45	NRS	no	personal
repose wedge	14	83.95	NRS	no	personal
hydrotilt chair	13	1,800.00	CCS	yes	personal
Kirton chair	13	1,611.43	NRS	yes	personal
deepdale chair	10	185.00	CCS	yes	personal

perching stool	3	41.95	NRS	yes	personal
rollator frame	3	23.33	NRS	yes	personal
sleeping					
profile bed	395	498.75	NRS	yes	personal
bed rails	269	31.55	NRS	yes	personal
pressure mattress	219	111.59	NRS	yes	personal
airflow mattress	172	625.00	CCS	yes	personal
bed bumpers	54	72.75	NRS	yes	personal
repose mattress	32	113.65	NRS	yes	personal
pro-pad mattress	29	125.95	CCS	yes	personal
bed sensor	14	111.99	NRS	yes	personal
bed lever	7	98.00	NRS	yes	personal
electric mattress	5	984.00	NRS	yes	personal
washing/toilet					
shower chair	240	84.95	NRS	yes	personal
bath hoist	181	209.95		not costed	shared
commode	151	24.95	NRS	yes	personal
bath chair	102	19.85	NRS	yes	personal
raised toilet seat	28	16.55	NRS	yes	personal
bath seat	22	19.85	NRS	yes	personal
parker bath	18	3,500.00		not costed	shared
non-slip mat	7	11.23	NRS	yes	personal
lap strap	4	84.00	NRS	yes	personal

EQUIPMENT FORM

Participant Number: ☐☐☐☐☐☐☐ nt Initials: ☐☐☐ o equipment please tick the box below   RA's Initials

Date of Baseline data collection	☐☐☐☐☐☐	☐	☐☐
Date of 3 month data collection	☐☐☐☐☐☐	☐	☐☐
Date of 6 month data collection	☐☐☐☐☐☐	☐	☐☐
Date of 9 month data collection	☐☐☐☐☐☐	☐	☐☐
Date of 12 month data collection	☐☐☐☐☐☐	☐	☐☐

Instructions

The following form should be used to record if the resident has bought or been given any equipment to help them cope with a health problem (e.g. frame, hoist, bath aids etc). At baseline (date of consent) we need to know what equipment the patient is using, irrespective of how long they have had it for. At 3, 6, 9 and 12 months, we need to know about any additional equipment purchased since the previous visit. Please record what equipment the resident has at the date of consent and during the trial. In the event that the resident does not have equipment aids at baseline, or where no equipment has been purchased since the last time point please tick the box above indicating no equipment purchased.

Each resident should have their own Equipment Form, which must be updated throughout the trial.

If yes, please specify the equipment in the table below and record whether the resident has purchased or been given it. If they bought it please also specify how much it cost: (Additional items can be included at the end of the list)

To identify who purchased the item of equipment please choose the appropriate abbreviation from the following:

1 Patient	2 Social Service	3 Health Budget	4 Care Home	5 Unknown

Item	Purchased by (insert number as appropriate)	Date received	Details

Falls in Care Homes Study
FinCH

Primary Care or Community Services log

This Primary Care or Community Services continuation is for use with the Baseline CRF, 3, 6, 9 and 12 months follow-up.

Participant Number: ☐☐ ☐☐☐ ☐☐☐ : ☐☐☐ Today's Date: ☐☐☐☐☐☐

Please indicate at which time point this continuation takes effect from: 3 months ☐ months ☐ months ☐ months ☐

Date	GP		Practice Nurse	District Nurse	Physio	OT	Podiatrist	Social Worker	Other	Addit
	(in hours)	(Out of hours)								

Falls in Care Homes Study

FinCH

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sheets and may be in the care home notes.

Participant Number: [ ][ ][ ][ ][ ][ ][ ] it Initials: [ ][ ]   If no meds or no change please tick the box below   RA's Initials

	Date	If no meds or no change	RA's Initials
Date of Baseline data collection	[ ][ ][ ][ ][ ][ ]	[ ]	[ ][ ]
Date of 3 month data collection	[ ][ ][ ][ ][ ][ ]	[ ]	[ ][ ]
Date of 6 month data collection	[ ][ ][ ][ ][ ][ ]	[ ]	[ ][ ]
Date of 9 month data collection	[ ][ ][ ][ ][ ][ ]	[ ]	[ ][ ]
Date of 12 month data collection	[ ][ ][ ][ ][ ][ ]	[ ]	[ ][ ]

Instructions

The following table should be used to record any medications taken by a resident from three mont and during the trial. Each resident should have their own Medication Form, which must be updated if any medications are stopped or new ones started. If medication was started pre-trial and start da start date. At each data collection time point please start collecting data from the date of the last e when end date is known. If the resident is still taking the medicine (with no changes) at the end of 'ongoing'.

For units/frequency and route please choose the appropriate abbreviation from the following:

Dose units:	Frequency:		Route:		
mg	h	every hour	IV	intravenously	R
µg	od	once daily	Inh	Inhalation	SC
g	qod	every other day	IM	intramuscularly	A
ml	bd	twice a day	Top	topical	Trans
mg / ml	tid	three times a day	O	Ophthalmic (eye)	
g / ml	qid	four times a day	N	Nasal	
other (specify)	ow	once weekly	Po	by mouth	
	Prn	as required			

Name of Drug	Start Date (dd/mm/yy) if known	Dose	Frequency

Appendix G -Data from HES; QoL (DemQol and EQ-5D-5L) Self Report QALY and Health Economic Analysis Plan

Data from HES

Care home records are known to be of poor quality in the monitoring of health care contacts made outside of the care home itself. To measure secondary care, including inpatient, outpatient and A&E, Hospital episode statistics (HES) were returned by NHS Digital, identified using NHS Number which was concealed to analysts.

Prior to analysis, we conducted plausibility checks on HES data, comparing participant information recorded on eCRF.

We matched records using month of birth and year of birth (full date of birth was concealed).

- Where month and year of birth did not match, we ascertained it was unlikely the HES data linked to the participant, and the NHS Number was probably incorrect. Therefore, we excluded these participants in HES analysis
- Where year of birth did not match, if the mismatch was for one digit (e.g. 1927 instead of 1937; 1941 instead of 1940) we ascertained this was probably a minor typo in eCRF, and the HES data linked to the participant.
- If more than one digit was incorrect (e.g. 1932 instead of 1917), we excluded these participants in HES analysis
- We ignored mismatch in month if the birth year matched.

Assessing baseline differences based on the 3 months before randomisation, we censored All HES datasets (Admitted, Outpatients and A&E) to 90days before randomisation ("preStudy") and 360 days after randomisation ("duringStudy")

For inpatient stays, if numerous episodes were listed for a single hospital stay, only the final episode was costed. This involved excluding records where ** Discharge destination = 98; Discharge date = 01jan1801 (1,890 observations deleted). The combined day case/ ordinary elective spell tariff was applied to all admissions unless the episode contains a diagnosis which is ambulatory care sensitive (as recorded in HES), in which case the non-elective spell tariff was applied.

A small number of reported HRGs were not linked to National Tariff 201718. For these, we applied the mean value:

HRG descriptions were available for mapped records, which included a brief description of principle reason for admission. We identified key falls-related phrases and created dummy variables where these appeared.

- gen fractureHRG = strpos(HRGname, "Fracture") > 0

- gen fortraumaHRG = strpos(HRGname, "for Trauma") > 0
- gen tendancyfallHRG = strpos(HRGname, "Tendency to Fall,") > 0
- gen anyfallsHRG = fracture + fortrauma + tendancyfall
- gen hipHRG = strpos(HRGname, "Hip") > 0
- gen armHRG = strpos(HRGname, "Arm") > 0

*** saved output in "HES APC Admission details inc Falls.txt"

n=1296 costed stays within observation period

n=669 participants with at least one hospital admission in observation period

Outpatient attendances were mapped to the National Tariff based on Treatment Specialty (variable "tretspef"). All attendances were classed as single professional. Unit costs were attributed to either first attendance (35%, mean cost £xxx) or follow-up (65%, mean costs xxx). Where Treatment Specialty was not available, mean imputation was applied based on all other available costs.

QoL (DemQol and EQ-5D-5L) Self Report QALY

DemQoL: Self-report responses available at each time point

	GtACH # available	% available (max=732)	GtACH score	Usual Care # available	% available (max=871)	Usual Care score
DemQ-SELF 0	158	22%	0.831	187	21%	0.810
DemQ-SELF 3	128	17%	0.789	142	16%	0.771
DemQ-SELF 6	114	16%	0.743	136	16%	0.716
DemQ-SELF 9	127	17%	0.689	142	16%	0.656
DemQ-SELF 12	130	18%	0.659	132	15%	0.603
DEMQoL Self Report QALY	**85**	**12%**	**0.722**	**91**	**10%**	**0.724**

EQ-5D-5L: Self-report responses available at each time point

	GtACH # available	% available (max=732)	GtACH score	Usual Care # available	% available (max=871)	Usual Care score
EQ5D-SELF 0	157	21%	0.525	187	21%	0.455
EQ5D-SELF 3	131	18%	0.467	148	17%	0.479
EQ5D-SELF 6	120	16%	0.440	136	16%	0.429
EQ5D-SELF 9	129	18%	0.439	143	16%	0.375
EQ5D-SELF 12	130	18%	0.431	137	16%	0.365
EQ5D Self Report QALY	**90**	**12%**	**0.459**	**95**	**11%**	**0.444**

Health Economics Analysis Plan

Health Economic Analysis Plan for the FinCH trial: Falls in Care Homes (FinCH)

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SECTION 1: ADMINISTRATIVE INFORMATION

1.1   Title: Health Economic Analysis Plan for the FinCH trial: Falls in Care Homes (FinCH)

1.2   Trial registration number: ISRCTN34353836

1.3   Source of funding:

National Institute for Health Research HTA Programme (NIHR HTA Project 13/115/29) is providing funding for research costs for the project duration to cover trial set up, trial conduct, analysis and report writing. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA programme, the NIHR, the NHS or the Department of Health.

1.4   Purpose of HEAP

This document will outline the methods to be used in the economic evaluation to be conducted alongside the FinCH Trial, including how data will be collected, analysed and reported. It will be finalised and reviewed prior to the trial database being locked to ensure it is appropriate to the aims of the trial and reflective of current practice. This HEAP has been written in line with the trial protocol and SAP in order to ensure there is consistency. Amendments to the health economics analysis plan will be described and justified in the final report of the trial.

1.5 Trial protocol version

This document has been written based on information contained in the trial protocol version 6.0, dated 14th November 2017.

1.6 Trial statistical analysis plan (SAP) version

SAP version: 0.1, 10TH April 2019

1.7 Trial HEAP version

HEAP version: 0.1, Date: 14th May 2019

1.8 HEAP revisions

Protocol Version	Updated HEAP version No	Section number changed	Description of and reason for change	Individual making the change	Individual making the change

1.9 Roles and responsibilities

This HEAP was written by the senior health economist (TS), who is a co-applicant on the grant, and Lisa Irvine (LI), the Research Fellow for the project. TS has inputted into the design of the wider trial as well as taken the lead on designing all aspects of the health economics analysis attached to the FinCH trial. TS will be advising on the economic analysis and writing up the within-trial economic. LI will undertake the within-trial analyses and contribute to and review the write-up for accuracy.

1.10 Signature(s):

The following people have reviewed the Health Economic Analysis Plan and are in agreement with its contents			
Name	**Role**	**Signature**	**Date**
Prof Tracey Sach	FinCH Co-investigator / CTU Health Economist		
Lisa Irvine	CTU Health Economist		
Associate Prof Sarah Armstrong	Trial Statistician		
Prof Pip Logan	Chief Investigator		

1.11 Abbreviations/glossary of terms/definitions

List any abbreviations and/or acronyms used within the HEAP alongside their meanings/definitions

Abbreviation	**Meaning**
CEA	Cost Effectiveness Analysis
CEAC	Cost Effectiveness Acceptability Curve
CUA	Cost Utility Analysis
DEMQOL- U	Dementia Quality of Life Utility version, self-complete
DEMQOL-P-U	Dementia Quality of Life Utility version, proxy-complete
EQ-5D-5L	EuroQol Five Dimensions Five Levels, self-complete
EQ-5D-5L-P	EuroQol Five Dimensions Five Levels, proxy-complete
HEAP	Health Economic Analysis Plan

ICER	Incremental Cost Effectiveness Ratio
NHS	National Health Service
QALY	Quality-Adjusted Life Year

SECTION 2: TRIAL INTRODUCTION AND BACKGROUND

2.1 Trial background and rationale:

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

The Guide to Action in Care Homes (GtACH) intervention aims to reduce fall rates by facilitating change in practice of care home staff. It was co-produced by a group of care home staff, clinicians, researchers, public, voluntary and social care organisations and includes care home staff training, support and documentation. With training, the GtACH takes on average 20 minutes to complete for each resident, compared to 2 hours per resident without training (Robertson 2012). An introductory GtACH paper has been published (Robertson 2012) and its content and delivery have been refined through a proof of concept study (Robertson 2010) and a Research for Patient Benefit (RfPB) funded randomised controlled feasibility trial (Walker 2016; REC number: 12/WM/0091).

