Home environmental assessments and modification delivered by occupational therapists to reduce falls in people aged 65 years and over: the OTIS RCT

Sarah Cockayne,[1*] Alison Pighills,[2,3] Joy Adamson,[1] Caroline Fairhurst,[1] Shelley Crossland,[4] Avril Drummond,[5] Catherine E Hewitt,[1] Sara Rodgers,[1] Sarah J Ronaldson,[1] Jennifer McCaffery,[1] Katie Whiteside,[1] Arabella Scantlebury,[1] Lyn Robinson-Smith,[1] Ann Cochrane,[1] Sarah E Lamb,[6] Sophie Boyes,[7] Simon Gilbody,[1] Clare Relton[8] and David J Torgerson[1] on behalf of the OTIS study

[1]York Trials Unit, Department of Health Sciences, University of York, York, UK
[2]Mackay Institute of Research and Innovation, Queensland Health, Mackay Base Hospital, Mackay, QLD, Australia
[3]Division of Tropical Health and Medicine, James Cook University, Townsville, QLD, Australia
[4]Leicestershire Partnership NHS Trust, Leicester, UK
[5]School of Health Sciences, University of Nottingham, Nottingham, UK
[6]Institute of Health Research, College of Medicine and Health, University of Exeter, Exeter, UK
[7]York Teaching Hospital NHS Foundation Trust, York, UK
[8]Institute of Population Health Sciences, Queen Mary University of London, London, UK

*Corresponding author sarah.cockayne@york.ac.uk

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Scientific summary

The OTIS RCT

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Scientific summary

Background

Falls and fall-related fractures are a serious cause of morbidity and cost to individuals and society. Thirty per cent of people aged ≥ 65 years, and half of those aged > 80 years, will fall each year.

Although the vast majority are not serious, falls are the most common cause of hip fractures and injury-related deaths in those aged > 75 years, costing the NHS in excess of £2B per year.

As many falls occur in the home, a home hazard assessment and modification programme may reduce falls. Environmental hazards in the home (such as loose rugs or a lack of handrails) have been identified as a major contributor to falls in a number of previous studies and recent reviews. However, further reviews of this research have shown that the effectiveness of home hazard assessment and modification programmes is equivocal. There is also little evidence regarding the use of fall prevention programmes with people who have fallen or who may be at risk of falling but who have not yet necessarily been hospitalised because of a fall.

Objective of OTIS

The objective was to determine the clinical effectiveness and cost-effectiveness of a home hazard assessment and recommended environmental modification delivered by occupational therapists for preventing falls in community-dwelling people aged ≥ 65 years at risk of falling, relative to usual care.

Methods

Study design

We undertook a modified cohort, pragmatic, two-armed randomised controlled trial, with an economic evaluation and nested qualitative study.

Participant recruitment

Recruitment took place within eight NHS trusts. Potential participants were identified by the following methods: database searches of cohorts of participants from previous trials held at the York Trials Unit and the Yorkshire Health Study; mail-out from general practitioner surgeries within the participating occupational therapist catchment areas; advertising for participants; and opportunistic screening by health-care professionals. Potential participants who were aged ≥ 65 years and were living in the community were sent a recruitment pack inviting them to take part in the study. Participants who returned a screening questionnaire and valid consent form were screened for eligibility.

People were eligible for inclusion if they:

- were aged ≥ 65 years
- were willing to receive a home visit from an occupational therapist
- were community-dwelling
- had experienced at least one fall in the previous 12 months, or reported a fear of falling on their screening questionnaire (comprising a single question 'During the past 4 weeks have you worried about having a fall?', and the response categories all of the time, most of the time, a good bit of the time, some of the time, a little of the time, and none of the time).

People were excluded if they:

- were unable to walk 10 feet (3.05 m), even with the use of a walking aid
- were unable to give informed consent, for example because they had dementia
- were living in a residential or a nursing home
- were unable to read or speak English and had no friend or relative to translate/interpret for them
- had received an occupational therapist assessment for falls prevention in the previous 12 months or were on the waiting list for an occupational therapist assessment.

Eligible participants were sent a baseline questionnaire and a pack of falls calendars. Participants who had neither had a fall in the past 12 months nor reported a fear of falling but were otherwise eligible for the trial were rescreened every 3 months. If these participants subsequently reported a fall or a fear of falling, and were still willing to take part in the study, they became eligible to be sent a baseline questionnaire and a pack of falls calendars. Participants who returned a completed baseline questionnaire and at least one monthly falls calendar were eligible to be randomised into the trial.

Sample size

We proposed to randomise 1299 participants in a 2 : 1 ratio (i.e. 866 to usual care and 433 to the intervention) to reduce the cost of delivering the intervention. This number allowed for 10% attrition and provided 90% power (using two-sided significance at the 5% level) to show a difference in the percentage of participants who experienced at least one fall in the 12 months following randomisation from 60% in the usual-care group to 50% in the intervention group.

