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# BMJ Open

## The OTIS study protocol: a modified cohort randomised controlled trial of whether an Occupational Therapist led home environmental assessment and modification can reduce falls among high risk older people?

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3 **The OTIS study protocol: a modified cohort randomised controlled trial of whether an**  
4 **Occupational Therapist led home environmental assessment and modification can reduce falls**  
5 **among high risk older people?**  
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16 Modified Cohort randomised controlled trial, home environmental assessment and modification,  
17 prevention of falls.  
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## ABSTRACT

**Introduction:** Falls and fall-related injuries are a serious cause of morbidity and cost to society. Environmental hazards are implicated as a major contributor to falls amongst older people. A recent Cochrane review found an environmental assessment, undertaken by an Occupational Therapist, to be an effective approach to reducing falls. However, none of the trials included a cost-effectiveness evaluation in the UK setting. This protocol describes a large multicentre trial investigating the clinical and cost-effectiveness of environmental assessment and modification within the home with the aim of preventing falls in older people.

**Methods and analysis:** A two arm, modified cohort, randomised controlled trial, conducted within England, with 1299 community dwelling participants aged 65 and above, who are at an increased risk of falls. Participants will be randomised 2:1 to receive either usual care or home assessment and modification. The primary outcome is rate of falls (falls/person/time) over 12 months assessed by monthly patient self-report falls calendars. Secondary self-reported outcome measures include: the proportion of single and multiple fallers, time to first fall over a 12-month period; quality of life (EuroQoL EQ-5D-5L), and health service utilisation at 4, 8 and 12 months. A nested qualitative study will examine the feasibility of providing the intervention, and explore barriers, facilitators, workload implications and readiness to employ these interventions into routine practice. An economic evaluation will assess value for money in terms of cost per fall averted.

**Ethics and dissemination:** This study protocol (including the original application and subsequent amendments) received a favourable ethical opinion from NHS West of Scotland REC 3. The trial results will be published in peer-reviewed journals and at conference presentations. A summary of the findings will be sent to participants.

**Trial registration:** Current Controlled Trials ISRCTN22202133 assigned 21/06/2016 assigned 21.06.2016.

## Article Summary

### Strengths and limitations of this study

- The largest randomised controlled trial in an English setting to assess the clinical and cost effectiveness of a home environmental assessment and modification for falls prevention.
- Investigates the feasibility of recruiting participants from databases of participants previously assembled whilst conducting cohort, falls prevention randomised controlled trials.
- Hosts three 'Studies within a Trial', which will add to the evidence base about recruitment strategies and ways to minimise missing data within trials.
- Results will be generalisable to a community dwelling population of older people within England.
- Uses an unblinded, patient self-report primary outcome measure, therefore, there is a possibility of reporting bias.

### Introduction

Falls in older people are common and can have serious consequences. Approximately 30% of people over the age of 65 years living in the community will have a fall each year [1, 2]. Around 85% of falls occur in the home [3]. A fifth of all falls are serious and require medical attention with 5% leading to a fracture [4]. Fall related fractures are a serious cause of morbidity and cost to society [5]. Repeated falls commonly precipitate admission to institutional care, and tend to be experienced by frail people in the older age range of 75 years and over. [1] [6]. The number of falls is likely to increase due to an ageing population and will have a major impact on health care resource use, primarily due to hip fractures resulting from a fall. The importance of fall related injuries has been recognised in the National Service Framework (NSF) for Older People [7] and in the NICE Guidelines [8]. The NSF calls for health improvement plans to be devised that will reduce the burden of fall related injuries.

It is well recognised that most falls result from an interaction between environmental hazards and a broad array of medical conditions and physiological impairments [9]. Environmental hazards are attributed by older people as primary factors in their falls and, thus, frequently cited in the literature as major contributors to falls. 'Accident/environment' related factors were identified as the primary cause of just under one third of falls in a review of twelve studies (mean of 31%, range 1-53%, n=3,628) [6]. Talbot et al [10] conducted a retrospective study and identified that

1 'accident/environment' related factors were perceived by older people as the second most  
2 common cause of falls, with key environmental contributors identified as objects on floors,  
3 external forces and wet, uneven and icy surfaces.  
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9 The theoretical approach underpinning environmental assessment and modification is the person-  
10 environment-occupation (PEO) conceptual model of Occupational Therapy practice [11]. This  
11 model posits that the person, environment and task being performed continually interact in ways  
12 that enhance or diminish a person's occupational performance and that environmental hazards  
13 are dynamic entities which occur through the interaction between these three elements. The PEO  
14 model underpins occupational therapy practice which aims to maintain, restore or create a  
15 balance between these elements [12].  
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23 The latest Cochrane review in this area (updated September 2012) [13] found that environmental  
24 assessment and modification was an effective approach to reducing falls (relative risk of falling  
25 0.88; 95% confidence interval 0.80 to 0.96). It also concluded that the effectiveness of an  
26 environmental intervention was increased if delivered by an Occupational Therapist (OT). Current  
27 National Institute for Health and Care Excellence (NICE) guidance suggests that "older people who  
28 have received treatment in hospital following a fall should be offered a home hazard assessment  
29 and safety intervention/modifications by a suitably trained healthcare professional". However, at  
30 the time of setting up the study there was no guidance with respect to environmental assessment  
31 for people living in the community who are at elevated risk of falling but have not yet received  
32 hospital treatment due to a fall. Indeed, there has only been one UK trial of environmental  
33 assessment by an OT, which was a pilot study conducted by some of the authors [14]. Whilst this  
34 study showed no evidence of a difference between the randomised groups on the primary  
35 outcome of fear of falling, a statistically significant reduction was observed in the number of falls  
36 (a secondary outcome). Consequently there is reasonable evidence to suggest occupational  
37 therapist delivered home hazard assessment and modification can lead to a reduction in falls. This  
38 large, multicentre trial builds on this previous work, and aims to undertake a high quality,  
39 adequately powered trial to evaluate the clinical and cost effectiveness of an environmental  
40 assessment and modification, delivered by an OT, for the prevention of falls.  
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## 56 Methods and analysis