Testing the effectiveness of interventions to prevent falls and injuries in those over 65 years of age is a priority (RoSPA, 2013). The FinCH trial is a cluster randomised controlled, 2 arm, parallel group trial comparing the GtACH fall prevention intervention against usual care for people living in care homes in England (with and without nursing). Care home is the unit of randomisation.

2.2 Aim(s) of the trial
Briefly, the FinCH trial aims to determine the clinical and cost effectiveness of the GtACH for fall prevention in care homes compared to usual care. A process evaluation will be

conducted in parallel with the trial to consider whether the intervention was implemented as intended and to describe usual care.

2.3 Objectives and/or research hypotheses of the trial

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

Secondary objectives include fall rates over later 3 month periods, frequency of fall injuries, frequency and type of fractures, physical activity, functional ability, Quality of life, Medication, number of days in hospital and number of deaths. The health economic analysis will focus on the costs and outcomes over the whole 12 months.

2.4 Trial population

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

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

Resident eligibility criteria are:
•   All long term care home residents providing informed consent
•   Residents without capacity to provide informed consent must have a relative/consultee who will provide advice on their behalf

Resident exclusion criteria
•   Residents in receipt of end of life care or in the home for short term care, respite care or for rehabilitation

2.5 Intervention and comparator(s)

Intervention: The specific technology under investigation is the Guide to Action Care Home (GtACH) fall prevention programme, delivered to care home residents by care home staff who have been trained and are supported (Walker 2016, Robertson et al 2010 and 2012). GtACH is a systematic falls risk assessment and action process, co-designed by care home

and NHS staff, based on NICE clinical guidelines. The assessment takes 15 minutes and actions take up to 2 hours per resident.

Control: The comparator to the intervention will be usual care, where usual care is defined as the absence of a systematic and coordinated falls prevention process. The control care homes will have the option to receive the GTACH training at the end of the trial.

2.6 Trial design
FinCH is a cluster randomised controlled with 2 arm parallel group trial design comparing the GtACH fall prevention intervention against usual care for people living in care homes in England (with and without nursing). The unit of randomisation is the Care Home.

2.7 Trial start and end dates
Recruitment of care homes started in November 2016 and finished in December 2017, but with some randomised in January 2018. The follow up period will run until early February 2019.

Full details of the trial are given in the protocol.

SECTION 3: ECONOMIC APPROACH/OVERVIEW

3.1 Aim(s) of economic evaluation
The aim of the economic evaluation is to address the question "What is the cost-effectiveness of The Guide to Action in Care Homes (GtACH) intervention compared to usual care (an absence of a systematic and coordinated falls prevention process) in UK care homes from an NHS and PSS perspective over the trial duration"?

3.2 Objectives(s)/hypotheses of economic evaluation
The primary objective of the within trial economic evaluation is to estimate the cost-effectiveness of The Guide to Action in Care Homes (GtACH) intervention compared to usual care in UK care homes from an NHS and PSS perspective over 12 months.

3.3 Overview of economic analysis
The Base case within-trial economic analysis will use individual resident level data collected over 12 months from the FinCH trial. The base case analysis will undertake a cost utility analysis from an NHS and PSS perspective estimating the incremental cost per QALY (as estimated using the DEMQOL-P-U) calculated by taking the ratio of the difference in the mean costs and mean effects. Two secondary analyses will be undertaken. Cost-utility will be re-estimated using utility estimated using the EQ-5D-5L proxy to estimate QALYS and for those residents with data available (due to mental capacity) the EQ-5D and DEMQOL-U self-complete. This secondary analysis is important due to uncertainties about how best to

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capture health utilities in this population (Rowen et al. 2012, Mulhern et al 2013, Herdman et al 2011).

The evaluation will adhere to published guidelines for the economic evaluation of health care interventions as appropriate (Drummond et al 2015; Ramsey et al 2015; Glick et al 2014; Husereau, D., 2013, NICE 2013).

3.4 Jurisdiction

The trial is being conducted in the UK which has a national health service (NHS), providing publicly funded healthcare which is largely free of charge at the point of use. Care home provision and Personal social services have mixed funding depending on ability to pay.

3.5 Perspective(s)

The analysis will take an NHS and PSS perspective in keeping with the NICE reference case (NICE 2013). All NHS and PSS resource use will be collected, not only that specific to falls.

3.6 Time horizon

The primary economic analysis will compare the costs and consequences of each arm over the first 12 month after randomisation.

SECTION 4: ECONOMIC DATA COLLECTION AND MANAGEMENT

4.1 Statistical software used for HE analysis

STATA MP 15.1 will be used to conduct the analysis.

4.2 Identification of resources

Identification of relevant health care and social care resources will be ascertained at an early stage by the trial health economists and in consultation with the clinical team. Items for costing will be identified from the pilot study (Fich), literature searches, and referring to the Database of Instruments for Resource Use (DIRUM www.dirum.org). The cost analysis will focus on high cost drivers and those resources which are expected to differ between study arms (Ramsey et al., 2005).

Resource use data will be collected from a variety of sources as detailed below:

<u>Intervention resource use</u>

Intervention costs belong in two categories – those that are fixed costs (i.e. incurred at the beginning no matter how many residents are recruited) and those that are variable and depend on how many residents participate.

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The fixed costs include the GtACH documentation, the GtACH training session which is to be delivered to at least 80% of care home staff by the site falls lead, the GtACH refresher training and support provided by the falls prevention leads in the first 3 months of delivery. Specific training details will be recorded by the Falls Lead at each site and multiple responses will be collated and an average annualised unit cost estimated. If costs vary widely between centres or individual falls leads, sensitivity analysis may be performed.

The variable costs of the intervention will be captured in the trial case report form (CRF) for each resident recording health and social care resource use items directly related to the intervention, including time spent undertaking the risk assessment, implementing the GtACH plan and adaptive equipment ordered as a result of the intervention (the equipment cost will be annualised to reflect the expected lifespan of the piece of equipment). Over the 12 month period any re-assessments using the GtACH, due to for instance a fall being experienced, will be captured.

Resource use associated with wider health and social care contacts

Routinely collected data will be obtained from the following record source by the research assistants at each care home:

Care home records (to collect data on falls, fractures, use of aids, health and social care service use, referral to secondary care, death).

Incident report forms (alternative source of data on falls)

Medication administration record (consent will be sought to allow clarification of medication data from GP records where necessary)

Hospital episode statistics (to collect data on inpatient admission, outpatient, and A&E visits sourced via NHS digital)

4.3 Measurement of resource use data
Baseline resource use will be collected as it is likely to predict future costs. This will monitor resource use three months prior to randomisation.

Resource use will be extracted from care home residents care plans by study research associates at baseline, and 3, 6, 9, and 12 month follow-up. Researchers will complete the extraction at the care home and enter the data directly to the study-specific website. This data collection method was piloted at a sample of care homes as part of the FiCH feasibility study.

4.4 Valuation of resource use data

All resource use will be valued in monetary terms using appropriate UK unit costs estimated for the most up to date cost year at the time of analysis.

Unit costs for the most recent year available will be applied based on annually published national sources such as National Schedule of Reference Costs, the PSSRU's Unit Costs of Health and Social Care, and the Prescription cost analysis (DH 2018, Curtis and Burns 2018, HSCIC 2018). If national costs do not exist for items of resource use, unit costs will be sourced locally or from published peer review journals. To ensure transparency and reproducibility, a table showing the main resource items, their costs and sources will be reported (See Appendix 1).

4.5 Identification of outcome(s)

The economic evaluation includes a generic outcome measure, EuroQol EQ-5D-5L and a dementia-specific outcome measure, the DEMQOL-U (Mulhern 2013, Rowen et al., 2012) both of which can be used to estimate Quality Adjusted Life Years (QALYs). Both have self-complete and proxy versions available, thus with concerns about poor reliability (Devine 2013) this trial will collect proxy estimates for all residents from their main carer. Those with capacity will be asked to self-report quality of life measures. We will then be able to compare likely bias. The feasibility study showed that residents with capacity were accepting towards completion of a relative self-report measure; the Barthel ADL (Collin 1988) and care staff were accepting of proxy completion.

The choice to use both instruments reflects the fact that the utility value sets, DEMQOL-U and DEMQOL-P-U, have only recently been published so have not been extensively used or validated as yet in funded trials. We are aware from previous research that measuring HRQL in care home populations can be problematic in terms of achieving good response rates due to high cognitive impairment (Gordon et al., 2010), however, the EQ-5D-5L has successfully been used in a care home population to inform the economic evaluation of exercise for depression (Underwood 2013).

The primary base case analysis will use the DEMQOL-P-U to estimates QALYs. Secondary analyses will consider the other utility alternatives. A further secondary analysis will undertake a cost effectiveness analysis reporting the incremental cost per fall prevented over the 12 months.

4.6 Measurement of outcome(s)

Residents or their proxy will complete outcomes questionnaires at baseline and at 3, 6, 9 and 12 months follow-up.

4.7 Valuation of outcome(s)

In the cost utility analysis, the responses received on the quality of life instruments will be

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converted to utility scores, the DEMQOL-P-U and DEMQOL-U using the valuation set published by Mulhern et al 2013 and Rowen et al 2012. Utility as captured on the EQ-5D-5L will be estimated using UK preference weights in line with current recommendations at the time of the analysis (NICE 2017; Devlin et al 2016). Following this, the utility values will be used to calculate the number of quality adjusted life years (QALYs) generated over the trial period of 12 months, using both linear interpolation and area under the curve analysis with and without baseline adjustment (Manca, 2005).

A secondary cost effectiveness analysis will be undertaken to report the cost per fall prevented over the 12 month trial period.

SECTION 5: ECONOMIC DATA ANALYSIS

5.1 Analysis population
The economic base-case analysis will take an intention to treat principle approach including all randomised residents with data available. The final number of residents included in the economic analysis will be stated, as this may be different from the primary clinical analysis. Since data on resource use and utility is collected from care home notes review and proxy completed residents who die during the course of the study will be included in the analysis to reflect the fact that the intervention may have an impact on rate of death.

5.2 Timing of analyses
The primary final analysis will be a within-trial analysis conducted once all residents have been followed for 12 months after GtACH training has taken place. The data will be cleaned and locked before analysis begins.

5.3 Discount rates for costs and benefits
As the trial is only for one year of resident follow-up, costs and outcomes will not be subject to discounting.

5.4 Cost-effectiveness threshold(s)
The estimated mean costs and QALYs per resident associated with each intervention option will be combined with a feasible range of values for decision makers' willingness to pay (λ), to obtain a distribution of net benefits at different levels of λ. The economic analysis will use a cost-effectiveness threshold (λ) of £20,000 per QALY.

5.5 Statistical decision rule(s)
As appropriate, all statistical tests will be two-sided with the statistical significance level set at 5%.

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5.6 Analysis of resource Use

Mean (sd) resource use per resident will be estimated for each randomised group. Mean difference (95% CI) in resource use per resident between arms will be presented.

5.7 Analysis of costs

Mean (sd) cost per resident will be estimated for each randomised group. Mean difference (95% CI) in cost per resident between arms will be estimated unadjusted and adjusted (for for type of care home (residential, nursing, dual registration), site, and any other variable deemed appropriate, for instance baseline cost).