Randomisation

Participants were randomised using the York Trials Unit's secure web-based randomisation system. The allocation sequence was generated by an independent data systems manager, who was not involved in recruiting participants. Block randomisation stratified by centre was used. Participants were randomised at a particular centre in batches as a single block, according to when the occupational therapists had capacity to undertake the home visits. Most commonly, a 2 : 1 allocation ratio in favour of the usual-care group was used, although alternative allocation ratios were employed if necessary. Blinding of participants and the research team was not possible.

Trial interventions
All participants received usual care from their general practitioner and other health-care professionals, as well as a falls prevention leaflet. In addition to this, those in the intervention group were offered one home environmental assessment to identify personal fall-related hazards and modifications, if required. The occupational therapist used the Westmead Home Safety Assessment tool to structure their assessment visit. The occupational therapist contacted the participant 4–6 weeks after the home visit to collect data on whether or not the recommendations had been acted on.

Follow-up
Participants were followed up for 12 months post randomisation using the monthly falls calendars to collect data on the number of falls they had sustained in the past month. Participants who reported a fall were telephoned, and further details about their fall, including the cause and whether or not an overnight stay in hospital had been required, were collected. Participants were also sent questionnaires at 4, 8 and 12 months to collect data on falls, quality of life and health service utilisation. Participants were prompted with reminder notices if they failed to return their questionnaires or falls calendars.

Primary outcome
The primary outcome was the number of falls per participant during the 12 months from randomisation. A fall was defined as 'an unexpected event in which the participant comes to rest on the ground, floor or lower level'.

Secondary outcomes
The secondary outcomes were the proportion of participants who reported at least one fall or multiple falls; fracture rate; fear of falling; time to fall; health-related quality of life, as measured using the EuroQol-5 Dimensions, five-level version; and health service utilisation.

Other data collected
Data on which sections of the Westmead Home Safety Assessment form were assessed and a list of equipment/modifications prescribed and delivered were collected. Any adverse events related to being in the study or to the intervention were reported.

Statistical methods
Analyses were conducted in Stata version 15 (StataCorp LP, College Station, TX, USA) following the principles of intention to treat. Significance tests were two-sided at the 5% level. Baseline data were summarised descriptively overall and by trial arm.

The primary outcome was analysed using mixed-effects negative binomial regression, adjusting for sex, age, history of falling and the allocation ratio used to randomise the participant as fixed effects, and centre as a random effect.

A complier-average causal effect analysis, using a two-stage instrumental variable regression approach with randomised group as the instrumental variable, was implemented to assess the impact of receiving the occupational therapist home assessment visit within 12 months of randomisation on the primary treatment estimate. Further sensitivity analyses investigated the impacts of missing data and therapist effects.

A chance imbalance in the proportion of participants in the two groups with Parkinson's disease at baseline was observed. A post hoc sensitivity analysis repeated the primary analysis including Parkinson's disease as an additional fixed effect.

We conducted a subgroup analysis for the primary outcome to assess for differential effects of the intervention based on whether or not a participant received hospital care as a result of a fall in the

4 months before baseline. The primary analysis was repeated including an interaction between this factor and treatment allocation.

The following secondary outcomes were analysed by mixed-effects logistic regression adjusted as in the primary analysis – the proportion of participants who:

- fell at least once over the 12 months from the date of randomisation
- sustained two or more falls over 12 months
- reported that they were worried about falling at 12 months.

The proportions of participants who suffered at least one fracture or multiple fractures resulting from a fall are reported but were not formally analysed owing to the rarity of these events.

Fear of falling was also analysed in its continuous form using a covariance pattern model incorporating all post-randomisation time points and adjusting for baseline fear of falling, sex, age, history of falling, allocation ratio, treatment group, time and a treatment group-by-time interaction, with participant and centre as random effects.

Time to fall was analysed by Cox proportional hazards regression using robust standard errors to account for repeat falls by participant, and adjusting for the same covariates as the primary analysis.

Economic analysis

The base-case analysis was undertaken from the perspective of the NHS and Personal Social Services, using a multiply imputed data set. The cost-effectiveness analyses evaluated participants' health-related quality of life over the study duration using the EuroQol-5 Dimensions, five-level version, data to estimate quality-adjusted life-years. The costs analysed in the base case comprised the cost of health service utilisation by participants and the cost of the intervention, which included the cost of staff time, training, and the equipment installed. A secondary analysis took a societal perspective, which included additional cost items regarding private/personal expenses; equipment purchased, expenditure on house modifications, and travel costs for health-care attendances. The following sensitivity analyses were undertaken to explore uncertainty around the findings: a complete-case analysis; the inclusion of service use for reasons other than falls; an alternative source of hospital stay data; an alternative equipment funding assumption; and an alternative scenario regarding paid care worker visit costs.

