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Cockayne, Sarah orcid.org/0000-0002-1288-5497, Pighills, Alison, Fairhurst, Caroline Marie orcid.org/0000-0003-0547-462X et al. (16 more authors) (2021) Home hazard assessment and environmental modification to prevent falls in older people:the OTIS trial. F1000research. 500. ISSN 2046-1402

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RESEARCH ARTICLE

Home hazard assessment and environmental modification to prevent falls in older people: the OTIS trial [version 1; peer review: 1 approved, 1 approved with reservations]

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Abstract

Background: Falls in older people are a major cause of morbidity and mortality. There is some evidence to suggest that home hazard assessment and environmental modification delivered by an occupational therapist may reduce falls. The objective of this study was to evaluate the effectiveness of this intervention, relative to usual care.

Methods: A pragmatic, two-arm modified cohort randomised controlled trial in eight NHS trusts in primary and secondary care in England. In total, 1331 community-dwelling adults aged 65 years and over with a history of falls or fear of falling were randomised in a 2:1 allocation to either usual care plus a falls prevention leaflet (n=901) or to receive the home hazard assessment and environmental modification intervention, plus usual care and a falls prevention leaflet (n=430). The primary outcome was the number of falls per participant over the 12 months from randomisation. Secondary outcomes included: proportion of fallers and multiple fallers, time to fall, and fear of falling.

Open Peer Review

Approval Status ? ✓

	1	2
version 1 25 Jun 2021	? view	✓ view

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Any reports and responses or comments on the article can be found at the end of the article.

Results: All 1331 randomised participants (mean age 80 years, 872 [65.5%] female) were included in the primary analysis. There was a small increase in the rate of falls in the intervention group relative to usual care (adjusted incidence rate ratio 1.17, 95% CI 0.99 to 1.38; p=0.07). A similar proportion of participants in the intervention (57.0%) and usual care group (56.2%) reported at least one fall over 12 months. There were no differences in any of the other secondary outcomes and no serious, related adverse events were reported.

Conclusions: Home hazard assessment and environmental modification delivered by an occupational therapist did not reduce falls in community-dwelling older people deemed at higher risk of falling recruited to this trial.

Keywords
Home hazard assessment and environmental modification, falls prevention, older adults, modified cohort randomized controlled trial

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How to cite this article: Cockayne S, Pighills A, Fairhurst C *et al.* **Home hazard assessment and environmental modification to prevent falls in older people: the OTIS trial [version 1; peer review: 1 approved, 1 approved with reservations]** F1000Research 2021, **10**:500 https://doi.org/10.12688/f1000research.52313.1

First published: 25 Jun 2021, **10**:500 https://doi.org/10.12688/f1000research.52313.1

Introduction

Falls in community-dwelling older people are a major source of morbidity and cost to society.[1,2] A third of people over the age of 65 years fall each year, and those over 75 years are more likely to experience repeated falls. This issue will increase, given the ageing population. For some, the consequences of falling are serious; approximately 20% of falls require medical attention, costing the NHS approximately £2 billion per year, due mainly to the cost of treating hip fractures.[3]

Older people often attribute environmental factors, such as uneven surfaces, as the cause of their falls.[4,5] Occupational therapists (OTs) routinely undertake environmental assessments of older peoples' homes and recommend fall-prevention strategies. At the time of designing the trial, there is some evidence from a Cochrane review to suggest that home hazard assessment and environmental modification is effective at reducing falls particularly in those at higher risk of falling and when delivered by an occupational therapist.[6] Guidance from the National Institute for Health and Care Excellence recommends that people who require hospital treatment following a fall should receive a home hazard assessment and environmental modification intervention by a suitably trained healthcare professional; however, no specific recommendations are provided for people at increased risk of falling but who have not required hospital treatment following a fall. A previous trial reported a reduction in falls as a secondary outcome following an OT-led home hazard assessment and environmental modification in this population.[7] However, this was a pilot trial that did not include a cost-effectiveness analysis. Therefore, in order to find out if these preliminary findings could be confirmed and if home hazard assessment and environmental modification is cost-effective, we undertook OTIS (the Occupational Therapist Intervention Study).[8,9]

Methods

Study design

We conducted OTIS,[9] a pragmatic, multicentre, two-arm, parallel-group, modified cohort randomised controlled trial, (cRCT)[10] between October 2016 and August 2019. The protocol was approved by West of Scotland Research Ethics Committee 3 (REC reference 16/WS/0154) and has been published.[8]

Setting and participants

We recruited participants from eight NHS trusts in England based in primary and secondary care. Participants were initially recruited into an observational cohort, after being informed about the embedded trial and the possibility of being offered an OT home assessment visit. Potential participants were identified using: (i) cohorts held at the Yorkshire Health Study[11] and York Trials Unit (YTU);[12-14] (ii) a database search of General Practitioner (GP) patients; (iii) advertising (*e.g.* in faith magazines and GP surgeries); and (iv) opportunistic screening by podiatrists and GPs. Once identified, potential participants were sent trial information including a screening questionnaire and consent form to complete and return to YTU if they wished to take part.

Participants were eligible for the cohort if they: (i) were aged 65 years or over; (ii) were community dwelling, *i.e.* not living in a nursing/residential home; and (iii) reported a fear of falling or a fall in the previous 12 months. Participants were excluded if they were unable to: (i) give informed consent (*e.g.* due to dementia or Alzheimer's disease); (ii) speak English and had no relative or friend to translate/interpret for them; (iii) walk 10 feet even using a walking aid; or (iv) if they had had an OT assessment for falls prevention in the past 12 months or were waiting for an assessment.