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## Trial design

The OTIS (Occupational Therapist Intervention Study) study is a modified cohort [15] pragmatic, two arm, open, randomised controlled trial (RCT) with an economic evaluation and nested qualitative study. The cohort randomised controlled trial (cRCT) design was chosen to avoid some of the key potential biases that can occur in a pragmatic trial, namely: high attrition and patient preference effects. In a cRCT patients are recruited initially into a cohort and there is usually an outcome run-in period. Given that outcome attrition occurs largely at the first follow-up time point, this attrition is largely avoided if an eligibility criterion for the randomised phase is completion of outcomes during the run-in period[16]. With respect to preference effects, although the control group are aware of the possibility of being offered an intervention (in this case Occupational Therapy) they are unaware of when the actual randomisation occurs: this might avoid those biases, due to patient preference effects, which relate to timing of the offer of the intervention. In this study the cmRCT design was modified in that both intervention and control groups were told about the intervention prior to randomisation and that which group they would be in, would be decided by chance/ randomisation. In the cmRCT design, the process of obtaining patient information and consent aims to replicate that in real world routine health care – where patients are never told prospectively that their care options will be decided by chance.

## OTIS main study aim

The main aim is to establish whether environmental assessment and modification delivered by an OT will lead to a reduction in the number of falls among those at elevated risk of falling living in the community.

## OTIS secondary aims include:

1. Establishing the cost-effectiveness of OT delivered environmental assessment and modification.
2. Assessing the impact of the intervention on participants' quality of life.
3. Exploring the barriers and facilitators of implementing the trial's findings among OT professionals and the wider community (e.g., commissioners of services).

## Participants

### *Participant recruitment*

One thousand two hundred and ninety-nine participants will be recruited by one of the following methods (see Figure 1):



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1. Database search of existing cohorts held by the York Trials Unit (YTU) and the Yorkshire Health Study

The YTU has assembled a cohort of participants who originally participated in either the REFORM [17], SCOOP [18] or CASPER[19] trials and agreed to be contacted about future research studies run by the YTU. These studies recruited participants aged 65 years and over, from either routine NHS podiatry clinics or GP practices. A database search of these cohorts and the Yorkshire Health Study cohort to identify participants over the age of 65 years [20] will be undertaken to identify participants living in the OTs' catchment area (Yorkshire and North Lincolnshire), who will be eligible for an invitation mailing. Participants known to live in a residential or nursing home will be excluded from the mail out. Potentially eligible participants will be sent an invitation pack asking if they would like to participate in the study. The pack will contain an invitation letter, participant information sheet, consent form, screening questionnaire and a pre-paid envelope. In some cases, the person receiving the invitation pack may decline participation in the study but a family member or friend may be interested in taking part. In such cases the original recipient will be asked to pass on the research team's contact details, so that the interested person can contact the study team.

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2. GP practices and other services

To increase the generalisability of the study's findings, participants will be recruited through GP practices in primary care. GP practices will be recruited to the study after a member of the study team or the local Clinical Research Network has contacted the practice and explained the study and the participants' involvement. A database search will be undertaken to identify community dwelling men and women over the age of 65 who will be sent a recruitment pack. Patients known to have dementia or Alzheimer's disease, or who live in a residential or nursing home will be excluded from the mail out.

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3. Opportunistic screening

Where there is capacity, opportunistic screening by other healthcare professionals (e.g. GPs, Rapid Assessment Teams, chronic obstructive pulmonary disease nurses, Heart Failure Nurses, Community Matrons, or NHS services (e.g. ambulance services) will take place. Potential participants will be given an invitation pack.

4. Advertising for participants

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2 Radio, newspaper, faith magazine, social media, or television advertisements may also be used to  
3 publicise the study and encourage potential participants to get in touch with the researchers.  
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5 Additionally, posters or flyers may be placed within the geographical area of recruiting sites in  
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7 places such as supermarkets, libraries, and community centres.  
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10 Individuals identified via any of the four approaches described above who wish to take part in the  
11 study will be asked to return their completed consent form and screening questionnaire by post to  
12 the YTU. Researchers will assess the screening form for participant eligibility according to the  
13 study eligibility criteria. Participants deemed to be ineligible will be informed in writing. If the  
14 respondent is assessed as being ineligible because they have not had a fall within the past 12  
15 months or do not report a fear of falling, but otherwise fulfil the eligibility criteria, they will be  
16 given the option to be re-screened in four to six months' time.  
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24 All eligible, consenting participants will be asked to complete a baseline questionnaire and  
25 monthly falls calendars by post. Participants who return a valid baseline questionnaire and at  
26 least one falls calendar will be randomised into the trial. Participants can withdraw from the study  
27 at any point. The reason for withdrawal will not have to be declared; however, if provided, this will  
28 be recorded. Participants who do not wish to take part in the main study are not required to  
29 return any forms to the YTU.  
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### Inclusion criteria

Participants will be eligible for the OTIS trial if they:

1. Are aged 65 years or over
2. Are willing to receive a home visit from an Occupational Therapist
3. Are community dwelling
4. Have at least one of the following risk factors for a fall in the next 12 months: either one fall in the past 12 months; or report a fear of falling on their screening questionnaire

### Exclusion criteria

Participants will be ineligible for the OTIS trial if they:

1. Are unable to walk 10 feet today (3.05 metres) even with the use of a walking aid
2. Are unable to give informed consent, for example, due to Alzheimer's disease or dementia
3. Live in a residential or nursing home
4. Are unable to read or speak English and have no friend or relative to translate/interpret for them
5. Have had an OT assessment for falls prevention in the previous 12 months
6. Are on a waiting list for an occupational therapy assessment
7. Have not returned at least one completed falls calendar in the three months prior to randomisation.