The primary analysis will include residents who died during the study. We will report separately the mean cost at each time point, the mean cost per intervention arm and mean (95% CI) difference in cost over the 12 month period excluding those who died during the study for comparison.

5.8 Analysis of outcomes

The primary outcome for the economic evaluation will be quality-adjusted life years (QALYs) of the resident at 12 months as valued using the DEMOQOL-P-U. Utility values will be obtained from the proxies and individuals' own (where they have mental capacity) health related quality of life responses to the DEMQOL-U and EQ-5D-5L questionnaire at baseline, 3, 6, 9 and 12 months. Responses will be converted into a utility using standard UK tariff values, the DEMQOL-P-U and DEMQOL-U using the valuation set published by Mulhern et al 2013 and Rowen et al 2012 and those for the EQ-5D-5L in line with recommendations at the time of analysis (NICE 2017; Devlin et al 2016) . These utilities will represent patients' overall quality of life and be multiplied by the time spent in each state to generate QALYs. Qalys will be estimated unadjusted and adjusted (Manca, 2005) using an appropriate regression model to adjust for any imbalance in baseline utility (however small) and the type of care home and site. These will be presented as mean (SD) utility and mean (sd) QALYS per resident per randomised group and mean difference (95% CI) in utility and QALYs between arms will be estimated unadjusted and adjusted (for centre and number of immediate family members with atopic disease (1, 2 or more than 2)).

The primary analysis will include residents who died during the study. We will report separately the mean utility at each time point, the mean QALY per intervention arm and mean (95% CI) difference in QALY over the 12 month period excluding those who died during the study for comparison.

5.9 Data Cleaning for analysis

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Before carrying out analyses, plausibility checks will be performed on the relevant data fields, such as resource use and reported outcome measures, such as quality of life. Where problems are identified, the health economist will contact the data manager of the trial for clarification.

5.10 Missing data

The economic analysis will examine the data for any missing data. Since resource use data is being collected from notes review and utility instruments are proxy completed this data should be available for all residents up to the point where they died or the study finished. Those that died during the study have censored data but will be included in the analysis using the data available until death. Those that died will only contribute to the rate of missing data where data is missing for the period whilst they were alive. If the share of missing data is less than 10% a complete case analysis will be undertaken as part of the base case analysis. If greater than 10% then the base case analysis will be undertaken using multiple Imputation (Faria et al 2004) assuming data are missing at random with sensitivity analysis conducting complete case analysis for comparison.

5.11 Analysis of cost-effectiveness

Mean cost and QALY data will be combined to calculate an incremental cost-effectiveness ratio (ICER) and net monetary benefit (NMB) statistic from the NHS and PSS perspective. Since this economic evaluation will be undertaken alongside a cluster randomised trial the analysis needs to reflect the increased uncertainty of randomising clusters rather than individuals. A number of approaches have been proposed for this, with each found to generate similar findings (Gomes 2012b, Gomes 2012a). Regression analysis of cost and QALYs, will be undertaken to adjust for important covariates as deemed appropriate (for instance, baseline cost and baseline utility).

5.12 Sampling uncertainty

It is likely that costs and outcomes will be skewed, therefore non-parametric bootstrapping will be used to determine the level of sampling uncertainty surrounding the mean ICERs by generating 10,000 estimate of incremental costs and benefits. These estimates will be plotted on a cost-effectiveness plane. In addition, Cost-Effectiveness Acceptability Curves will be produced, which will show the probability that each of the intervention arms is cost effective at different values of willingness to pay.

5.13 Subgroup analysis/Analysis of heterogeneity

No subgroup analyses are planned.

5.14 Sensitivity analyses

Sensitivity analyses will be undertaken to explore uncertainties surrounding key parameters in the economic evaluation in order to investigate how robust the findings are. The following sensitivity analyses will be undertaken if appropriate:

1.   Dealing with missing data, see section 5.10.
2.   The cost of the GtACH intervention will be varied to test the impact this has on the incremental cost per QALY estimated using the DEMQOL-P-U. Values will be varied to find at what cost, if any, the intervention would switch from being cost effective to cost ineffective or vice versa.

Additional analyses using the health economic data beyond that described in this document may be possible, in particular, further work could be undertaken to compare the performance of the EQ-5D-5L and DEMQOL-U as well as a using the HES data (subject to approvals) to estimate the cost of a fall. This work will not be reported within the NIHR Journals monograph.

SECTION 6: MODELLING AND VALUE OF INFORMATION ANALYSES

6.1 Extrapolation or Decision analytic modelling

The within-trial base case time horizon will be 12 months. It is expected that the majority of costs and benefits associated with the intervention will be captured in this period, and therefore it is not considered necessary to develop a decision-analytic model.

SECTION 7: REPORTING/PUBLISHING

The economic analysis will be published alongside the clinical analysis in a peer-reviewed journal as appropriate.

7.1 Reporting standards

The CHEERS reporting quality guidelines will be followed when writing up the health economic evaluation (Husereau et al 2013).

7.2 Reporting deviations from the HEAP

Any deviations necessary from the HEAP will be described and justified in the main study report (NIHR HTA monograph).

SECTION 8: Appendices

8.1 Appendices: Example Tables

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Unit Costs Table (UK£ sterling, Price Year)

Cost Item	Unit of measure	Unit Cost (£)	Source
Intervention			
Development			
Delivery			
NHS Care			
GP (in hours)	Appointment / telephone call / home visit		PSSRU
GP (out of hours)	telephone call / home visit		PSSRU
Practice Nurse	Appointment / telephone call / home visit		PSSRU
District Nurse	Appointment / telephone call / home visit		PSSRU
Physiotherapist	Per appointment		PSSRU
Occupational Therapist	Per appointment		PSSRU
Chiropodist/Podiatrist	Per appointment		PSSRU
Social worker	Per appointment		PSSRU
Pharmacist	Per appointment		PSSRU
Inpatient stay	Bed day		NHS Reference costs
Tests or procedures	Per test		NHS Reference costs
Other (incl. secondary care not covered above)			
Prescribed medication	Per item		Prescription cost analysis

Mean (sd) resource use and mean (95% CI) difference in resource use at 24 months

Cost Item	GtACH Intervention (n=)	Usual care (n=)	Mean difference (95% CI)
Intervention			
Development			
Delivery			
NHS Care			

GP (in hours)			
GP (out of hours)			
Practice Nurse			
District Nurse			
Physiotherapist			
Occupational Therapist			
Chiropodist/Podiatrist			
Social worker			
Pharmacist			
Inpatient stay			
Tests or procedures			
Other (incl. secondary care not covered above)			
Prescribed medication			

Mean (sd) cost and mean difference in cost at 24 months

Cost Item	GtACH Intervention (n=)	Usual care (n=)	Mean difference (95% CI)
Intervention			
Development			
Delivery			
NHS Care			
GP (in hours)			
GP (out of hours)			
Practice Nurse			
District Nurse			
Physiotherapist			
Occupational Therapist			
Chiropodist/Podiatrist			
Social worker			
Pharmacist			
Inpatient stay			
Tests or procedures			

Other (incl. secondary care not covered above)			
Prescribed medication			

Utility and QALYs

	GtACH Intervention (n=)		Usual Care (n=)		
	Mean	Std dev	Mean	Std dev	n
Proxy Completed					
DEMQOL-P-U baseline					
DEMQOL-P-U 3 months					
DEMQOL-P-U 6 months					
DEMQOL-P-U 9 months					
DEMQOL-P-U 12 months					

QALYs (DEMQOL-P-U) at 12 months					
EQ-5D-5L-P baseline					
EQ-5D-5L-P 3 months					
EQ-5D-5L-P 6 months					
EQ-5D-5L-P 9 months					
EQ-5D-5L-P 12 months					
QALYs (EQ-5D-5L-P) at 12 months					
Self-completed					
DEMQOL-U baseline					
DEMQOL-U 3 months					
DEMQOL-U 6 months					
DEMQOL-U 9 months					
DEMQOL-U 12 months					
QALYs (DEMQOL-U) at 12 months					
EQ-5D-5L baseline					
EQ-5D-5L 3 months					
EQ-5D-5L 6 months					
EQ-5D-5L 9 months					
EQ-5D-5L 12 months					
QALYs (EQ-5D-5L) at 12 months					

Appendix H - Fidelity Checklists used in the Process evaluation

Fidelity Checklist for the Falls Leads Training

Assessment of fidelity for the GtACH training in the Falls in Care Homes trial

Aim:

To ensure that the training completed by the Falls Leads is consistent with the Train the Trainer session and across the trial sites.

Method:

The qualitative researchers (and sometimes the PPI) will observe training sessions, across each of the six process evaluation homes. The qualitative researchers will observe the first training session completed in each home, enabling advice to be provided and acted upon. The PPI may then observe some of the subsequent training sessions.

Participant ID: Date:

Care Home ID:

Time training commenced: Time training completed:

Circle appropriate response below

Did any staff arrive late for the session?   Yes: No:

Comments:

Did all staff stay for the entire session?   Yes: No:

If no, record reasons for staff leaving e.g. telephone call/asked to assist resident:

Were there any interruptions to the session?   Yes: No:

If yes, record reasons for interruptions: residents entering the room/fire alarm/queries from other staff:

Tick each of the listed activities observed during the session, and add a brief description if necessary

Activity	Obs √	Comments
Falls Lead outlined purpose of the study		
Falls Lead outlined purpose of the training		
Falls lead outlined prevalence of falls in care homes		
Falls lead explained GtACH history		
Falls Lead explained how to complete GtACH forms (including the need to outline/highlight risk factors/tick corresponding risk factor boxes/read suggested actions/document actions/sign and date the form)		
Falls Lead outlined who should complete the GtACH forms and team approach		
Falls Lead outlined where to file completed GtACH forms		
Falls Lead outlined what to do if resident falls		
Falls lead outlined when GtACH should be repeated and reviewed		
Attendees given time to complete case study and GtACH individually		
Attendees given time to ask questions and share outcomes		
Falls Lead showed and discussed GtACH manual		
Falls Lead provided their contact details		

Falls Lead provided name and explained the role of the Falls Champion in the home		

Any distinct observations in the training session observed?

Details:

Fidelity of Treatment observed visit summary		
Meets fidelity requirements	YES? ☐	NO? ☐
Signed : Assessor (Print Name):		Date:
If there are any suggested actions, please complete below:		

Actions by Assessor	Actions by Falls Lead	Resolved	
Actions resolved?			

	YES? ☐	NO? ☐
Signed :		
Reviewer (Print Name):	**Date:**	

Fidelity Checklist for Care Home staff implementing GtACH

Aim:

To ensure that the GtACH is implemented consistent with the training delivered and across the trial sites

Method:

The qualitative researchers will observe care home staff implementing the GtACH, across each of the six process evaluation homes. The qualitative researchers will spend a day in each home and observe several care home staff completing the GtACH checklist, incorporating both assessment and actions taken.

Care Home Staff Participant ID:

Care Home ID: Date:

Circle appropriate response below

Was this the first GtACH assessment for the staff member: Yes: No:

Was this the first GtACH assessment for the resident: Yes: No:

If no, was this a routine review or post fall assessment?

Time observation started: Time observation completed:

Where was GtACH completed? (e.g. office/lounge/resident room):

Was GtACH completed away from others: Yes: No:

Comments:

Was GtACH completed using a variety of sources? (e.g. with resident/use of care home notes/MARS sheet/incident forms). Please state:

Tick each of the listed activities observed during the session, and add a brief description if necessary

Activity	Obs √	Comments
Did staff member outline or highlight risk factors		
Did staff member tick corresponding risk factor boxes		
Did staff member read the suggested action column		
Did staff member document actions to be taken		
Did staff member take any actions? If not, why not?		
If actions taken was this dated and signed		
Did staff member sign and date when assessment completed at the bottom of the form		
Did staff member refer to the manual		
Where did staff member file the GtACH		

Any distinct observations from the GtACH assessment observed?

Details:

Fidelity of GtACH implementation observation summary			
Meets fidelity requirements		**YES?** ☐	**NO?** ☐
Signed : **Assessor (Print Name):**		**Date:**	
If there are any suggested actions, please complete below:			
Actions by Assessor	**Actions by staff member**	**Resolved**	
Actions resolved?		**YES?** ☐	**NO?** ☐
Signed : **Reviewer (Print Name):**		**Date:**	

Appendix I - Focus group and interview topic guides used in the Process evaluation

Focus Groups: (Stage 1)

[The focus group schedule is iterative and will be developed as the study proceeds].