Eligible participants were sent a baseline questionnaire and monthly falls calendars to record when they fell and the number of times, to post back to YTU. Participants were eligible to be randomised once they had returned a completed baseline questionnaire and at least one falls calendar in the preceding three months.

Randomisation and blinding

Participants were randomised using the YTU's secure, remote, web-based randomisation service, stratified by centre. When OTs had capacity to deliver the intervention visits, a member of the trial team at YTU randomised a batch of eligible participants from that centre in a single block. The size was determined by the number of participants available to randomise and the number the centre had capacity to deliver the intervention to within a reasonable timeframe. The allocation sequence was generated by an independent data systems manager, who was not involved in recruitment. To reduce costs, unequal allocation was used in favour of the usual care group, usually 2:1; however, on occasion, other allocation ratios were used. For example, towards the end of recruitment, some centres had capacity to see more, or fewer, than a third of the remaining eligible participants who were pending randomisation, so ratios ranging from 1:1 to 9.7:1 (usual care:intervention) were used to allow as many eligible participants to be randomised as possible. It was not possible to blind trial participants, the research team actively involved in the day-to-day running of the study or the statistician to treatment group, due to the unequal allocation ratio. However, data entry staff were blinded.

Intervention and comparator

Both groups were sent a falls prevention leaflet produced by Age UK ('Staying Steady', published in June 2015) and continued to receive their usual healthcare from their GP or other healthcare professionals irrespective of the trial. In addition, the intervention group were offered one OT home hazard assessment and environmental modification. The intervention was delivered by Health and Care Professions Council registered OTs, who were trained by the study team to use the Westmead Home Safety Assessment Form (WeHSA).

The assessment was guided by the validated WeHSA form.[15] This validated tool, consisting of 57 items, split into 15 domains was developed in Australia for older people. The OTs used this assessment tool to help identify potential falls hazards and risk-taking behaviours when walking through the participant's home. A list of recommendations was agreed and a record of any suggested equipment made. This included: steps; outdoor lights; external rails to the outside of the property; ramp; wheelchair; grab rails/bannister; mobility aids; furniture raisers; shower rails/bath safety bars; bath lift; removable bath board; raised toilet seat; toilet frame; step; safety aids; sensor-operated or remove control lights; emergency alarms; assistive technology devices; light bulbs; bed hoist; bed; key safe; ferrules; walking aid parking devices; ladders; carpet glue/reflective anti-slip tape; alterations to house; or other miscellaneous items. The visits lasted approximately one hour during which recommendations on appropriate home modifications such as improving lighting were made.

Treatment fidelity was explored by observations of the home visits, audits of training methods and case report forms completed by OTs, and semi-structured interviews.

Outcome measures

The primary outcome was the rate of falls sustained per participant over 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.[16] Falls were reported *via* the monthly falls calendars and we also asked about number of falls in the past four months on questionnaires posted to participants at four, eight and 12 months post-randomisation. Participants who indicated on their falls calendar that they had fallen were telephoned to complete a Falls Data Collection Sheet (FDCS) to ascertain cause, location and consequences of the fall (*e.g.* superficial injury, fracture, hospital admission). Secondary outcomes:

- fear of falling (participant questionnaires at four, eight and 12 months, *via* the question, "During the past 4 weeks have you worried about having a fall?". Response categories were: 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. These were scored 1 to 6 and treated as continuous in the analysis. This measure has not been validated but was used by some of the authors in the earlier REFORM trial,[12] where it correlated moderately well (r=0.6) with the validated Short Falls Efficacy Scale (Short FES-I),[17] and it is quicker to complete;

- fracture rate (*via* self-reported FDCS);

- time to each fall (falls calendars);

- proportion of participants reporting at least one fall or multiple (two or more) falls over 12 months; and

- adverse events (collected *via* follow-up questionnaires or during phone calls).

Participants who did not return falls calendars or questionnaires were telephoned for data and/or posted reminders. The primary source of falls data was the post-randomisation monthly falls calendars, but where none were returned, falls data from the follow-up questionnaires were used, if provided. The economic analysis will be published separately.

Sample size

We proposed to randomise 1299 participants 2:1 to usual care (n = 866) or intervention (n = 433). This allowed for 10% attrition and provided 90% power (two-sided, α = 0.05) to show a difference in the percentage of participants who fall at least once in the 12 months following randomisation from 60% in the usual care group to 50% in the intervention group. The sample size is based on a binary outcome rather that the primary outcome as power calculations for count data require greater assumptions and parameter estimates and, at the start of this trial, we felt there was insufficient data on which to reliably base this calculation.

Statistical methods

Statistical analyses were performed using Stata v15[18] on an intention-to-treat (ITT) basis, using two-sided tests at the 5% significance level. Stata (RRID: SCR_012763) is a proprietary software; an open-access alternative that can perform an equivalent function to Stata for analysis is R, a free software environment for statistical computing and graphics (RRID: SCR_001905).

For the primary analysis, mixed-effects negative binomial regression was used adjusting for sex, age at randomisation, history of falling (number of falls in 12 months prior to recruitment: <2/≥2) and allocation ratio as fixed effects, and centre as a random effect. The model included an exposure variable for the number of months that the participant provided falls data. Where no falls data were provided at all, we assumed zero falls over a negligible follow-up time of 0.1 months to achieve a strict ITT analysis. The adjusted incidence rate ratio (IRR), 95% confidence interval (CI) and p-value are presented.