### Randomisation

Participants will be enrolled into the study if they fulfil the eligibility criteria and provide written consent to take part in the study; they will then be randomised to either the intervention or control arm when they have returned a valid baseline questionnaire and at least one falls calendar within three months prior to the point of randomisation. Randomisation will be carried out using the YTU secure web-based computer randomisation service based on an allocation sequence generated by an independent data systems manager, who is not involved in the recruitment of participants. Participants will be randomly allocated to either the control group or the intervention group in a 2:1 ratio in favour of the control group (to reduce costs). Up to 12 participants from a particular site will be randomised at a time in a single block according to when sites state they have capacity to undertake intervention appointments and for how many participants. The allocation ratio used may go up to 3:1 in a block if the OTs have reduced capacity

1 to carry out the assessment. The YTU will write to the participant's GP informing them of study  
2 participation and to participants who are allocated to the intervention group.  
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### 5 6 7 Sample size

8 We propose to recruit and randomise 1299 participants to the OTIS trial in a 2:1 ratio (i.e., 866 to  
9 usual care and 433 to intervention). This number allows for 10% attrition and provides 90% power  
10 (using two-sided significance at the 5% level) to show a difference in the percentage of  
11 participants who experience at least one fall in the 12 months following randomisation from 60%  
12 in the control group to 50% in the intervention group, accounting for the unequal randomisation  
13 (StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP.). In the  
14 REFORM trial, previously conducted by some of the authors, an absolute difference of 5% was  
15 observed in the percentage of participants experiencing a fall (Intervention group 50%; Control  
16 group 55%), with a lower confidence limit of 13%; therefore, the decision was made to power this  
17 trial for a 10% absolute difference. In the event that sites are struggling with capacity to  
18 undertake assessments, we will consider using an allocation ratio of 3:1 (usual care to  
19 intervention) to reduce the number of participants they would have to see. If the final ratio was  
20 3:1 (i.e., 974 to the usual care and 325 to the intervention) we would have 85% power under the  
21 same conditions. The primary outcome is actually a count variable (number of falls, whilst  
22 proportion of participants experiencing at least one fall over the 12 months is a key secondary  
23 outcome); however, powering a trial for count data is more complex and requires greater  
24 assumptions and so a binary approach to the sample size calculation has been taken here.  
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### 40 Blinding

41 Control participants will be blind to when the intervention takes place; however, due to the nature  
42 of the intervention participants in the intervention group will not be blind. It is also not possible to  
43 blind members of the research team who are actively involved in the administration of the study,  
44 the statistician or health economist. Data entry staff will be blind to group allocation.  
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### 50 Trial Intervention

#### 51 OTIS trial usual care group

52 Participants will receive usual care from their General Practitioner and other health care  
53 professionals which may include referrals to a falls clinic. Participants will receive a falls  
54 prevention advice leaflet produced by Age UK ('Staying steady' published in June 2015) with their  
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1 baseline questionnaire in the post. A group specific newsletter will be sent to participants at three  
2 months post randomisation and two weeks before their 12 month follow up questionnaire is due,  
3 informing them about study progress. All participants will receive a pen and £5 with their 12  
4 month follow-up questionnaire in recognition of their participation and to offset any incidental  
5 expenses associated with completing the questionnaires.  
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### 10 11 12 OTIS trial intervention group 13

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15 In addition to the usual care and falls prevention leaflet described above, participants allocated to  
16 the intervention arm will be offered a home environmental assessment to identify personal fall  
17 related hazards and behaviours. The assessment will be undertaken by a Health and Care  
18 Professions Council registered OT and will take approximately two hours to conduct. If the  
19 assessment is too demanding for the participant, the appointment may be split over two visits.  
20 OTs will attend a one-day face-to-face training session on how to conduct the assessment. This  
21 will be provided by either the researcher who carried out the pilot trial (AP) or two of the OT  
22 researchers (SCr and AD) who will be trained by AP to deliver the training in a standardised way.  
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31 The environmental assessment will begin with an initial discussion about the participant's history  
32 of falling, lifestyle, patterns of usage of areas in the home, risk taking behaviour, strategies already  
33 adopted to reduce falls, environmental changes already in place prior to the assessment and  
34 functional vision. This will then be followed by the Timed Up and Go (TUG) test and an  
35 environmental assessment using the Westmead Home Safety (WeHSA) tool [21]. The WeHSA was  
36 developed in Australia in 1997 for older adults and consists of a 57 item standardised, valid and  
37 reliable checklist of fall hazards in the following domains: internal/ external traffic ways, general/  
38 indoors, living area, seating, bedroom, toilet, bathroom, kitchen, laundry, mobility aid, footwear,  
39 pets, medication management and safety call systems. The OT and the participant will move  
40 through the house together and a functional assessment will be completed. Items on the checklist  
41 will be rated as either relevant (i.e., deemed to be a hazard) or not relevant (i.e., not deemed to be  
42 a hazard or not present). The OT will discuss any potential falls hazards identified by either the  
43 participant or the OT during the assessment and problem solve with the participant to engage  
44 them in identifying possible solutions. A list of recommendations will be agreed. If possible, any  
45 identified hazards will be removed. If required, the OT will make referrals to other agencies for  
46 equipment or a handyman for other minor modifications. They may also make recommendations  
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1 for equipment that cannot be provided by Social Services, such as lightweight step ladders with  
2 handles and height adjustable rotary washing lines. In such cases the OT will liaise with the client  
3 or a family member regarding purchase of such equipment. The OT will make a clinical judgement  
4 whether an additional home visit is required. Four weeks after the assessment the OT or member  
5 of the OTIS research team will telephone the participant to check adherence to the  
6 recommendations.  
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### 13 Treatment Fidelity

14 Treatment fidelity will be assessed using the following strategies.

#### 15 1. Provider Training

16 A standard face-to-face training package will be used to standardise provider training. Training  
17 sessions will be recorded where possible. A checklist will be used to document whether all aspects  
18 of the training are covered when provided by different facilitators. Occupational Therapists will  
19 have the option to additionally undertake an on-line training course.  
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#### 27 2. Delivery of treatment