GtACH training:

How do you feel about taking part in the research trial?

Can you tell me if you all attended the GtACH training, and if not, why not?

Was you all able to stay for the entire GtACH training session, and if not, why not?

Can you tell me what the training was like? (Prompts: What did you think of the information given during the session? What did you think about the practical component of the session? Did you feel encouraged to start using the GtACH following the training?)

Can you give me any examples of what you felt you learnt from the training session?

How confident did you feel that the training session offered sufficient support for you to start using the GtACH?

What do you think of the GtACH? Please be honest with your views.

Did you feel that you left the training session with the necessary skills to use the GtACH, and if not, what were your concerns?

How motivated and enthusiastic did you feel about using the GtACH after the training session?

Since the training session have any of you used the GtACH, and if so, how have you found it?

For those of you that have used the GtACH, can you tell me about any actions you have identified?

Have you been able to put those actions into place, and if not, why not?

Has using the GtACH changed anything for you or the residents?

For those if you that have not yet used the GtACH, what has stopped you from using it?

At this stage, do you feel you need any additional support to use the GtACH? And if yes, what would help?

You have been allocated a Falls Champion for the home, is this a role that you are familiar with, and do you think it will be a helpful role in the home? And if so, in what way?

And finally, do you feel the GtACH is a valuable tool to use in this home, and if yes, in what way?

Many thanks for your time, do you have any questions for me

Focus Groups: (Stage 2) Provisional questions- will be developed on the back of interviews

Have any of you had the opportunity to use the GtACH and if so, can you tell me about your experience of using this tool?

Prompts: How straightforward did you find the tool?

Did you have any difficulties or concerns, and if so can you tell me about them?

Can you tell me about any actions, and give examples, that you identified to be taken to reduce falls risk factors for the resident(s) you were assessing, using the GtACH?

Have you been able to put any of those actions into place, and if not, why not? (Are the actions outside their level of responsibility?)

Has using the GtACH enabled you to identify any risk factors which would not have been identified if this tool was not available?

Has anyone completed a GtACH more than once on the same resident (re-assessment)? And if so, can you tell me about that?

Prompts: Was the reassessment completed due to a fall, a change in the resident's medical or cognitive condition, or a 3-6 month review?

What was the outcome (did it change any aspects of resident's care)?

Are you aware of the role of the Falls Champion in this Care home? [If 'yes'] what do you know about this role?

Have there been any occasions when you have contacted your Falls Champion or the Falls Lead with any queries or difficulties around using the GtACH? Can you tell me about this?

Prompts: Can you give me details of what the difficulties or queries related to?

What response did you receive?

Can you tell me what support you can use when you are completing the GtACH assessment for a resident?

Can you tell me what support you have actually used whilst completing the GtACH?

Prompts: How was this support accessed/how did you obtain/access this support?

How do you feel about using the GtACH?

Do you think that the GtACH has changed anything for you (in the way that you work) or for the residents?

Prompts: How useful do you think the GtACH is in this home?

Potential Questions for Participant Care Staff who report never having used the GtACH

[Confirm attendance at Falls Lead training] Did you attend any of the falls lead training for the GtACH?

[**If did not attend Falls Lead Training**] Can you give me the reason for your answer?

[**If attended Falls Lead Training**] I know it was a long time ago but can you tell me what you learned from this training about the GtACH and its use as a falls risk assessment in Care Homes?

Did the training increase your existing knowledge, prior to this training, in assessing residents' risk factors for falls? Can you tell me how/ in what way(s)? **OR** reasons why not?

Apart from the training session, have you gained any other knowledge of the GtACH from any source, i.e other care staff members/ manual? [**If response is 'yes'**] Can you tell me more about this and where and how this knowledge was gained?

Have you received any feedback from other staff regarding the use of the GtACH and if so can you tell me about it (what and from whom- role in care home- not names)?

Can you tell me what has stopped you from using the GtACH?

Can you tell me what other reasons there might be why you might not use the GtACH with a resident?

All participants:

To finish, what are your thoughts around continuing to use the GtACH once the study has finished?

That is all the questions I have to ask, is there anything else you would like to add about the GTACH before we finish?

Interview schedule (staff)

[It is anticipated that the interviews will be conducted following observation of staff completing the GtACH with residents, and hence the questions are iterative, and will be developed as a result of individual observations]

1. Can you tell me if you attended the GtACH training, and if not, why not? If you did attend the training session was you able to stay for the entire session, and if not, why?

2. a).The GtACH Manual is a resource for the Care Home, as identified during the Falls Lead training session, can you tell me where this is stored in this Care Home?
    b) When would you use it?
    c) Have you used the GtACH Manual (as demonstrated during the Falls Lead Training) and if so [when and why] in what circumstances?

3. Can you tell me how you felt about completing the GtACH with/for the resident?
    Prompts: a. Can you tell me the reason why you completed the GtACH with/for the resident?

    b. Did you find the GtACH straight forward to use or did you have any concerns when using it, and if so, can you tell me about that?

    c. Did you feel you had the necessary skills to complete the GtACH?

    d. If you attended a GtACH training session, how confident did you feel to use the GtACH following this session?

    f. If you have not attended a training session can you tell me the reason for this? Do you feel missing the session has made it more difficult to use the GtACH?

4. Can you tell me where you found all the information to identify [resident name] risk factors for falls?

Prompts: a. Did you have any difficulty finding all the necessary information to identify [resident name] risk factors for falls. And if so, tell me about that?

    b. Do you consider all of the resident's risk factors for falls were identified?

    - How do you know this?
    - How was this confirmed? [i.e. prior knowledge; care plan; observation]
    c. Can you give me any examples of any actions you identified using the GtACH to reduce the resident's falls risk(s)?

If the participant used the care plan as the main source of information, ask the following: (if not, go to question 5 below)

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a. Do the residents' care plans provide you with the main source of information?
b. If you used information from the resident's care plan, how do you know this is up to date?
c. How often are the residents' care plans usually updated?
d. Do you consider you have enough time to read the care plan(s) to provide you with the information required for assessing the resident's risk factors for falls? If 'yes' when? How often?

5. Are there other sources, apart from those that you used during the observation [or used for the GtACH if an observation was not completed], where you could collect information on the residents' risk factors for falls, and if so can you tell me where you might go to collect this information?

6. Do you feel you have the necessary skills to complete the GtACH, and if not, what are the areas that concern you?

   Prompt: Do you feel you have received sufficient support to use the GtACH and if not, what additional support might be helpful?

7. Do you use the care homes current falls risk assessment?

   Prompt: Do you feel the GtACH offers anything different/additional to the current care home assessment, and if so what?

8. If you came up against any difficulties completing the GtACH who would you go to for support? (i.e. in home support/external support)

9. Do you think the GtACH has been useful or not for [resident name]? Can you tell me why?
Prompt: a. What do you think has been good or not so good about the GtACH for [resident name]?

   b. In what way do you feel the GtACH may or may not be a valuable tool to use in this home?

   c. Having used the GtACH for the observation, what are your thoughts and opinions about continuing to use this tool with residents in order to assess their risk factors for falls?

10. Finally, is there anything else you would like to say about the GtACH that we have not covered?
    Many thanks for your time, do you have any questions for me?

Interview schedule (staff and residents)

(Version 2: 2/06/17)

[It is anticipated that the interviews will be conducted following observation of staff completing the GtACH with residents, and hence the questions are iterative, and will be developed as a result of individual observations]

Staff: 1. Can you tell me if you attended the GtACH training, and if not, why not? If you did attend the training session was you able to stay for the entire session, and if not, why?

2. a. The GtACH Manual is a resource for the Care Home, as identified during the Falls Lead Training session; can you tell me where this is stored in this Care Home?
    b. Have you used the GtACH Manual (as demonstrated during the Falls Lead   Training) and if so when and why?

3. Can you tell me how you felt about completing the GtACH with/ for the resident?
    Prompts:

    a. Can you tell me the reason why you completed the GtACH with/ for the resident?

    b. Did you find the GtACH straight forward to use or did you have any concerns when using it, and if so, can you tell me about that?

    c. Did you feel you had the necessary skills to complete the GtACH?

    d. If you attended a GtACH training session, how confident did you feel to use the GtACH following this session?

    f. If you have not attended a training session can you tell me the reason for this? Do you feel missing the session has made it more difficult to use the GtACH?

Resident: How did you feel about being asked the GtACH questions?

Prompts: a. What did you think about the GtACH questions?

   b. Did you feel comfortable being asked the questions?

   c. Did you feel that other residents could or could not over- hear what was being said when the GtACH was being completed?

   d. How confident do you feel that the GtACH will help reduce the risk of you falling in the future?

4. Staff: Can you tell me where you found all the information to identify [resident name] risk factors for falls?

Prompts: a. Did you have any difficulty finding all the necessary information to identify [resident name] risk factors for falls. And if so, tell me about that?

   b. Do you consider all of the resident's risk factors for falls were identified?
     • How do you know this?
     • How was this confirmed? [i.e prior knowledge; care plan; observation]
   c. Can you give me any examples of any actions you identified using the GtACH to reduce the resident's falls risk(s)?

   If the participant used the care plan as the main source of information, ask the following:

   a. Do the residents' care plans provide you with the main source of information?
   b. If you used information from the resident's care plan, how do you know this is up to date?
   c. How often are the residents' care plans usually updated?
   d. Do you consider you have enough time to read the care plan(s) to provide you with the information required for assessing the resident's risk factors for falls? If 'yes' when? How often?

5. Staff: Are there other sources where you could collect information on the residents' risk factors for falls, and if so can you tell me where you might go to collect this information?

6. Staff: Do you feel you have the necessary skills to complete the GtACH, and if not, what are the areas that concern you?

Prompt: a. Do you feel you have received sufficient support to use the GtACH and if not, what additional support might be helpful?

7. Staff: Do you use the care homes current falls risk assessment?

Prompt: Do you feel the GtACH offers anything different/additional to the current care home assessment, and if so what?

Resident: Have you fallen before, and if so, can you tell me about that?

Prompt: a. Do you have any worries about falling, and if so, can you tell me about that?

8. Staff: Thinking back to the resident were you able to complete the actions to take to reduce their risks of falls?

Prompt: a. Have you been able to complete the actions identified on [resident name] GtACH, and if not, can you tell me what has prevented the actions being completed?

Resident: Are you aware if any actions have been taken to reduce your risk of falls since the GtACH was completed with you? If yes, can you tell me about what has been done?

9. **Staff:** If you came up against any difficulties completing the GtACH who would you go to for support? (i.e in home support/ external support)

10. **Staff:** Do you think the GtACH has been useful or not for [resident name]? Can you tell me why?

Prompt: a. What do you think has been good or not so good about the GtACH for [resident name]?

b. In what way do you feel the GtACH may or may not be a valuable tool to use in this home?

c. Having used the GtACH for the observation, what are your thoughts and opinions about continuing to use this tool with residents in order to assess their risk factors for falls?

Resident: Do you think the GtACH assessment has been useful or not for you? Can you tell me why?

Prompt: a. What do you think is good or not so good about the GtACH?

11. **Staff /resident:** Finally, is there anything else you would like to say about the GtACH that we have not covered?

Many thanks for your time, do you have any questions for me?

Care Home Manager Interview Schedule

[The interview schedule is iterative and will be developed as the interviews and focus groups proceed].

1. Can you start by telling me what interested you in taking part in the FinCH study?

Prompt: a. Has the home taken part in any previous research trials or is research a new experience for the staff in this home?

2. Have you attended a GtACH training session, and if so, what are your thoughts on the training?

Prompts: a. What did you think of the information given during the session?

b. What did you think about the practical component of the session?

c. Did the training session increase your existing knowledge in the assessment of resident's risk factors for falls? And if so in what way?

d. How motivated and encouraged did you feel to use the GtACH within this care home following the training session?

e. At the end of the session, did you feel that the staff, and yourself, had the necessary skills to use the GtACH with your residents?

f. How confident did you feel that the training session offered sufficient support for staff to start using the GtACH?

g. Did you anticipate any difficulties with using the GtACH in your home after attending the training session, and if yes, what were these difficulties? Have any of those difficulties subsequently arisen?

h. If you have not attended a training session can you tell me the reason for this?