A Complier Average Causal Effect (CACE) analysis[19-21] to assess the impact of receiving the OT home assessment visit within 12 months of randomisation on the primary estimate was undertaken, using a two-stage instrumental variable (IV) regression approach with randomised group as the IV.

A *post hoc* sensitivity analysis, including Parkinson's disease as a covariate in the primary model, was undertaken due to a chance baseline imbalance in the proportion of participants in the two groups with this disease. Further sensitivity analyses considered the impact of missing data and clustering by OT. Pre-specified subgroup analyses assessed differential effects of the intervention based on whether a participant received hospital care as a result of a fall in the four months before baseline.

Fear of falling was analysed using a mixed effects, 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-by-time interaction, with participant and centre as random effects. Logistic regression models explored the likelihood of reporting at least one fall, more than one fall, and a fear of falling (at least "some of the time") at 12 months. Time between falls was analysed using the Andersen and Gill method for repeated events, *via* a Cox Proportional Hazards regression model with robust standard errors to account for dependent observations by participant. These models adjusted as for the primary outcome.

Results

Participant flow and characteristics

Between October 2016 and August 2018, we mailed out to 19308 potential participants (Figure 1); a total of 3100 screening forms were returned and reviewed for eligibility. We randomised 1331 participants to the intervention (n = 430) or usual care group (n = 901), with 381 (88.6%) intervention participants receiving an OTIS intervention visit within 12 months of randomisation (Figure 2).

Baseline characteristics were comparable between the groups (Tables 1 and 2), apart from a chance imbalance in the proportion of participants with Parkinson's disease (intervention n = 14, 3.3%; usual care n = 9, 1.0%).

Outcomes

Overall, 1303 (97.9%) participants returned at least one falls calendar following randomisation (intervention n = 419, 97.4%; usual care n = 884, 98.1%); a further five (four usual care, one intervention) provided falls data *via* a participant questionnaire. Questionnaire data were used for analysis for these participants. In total, 2260 falls were reported: 826 in the intervention group (mean 1.9 per participant, SD 5.5, median 1, range 0 to 94) over a mean of 338 days (median 365), and 1434 in the usual care group (mean 1.6, SD 3.0, median 1, range 0 to 41) over a mean of 345 days (median 365). The adjusted negative binomial model indicated an increase in fall rate in the intervention group relative to usual care (IRR 1.17, 95% CI 0.99 to 1.38; p = 0.07); this was not statistically significant. This result was robust to sensitivity analyses (Table 3).

About a tenth of participants (intervention group n = 41, 9.5%; usual care group n = 83, 9.2%) reported that they attended hospital for a fall in the four months before baseline. There appeared to be a qualitative interaction between this factor and treatment group, with those in this subgroup benefiting from the intervention (IRR 0.86, 95% CI 0.50 to 1.47) compared with those who did not attend hospital for a fall in the four months before baseline (IRR 1.21, 95% CI 1.01 to 1.44); however, the interaction term between this factor and treatment group included in the primary model was not statistically significant (p = 0.24).
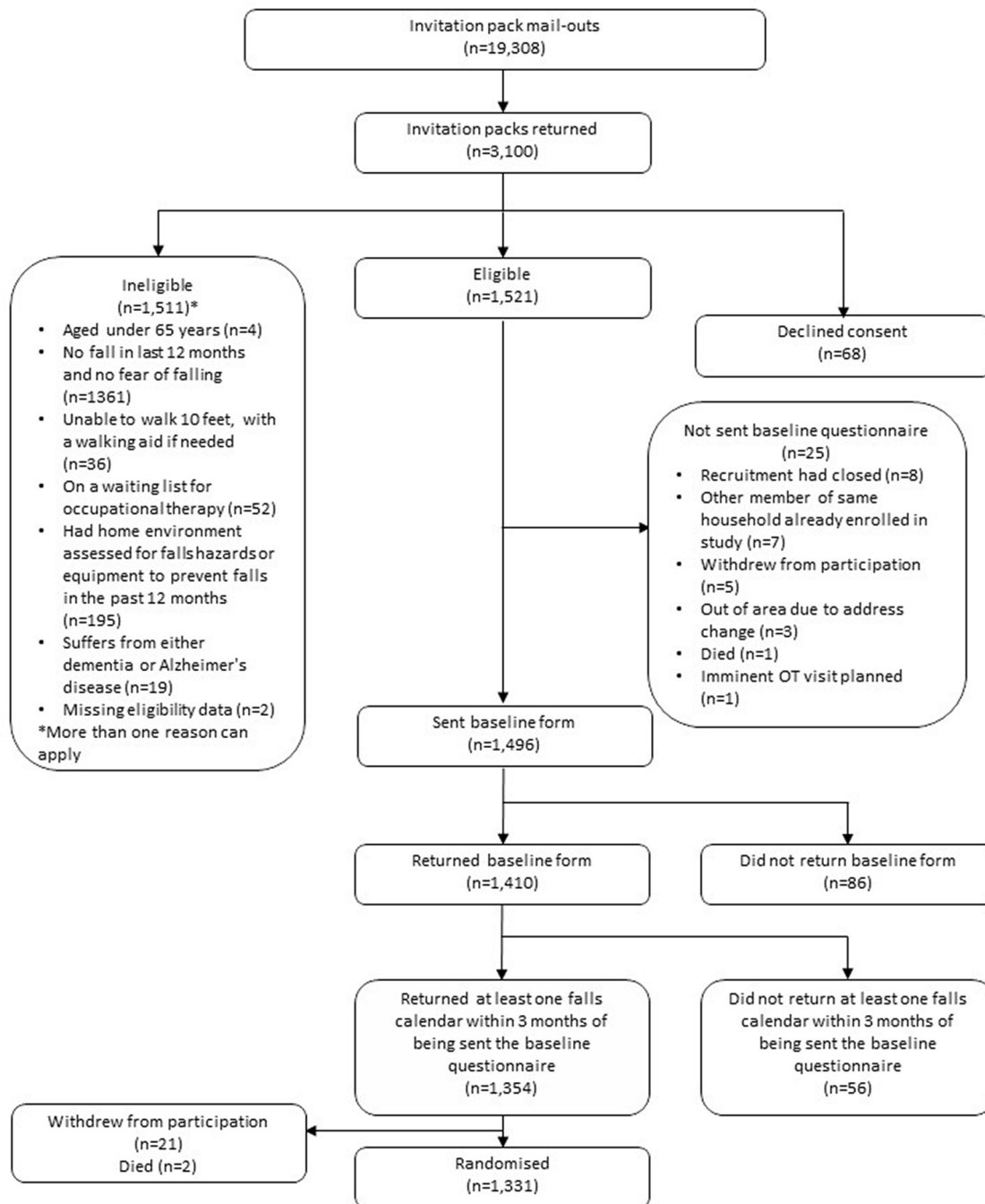
Figure 1. Pre-randomisation flow chart.

