A multidomain decision support tool to prevent falls in older people: the FinCH cluster RCT

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

The FinCH cluster RCT

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Scientific summary

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 in Care Homes (GtACH) programme: an intervention in which care home staff are trained and supported in the systematic use of a multidomain decision support tool to assess individual residents and generate a falls prevention care plan.

Objective

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

Method

Trial design

The trial was a multicentre, cluster, parallel, 1 : 1 randomised controlled trial to evaluate the GtACH programme compared with usual care (the absence of a systematic and co-ordinated 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 implementation of and the mechanisms triggered by the introduction of the GtACH programme. A hub-and-spoke approach was used to include care home residents, family members, care home 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 $\geq$ 10 potentially eligible residents
- routinely recorded falls in residents' personal records and on incident sheets
- had written agreement of the care home manager to comply with the study protocol.

Care homes were excluded if they:

- had participated in the GtACH pilot/feasibility studies
- primarily provided care for those with learning difficulties or substance dependency
- had contracts with health-care or social care providers that were under suspension or under investigation by the regulator of care homes (the Care Quality Commission)
- had a significant proportion of beds taken up by health-service commissioned intermediate care services
- 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 were 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 Care Quality Commission website, presenting the study at National Institute for Health Research's Enabling Research in Care Homes network events and liaising with Clinical Research Network staff. Care home managers were telephoned and/or sent a letter inviting them to participate. If they responded to the invitation, a researcher visited the care home to confirm eligibility and recruit the home. Eligible residents in 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 member or care home manager consultee was asked to agree to the resident being recruited.

Intervention: the GtACH programme

The GtACH programme comprised a training package delivered by local NHS falls leads to care home staff, a GtACH reference 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 in the home, and a GtACH 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. A total of 30 corresponding suggested actions were included alongside the relevant risk factors to prompt actions 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 Health and Care Excellence clinical guidelines for falls prevention.

Control: usual care

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

Outcomes

The primary outcome for the randomised controlled trial was the rate of falls per participating resident in the 90-day period between 91 and 180 days (a 3-month period, i.e. 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 and 90 days (months 1–3) post randomisation, 181 and 270 days post randomisation (months 7–9) and 271 and 360 days (months 10–12) post randomisation.
- Physical activity (as measured using the Physical Activity and Mobility in Residential Care questionnaire and completed by care home staff).
- Activities of daily living (as measured using the Barthel Index and completed by care home staff).
- Quality of life (as measured using the Dementia Quality of Life Utility version-5 dimensions and EuroQol-5 dimensions, five-level version) for participants, completed where the participant had capacity.
- Quality of life (as measured using the Dementia Quality of Life, proxy complete-4 dimensions, and EuroQol-5 dimensions, five-level version) 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 taken (as recorded on care home medication administration records).
- 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 and 180 days post randomisation. Assuming a falls rate of 2.5 falls per year (0.625 falls in 3 months) in the control arm, 80% power and a two-sided significance level of 5%, 189 residents per arm were required to detect a 33% reduction in falls rate in the GtACH arm. The adjustment for clustering assumed an average cluster size of 20 residents and an intracluster coefficient of 0.1, and gave a sample size of 549 residents per arm. Incorporating a further 16% into the sample size to account for potential attrition, the original aim was to recruit a total of 1308 residents (654 to the GtACH arm and 654 to the control arm) from 66 care homes. 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 than 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 1474 participating residents.

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 via a secure web-based randomisation service. Care homes were submitted for randomisation 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 participating residents or care home staff to treatment arm allocation because the nature of the intervention required them to be aware of and engage with it. Researchers were blind to allocation when they collected the follow-up data. The Trial Management Group and the Data Monitoring Committee were not blinded to the intervention.

Analysis

The primary analysis was intention to treat based on the arm to which participants were randomised. The primary outcome, rate of falls per participating resident during the 90-day period between 91 and 180 days post randomisation, was expressed as the number of falls per 1000 participating resident-days for each arm. The number of falls per resident was compared between arms using a negative binomial regression model (generalised estimating equation).

The cost-effectiveness analysis took a health and personal social service provider perspective. The cost–utility analysis was calculated based on the EuroQol-5 dimensions, five-level version, proxy complete. The primary analysis was a cost–utility analysis and presents proxy-reported outcomes as quality-adjusted life-years. 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 that had received the GtACH intervention programme. Data were collected using a combination of interviews, focus groups, fidelity observations, a documentary review and a falls-rate review. Data were primarily collected during a 3-month period following the introduction of the GtACH programme, with an additional home visit made 6 months after the introduction of the GtACH programme. GtACH training was observed in each care home using a checklist to assess fidelity to the training protocol. Data were analysed qualitatively using framework analysis and discussed in relationship to the falls rates.

Results

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

Primary randomised controlled trial outcome data were available for 630 GtACH and 712 control participants. The primary randomised controlled trial outcome result showed an unadjusted incidence rate ratio of 0.57 (95% confidence interval 0.45 to 0.71; $p < 0.01$) in favour of the GtACH programme. The falls rates over this period were 6 out of 1000 residents in the GtACH arm and 10.4 out of 1000 residents in the control arm. This translates to a falls rate per participant per year of 2.2 for the GtACH arm and 3.8 for the control arm.

The secondary randomised controlled trial outcome results saw a significantly lower falls rate in the GtACH programme participants for the 1- to 3-month period, but not in the 7- to 9-month or 10- to 12-month periods. There were no differences between arms 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 control arm, giving a mean (adjusted) difference in cost of £108 (95% confidence interval –£271.06 to £487.58). In the base case, the Dementia Quality of Life Utility version, proxy complete-based quality-adjusted life-years were 0.578 in the GtACH arm and 0.581 in the control arm, with (adjusted) incremental quality-adjusted life-years of 0.005 [95% confidence interval 0.019 to 0.03 (adjusted) incremental quality-adjusted life-years]. The corresponding numbers for EuroQol-5 dimensions-based quality-adjusted life-years were 0.266 and 0.232, with (adjusted) incremental quality-adjusted life-years of 0.024 [95% confidence interval 0.004 to 0.044 (adjusted) incremental quality-adjusted life-years]. The incremental cost per Dementia Specific Quality of Life-based quality-adjusted life-year was £20,889 and £4544 per EuroQol-5 dimensions-based quality-adjusted life-year. The base-case incremental cost per fall averted was £191.

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

The patient and public involvement study found that using 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. Patient and public involvement members were also able to effectively contribute to data analysis, dissemination of results and writing reports.

Conclusion

Implementing the GtACH programme reduced falls rates by 43% in this large multicentre UK study in care homes for older people. Given current willingness to pay per quality-adjusted life-year thresholds in the UK (< £30,000), 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 (£20,000–30,000 using the Dementia Quality of Life Utility version, proxy complete, compared with < £20,000 using the EuroQol-5 dimensions, five-level version) showed that economic evaluation is challenging in this group of people.

Trial registration

This trial is registered as ISRCTN34353836.

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This report

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