28 An observational study will be undertaken over the course of the trial to assess how the treatment  
29 was delivered. An OT who delivered the intervention training will shadow OTs whilst they visit  
30 participants. A checklist will be used to record which elements of the intervention are delivered.  
31 We will purposively sample OTs for shadowing to ensure we select a sample of OTs who attended  
32 different training sessions and who delivered either several or few assessments. Approximately 10  
33 OTs will be observed. Consent for an additional, observing OT to attend the home visit will be  
34 obtained from the participant. Participants will be able to decline the second OT attending the  
35 visit at any point during the process, and will still be able to receive a home visit. Elements of  
36 fidelity will also be included in the qualitative interviews. A similar sampling strategy to that  
37 detailed above will be used.  
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#### 48 3. Demonstration of adherence

49 In order to demonstrate adherence, completion rates of the individual items on the WeHSA will be  
50 summarised. In addition to this an OT who was involved in teaching the delivery of the  
51 intervention, will review the WeHSA data collected by the OT for each participant. A checklist will  
52 be used to document whether the key elements had been covered during the consultation.  
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57 Outcome measures

### Primary outcome measure for the OTIS trial

The primary outcome is the number of falls per participant over the 12 months from randomisation. A fall is defined as ‘an unexpected event in which the participant comes to rest on the ground, floor or lower level’ [22]. Data will be collected via participant self-reported monthly falls calendars, on which participants will be asked to mark the number of falls they have on each day, or indicate that they have had no falls that month. An explanation of what the researchers consider to be a fall will be included in the participant information sheet and on the falls calendars. If a participant is uncertain as to whether an event is classed as a fall, then they will be encouraged to ring the research team at the YTU to discuss. Participants who do not return their falls calendar within ten days of the due date will be either telephoned or sent a letter by the YTU to obtain missing data. Participants will be given a Freephone number to ring during office hours to report any falls as soon as possible after the event and when it is safe and convenient to do so. Participants who ring to report a fall will be asked for further details. Participants who indicate on their falls calendar that they have sustained a fall will be telephoned by the research team for further information. Information collected during the telephone call will include: cause/reason for fall, consequence of fall e.g., superficial wound (bruising, sprain, cut, abrasions), fractures (including type of fracture) and hospital admissions. Data collected from the 4, 8 and 12 month follow-ups questionnaires will include falls data and will be used for those participants who do not return their monthly falls calendars.

### OTIS trial secondary outcomes

All secondary outcomes will be self-reported by the participant and collected via questionnaires at baseline, 4, 8 and 12 months, or by monthly falls calendars. They include: proportion of participants reporting at least one fall in the 12 months from randomisation; proportion of participants reporting multiple (2 or more) falls in the 12 months from randomisation; time to first fall from date of randomisation; health-related quality of life as measured by the EQ-5D-5L [23]; fracture rate; fear of falling as measured by the question “During the past 4 weeks have you worried about having a fall?”; and health service utilisation.

### Nested qualitative study

To inform potential large-scale implementation of Occupational Therapy environmental assessment, qualitative interviews will take place with key stakeholder groups involved in

1 intervention delivery (Occupational Therapists, those who have clinical lead/practitioner roles for  
2 falls prevention services). Data will be collected on the feasibility of routinely providing this  
3 intervention, barriers and facilitators to implementation, workload implications and readiness to  
4 employ this intervention into their regular falls prevention practice. Normalisation Process Theory  
5 [24] will be used to guide data collection, and to frame the analysis, to understand how easy it is  
6 to implement these interventions into routine practice.  
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13 Fifteen OTs delivering the intervention in the trial and ten clinical leads who run falls prevention  
14 services/care of older people services from organisations involved in the trial and five external to  
15 the trial will be purposively selected. Participants will be invited to attend a telephone interview.  
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### 20 Adverse events

21 This study will record and report details of any adverse events (AEs) that are required to be  
22 reported to the Health Research Authority (HRA) i.e., events which are related to taking part in the  
23 study and are unexpected. The AE reporting period begins as soon as the participant consents to  
24 be in the study and ends twelve months after they are randomised.  
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30 Details of any adverse events will be recorded using a trial adverse event form. Serious adverse  
31 events reported by the OT should be reported within 48 hours of the OT becoming aware of the  
32 event or within 14 days for non-serious events. A follow-up report will be completed if additional  
33 information becomes available.  
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39 For this trial a Serious Adverse Event (SAE) is defined as any untoward occurrence that:  
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- 43 (a) Results in death
  - 44 (b) Is life threatening
  - 45 (c) Requires hospitalisation or prolongation of existing hospitalisation
  - 46 (d) Consists of a congenital anomaly or birth defect; or
  - 47 (e) Is otherwise considered medically significant by the investigator
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53 An event is defined as 'related' if the event was due to the administration of any research  
54 procedure. Whereas an 'unexpected event' is defined as a type of event not listed in the protocol  
55 as an expected occurrence.  
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3 The relatedness of an event will be reviewed by the Chief Investigator and the Trial Steering  
4 Committee. Incidents of hospitalisations, disabling / incapacitating / life-threatening conditions,  
5 aging-associated diseases (such as cancer, cardiovascular disease, diabetes, arthritis, osteoporosis,  
6 dementia), other common illnesses such as depression, falls and deaths are expected in the study  
7 population due to the age of the cohort. Similarly, any hospitalisation that was planned prior to  
8 entry into the study or cannot be attributed to taking part in the study or prolongation of an  
9 existing hospitalisation due to social reasons will not be recorded as a SAE.  
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### 16 17 Statistical analysis

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19 There are no planned interim analyses, therefore, the statistical analysis will be undertaken at the  
20 end of the trial and will be conducted using STATA version 15 or later (StataCorp, 4905 Lakeway  
21 Drive, College Station, Texas 77845, USA). All analyses will be conducted on an intention-to-treat  
22 (ITT) basis, including all randomised patients in the groups to which they were originally allocated.  
23 Participant baseline data will be summarised descriptively by group, for all those who have been  
24 randomised and for all those who are included in the primary outcome analysis by randomised  
25 arm. No formal statistical comparisons will be undertaken. Continuous measures will be reported  
26 as means and standard deviations while the categorical data will be reported as counts and  
27 percentages.  
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### 36 Statistical analysis of the OTIS primary outcome