There was no evidence of a difference in any of the secondary outcomes or other data (Table 3 and Table 4) and no serious related adverse events reported.

The data suggested that the OTs received adequate training and delivered the intervention, mainly as intended. OTs commented that some trial participants did not reflect those seen in their 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. A full account of the assessment of treatment fidelity will be published separately.
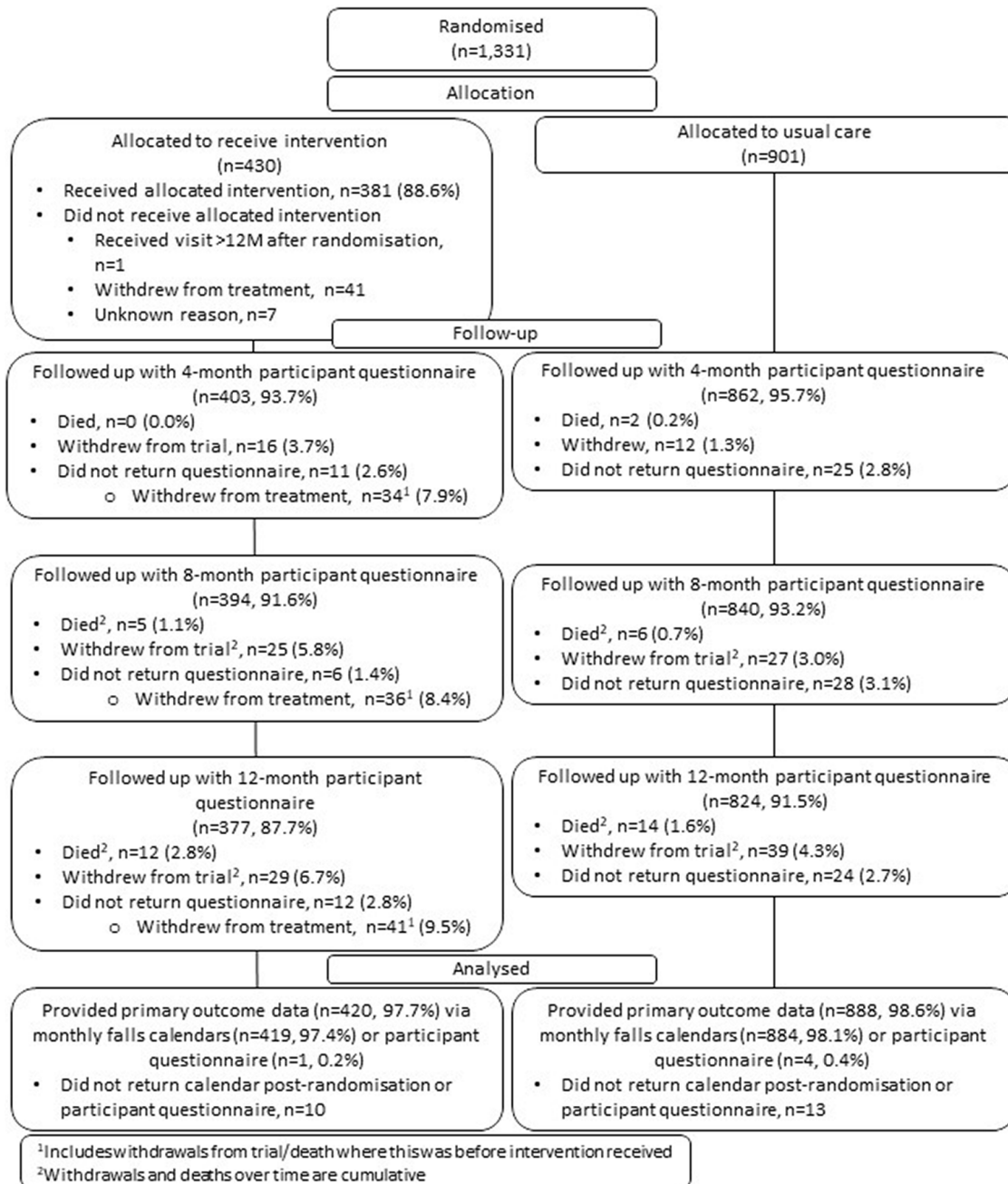
Figure 2. Post-randomisation flow chart.