3. How easy or difficult was it to rota staff onto the GtACH training sessions?

Prompts: a. Have the sessions been flexible enough to fit around shift patterns and around the routine of the home?

b. Have any difficulties arisen around staff attending the training sessions, and if so, tell me about those difficulties?

c. Have you received any feedback from the staff on their views and opinions of the GtACH training session, and if so, tell me about the feedback received?

4. Have you completed the GtACH with any residents, and if so, how do you feel about using the GtACH?

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Prompts: a. Do you perceive that the GtACH has been useful or not?

         b. Have staff fed back their views on what they think is good or not so good about the GtACH, and if yes can you tell me about their views?

         c. Are you aware of any difficulties that staff have encountered using the GtACH, and if so, can you tell me about those difficulties?

         d. Have staff reported any difficulties completing the actions highlighted on the GtACH, and if so, can you tell me about those difficulties?

         e. Have any residents or their family fed back their views on what is good or not so good about the GtACH, and if yes, can you tell me about their views?

         f. In what way do you feel the GtACH may or may not be a valuable tool for your home?

         g. Do you think the GtACH could be improved in any way, and if so, can you tell me about that?

5. Do you feel that you and your staff have received enough support to use the GtACH, and if not, what extra support would have been helpful?

Prompts: a. How helpful have you found the Falls Lead, both in terms of the training provided and the subsequent support to implement the GtACH?

         b. Do you feel that 3 months is a sufficient period of time for support from the Falls Lead, or would you recommend a shorter or longer period of time?

6. Before taking part in this research study were you familiar with the role of champions in care homes, and if yes, have you any champions already in the home? Can you tell me about that?

Prompts: a. Were you able to allocate someone in the home to the role of a Falls Champion, and if so, how helpful do you feel this role has been?

7. Do you feel that using the GtACH in your home has changed anything for you or your residents, and if yes, in what way?

8. What are your thoughts around continuing to use the GtACH once the study has finished?

9. Finally, is there anything else you would like to say about the GtACH that we have not covered?

Many thanks for your time, do you have any questions for me?

Falls Champion Interview Schedule

[The interview schedule is iterative and will be developed as the interviews and focus groups proceed].

1. How do you feel about taking part in the research trial?

2. How did you feel about being the Falls Champion for the home?

Prompts: a. Before taking part in this research trial was you familiar with the term of 'Champion', and do you have other Champions in the home?

b. Do you have much past experience around falls prevention, and if so, can you tell me about this experience?

3. Have you attended a GtACH training session, and if so, what are your thoughts on the training?

Prompts: a. What did you think of the information given during the session?

b. What did you think about the practical component of the session?

c. Do you feel more knowledgeable on the risks associated with falls and how to reduce those risks following the training session?

d. How confident did you feel that the training session offered sufficient support for you and the staff in the home to use the GtACH?

e. How motivated and enthusiastic do you feel the staff are around using the GtACH in the home?

f. Do you feel that you and the staff in the home have the necessary skills to use the GtACH?

g. After attending the training, did you anticipate any difficulties around using the GtACH, and if yes, what were the difficulties? Have any of those difficulties subsequently arisen?

h. If you have not attended a training session can you tell me the reason for this?

4. How helpful have you found the Falls Lead in offering support?

Prompts: a. Do you feel you have received sufficient support for this role?

b. In what way has the support been helpful or not helpful?

c. Is there any additional support that you feel would have been helpful?

d. Do you feel that 3 months is a sufficient period of time for support from the Falls Lead, or would you recommend a shorter or longer period of time?

5. Have staff come to you when they have needed help or support with the GtACH?

Prompts: a. What difficulties have they encountered?
   b. what help and support has been needed?

   c. Have staff identified any difficulties completing the actions highlighted on the GtACH, and if so, can you tell me about those difficulties?

   d. Have any residents or their family spoken to you about their views on the GtACH, and if so, can you tell me about their views?

6. What do you think is good or not so good about the GtACH?
Prompts: a. Do you perceive that the GtACH has been useful or not in the home?

   b. Do you think the GtACH could be improved in any way, and if so, can you tell me your views?

   c. Do you feel that using the GtACH has changed anything for you or the residents, and if yes, in what way?

   d. What are your thoughts around continuing to use the GtACH once the study has finished?

7. Finally, is there anything else you would like to say about the GtACH that we have not covered?

Many thanks for your time, do you have any questions for me?

Appendix J - Analytic Code Book

	Code	Description
Theme 1.0 - General Codes		
1.1	***Already Falls Aware-proactive***	Already confident to address falls / already doing falls prevention. Aware of impact of falls; assess & take actions to prevent falls already. Everyday role
1.2	***Reactive rather than proactive***	Only considered to be used when someone has fallen and not as a proactive assessment to prevent falls
1.3	***Residents will fall***	Realistic recognition that despite interventions, residents will still fall (can reduce risks but not stop all falls).
1.4	***Desire to learn***	Positive re: learning; Positive about learning new skills; Always room for improvement; Disseminate to others in the home. Staff motivated.
1.5	***Value of staff experience***	GtACH may be more challenging for less experienced carers; more challenging for carers than seniors/manager; Advantage of staff experience; Aids in knowing residents; Already have knowledge; care staff have different knowledge/experience of residents than seniors
1.6	***Work as a team***	Will support each other- importance of a cohesive team/importance of team leader
1.7	***Whole team approach to falls management***	Falls are everyone's business; Seniors consulting care staff re completion of GtACH information.
1.8	***Falls risks/actions/training are being cascaded***	GtACH cascaded to other staff
1.9	***Desire to help residents***	Research may improve resident care; Don't want residents to fall. Improve care
1.10	***Not my role***	Role culture/misconception around what is expected of staff Completing care plans/paperwork (only CTMs do paperwork);any issues/concerns re resident referred to senior .Not all care staff have access to information required for completion of GtACH
1.11	***Advantage of knowing resident well***	Aware of their medical history and their "capabilities", i.e. level of mobility and consequently increases confidence and recognition of any deterioration. Not needing to refer to the resident's care plan
1.12	***Able to identify actions***	In answer to Interview question
1.13	***Need to refer to care plan, accident reports/residents existing records/other sources***	Importance of referring to Care plan record for information relating to the residents relating to the information required to complete the GtACH.
1.14	***Value of involving resident***	Nice to involve residents when they are able to communicate effectively.
1.15	***Have necessary skills to use GtACH***	In answer to interview question
1.16	***Lack of Information at Handover***	Not discussed at team meetings/ staff handover.
1.17	***Care homes have a lot of paperwork***	Care staff have a lot of routine paperwork to complete in the care homes already
1.18	***Family members may not follow CH procedures to reduce falls risks/engage with GtACH***	Resident's family members may request care actions, which the care home management do not agree with.
1.19	***Lots of Falls Occurring***	Falls are a big issue in the home. Falls prevention is a current and big concern in the care homes.

	Code	Description
1.20	*Engagement in the study considered to be positive for home*	Participating in FinCH considered to enhance care home status with inspectors and CQC; considered positive for care home; GtACH a positive tool to show inspectors/families/others
1.21	*Not many falls in the home*	As stated by care staff member(s)
1.22	*Problems accessing [outside] services to address residents' needs*	Falls won't reduce if needs are not addressed
1.23	*Benefit of external expertise (i.e. NHS services)*	I.e. regarding specialist equipment/adaptations needed for individual's needs/medication & treatment

Theme 2.0 - *Positives Re: GtACH*		
2.1	*GtACH can be completed by all staff*	GtACH completed by carers as well as management
2.2	*GtACH promotes a proactive rather than a reactive approach*	GtACH provides knowledge to enable care staff to be proactive rather than just reactive in falls prevention
2.3	*Condensed*	Everything in one place; All together; less paperwork- one sheet of paper; quick reference tool
2.4	*Easy to Complete*	Clear; Not complicated; straight forward; quick; self-explanatory. Will use/has used the GtACH manual. Aware of manual location.
2.5	*GtACH Thorough- supports theory 1*	Comprehensive. Get to know the resident well. Extra information provides suggested 'actions to take' to reduce falls risks? More accurate measurement of risk factors; provides prompts/reminders. Can complement existing falls assessment tool. Reassures staff they have covered everything.
2.6	*Useful tool*	Like the tool/good tool; Interesting tool; Accurate tool
2.7	*Good layout*	? One sheet of paper; participant liked layout although GtACH may not be providing new information; Tick boxes ; same information [as in existing CH falls assessment] written in a different way
2.8	*Would use in future*	In answer to question, carers would use the GtACH again.
2.9	*GtACH useful for new residents*	More helpful for residents new to the Care Home/residents who have started to fall or become ill or become cognitively impaired
2.10	*Shared Communication Tool*	Staff can see what has been completed and what needs actioning ; "staff can follow on"; Enables staff to review actions taken and consider new/alternative actions
2.11	*Evidence*	GtACH provides evidence of action taken. Evidence to show families the care provided to reduce falls risks and CQC
2.12	*GtACH is less complicated than existing Falls assessment paperwork*	
2.13	*Preference for GtACH over existing paperwork*	Found GtACH more detailed and informative than existing paperwork.
2.14	*Confident to use GtACH*	At ease. Confident to use GtACH although looking to researcher for guidance. Confident to follow recommended actions.
2.15	*Aids knowledge of resident*	GtACH helps getting to know the resident(s) better
2.16	*GtACH Provides a prompt*	Informal use of GtACH (implicit) good for prompting memory for knowledge/actions already taken.
2.17	*Residents/family interested in study/GtACH*	

	Code	Description
2.18	*No further falls since GtACH assessment*	No further falls since GtACH actions identified/reviewed
Theme 3.0 - *Negatives re: GtACH*		
3.1	*Familiarisation with the tool (07/11/17:-researchers note: This code more focussed on feelings of respondents; whilst 'Initial Time Investment' code is about practicality and the time needed to use a new & unfamiliar tool)*	GtACH new and scary; staff overwhelmed/anxious about completing the GtACH
3.2	*GtACH secondary to existing paperwork*	GtACH secondary to existing paperwork
3.3	*Recommendations for layout of GtACH*	GtACH needs to be electronic; Difficult to read (including small print) and includes preference for landscape over portrait; electronic version may be helpful; colour of paper GtACH printed on may be helpful for readability; Recommend more columns on GtACH for reviews (FC/Nurse 07). Difficult to read others handwriting. Not enough space to write on GtACH. Different languages.
3.4	*Staff struggle to complete the action column*	This was also observed in fidelity observation in 0402; staff struggle to "connect suggestion to action" on GtACH tool
3.5	*GtACH needs to be in different languages*	
3.6	*Preference for existing paperwork over GtACH*	Care staff members prefer to use existing paperwork and will continue to use this unless told otherwise
3.7	*Limited effectiveness*	Limited effectiveness unless reviewed or actioned promptly
3.8	*GtACH delegated by management*	Decision to complete GtACH determined by management (no personal ownership); GtACH delegated by management to seniors only
3.9	*GtACH complicated*	Not straightforward. Staff struggle to find all the necessary information. Too complicated for a residential home. Too complicated for care staff.
3.10	*GtACH too long*	Could be shortened, particularly in light of lots of other paperwork
3.11	*Sections of GtACH not applicable to resident*	Too comprehensive
3.12	*Lots of paperwork*	Doing the same thing repeatedly in response to a fall generally. Repeating GtACH due to repeated falls- same information.
3.13	*Time consuming*	Need time to complete the assessment properly/thoroughly; particularly if completing for all residents. Insufficient time to complete with some residents.
3.14	*Initial time investment (06/11/17- focusses on practical implications of using a new 'tool')*	Once GtACH completed with all residents it will be more manageable; Takes time for staff to learn the paperwork; will need to implement it slowly through all the residents; Needs time to familiarise self with tool; GtACH difficult on first attempt; initial time investment; Insufficient time to practice GtACH; limited time to practice completing GtACH before FL gave 'answers'; Support needed initially;
3.15	*Time/other commitments hampering engagement in study generally*	Think taking part in the study is a good thing but concerned about the amount of time it will involve owing to ongoing commitments within the care home generally. Change in management/staffing impacting on ability to engage in the study. Staff/resident sickness. Change in