Intervention fidelity

Intervention fidelity was assessed by a combination of the following methods: (1) observations of the home visits; (2) documentary audits of both the training methods and the case report forms completed by the occupational therapists at each visit; and (3) semistructured interviews. Interviews with a purposive sample of 17 occupational therapists from seven of the eight trusts were conducted over the telephone. Topic guides were developed by the research team and steering group, which included occupational therapists; the guides were informed by normalisation process theory and provided a framework for the interviews. Following transcription, the interviews were analysed thematically.

Results

Between October 2016 and April 2018, 19,308 recruitment packs were distributed, and 3100 (16.1%) potential participants returned a screening questionnaire and a valid consent form and were assessed for eligibility. Of these, 1331 participants were randomised into OTIS: 430 (32.3%) to the intervention group and 901 (67.7%) to usual care. The mean age of participants was 80 years (range 65–98 years), and two-thirds ($n = 872$, 65.5%) were female. Three-quarters ($n = 999$, 75.1%) of the participants had sustained a fall in the 12 months prior to enrolment; of these, 20% had attended a hospital for treatment following a fall.

A total of 381 (88.6%) intervention participants received an environmental assessment and modification visit within 12 months of randomisation (median 27 days). The assessments were conducted by 23 occupational therapists (median of 16 visits per occupational therapist, range 1–54 visits) and lasted a median of 90 minutes (range 25–180 minutes).

In total, 1303 (97.9%) trial participants returned at least one falls calendar following randomisation (intervention group, 97.4%; usual-care group, 98.1%), with 1204 (90.5%) returning a complete 12 months' worth (intervention group, 87.7%; usual-care group, 91.8%). Overall, 2260 falls were reported: 826 in the intervention group (mean 1.9 falls, standard deviation 5.5 falls; median 1 fall, range 0–94 falls) over an average of 338 days (median 365 days), and 1434 in the usual-care group (mean 1.6 falls, standard deviation 3.0 falls; median 1 fall, range 0–41 falls) over a mean of 345 days (median 365 days). The intention-to-treat primary analysis indicated weak evidence of a difference in falls, with an increase in the intervention group relative to usual care (incidence rate ratio 1.17, 95% confidence interval 0.99 to 1.38; $p = 0.07$). The complier-average causal effect estimate of the intervention effect was very similar (incidence rate ratio 1.18, 95% confidence interval 0.98 to 1.43; $p = 0.08$). Other sensitivity analyses produced very similar estimates. Adjusting for Parkinson's disease decreased the incidence rate ratio to 1.11 (95% confidence interval 0.94 to 1.31; $p = 0.23$). When an interaction between receipt of hospital treatment because of a fall in the 4 months prior to baseline and treatment allocation was included in the primary model, the interaction was not observed to be statistically significant ($p = 0.24$).

In total, 245 out of 430 (57.0%) intervention participants and 506 out of 901 (56.2%) usual-care participants reported at least one fall (odds ratio 1.06, 95% confidence interval 0.83 to 1.34; $p = 0.65$). The proportion of participants who reported two or more falls was 34.4% in the intervention group and 33.1% in the usual-care group (odds ratio 1.11, 95% confidence interval 0.86 to 1.43; $p = 0.42$). Fifty-four participants reported a fracture from a fall (intervention group, 16/430, 3.7%; usual-care group, 38/901, 4.2%). Only two participants, both in the usual-care group, reported more than one fracture resulting from a fall.

There was no evidence of a difference between the two groups in the likelihood of participants reporting a fear of falling at 12 months (odds ratio 1.00, 95% confidence interval 0.78 to 1.29; $p = 1.00$), nor in continuous fear of falling score at any post-randomisation time point.

There was no evidence of a difference in time to fall between the intervention and usual-care groups (adjusted hazard ratio 1.24, 95% confidence interval 0.94 to 1.63; $p = 0.12$).

There were no serious or non-serious related adverse events.

The cost of the occupational therapist intervention was estimated to be £137 per participant on average. The base-case analysis found the intervention to be £19 more expensive and generate 0.004 fewer quality-adjusted life-years per participant, on average, when compared with usual care. Hence, the observed differences between the groups in both costs and effects were small. The intervention was found to be dominated by usual care and hence does not provide a cost-effective option. Uncertainty was demonstrated around the findings, with sensitivity analyses showing that the economic results changed when different scenarios were considered, in particular for the complete-case analysis, and for scenarios including the costs of non-falls-related resource use and paid care workers.

The occupational therapists received adequate training and delivered the intervention largely as intended, but they commented that some trial participants did not reflect those seen in usual clinical care as they were higher functioning. Recommendations were followed to varying degrees and depended on whether they were provided by health or social care services.

Conclusions

We did not find any effect on the rate of self-reported falls among a population of older people with an elevated falls risk. Consequently, we do not recommend occupational therapist-led home assessment for patients who have characteristics similar to those of patients included in our study. Scarce occupational therapist resources would be better employed elsewhere.

Trial registration

This trial is registered as ISRCTN22202133.

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This report

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