Discussion

We found no evidence that OT-delivered home hazard assessment and environmental modification reduced falls in community-dwelling older people. A 17% increase in fall rate was observed in the intervention group compared with usual care, but this was not statistically significant, nor were there any statistically significant differences in any secondary outcome. The number of control participants receiving a home visit or attending a falls clinic was low (9.2% and 4.6%, respectively) and unlikely to account for the lack of difference in falls rate. Whilst the OTs delivered the intervention mainly as intended, the recommendations were followed in varying degrees by participants.

Table 1. Baseline demographic characteristics of randomised participants.

Characteristics	Intervention (n = 430)	Usual care (n = 901)	Total (n = 1331)
Age, years			
Mean (SD)	79.9 (6.4)	80.2 (6.3)	80.1 (6.3)
Median (min, max)	79.7 (67.3, 98.0)	80.3 (65.5, 98.7)	80.1 (65.5, 98.7)
Gender, n (%)			
Male	145 (33.7)	314 (34.9)	459 (34.5)
Female	285 (66.3)	587 (65.1)	872 (65.5)
Taking >4 medications prescribed by a doctor, n (%)			
Yes	212 (49.3)	455 (50.5)	667 (50.1)
No	216 (50.2)	437 (48.5)	653 (49.1)
Missing	2 (0.5)	9 (1.0)	11 (0.8)
Comorbidities, n (%)[a]			
Osteoporosis	67 (15.6)	136 (15.1)	203 (15.3)
High blood pressure	192 (44.7)	415 (46.1)	607 (45.6)
Pain	219 (50.9)	452 (50.2)	671 (50.4)
Angina or heart troubles	94 (21.9)	194 (21.5)	288 (21.6)
Parkinson's disease	14 (3.3)	9 (1.0)	23 (1.7)
Arthritis (rheumatoid/osteo)	226 (52.6)	461 (51.2)	687 (51.6)
Anxiety or depression	55 (12.8)	115 (12.8)	170 (12.8)
Stroke	25 (5.8)	67 (7.4)	92 (6.9)
Urinary incontinence	89 (20.7)	167 (18.5)	256 (19.2)
Chronic lung disease	34 (7.9)	54 (6.0)	88 (6.6)
Diabetes	81 (18.8)	153 (17.0)	234 (17.6)
Meniere's disease/vertigo/ conditions affecting balance/	32 (7.4)	86 (9.5)	118 (8.9)
Poor vision	83 (19.3)	178 (19.8)	261 (19.6)
Cancer	51 (11.9)	65 (7.2)	116 (8.7)
Other	159 (37.0)	341 (37.8)	500 (37.6)

[a]Note more than one option can be chosen.

Intervention participants may have reported more falls due to reporting bias, if they were more mindful of the need to report falls following their assessment. This may have a positive impact in practice if fallers are more likely to acknowledge their falls and seek further assistance. Alternatively, following the OT visit, intervention participants may have felt more confident and less concerned about falling, leading them to undertake more risk-taking behaviours and falling more.

One participant, in the intervention group, reported 94 falls, which was substantially higher than the next largest number of falls of 41 (usual care group). This high value is likely to have influenced the magnitude of the treatment effect. The participant had Parkinson's disease and we observed a difference in the proportion of participants with Parkinson's disease between the two groups. In the *post hoc* sensitivity analysis adjusting for Parkinson's disease, the treatment effect was reduced.

OTIS results were not consistent with a previous pilot RCT, which found a statistically significant reduction in falls among participants receiving a home assessment.[7] This may be due to OTIS participants having a lower risk of falls, as fewer fell during the 12-month follow-up than in the pilot trial (56% *versus* 66%).

Table 2. Baseline characteristics.

Characteristics	Intervention (n = 430)	Usual care (n = 901)	Total (n = 1331)
Fall in last 12 months, n (%)			
Yes[*]	323 (75.1)	676 (75.0)	999 (75.1)
***If yes, number of falls**			
Median number of falls (min, max)	1 (1, 40)	1 (1, 24)	1 (1, 40)
***If yes, did you attend hospital for any of the falls? n (%)**			
Yes	60 (18.6)	137 (20.3)	197 (19.7)
History of falling in previous 12 months, n (%)			
No or one fall	283 (65.8)	568 (63.0)	851 (63.9)
Two or more falls	147 (34.2)	333 (37.0)	480 (36.1)
Fear of falling, n (%)			
All of the time	13 (3.0)	37 (4.1)	50 (3.8)
Most of the time	31 (7.2)	75 (8.3)	106 (8.0)
A good bit of the time	67 (15.6)	114 (12.7)	181 (13.6)
Some of the time	120 (27.9)	279 (31.0)	399 (30.0)
A little of the time	117 (27.2)	229 (25.4)	346 (26.0)
None of the time	82 (19.1)	167 (18.5)	249 (18.7)
Judgement of balance, n (%)			
Good and want to keep it that way	116 (27.0)	241 (26.7)	357 (26.8)
Quite good but would like to improve it	166 (38.6)	327 (36.3)	493 (37.0)
Some problems with balance that want to overcome	144 (33.5)	328 (36.4)	472 (35.5)
Missing	4 (0.9)	5 (0.6)	9 (0.7)
Risk of falling, n (%)			
High/intermediate[a]	373 (86.7)	775 (86.0)	1148 (86.3)
Low	52 (12.1)	119 (13.2)	171 (12.8)
Missing	5 (1.2)	7 (0.8)	12 (0.9)

[a]Balance problems whilst walking or dressing, or at least moderate problems doing usual activities, or one or more fall in previous 12 months.