	Code	Description
		management structure/staff impacting on ability to engage in the study. Mandatory training.
3.16	*Already covered in existing paperwork*	GtACH not providing new information. Already covered in existing paperwork; no new actions identified; refer to care plan for more comprehensive/detailed information; (It's nothing new) Doing it already it's just worded differently; already covered in existing paperwork; already falls aware/ proactive; (No new actions identified) Actions suggested on GTACH for resident have already been completed
3.17	*GtACH information not shared amongst the team (conflicts with 'shared communications tool' code)*	
3.18	*Care staff struggle with paperwork*	Care staff generally don't like paperwork and GtACH quite 'wordy'; Care staff not good completing/reluctant to complete paperwork as assessments completed by senior care staff; Care staff only complete 'daily logs' and accident forms usually.
3.19	*Care staff may struggle with terminology*	Both international and non-international staff didn't understand some of the terminology used on the GtACH
3.20	*Perception that completion of GtACH takes time away from resident care*	Care staff members concerned completing the GtACH will take up time they need to provide resident care.
3.21	*Too much depth for residential setting*	
Theme 4.0 - *Negativity re: Falls Champion (FC)*		
4.1	*FC not identified*	Unaware of who FC is; FC not yet identified by Care Home
4.2	*Delays in nominating Falls Champion*	FC not identified until after Falls Lead commenced training in the care home
4.3	*FC not popular*	Unpopular choice (possible personality clashes)
4.4	*FC nominated rather than volunteered*	FC nominated by Care Home management
4.5	*Accessibility of FC*	FC needs to be accessible/needs to be the right person; more than one-needs to be on shift
4.6	*Concern re: time/responsibility/ demands of FC role*	Unwillingness to take on role of FC by participant(s); concern re: amount of work involved and amount of time available to conduct this role within the care home (anticipated concerns)
4.7	*FC role unclear*	FC role not clearly defined. No specific training provided to the FC for this study.
4.8	*Part time work- barrier to FC Role*	Part-time work limits availability to provide support to staff members
4.9	*Will not seek advice from FC*	Will seek advice elsewhere (i.e. team leader)
4.10	*Unfamiliar/negative re: Champion role*	Unfamiliar/negative with champion role generally (not necessarily specific to FC Role) (amended description after QQQ rating Focus Group 0803 [2nd initial focus group])
4.11	*FC needs to be a nurse/senior carer*	
Theme 5.0 - *Positivity re: Falls Champion (FC) role*		

	Code	Description
5.1	*Aware of staff member nominated as FC*	Staff know who is the nominated falls champion
5.2	*Positive about Falls Champion*	'Positive about FC' so can incorporate positivity from FC and other staff members
5.3	*Will go to the FC for help with GtACH*	
5.4	*FC experienced in falls prevention*	
5.5	*Positive about champion role*	Generally, not specific to falls champion
5.6	*Beneficial to have more than one FC*	
5.7	*Awareness/knowledge of FC role*	
Theme 6.0 - *Positives re: Training [in care homes]*		
6.1	*Training provided a tool to put into practice*	
6.2	*Training flexible enough to fit around shift patterns/home routine*	
6.3	*Training session was short*	
6.4	*Falls are reducing*	Although care staff not using the GtACH training has aided in raising awareness which it is believed has contributed to a reduction in falls
6.5	*Training encouraged team working*	Learned from each other during practical session within the training. Swapped ideas
6.6	*Training Provided Confidence and skills*	Apparently unfazed by prospect of using the GtACH following training. Confident not to need FL.
6.7	*Training was enjoyable- interesting*	Room for improvement. Training provided new information; helpful/useful
6.8	*Turned to colleagues for assistance; learned from each other*	Training staff together meant they could support each other when completing the GtACH; Bounced ideas of each other in training
6.9	*Training did provide learning*	Makes you think more about what you do, including new information;
6.10	*Trainer (FL) explains*	Clear explanations by the trainer
6.11	*Practical component of training was useful*	Practical component was good
6.12	*Following training- more falls aware*	
6.13	*Training encouraged a proactive response*	Proactive rather than a reactive response to assessment following training
6.14	*Attendance across staff grades at training*	All grades of staff attended training including RGNs, Senior care staff and care staff members CH released staff for FL training; Staff encouraged/ enabled to attend training
6.15	*Training provided a refresher/prompt*	Training refreshed previous knowledge re: falls risk assessment; prompted falls risk action(s) generally [not directly related to using GtACH as an assessment tool]

	Code	Description
6.16	*Falls Lead (FL) reported training straightforward*	FL reported no difficulties experienced with providing training
Theme 7.0 - *Negatives Re: Training*		
7.1	*GtACH Training information not cascaded to non-attendees*	Care staff members not attended FL training unaware of the GtACH assessment
7.2	*Training was rushed*	Had to cover too much in time allocated; too much information at once; insufficient time to explain; repetition of information already known; more time needed in case study; staff overwhelmed by amount of information;
7.3	*Training not protected time*	Conflict between training & meeting resident's needs: Care Home Routines –implication that this may have a negative impact on attendance at Falls Lead training. Staff completed training in own time.
7.4	*Concern international staff struggled with training*	English not first language; noticed to lack full participation in the training session
7.5	*Training provided mixed levels of confidence to use GtACH*	FLs observed some staff showed understanding of using the GtACH straight away, [whilst others struggled and required more practice- as included in other codes]
7.6	*Training did not provide confidence, knowledge and skills*	Did not provide confidence, knowledge and skills to use GtACH; more support and explanation needed
7.7	*More practice/ support/reassurance with GtACH needed*	Refresher training. Need for several sessions. (This was also picked up in observations).
7.8	*Online training recommended over face to face*	(This was picked up in observations)
7.9	*Difficulty writing actions/anxiety writing actions*	(This was observed in the fidelity checks in 0402). Care staff experience difficulty completing specific actions on GtACH
7.10	*(This code has been deleted as it was repeated elsewhere)*	
7.11	*Difficult assessing staff level of understanding*	Unable to assess/ evaluate staffs level of understanding when completing prescribed falls Lead training
7.12	*Not confident to use GtACH following training*	Confidence to complete GtACH not increased following training
7.13	*Gap in training knowledge*	Unaware carers had to complete GtACH; unsure when to complete GtACH; looking to researcher for clarification/advice; Unaware had to complete GtACH regardless of whether residents had fallen; Unaware of manual/it's location. Unaware of who is the Falls Lead. Unaware of what to do with GtACH when it has been completed- added 24/09/18 following discussion with JD
7.14	*More support/explanation needed*	May be challenging for less experienced
7.15	*Falls are not reducing*	
7.16	*Information from case study insufficient for full understanding*	Carers expressed preference for using known residents as example in the training as opposed to the case study which lacked insufficient information
Theme 8.0 - *Implementation of GtACH*		
8.1	*Practical Component unhelpful*	Unable to complete GtACH following completion of case study

	Code	Description
8.2	*Carers supported/encouraged to use GtACH/attend the training by senior staff/management/FC*	Plus supported to attend training
8.3	*Conflict between completing GtACH and resident care*	
8.4	*Use of GtACH dependent on CH owner/management*	Interview with FC from corporate org. Implementation of GtACH in the care home would depend on the adoption of it by the organisation. Staff have to adhere to care home protocols (i.e. contact NHS services if residents fall)
8.5	*Knowledge of GtACH has not changed practice*	
8.6	*Concern that GtACH is limited to form completion rather than a generalised change of practice*	
8.7	*Few or no GtACHs completed since the training*	Long time since attended training and not yet completed GtACH; habit; forgotten to use it; GtACH not used since training
8.8	*Engagement in study encourages a more proactive approach for falls management*	
8.9	*Prior experience using GtACH*	Familiarity with GtACH through prior use, i.e. in clinical practice, not influential on FL role
8.10	*GtACH completed to varying standards*	
8.11	*Engagement in research seen as an opportunity for training*	
8.12	*Unlikely to continue using GtACH post study*	
8.13	*Difficult to complete GtACH as care plan not up to date/inaccurate*	
8.14	*Care staff would benefit from ongoing support from FL*	
8.15	*Not referred to the manual*	
8.16	*Resident capacity affects use of GtACH*	
Theme 9.0 - *Positives re: Falls Lead Role*		
9.1	*Previous experience of working in care homes*	Aware of potential challenges
9.2	*Experience in providing training*	Falls Lead has previous experience in providing falls prevention training
9.3	*Role working well*	"Seamless"; positive about the role
Theme 10.0 - *Falls lead Challenges*		
10.1	*Staff requested little support from FL*	Staff not contacted the FL. Staff stating that less than 3 months support from FL is needed.

	Code	Description
10.2	*Need for FL to take a more proactive approach*	
10.3	*Unsure/unfamiliar with provision of FL support*	Unsure if staff remembered FL support available. Care staff unfamiliar with FL support; tendency to use familiar sources of support, i.e. Falls team; senior carers
10.4	*Need for flexibility*	Falls Lead flexible with times/days for training in order to accommodate most convenient days/ times for care home staff; Challenge of juggling workload
10.5	*Difficulty with management*	Manager dominated Falls Lead training; delayed start to training as had to go and find manager and remind them to attend. Training time not protected for staff to attend. Lack of management agreement.
10.6	*Contacting care homes*	Difficult to arrange training/obtain training log within 2 week period, owing to difficulties contacting care home manager/staff to arrange these
10.7	*Need for several training sessions*	Several session (i.e. more than 2) needed to accommodate the care home
10.8	*Challenge of staff turnover*	Issues with staff changing regularly in care homes, therefore, names on initial list for trainees may change
10.9	*Frustration around arranging training*	Challenging arranging training within recommended timescale
10.10	*Challenge of being a clinician delivering training*	Influence of being a clinician on delivery of training
10.11	*Lack of control(over care homes or recruitment process)*	Frustrating when care homes have 'signed' up for the research but then do not undertake the activities requested in order to take part; lack of control over training
10.12	*Low staff attendance at some training sessions (FL 700)*	Comment made by a Falls Lead- 2 staff attended.
10.13	*Research not disseminated to staff*	Falls lead uncertain how well informed care staff are regarding the research project; getting staff to attend training which they don't know much/anything about can be difficult; Need to educate staff about the research; Staff expecting training on falls prevention.
10.14	*Value of support for FLs*	Regular meet-ups/peer support helped 'bridge' the gap between training and delivery
10.15	*Poor Staff Motivation [in training]*	Poor Staff Motivation
10.16	*Care Home Routines*	Implication that this may have an negative impact on attendance at Falls Lead training as staff have to be taken off the 'floor' to attend the training, whilst the CH daily routines have to continue
10.17	*Inappropriate training room*	Training environment negatively affected training (participants able to withdraw/'hide'). Interruptions by residents as their communal room
10.18	*Delivering according to the protocol*	Challenging remembering to deliver falls lead training according to the prescribed protocol
10.19	*Training session interrupted*	Training session interrupted by a residents "wandering in" to the room whilst training taking place
10.20	*Chase home for appointments*	
10.21	*Cultural Challenges*	Culture in care homes. Usual practice is to complete paperwork away from the resident.