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38 The number of falls per person will be analysed using Poisson regression (or negative binomial  
39 regression, as appropriate) adjusting for gender, age, history of falling and the allocation ratio  
40 used to randomise the participant as fixed effects. The model will include an exposure variable for  
41 the number of months that the participant returned a monthly falls calendar. A sensitivity analysis  
42 will be conducted to account for potential clustering effects by the OT by assigning every  
43 randomised participant an OT irrespective of group allocation. For intervention participants, this  
44 will be the OT delivering their intervention; whereas for control participants, a counterfactual  
45 therapist i.e., one that they could have seen had they been randomised to the intervention group,  
46 will be randomly assigned to them. Therapist will then be included as a random effect in the  
47 primary analysis model. Additionally, a Complier Average Causal Effect (CACE) analysis to assess  
48 the impact of compliance on treatment estimates will be undertaken for the primary analysis.  
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## Secondary analysis

The following outcomes will be analysed by logistic regression adjusted for the same covariates as the primary analysis model: the proportion of participants who fall at least once over the 12 month period from the date of randomisation; the proportion of multiple fallers (2 or more falls in the 12 months from randomisation); the proportion of participants having at least one fracture over the 12 month follow-up; the proportion of patients obtaining multiple fractures (from different events, if this occurs a sufficient number of times); and the proportion of participants who report that they are worried about falling at 12 months post-randomisation.

Fear of falling will also be analysed in its continuous form using a covariance pattern model incorporating all post randomisation time points in the analysis and adjusting for baseline score, gender, age, history of falling, allocation ratio, treatment group, time and a treatment group-by-time interaction. The correlation of observations within patients over time will be modelled.

The time to the first fall will be derived as the number of days from randomisation until the patient reports having a fall as detailed in the participant's falls calendars. Time between any subsequent falls will also be calculated. Participants who have not had a fall will be treated as censored at their date of trial exit, or date of last available assessment or 365 days/trial cessation, as appropriate. The proportion of patients yet to experience a fall will be summarised by a Kaplan Meier survival curve for each group. Time to fall will be analysed using the Andersen and Gill method for analysing time to event data when the event can be repeated. The analysis treats each time to event or censoring as a separate observation. The data will be analysed by Cox Proportional Hazards regression using robust standard errors to account for dependent observations by participant, and adjusting for the same covariates as in the primary analysis model.

Adherence to the WeHSA will also be summarised descriptively.

Sub-group analysis: The primary analysis will be repeated including an interaction term between the treatment allocation and whether or not a patient received care in a hospital (outpatient appointment, day case, A&E presentation, or hospital admission) as a result of a fall in the 4 months prior to completion of the baseline questionnaire.

### Missing data

The amount of missing data will be reported by trial arm. A comparison of the baseline characteristics of participants who are included in the primary analysis will be undertaken to ensure that any attrition has not produced imbalance in the groups in important baseline covariates. A logistic regression model will be used to predict non-response (no falls data received post-randomisation) including all variables collected prior to randomisation. The primary analysis will then be repeated, including as covariates all variables found to be significantly predictive of non-response, to determine if these affect the parameter estimates and study conclusions.

### Qualitative analysis

All interviews will be audio recorded digitally and transcribed verbatim. A computer package such as ATLAS-ti may be used to manage the data. Initially, following transcription, the interview material will be organised according to analytical headings using a constant comparison approach [25]. Following familiarisation with the data, key themes will be identified which will then be contextualised in relation to the broader dataset and will be interpreted within the context of theoretical themes relevant to the interview material. If environmental assessment and modification is found to be an effective and cost-effective intervention, we will maintain a sharp focus on the relevance of any findings to implement in the qualitative analysis, in order to develop an implementation plan for Occupational Therapy falls environmental assessment

### Adverse event data

Adverse event data will be summarised descriptively by randomised arm.

### Trial monitoring

A Trial Steering Committee and Data Monitoring and Ethics Committee will monitor the trial at least every 12 months, or more frequently if the committee requests. The role of this committee will include the review of all serious adverse events which are thought to be treatment related and unexpected.

### Economic evaluation

The health economic evaluation aims to establish the cost-effectiveness of OT delivered environmental assessment and modification in terms of preventing falls, and assess the impact of the intervention on participants' quality of life. The economic analysis will be performed using