The strength of OTIS lies in its robust methodology. The modified cRCT design allowed us to maximise recruitment as we were able to rescreen participants who were initially ineligible for the trial. Post-randomisation attrition rates were minimised by the use of a pre-randomisation run-in period, during which time participants engaged in returning falls calendars. Resentful demoralisation in the control group was minimised as only those in the intervention group were notified of group allocation. Collecting falls data by monthly calendar, and the ability to report falls by telephone, minimised participant recall bias. The main limitation was that outcome data relating to falls were self-reported, which could have led to inaccuracies. In addition, despite the fact that over 90% of participants returned outcome data, a *post hoc* power calculation for the primary outcome, based on negative binomial regression and using parameters estimated from this and our previous REFORM trial,[12] indicated we were only powered at about 70% to detect the 17% increase in falls we observed.

In conclusion, this large, high-quality trial did not find any benefit of an OT-led home environmental assessment on self-reported falls among a population of older, community-dwelling people who had an elevated falls risk due to a previous recent fall or a fear of falling.

Table 3. Summary of analysis results.

Outcome and analysis	Intervention (n = 430)	Usual care (n = 901)	Adjusted treatment effect estimate (95% CI)	p-value
Primary analysis				
Number of falls per person[a]	826	1434		
Mean (SD)[a]	1.9 (5.5)	1.6 (3.0)	IRR 1.17 (0.99 to 1.38)	0.07
Sensitivity analyses[a]				
Rate of falls adjusted for Parkinson's disease Missing data[c] Therapist effect CACE			IRR 1.11 (0.94 to 1.31) IRR 1.17 (0.99 to 1.38) IRR 1.17 (0.99 to 1.38) IRR 1.18 (0.98 to 1.43)	0.23 0.07 0.07 0.08
Secondary analyses				
1+ falls[a], n (%)	245 (57.0)	506 (56.2)	OR 1.06 (0.83 to 1.34)	0.65
2+ falls[a], n (%)	148 (34.4)	298 (33.1)	OR 1.11 (0.86 to 1.43)	0.42
Median time to fall (95% CI), days	119 (105 to 133	144 (132 to 155)	HR 1.24 (0.94 to 1.63)	0.12
Fear of falling[b], n (%)	197 (45.8)	440 (48.8)	OR 1.00 (0.78 to 1.29)	1.00
Fear of falling[b] (continuous), mean (SD)	4.2 (1.3)	4.1 (1.3)	MD -0.01 (-0.13 to 0.11)	0.87
1+ fracture from a fall[a], n (%)	16 (3.7)	38 (4.2)	N/A	

IRR incidence rate ratio; OR odds ratio; HR hazard ratio; MD mean difference; N/A not applicable as outcome not formally analysed.
[a]Over 12 months.
[b]At 12 months post-randomisation.
[c]Logistic regression was used to assess whether any baseline factors were associated with missing falls outcome data. Participants who had had at least one previous fall were more likely to have missing outcome data (OR 5.84, 95% CI 1.13 to 30.21; p = 0.04). This was added as a covariate in the primary analysis.

Table 4. Mean resource use, based on all available cases (falls-related only).

Type of resource use	Intervention Mean (SD)	Missing, n (%)		Usual care Mean (SD)	Missing, n (%)	
GP visit at GP practice/home						
Baseline	0.28 (1.88)	139	32.3	0.16 (0.54)	297	32.7
4 months	0.20 (2.34)	134	31.2	0.09 (0.43)	290	32.2
8 months	0.13 (0.63)	132	30.7	0.12 (0.52)	296	32.9
12 months	0.10 (0.69)	156	36.3	0.16 (0.66)	296	32.9
Nurse visit at GP practice/home						
Baseline	0.13 (0.80)	143	33.3	0.16 (1.04)	314	34.9
4 months	0.09 (0.67)	147	34.2	0.70 (0.40)	273	30.3
8 months	0.11 (0.81)	141	32.8	0.18 (1.22)	314	34.9
12 months	0.06 (0.37)	167	38.8	0.18 (1.00)	314	34.9
Occupational therapist visit						
Baseline	0.03 (0.23)	129	30.0	0.02 (0.18)	295	32.7
4 months	0.17 (0.57)	139	32.3	0.06 (0.48)	252	28.0
8 months	0.06 (0.36)	131	30.5	0.08 (0.74)	287	31.9
12 months	0.06 (0.45)	153	35.6	0.07 (0.62)	284	31.5