	Code	Description
10.22	*At least 3 months support from FL needed*	

Theme 11.0 - *Training for Falls Lead*

	Code	Description
11.1	*Training day useful*	Fall lead training day was useful
11.2	*Training comprehensive*	Falls lead training "covered everything"
11.3	*Training perceived as prescriptive*	Prescribed GtACH training not how FL would normally deliver training; different to their usual approach ("quite dry"; lacked inclusion of discussion with Care Home staff and "animation" in the delivery)
11.4	*Training limited to GtACH Completion*	Training limited to the completion of the GtACH form only; not included different case studies and activities, including increased interactions between trainer and trainees
11.5	*Interval between FL training and delivery in care homes*	Time lapse between receipt of training and providing GtACH training; uncertainty/ difficulty planning
11.6	*Voluntary Participation in training*	Falls leads have no control over who attends training; Training not mandatory; Care home not part of NHS;
11.7	*Training support identified*	

Theme 12.0 - *Falls Lead Positives*

	Code	Description
12.1	*Staff engaged*	Staff motivated to FL training
12.2	*Management supportive*	

Theme 13.0 – *Recommendations*

	Code	Description
13.1	*Suggest training Seniors separately from carers*	Seniors have different training needs to the carers & vice versa
13.2	*Recommendation- helpful to have 1-1 support when first completing the GtACH*	
13.3	*Recommendation- On-line training module recommended*	Care Homes use on-line training modules. Could incorporate different languages into on-line modules

Theme 14.0 - *Resident codes*

	Code	Description
14.1	*Resident had lots of falls*	2 or more recent falls
14.2	*Slip/trip hazards (external cause of fall) reported*	
14.3	*Health related falls (internal cause of fall) reported*	
14.4	*Resident fallen in the care home*	
14.5	*(Code deleted after team discussion)*	
14.6	*Falls not resulted in hospital admissions*	
14.7	*Resident not worried about falling*	Easily able to summon help following fall

	Code	Description
14.8	*Resident unaware/unable to remember GtACH assessment*	
14.9	*Aware of actions taken to reduce risk of falls*	
14.10	*Fall made resident feel silly*	
14.11	*Close staff supervision*	to include care home staff and clinicians outside of care home (added in agreement with JD 24/09/18)
14.12	*Feel actions taken are helpful*	
14.13	*Actions leave resident feeling like a child*	
14.14	*Resident hurt from fall*	
14.15	*Stoical/accepting of situation/advice*	
14.16	*Fallen despite actions/may still fall despite actions*	
14.17	*Shock from fall*	
14.18	*(Code deleted after team discussion)*	
14.19	*Resident uses mobility aids to reduce risk of falls*	
14.20	*Resident tries to think of strategies to prevent falls*	Resident is taking preventative actions
14.21	*Quick/efficient response from staff when fell*	
14.22	*Praised staff*	
14.23	*Resident knew reason for fall*	
14.24	*Resident not hurt by fall*	
14.25	*(Code deleted after team discussion)*	
14.26	*No falls since actions instigated*	
14.27	*Resident had no recollection of falls*	
14.28	*Resident reported short-term memory problems*	
14.29	*Positive about the GtACH assessment*	

Appendix K -Unadjusted Falls Count at baseline and primary endpoint

CareHome ID (control arm)	Total no of falls (90 days prior to randomisation)	Total no of falls (days 91-180 post randomisation)	CareHome ID (GtACH arm)	Total no of falls (90 days prior to randomisation)	Total no of falls (days 91-180 post randomisation)
102	7	16	101	19	19
103	5	10	107	12	20
104	17	28	201	12	5
105	10	13	203	7	7
106	8	12	207	6	2
204	8	20	208	10	6
205	3	1	209	9	3
206	5	5	211	1	0
210	11	12	302	8	16
301	12	16	303	8	15
404	6	2	401	4	1
405	1	3	402	14	20
406	18	11	502	1	2
504	20	8	503	2	6
505	2	3	506	0	0
601	5	7	602	12	9
603	7	9	605	6	9
604	11	32	607	9	4
606	12	27	609	3	9
608	11	7	612	11	18
610	11	15	613	9	2
611	8	35	615	1	3
614	5	9	701	2	0
702	0	3	703	6	4
706	3	3	704	7	8
707	5	10	705	3	9
709	4	4	708	3	13
710	6	9	711	2	3
712	3	5	803	12	19
801	15	50	804	8	1
802	22	116	806	5	9
805	3	3	810	9	10
807	7	11	811	19	28
808	10	9	901	5	2
809	6	8	906	7	0
812	25	53	908	9	11
902	7	18	909	7	4
903	5	3	910	6	1
904	4	2	911	4	13
905	7	1			
907	5	5			

912	8	4
1001	5	11
1002	0	3
1003	11	4

- Long list of CMO configurations generated during the process evaluation for each home

		Care home A (0803)			
	Contexts		Mechanism	Outcome	
1	Corporate, large home	Knowledgeable staff	Little **motivation** to change	GtACH not adopted. Persistence of existing practice	Weak
2a	Corporate, large home	Effective falls systems in place which staff are happy with	**Inertia** (inhibits innovation)	GtACH not adopted or only used when observed	Strong
2 b	Corporate, large home	Effective falls systems in place which staff are happy with, therefore no perceived benefit of using GtACH and no risk to residents if GtACH not used.	No **incentive** to change	GtACH not adopted or only used when observed	
3	Corporate, large home	Existing heavy administrative/paperwork burden	Lack of **appetite** for more paperwork	GtACH not adopted as seen as extra to existing paperwork	Moderate
4a	Corporate, large home	Staff respond reactively rather proactively to falls	Staff **accepting** of current practices	Partial adoption of GtaCH- only used reactively	Moderate
4 b	Corporate, large home	Staff respond reactively rather proactively to falls	Staff are only **accountable** for current paperwork, used after falls	Partial adoption of GtaCH- only used reactively following home paperwork	Moderate
5a	Corporate, large home	Clear internal and external management hierarchy	Lack of **ownership** on the part of **staff**	GtACH not adopted due to lack of authority/drive	Weak
5 b	Corporate, large home	Clear internal and external management hierarchy	Lack of **ownership** on part of local **management**	GtACH not adopted due to lack of authority- changes need corporate approval	Weak
5c	Corporate, large home	Clear internal and external management hierarchy	Lack of **awareness** at corporate level	GtACH not adopted. Lack of authority – changes need corporate approval	Weak
6	Corporate, large home	Home has not adopted Champion roles. Staff did not feel FC would be a useful role	Lack of **appetite** by staff at all levels to adopt FC role	FC role will not be adopted	Moderate
7a	Corporate, large home	Staff allocated clear roles. Only seniors complete documentation and medication. Carers complete hands on care and daily logs	**Inflexibility** in structured job roles	Partial or no adoption. GtACH will only be adopted if instigated by management and only used by seniors	Moderate
7 b	Corporate, large home	Staff allocated clear roles. Only seniors complete documentation. Carers complete hands on care and daily logs	Staff **inhibited** to break system	Partial or no adoption. GtACH will only be adopted if instigated by	Moderate

				management and only used by seniors	
7c	Corporate, large home	Staff allocated clear roles. Only seniors complete documentation. Carers complete hands on care and daily logs	Lack of care staff **ownership**	Partial or no adoption. GtACH will only be adopted if instigated by management and only used by seniors	Moderate
7d	Corporate, large home	Staff allocated clear roles. Only seniors complete documentation Carers complete hands on care and daily logs. Carers feel time spent doing paperwork would be detrimental to their caring role.	Lack of **incentive** to change	Partial or no adoption. GtACH will only be adopted if instigated by management and only used by seniors	Moderate
		0703 Care home B			
1a	Corporate (small local chain) Medium sized.	FiNCH increased awareness and knowledge of falls risks and prevention among all staff (inc domestics and cooks). Staff became more mindful of falls risks	**Increased appetite** to reporting falls risks	The training, rather than the GtACH (as a tool), may result in a reduction in the number of falls in the home as a result of raised awareness and knowledge of falls risks.	Moderate
1b	Corporate (small local chain) Medium sized.	FiNCH increased awareness and knowledge of falls risks and prevention among all staff (inc domestics and cooks). Staff became more mindful of falls risks	**Increased staff confidence** to identify and report falls risks	The training, rather than the GtACH (as a tool), may result in a reduction in the number of falls in the home as a result of raised awareness and knowledge of falls risks.	Moderate
2a	Corporate (small local chain) Medium sized.	GtACH similar to home's existing paperwork and seen as secondary. Staff feel that they have too much existing documentation already following a fall and GtACH adds to this	**Lack of motivation** to implement GtACH over and above existing documentation	GtACH may only be adopted during the trial & not be used long term- home will complete its own documentation in preference to the GtACH.	Strong
2b	Corporate (small local chain) Medium sized.	GtACH similar to home's existing paperwork and seen as secondary. Staff feel that they have too much existing documentation already following a fall and GtACH adds to this, leaving less time for care.	Lack of **incentive** to change	GtACH may only be adopted during the trial & not be used long term- home will complete its own documentation in preference to the GtACH.	
3a	Corporate (small local chain)	Clear internal hierarchy. Staff allocated clear roles, only seniors/nurses complete	**Inflexibility** in structured job roles	Partial adoption. GtACH will only be adopted if	Weak

	Medium sized.	documentation, Carers complete hands on care and daily logs		management take ownership and then only used by seniors/nurses	
3 b	Corporate (small local chain) Medium sized.	Clear internal hierarchy. Staff allocated clear roles, only seniors/nurses complete documentation, Carers complete hands on care and daily logs	Staff **inhibited** to break system	Partial adoption. GtACH will only be adopted if management take ownership and then only used by seniors/nurses	Weak
3c	Corporate (small local chain) Medium sized.	Clear internal hierarchy. Staff allocated clear roles, only seniors/nurses complete documentation, Carers complete hands on care and daily logs	Lack of care staff **ownership**	Partial adoption. GtACH will only be adopted if management take ownership and then only used by seniors/nurses	Weak
4	Corporate (small local chain) Medium sized.	Staff respond reactively rather than proactively to falls as per existing practice in the home.	Staff lacked **incentive** to change current practices	Partial adoption of GtACH- if GtACH is adopted it will only be used reactively rather than proactively	Strong
5	Corporate (small local chain) Medium sized.	Recent changes in management resulting in a heavy workload for staff taking over the managerial role	Lack of **motivation** by **management** to take on new practices or new documentation during period of upheaval	GtACH will only be adopted if the new management take ownership of it	No evidence
6	Corporate (small local chain) Medium sized.	The home have not adopted Champion roles and staff did not feel the Falls Champion would be a useful role	Lack of **motivation** by **staff** at all levels to adopt the Falls Champion role	Falls Champion role will not be adopted.	Weak
	0402 Care home C				
1a	Corporate local chain. Medium	Systems/documentation are filtered down through the external chain. Any changes to systems/documentation require organisation approval and the entire chain to adopt the changes	Lack of **staff ownership**	GtACH may be adopted during the trial but it is unlikely to be used long term as its continued use requires adoption by the chain.	Moderate
1 b	Corporate local chain. Medium	Systems/documentation are filtered down through the external chain. Any changes to systems/documentation require organisation approval and the entire chain to adopt the changes	Lack of **management ownership**	GtACH may be adopted during the trial but it is unlikely to be used long term as its continued use requires adoption by the chain.	Moderate

1c	Corporate local chain. Medium	Systems/documentation are filtered down through the external chain. Any changes to systems/documentation require organisation approval and the entire chain to adopt the changes	Lack of **awareness** at corporate level	GtACH may be adopted during the trial but it is unlikely to be used long term as its continued use requires adoption by the chain.	Moderate
2a	Corporate local chain. Medium	Staff reported that the practical component of the training session was insufficient to enable independent use of the GtACH.	Staff **felt daunted and overwhelmed** by the GtACH	Partial adoption- not all staff will use the GtACH.	Moderate
2 b	Corporate local chain. Medium	Staff reported that the practical component of the training session was insufficient to enable independent use of the GtACH.	**Lack of confidence** amongst all grades of staff to use the GtACH	Partial adoption- not all staff will use the GtACH.	Moderate
3	Corporate local chain. Medium	Staff (including the Falls Champion) that they were going to receive falls awareness training, not specific GtACH training. Some of the staff struggled to recall the training, and elements of the training had not been processed.	Staff felt **daunted and bewildered** by the prospect of completing the GtaCH	Partial adoption of GtACH- it will only be used by staff who feel they gained enough knowledge and skills from the training session to complete the GtACH.	Weak
4	Corporate local chain. Medium	Effective falls prevention systems/procedures/documentation already in place.	**No incentive** to use new paperwork	GtACH only completed during researcher observations. Unlikely to be adopted post study.	Weak
5	Corporate local chain. Medium	Existing systems working at full capacity – heavy administrative and/or paperwork burden	**lack of appetite for more paperwork**	GtACH not adopted- Existing documentation and systems/procedures take precedence. The GtACH duplicates rather than adds new information.	Strong
6	Corporate local chain. Medium	Staff respond reactively rather than proactively to falls as per existing practice in the home.	**staff accepting of current practices**	Partial adoption of GtACH- if GtACH is adopted it will only be used reactively rather than proactively	Weak
7	Corporate local chain. Medium	The Falls Champion was a senior who was also the Moving and Handling Lead and very influential on whether or not the GtACH was completed.	Adoption of GtACH influenced by **enthusiasm** from those above (i.e. those in the Falls Champion role or respected seniors/management)	GtACH will only be adopted if advocated by senior/management level in the home.	Strong