1 individual patient level data on an ITT basis. The analytical approach will take the form of cost-  
2 effectiveness and cost-utility analyses. The cost-effectiveness approach will assess value for  
3 money in terms of cost per fall averted, and the cost-utility analysis will assess cost per quality  
4 adjusted life-year (QALY) gained. The perspective for both analyses will be that of the UK NHS and  
5 personal social services, as well as secondary analyses undertaken from a societal perspective.  
6 Discounting for future cost and health benefit will not be undertaken given the time frame for the  
7 trial is 12 months after randomisation. The year of pricing will be set as the mid-year of the trial.  
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10 Health benefits associated with the treatments will be measured in terms of both estimates of the  
11 mean number of falls, corresponding to the main outcome of the trial, and mean QALYs, defined  
12 as a year lived with full health. In line with NICE recommendations [26], the EuroQol EQ-5D [27]  
13 will be used to elicit patient utility values at different points in time and used to calculate QALYs  
14 for each patient, using the area under the curve approach [28, 29]. These utility values are used as  
15 'quality adjustment' for each patient's survival time. Specifically, the EQ-5D-5L will be used.  
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18 Cost data will be collected for each patient regarding health care resource use; specifically within  
19 primary care and the community (i.e., GP, nurse, physiotherapist, occupational therapist visits)  
20 and the hospital setting (i.e., outpatient attendances, day cases, inpatient stays and accident and  
21 emergency attendances). Unit costs will then be applied to estimate the total cost per patient.  
22 Additional information will be collected regarding intervention costs and private/personal  
23 expenses that feed into the societal perspective analysis (e.g., activities of daily living equipment,  
24 travel costs for health care attendances). Unit costs will be obtained from established costing  
25 sources such as NHS Reference Costs [30] and PSSRU Unit Costs of Health and Social Care [31].  
26 Data on the cost and utility measures will be collected prospectively at baseline, four, eight and 12  
27 months via self-reported questionnaires.  
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30 Mean within-trial estimates of cost and health benefits will be estimated using regression  
31 methods, allowing for the correlation between costs and effects, as well as adjusting for  
32 covariates. The results will be presented as incremental cost-effectiveness ratios (ICERs), where  
33 the difference in mean cost estimates between the two arms is divided by the difference in mean  
34 health benefit between the two arms. Findings will also be presented in terms of net health  
35 benefit [32]. Multiple imputation methods will be used to handle missing data where needed  
36 [33].  
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3 The uncertainty surrounding the decision to accept a treatment as the most cost-effective will be  
4 explored in cost-effectiveness acceptability curves (CEACs) [34]. These curves depict the  
5 probability of accepting a treatment as being cost-effective for a large range of willingness to pay  
6 values for an extra unit of health benefit. Sensitivity analysis will be conducted to explore the  
7 impact of underlying assumptions of the analysis and the range of unit costs on the cost-  
8 effectiveness results.  
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15 The main outcome of the trial, falls reduction, is associated with a reduction in fractures.  
16 However, due to the restriction in the length of follow-up, the long term effect in terms of the  
17 decreasing number of fractures might not be observed in the current trial. Therefore, a further  
18 analysis will explore the possible long term impact of the trial, assuming that a falls reduction  
19 should also lead to a fracture reduction. A decision analytic model approach will be adopted to  
20 perform this task. The perspective will be the UK NHS and personal social services, with a lifetime  
21 time horizon whereby every participant in a hypothetical cohort is followed up until the last  
22 participant dies. The hypothetical cohort will be constructed, based on the characteristics of the  
23 trial population, to estimate the QALY yield and cost saving of the long term effect of the  
24 intervention. The model parameters which are not collected in the trial will be extracted from the  
25 existing literature.  
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36 The model outputs will be the estimated expected mean costs, effectiveness, and QALYs  
37 associated with each alternative treatment. Estimated total costs and outcomes will be  
38 discounted according to the latest health technology appraisal guidance [26]. Uncertainty  
39 regarding cost-effectiveness will be evaluated using probabilistic sensitivity analysis, where inputs  
40 into the analysis are defined as probability distributions which reflect uncertainty [35]. The  
41 uncertainty surrounding the decision to adopt a given treatment option as a cost-effective  
42 treatment at different levels of willingness to pay will be represented in CEACs. The impact of  
43 assumptions undertaken in the analysis regarding the evidence over parameters or relating to the  
44 decision model (such as extrapolation) will be evaluated in sensitivity analysis, if possible.  
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### 53 Studies within trials

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57 In addition to the main OTIS study, three 'Studies within a Trial' (SWATS) are being conducted.  
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### Pen sub-study

The aim of this sub study is to evaluate the effectiveness of including a pen with the trial invitation pack on recruitment of participants to the OTIS study. Any patient identified in the GP mail out as eligible to receive an OTIS trial invitation pack will be entered into the pen sub-study. Block randomisation will be used to allocate participants in a 2:1 ratio in favour of the control group. Generation of the allocation sequence will be undertaken independently by a researcher not involved with the production of the recruitment packs. A single block the size of the number of participants from each GP practice will be used. The intervention group will receive a pen with the York Trials Unit logo/details on it; the control group will not receive a pen at the point of being invited to take part in the study. The primary outcome is the proportion of participants who go on to be randomised to the OTIS trial. Secondary outcomes include: the proportion of participants who return a screening form; time to return screening form; the proportion of participants who fulfil the eligibility criteria apart from the criterion relating to falls within past 12 months or fear of falling; the proportion of participants who are eligible for randomisation; and the proportion of participants who remain in the trial at three months post randomisation. Categorical data will be compared using logistic regression and time to response via a Cox proportional hazards model.

### Invitation letter sub-study

The aim of this sub study is to evaluate the effectiveness of writing the potential participant's name by hand on the invitation letter, versus printing their name, on the recruitment rate to the study. Participants will be eligible for this sub-study if are they due to be sent an invitation pack about the OTIS trial in the first mail out undertaken by the Yorkshire Health Study. Block randomisation will be used to allocate participants in a 1:1 ratio to receive either a hand written name on the invitation letter (intervention group) or printed name on the invitation letter (control group). Generation of the allocation sequence will be undertaken independently by a researcher not involved with the production of the recruitment packs. The primary outcome is the proportion of participants who go on to be randomised to the OTIS trial. Secondary outcomes include: the proportion of participants who return a screening form; time to return screening form; the proportion of participants who fulfil the eligibility criteria apart from the criterion relating to falls within past 12 months or fear of falling; the proportion of participants who are eligible for randomisation; and the proportion of participants who remain in the trial at three months post randomisation. Categorical data will be compared using logistic regression and time to response via a Cox proportional hazards model.

### Text message sub-study

The aim of this sub study is to evaluate the effectiveness of a personalised text message compared with a standard text message on postal questionnaire response rates. Participants who are due to be sent their four month follow-up questionnaire and who have provided a mobile phone number and consented to be contacted by text message will be randomised. Block randomisation will be used to allocate participants in a 1:1 ratio, to receive either a personalised (intervention group) or a standard text message (control group) at the same time as they are due to receive their postal follow-up questionnaire (i.e., two to four days after the questionnaire is sent). The randomisation will be stratified by main trial allocation. Generation of the allocation sequence will be undertaken independently by a researcher not involved with the delivery of the text messages.