Table 4. *Continued*

Type of resource use	Intervention			Usual care		
	Mean (SD)	Missing, n (%)		Mean (SD)	Missing, n (%)	
Physiotherapist visit						
Baseline	0.18 (0.89)	132	30.7	0.11 (0.63)	300	33.3
4 months	0.14 (0.74)	136	31.6	0.07 (0.56)	258	28.6
8 months	0.13 (0.80)	131	30.5	0.14 (0.90)	290	32.2
12 months	0.21 (1.09)	154	35.8	0.13 (0.86)	299	33.2
Hospital outpatient visit						
Baseline	0.11 (0.48)	132	30.7	0.17 (0.81)	295	32.7
4 months	0.08 (0.47)	131	30.5	0.13 (1.03)	255	28.3
8 months	0.08 (0.43)	133	30.9	0.10 (0.52)	289	32.1
12 months	0.19 (1.18)	151	35.1	0.14 (0.74)	292	32.4
A&E visit						
Baseline	0.08 (0.30)	118	27.4	0.12 (0.67)	267	29.6
4 months	0.07 (0.37)	122	28.4	0.06 (0.30)	234	26.0
8 months	0.08 (0.31)	129	30.0	0.08 (0.33)	270	30.0
12 months	0.06 (0.26)	143	33.3	0.09 (0.37)	272	30.2
Day case hospital visit						
Baseline	0.03 (0.18)	127	29.5	0.07 (0.71)	287	31.9
4 months	0.06 (0.36)	110	25.6	0.06 (0.40)	241	26.8
8 months	0.03 (0.20)	126	29.3	0.04 (0.26)	262	29.1
12 months	0.05 (0.27)	130	30.2	0.07 (0.50)	265	29.4
Inpatient hospital overnight stay						
Baseline	0.11 (0.83)	121	28.1	0.18 (1.42)	274	30.4
4 months	0.12 (1.02)	112	26.1	0.19 (1.38)	227	25.2
8 months	0.14 (1.86)	123	28.6	0.38 (3.30)	250	27.8
12 months	0.05 (0.61)	132	30.7	0.28 (3.26)	254	28.2
No. (%) participants who received a falls prevention visit (non-OTIS) over the 12 months	83 (19.3)	58	13.5	83 (9.2)	86	9.5
No. (%) participants who attended a falls service/ clinic over the 12 months	24 (5.6)	57	13.3	41 (4.6)	82	9.1

Data availability

Underlying data

Full underlying (non-aggregated) data cannot be made publicly available since the ethics approval of this study does not cover openly publishing non-aggregated data.

In order to access this data, it must be requested from the corresponding author. Data requestors will have to provide: i) written description and legally binding confirmation that their data use is within the scope of the study; ii) detailed written description and legally binding confirmation of their actions to be taken to protect the data (*e.g.* with regard to transfer, storage, back-up, destruction, misuse, and use by other parties), as legally required and to current national and international standards (data protection concept); and iii) legally binding and written confirmation and description that their use of this data is in line with all applicable national and international laws (*e.g.* the General Data Protection Regulation of the EU).

Reporting guidelines

Open Science Framework: CONSORT checklist for 'Home hazard assessment and environmental modification to prevent falls in older people: the OTIS trial', https://doi.org/10.17605/OSF.IO/P8AU2.[22]

Consent

All participants will give written informed consent prior to entry to the study.

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Version 1

Reviewer Report 21 April 2022

✔️ **Alex McConnachie** [iD]

Robertson Centre for Biostatistics, Institute of Health and Wellbeing, MVLS, University of Glasgow, Glasgow, UK

Cockayne et al present the results of a cohort randomised controlled trial of a falls prevention intervention. No evidence is found that the intervention is beneficial. This review focuses mainly on the statistical aspects of the paper.

Overall this is a good write-up of a very good study. My comments are fairly minor.

There is a statement that the statistician could not be blind during the study due to the unequal allocation ratio. I think this is a little weak – if the statistician was blind to the randomisation, they will not know who is in each group, regardless of the allocation ratio. Still, there are many practical reasons for being unable to keep the statisticians blind in a trial such as this, and it is unlikely to have adversely affected the study, so this is not a major issue.

The fear of falling question, collected on a 6-point scale, is analysed as if it were continuous. This might be OK, depending on whether the modelling assumptions are met. Otherwise, an ordinal regression might be better for this outcome.

The main sample size calculation checks out OK, but I do not see what the post-hoc calculation adds to the paper. If the intervention effect observed is not statistically significant, then it seems obvious that the study was not powered to detect it. I would leave it out.

For the primary analysis, the allocation ratio is included as a fixed effect. Maybe I am missing something, but I cannot see why the outcome should vary systematically in relation to the allocation ratio. The problem with varying allocation ratios (as I understand it) is that the population, or the intervention, might vary over time, or from place to place, and populations randomised with different allocation ratios should be treated as separate subpopulations. One option might be to treat each randomisation "batch" as a separate group (i.e. include random effects for batches within centres). I doubt it will have a major impact on the intervention effect

estimate, but I do not think the current analysis model makes sense.

Personally, I do not feel that including those with no outcome data by imputing no events in almost no time is worth doing. At best, this has no effect on the analysis. In my opinion, ITT is about the intention to treat, not the intention to follow up, and missing outcome data should be dealt with separately in sensitivity analyses. However, I accept that there are differing views on this.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Partly

Are all the source data underlying the results available to ensure full reproducibility?
Partly

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Biostatistics, Clinical Trials

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 08 July 2021

https://doi.org/10.5256/f1000research.55574.r88201

?   **Carina U. Persson**
Department of Clinical Neuroscience, Rehabilitation Medicine, Institute of Neuroscience and Physiology, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden

The aim of the study was to evaluate the effectiveness of home hazard assessment and

environmental modification delivered by an occupational therapist. The primary outcome was the number of falls per participant over the 12 months from randomization. The secondary outcomes were fear of falling, fracture rate, time to each fall, the proportion of fallers, and adverse events.

This two-arm modified cohort randomized trial included 1,331 community-dwelling adults aged 65 years or older deemed at higher risk of falling (with fear of falling or a history of falls). By using a web-based randomization service and an unequal allocation (2:1 in favour of the usual care group), the participants were randomized to either an intervention group or a usual care/control group. The intervention group was given a home hazard assessment and an environmental modification beyond usual care and a falls prevention leaflet to prevent falls compared with usual care and a falls prevention leaflet.