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8a	Corporate local chain. Medium	Clear internal hierarchy of responsibility with staff allocated clear roles. The seniors complete all documentation. Carers did not have access to information required for GtACH completion.	**inflexibility** in structured job roles	Partial adoption of	Strong
8 b	Corporate local chain. Medium	Clear internal hierarchy of responsibility with staff allocated clear roles. The seniors complete all documentation. Carers did not have access to information required for GtACH completion.	**care staff inhibited** to break system	GtACH –if adopted the GtACH will only be completed by seniors.	Strong
8c	Corporate local chain. Medium	Clear internal hierarchy of responsibility with staff allocated clear roles. The seniors complete all documentation. Carers did not have access to information required for GtACH completion.	Lack of care staff **ownership**	Partial adoption of	Strong
8 d	Corporate local chain. Medium	Clear internal hierarchy of responsibility with staff allocated clear roles. The seniors complete all documentation. Carers did not have access to information required for GtACH completion.	care staff **anxious** about the responsibility of completing documentation	GtACH –if adopted the GtACH will only be completed by seniors.	Strong
		0302 Care home D			
1a	National, corporate chain Medium size.	Systems/paperwork filtered down through the external chain. Clear internal hierarchy of management and responsibility. Only the Seniors complete the care plans.	**Lack of staff ownership** on the part of **staff**	GtACH will only be adopted during the trial. It is unlikely to be used long term as its continued use requires adoption by the national chain	Moderate
1 b	National, corporate chain Medium size.	Systems/paperwork filtered down through the external chain. Clear internal hierarchy of management and responsibility. Only the Seniors complete the care plans.	**lack of ownership on the part of local management**	GtACH will only be adopted during the trial. It is unlikely to be used long term as its continued use requires adoption by the national chain	Moderate
1c	National, corporate chain Medium size.	Systems/paperwork filtered down through the external chain. Clear internal hierarchy of management and responsibility. Only the Seniors complete the care plans.	Lack of **awareness at corporate level**	GtACH will only be adopted during the trial. It is unlikely to be used long term as its continued use requires adoption by the national chain	Moderate
2a	National, corporate chain Medium size.	Established/fixed roles.	**inflexibility** in structured job roles	Partial adoption of GtACH – if the GtACH is used it will only be used by Seniors/managemen t	Strong

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2 b	National, corporate chain Medium size.	Established/fixed roles.	**staff inhibited** to break system	Partial adoption of GtACH – if the GtACH is used it will only be used by Seniors/management	Strong
2c	National, corporate chain Medium size.	Established/fixed roles.	**staff lack access/authority for elements of GtACH**	Partial adoption of GtACH – if the GtACH is used it will only be used by Seniors/management	Strong
3	National, corporate chain Medium size.	Effective & thorough systems already in place.	**Inertia**: Long-standing systems and processes inhibit innovation	Partial adoption of GtACH – if the GtACH is used it is likely that only elements of the tool will be used alongside the pre-existing paperwork/systems	Strong
4	National, corporate chain Medium size.	Staff respond reactively rather than proactively to falls and few falls had occurred (during the day) during the period of study	**staff accepting of current role**	Partial adoption of GtACH	Strong
5	National, corporate chain Medium size.	Knowledgeable staff who had received internal training on falls prevention.	**little motivation** for change (inertia?)	Partial adoption-persistence of existing practice	Strong
6	National, corporate chain Medium size.	GtACH training increased knowledge base of staff	Staff may use the GtACH as a prompt/reminder to identify risks/actions rather than as a stand-alone tool. **Staff accepting of existing paperwork/systems**	Partial adoption-GtACH only used as a visual prompt/reminder	Strong
7	National, corporate chain Medium size.	Residential home with no nursing provision. Some of the GtACH components are perceived as inappropriate for the residential care setting (i.e. measuring blood pressure).	Staff reluctant to complete the GtACH through **fear it will completed incorrectly**	Partial adoption-reluctance by some seniors to complete GtACH through fear of completing incorrectly	No evidence
		0209 Care home E			
1	Small independent home	Effective system already in place. These systems take precedence with stipulated deadlines for completion.	**Inertia**	Partial adoption of GtACH – if the GtACH is used it is likely that	Strong

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				management will pick & choose elements to improve existing paperwork.	
2a	Small independent home	Established/fixed roles.	**inflexibility** in structured job roles	Partial adoption of GtACH – if the GtACH is used it will only be used by Seniors/management	No evidence
2 b	Small independent home	Established/fixed roles.	staff **inhibited** to break system	Partial adoption of GtACH – if the GtACH is used it will only be used by Seniors/management	No evidence
2c	Small independent home	Established/fixed roles.	**Accountability** for paperwork rests with senior staff- care staff do not want to be resonsible	Partial adoption of GtACH – if the GtACH is used it will only be used by Seniors/management	No evidence
3a	Small independent home	Top down approach to management (manager led). Experienced manager in place for 3 years & is visible on the floor. Manager did not attend the GtACH training	**Lack of staff motivation to implement GtACH**.	GtACH will only be adopted during the trial & unlikely to be used long term	Weak
3 b	Small independent home	Top down approach to management (manager led). Experienced manager in place for 3 years & is visible on the floor. Manager did not attend the GtACH training	**lack of ownership on the part of staff**	GtACH will only be adopted during the trial & unlikely to be used long term	Weak
4	Small independent home	Many high functioning residents who self-care & have few medical needs. Few residents with dementia Few residents considered to be a high risk of falls.	**Inertia**	Partial adoption of GtACH- not used as intended as a proactive tool	Moderate
5	Small independent home	Staff know the residents well. Staff support residents to be independent & make choices/take risks.	**Inertia**: Little motivation to adopt a tool which duplicates, rather than adds, to information about the residents.	Partial adoption of GtACH	Moderate
6	Small independent home	Paperwork not standardised by a chain. Adopt their own paperwork, & pick up ideas & tools from external sources.	**Staff appetite** to seek out new tools that can either be adopted or adapted	GtACH may be implemented if found favourable once trialled, or may be adapted to incorporate into existing tools	Strong

7	Small independent home	Isolated from other homes. Less opportunities for training & support because an isolated home. Manager/deputy attend external training & cascade down to staff.	**Staff motivated** to attend training	Good attendance at the GtACH training (as in-house).	Moderate
8	Small independent home	Carers lack confidence completing paperwork. Residential setting so not comfortable with nursing tasks (i.e. BP monitoring) & medical terminology. Need reassurance they are completing GtACH correctly.	Staff reluctant to complete the GtACH through fear it will be incorrect and they will be **accountable**	Partial adoption- GtACH not completed as intended- only Senior staff/management will adopt GtACH	Contextual evidence only
9	Small independent home	Established/fixed roles. Seniors, not carers write care plans	**inflexibility** in structured job roles		
	0107 Care home F				
1	Small local chain Large size.	Clear internal hierarchy of responsibility with staff allocated clear roles. Frequent changes in management impacting on working practices in the home.	**Lack of staff ownership** on the part of staff working on the floor. Practices determined by management.	GtACH will only be adopted if management take ownership. Staff have no authority to use the GtACH unless management insert the GtACH into the resident notes	Moderate
2a	Small local chain Large size.	Established/fixed roles. Only staff in senior or management roles complete documentation. Care staff provide the hands on care & report back to the staff in senior or management roles	**inflexibility** in structured job roles	Partial adoption of GtACH – GtACH will only be used by staff in senior or management roles	Moderate
2 b	Small local chain Large size.	Only staff in senior or management roles complete documentation. Care staff provide the hands on care & report back to the staff in senior or management roles	Lack of **incentive** to change working systems	Partial adoption of GtACH – GtACH will only be used by staff in senior or management roles	Moderate
2c	Small local chain Large size.	Established/fixed roles. Only staff in senior or management roles complete documentation. Care staff provide the hands on care & report back to the staff in senior or management roles	**staff lack access/authority** for elements of GtACH	Partial adoption of GtACH – GtACH will only be used by staff in senior or management roles	Moderate
3	Small local chain Large size.	GtACH perceived as more robust than existing documentation & useful for information provision when liaising with medical professionals	Staff **motivated** to use GtACH as an aid to memory and a prompt to complete own documentation	Partial adoption of GtACH – GtACH is likely to be used alongside (not instead) of pre-existing paperwork/systems	Strong
4a	Small local chain Large size.	Staff respond reactively rather than proactively to falls	staff **accepting** of current practices	Partial adoption of GtACH	Strong

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4 b	Small local chain	Staff respond reactively rather than proactively to falls as their responsibility is for corporate and government reporting of adverse events	Lack of **incentive** to change practice	Partial or no adoption of GtACH	
5a	Small local chain Large size.	Neither the acting 'compliance manager' nor the permanent manager were working in the home at the initiation of the Process Evaluation or attended the training	lack of **incentive** to implement GtACH	GtACH will only be adopted if management take ownership & filter it down to the staff on the floor.	Contextual evidence only
5 b	Small local chain Large size.	Neither the acting 'compliance manager' nor the permanent manager were working in the home at the initiation of the Process Evaluation or attended the training	Lack of **ownership** on the part of staff	GtACH will only be adopted if management take ownership & filter it down to the staff on the floor.	Contextual evidence only
5c	Small local chain	Neither the acting 'compliance manager' nor the permanent manager were working in the home at the initiation of the Process Evaluation or attended the training	Lack of staff **autonomy**	GtACH will only be adopted if management take ownership & filter it down to the staff on the floor.	
6a	Small local chain Large size.	Staff were keen to attend the training as there is little on falls awareness training provided in the locality. The training sessions were prioritised in the home.	Staff **motivated** to attend training	Partial adoption- not all staff will use the GtACH with some preferring to continue using familiar documentation	Weak
6 b	Small local chain Large size.	Staff were keen to attend the training as there is little on falls awareness training provided in the locality. The training sessions were prioritised in the home.	Staff **anxious** completing the GtACH as represents new & unfamiliar documentation	Partial adoption- not all staff will use the GtACH with some preferring to continue using familiar documentation	Weak
7a	Small local chain Large size.	This was a site which joined the study late & the Falls Lead was not trained alongside the other Falls Leads, receiving her training via the site initiation visit.	Lack of **confidence** to use the GtACH as a result of insufficient knowledge	Partial adoption- not all staff will use the GtACH	Weak
7 b	Small local chain Large size.	This was a site which joined the study late & the Falls Lead was not trained alongside the other Falls Leads, receiving her training via the site initiation visit.	Lack of **confidence** to use the GtACH as a result of insufficient support	Partial adoption- not all staff will use the GtACH	Weak
7c	Small local chain Large size.	This was a site which joined the study late & the Falls Lead was not trained alongside the other Falls Leads, receiving her training via the site initiation visit.	**Inertia:** to use the GtACH due to misperception that it is limited to the study rather than a broader	Partial adoption- not all staff will use the GtACH	Weak

			tool for reducing falls risks		
8a	Small local chain Large size.	Successive/late changes in management at this home at the beginning of the study	**Uncertainty / lack of leadership** to implement study	Late adoption. GtACH not placed in resident notes until 5 months into the study	No evidence
8 b	Small local chain Large size.	Changes in management resulted in slow implementation of the GtACH in this home with the GtACH not inserted into the resident's notes until 5 months into the Process Evaluation period.	Lack of Knowledge at management level	Late adoption- the GtACH will only be adopted once management take ownership of the GtACH and insert it into the residents notes	Contextua l evidence only
8c	Small local chain Large size.	Changes in management resulted in slow implementation of the GtACH in this home with the GtACH not inserted into the resident's notes until 5 months into the Process Evaluation period.	Lack of **ownership** at management level	Late adoption- the GtACH will only be adopted once management take ownership of the GtACH and insert it into the residents notes	Contextua l evidence only
8 d	Small local chain	Changes in management resulted in slow implementation of the GtACH in this home with the GtACH not inserted into the resident's notes until 5 months into the Process Evaluation period.	Lack of staff **autonomy**	Late adoption- the GtACH will only be adopted once management take ownership of the GtACH and insert it into the residents notes	

Appendix M - Adapted research cycle