The personalised text message will read *“OTIS Trial: [Title, surname of participant] you should have received a questionnaire in the post by now. Your answers are important; so please help by returning it as soon as you can. Thanks.”*

The standard text message will read *“OTIS Trial: you should have received a questionnaire in the post by now. Your answers are important; so please help by returning it as soon as you can. Thanks”*. The primary outcome is the proportion of participants in each group who return the questionnaire. Secondary outcomes include time to response, completeness of response, whether a reminder notice is required and cost-effectiveness. Categorical data will be compared using logistic regression and time to response via a Cox proportional hazards model. All models will adjust for main trial allocation.

### Sample size for the SWATs

As is usual with an embedded trial within a trial, no formal power calculation will be undertaken for the pen and text message sub-studies, as the sample size will be constrained by the number of participants available to either mail out to, or contact. We will, however, randomise 314 participants, who are due to be mailed out by the Yorkshire Health Study an invitation pack about the OTIS trial. This sample size will allow us to detect a 10% difference in the percentage of participants who go on to be randomised (from 10 to 20%) between the two groups at 80% power and a two-sided alpha level of 0.1.

## Ethics and dissemination

### Ethics

All participants will give written informed consent prior to entry to the study. Further consent will be obtained for the qualitative interviews and fidelity observations.

### Dissemination

The results of the study will be disseminated through high impact peer-reviewed journals, through national and international research conferences and Occupational Therapy specific journals and newsletters. A short summary of the results will be sent to participants who request this at the end of the trial.

### Discussion

The authors have previously conducted three cohort randomised controlled trials (cRCT) [36]. Participants in these trials were recruited from either routine NHS podiatry clinics [17] or from General Practices [18, 19]. All were aged at least 65 years and over and therefore had an elevated risk of falling. One key feature of the cRCT design is the capacity to undertake multiple randomised controlled trials over time. During the recruitment phase of the OTIS study, we will test the feasibility of recruiting participants from these cohorts and determine whether it is a quick and cost-effective means to recruit participants.

In addition to the main OTIS trial, we have taken the opportunity to undertake three SWATs. The results of these studies will add a significant contribution to the body of evidence about strategies to improve recruitment to trials and minimise the amount of missing data.

Falls in older people are a major health problem. A recent Cochrane review found environmental assessment, undertaken by an Occupational Therapist, to be an effective approach to reducing falls in older people. As far as we are aware, none of the trials included a cost effectiveness evaluation within a UK setting. The OTIS protocol aims to evaluate the clinical and cost-effectiveness of an environmental assessment and modification for preventing falls in older people, and will be the largest trial to evaluate this intervention in isolation.



### Trial status

Recruitment and follow-up are in progress. Recruitment to the study began in October 2015 and will continue until approximately summer 2018. Participants will continue to be followed-up until winter 2019.

### Acknowledgments

The research team would like to thank the independent members of the Trial Steering/Data Monitoring and Ethics Committee: Professor Roger Francis, Dr Ranjit Lall, Dr Claire Ballinger, Professor Lindy Clemson and Mrs Margaret McCabe for their advice, overseeing the study and reviewing adverse event data. The authors also extend very grateful thanks to the Patient Involvement Group, the study participants, Occupational Therapists for delivering the intervention and to the CRN for assistance with the GP mail out of recruitment packs.

### Author's Contributions

DT and AP wrote the original protocol. JA, SB, SC, SCr, AD, CF, SG, CH, SL, AP, CR, SR, SJR, DT were either applicants on the NIHR HTA funding application or helped to refine the protocol. SC wrote the first draft of this article with input from CF. All authors read and approved the final manuscript.

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### Competing Interest

Catherine Hewitt declares membership of the HTA Commissioning board, and Sarah Lamb declares membership of the HTA Prioritisation board. No other competing interests are declared.

### Ethics approval

This study protocol (version 7, 19.10.2017) including the original application and subsequent amendments received a favourable ethical opinion from NHS West of Scotland REC 3, the University of York, Department of Health Sciences Research Governance and NHS Trust Research and Development approval at recruiting sites.

### Peer review

This study was peer reviewed for ethical and funding approval prior to submission.

### Data sharing statement

Requests to access OTIS data can be made to the corresponding author, and will be considered on a case-by-case basis by the Trial Management Group. All data requests will be managed according to York Trials Unit, University of York processes and procedures.