Statistical methods used were mixed-effects negative binomial regression, Complier Average Causal Effect analysis, mixed-effects, covariance pattern model, and Cox proportional hazards regression model. The compliance with the recommendations was followed in varying degrees by participants. The authors did not find any evidence that OT-delivered home hazard assessment and environmental modification reduced falls in community-dwelling older people, nor did they find any difference between the groups regarding any of the secondary outcomes.

Thank you for showing me confidence in reviewing your interesting paper: **Home hazard assessment and environmental modification to prevent falls in older people: the OTIS trial.**

I can see that you have spent many hours on your research project and the current article. Although it is well-written, I have some suggestions which I hope and believe can contribute to improvement:

Abstract
  ○ I understand that for reasons of space, it can be difficult to fit everything within given words. However, not all readers are familiar with the abbreviation of NHS as National Health Service.
  ○ Secondary outcomes and adverse events are described in the Methods and Results, but they are not mentioned as objectives as expected.
  ○ The keywords used are definitely informative. However, they are not MeSH terms.
    Please consider whether you should use MeSH terms (for example "Safety", "Accidental falls" and "Adult").

Introduction
  ○ Please clarify the aim of the current study. The last sentence is somewhat confusing since it seems to involve both the aim of the current study and the primary drivers to undertake OTIS from the original beginning.

Methods
  ○ Study design: Please inform the readers what the modification refers to.

  ○ Setting and participants, third paragraph: Please clarify what the baseline questionnaire involves (self-reporting of the number of prescribed medications, comorbidities, fall in last 12 months, and so on).

○ Randomisation and blinding, line 4: "…to deliver the intervention within a reasonable timeframe". Please clarify the definition of "reasonable".

○ Concerning Outcome measures and the secondary outcomes: Adjust/mention the adverse events in the Abstract and clarify the objectives in the Introduction accordingly.

○ Concerning Outcome measures and the secondary outcome fear of falling: The six response categories described for fear of falling seem to be ordinal data. For ordinal data, the distances between the scale steps are unknown. Consequently, ordinal data should not be analyzed as continuous data.

○ Was fracture data using the FDCS validated by a review of the medical records?

○ Concerning Outcome measures and the secondary outcome, adverse events: Please define "adverse events".

○ Last paragraph: I suggest the authors be stringent and add HR, 95% CI, and p-value where you write about the Cox Proportional Hazards regression model.
Note: For the statistical analyses used, at least those first described, I suggest a review by a qualified statistician.

Results
○ Please consider if the initial part of the first sentence should be moved to the Methods.

○ Currently, a presentation of the environmental modifications, the intervention in question, is missing and requested. Now it is unclear how many and what kind of modifications were completed.

○ Outcomes, first paragraph: Please consider referring to Table 3. At present, there is some duplication of data (also in other paragraphs).

○ Please extend the data commentary for Table 4. At present, I think it is far too vague.

○ Table 2: I am curious about how many had not experienced a fall in the previous 12 months.

○ Table 2 and the characteristic risk of falling: Please consider to, in the footnote, give the definition of "balance problems" and of "moderate problems" beyond at least one fall in the previous 12 months. Was it a subjectively based need of supervision or tactile support and/or experience of protective reactions whilst walking, dressing, and performing usual activities? Or was "balance problems" and "moderate problems" based entirely on the individual's own interpretation of balance problems, without a given definition (with the exception related to experienced falls)?

○ Table 3, first line "Number of falls per person": Please delete "per person". Please consider whether you instead should write "Total number of falls".

○ Table 3, second line "Mean (SD)": Please add "Number of falls per person" in front of "mean (SD)".

○ Table 3, under the heading sensitivity analyses: Explain the abbreviation CACE in the footnote.

○ Regarding "mean resource use" in Table 4: Mean resource use is not included in the aim or as a primary or secondary outcome. Please adjust the Introduction and Methods accordingly. Is mean resource use a description of actual usual care? If so, the title should be changed so that it is clear.

○ Table 4: Give the number of participants (i.e. n=) for the "Intervention" and "Usual care" in the heading.

○ Table 4: Enter the units for the two mean (SD) columns (namely, number of visits and overnight stays). Adjust the first column accordingly, i.e. keep just the professions (GP, Nurse, Occupational Therapist, and so on) and the place for care. Finally, explain the abbreviation A&E.

○ What about missing data in Table 5?

○ Unfortunate and a weakness is that a full account of the compliance with the recommendations, the intervention under investigation, is not reported in the current publication. The data is needed in this publication for the reader to be able to interpret the results correctly.

○ Last paragraph, first sentence: Please clarify the reasoning/data presentation related to the data commentary on adequate training.

Discussion

○ Please consider using your second sentence also in the Abstract since this sentence is more straightforward.

○ Please clarify any circumstances concerning or reflect about the 41 who "withdrew from treatment".

○ Please add a paragraph in which you discuss your results in relation to previous research in the field.

○ Please consider commenting on any significance of the method used (advertising) to identify potential participants.

○ Please consider commenting on any cultural/environmental differences between England and Australia, about the fact that the WeHSA form was developed in Australia.

○ Please consider discussing any similarities between the items/domains included in the WeHSA form and "Staying Steady", respectively, and how this may have affected the outcome/s.

- ○ Please consider including a reflection on the expected impact on recommendations obtained from a professional versus a leaflet.

- ○ Please consider discussing the low response rate, that the majority were women, and the generalizability of the results.

General
- ○ Please use the radix character (comma) to separate groups of thousands, as you do in Figure 1 and Figure 2.

Once again, thank you, and good luck with the current and future research projects. Best wishes.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Partly

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: My expertise is within research concerning fall/falls, rehabilitation medicine and psychometric properties.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

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