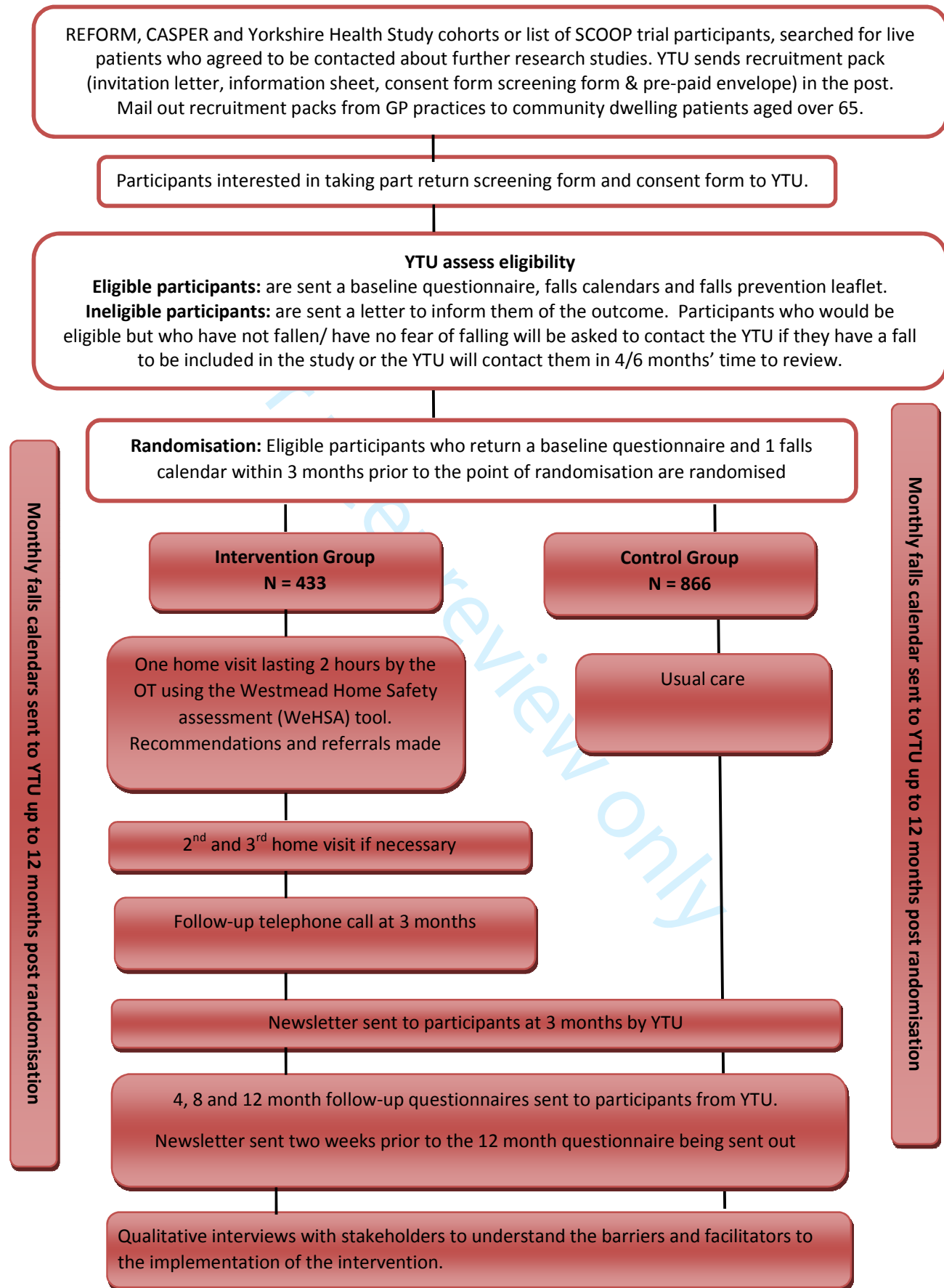
## REFERENCES

1. Morris M, Osborne D, Hill K, Kendig H, Lundgren-Lindquist B, Browning C, et al. Predisposing factors for occasional and multiple falls in older Australians who live at home. *Australian journal of physiotherapy*. 2004;50(3):153-9.
2. Campbell AJ, Borrie MJ, Spears GF, Jackson SL, Brown JS, Fitzgerald JL. Circumstances and consequences of falls experienced by a community population 70 years and over during a prospective study. *Age and ageing*. 1990;19(2):136-41.
3. Tideiksaar R. Fall prevention in the home. *Topics in Geriatric Rehabilitation*. 1987;3(1):57-64. PubMed PMID: 00013614-198710000-00010.
4. Vetter NJ LP, Ford D. . Can health visitors prevent fractures in elderly people? . *British Medical Journal* 1992;304(6831):888-9.
5. Iglesias C, Manca A, Torgerson D. The health-related quality of life and cost implications of falls in elderly women *Osteoporos Int* (2009) (20):869–78 DOI 10.1007/s00198-008-0753-5.
6. L R. Falls in older people: epidemiology, risk factors and strategies for prevention. *Age and Ageing* 2006;35-S2:ii37-ii41.
7. (DH). DoH. National service framework for older people. <https://www.gov.uk/government/publications/quality-standards-for-care-services-for-older-people> (accessed 20 Oct 2014).2001.
8. National, Institute, for, Health, and, Care, et al. Falls in older people: assessing risk and prevention. NICE Guideline (CG161)2013.
9. Lord S, Sherrington C, Menz H, Close J. Falls in older people: risk factors and strategies for prevention: Cambridge University Press, Cambridge; 2007.
10. Talbot LA MR, Witham EK, Metter EJ. . Falls in young, middle-aged and older community dwelling adults: perceived cause, environmental factors and injury. . *BMC Public Health* 2005;5(1):1
11. Law M CB, Strong S, Stewart D, Rigby P, Letts L. The Person-Environment-Occupation Model: A Transactive Approach to Occupational Performance *Canadian Journal of Occupational Therapy* 1996;63(1):9-23.

12. Todd CJ, Ballinger C, Whitehead S. A global report on falls prevention: reviews of socio-demographic factors related to falls and environmental interventions to prevent falls amongst older people living in the community. World Health Organization. 2007.
13. Gillespie L, Robertson M, Gillespie W, Lamb S, Gates S, Cumming R, et al. Interventions for preventing falls in older people living in the community. *Cochrane Database Syst Rev* 2009;2:CD007146.
14. Pighills AC, Torgerson DJ, Sheldon TA, Drummond AE, Bland JM. Environmental assessment and modification to prevent falls in older people. *Journal of the American Geriatrics Society*. 2011;59(1):26-33.
15. Relton C, Torgerson D, O'Cathain A, J N. Rethinking pragmatic randomised controlled trials: introducing the "cohort multiple randomised controlled trial" design. *BMJ*. 2010;340:Mar 19;340:c1066. doi: 10.1136/bmj.c.1066.
16. Dascanio VB, Yvonne; Clark, Laura Kate; Fairhurst, Caroline; MacPherson, Hugh; Torgerson, David J. Randomized cohort trial was shown to be feasible for evaluating treatments in low back pain. *Journal of Clinical Epidemiology*. 2014;67(No. 8): 940-6.
17. Cockayne S AJ, Clarke A, Corbacho B, Fairhurst C, Green L et al. . Cohort Randomised Controlled Trial of a Multifaceted Podiatry Intervention for the Prevention of Falls in Older People (The REFORM Trial). *PLoS One* 2017 12(1).
18. Shepstone L FR, Lenaghan E, et al. . A pragmatic randomised controlled trial of the effectiveness and cost-effectiveness of screening older women for the prevention of fractures: rationale, design and methods for the SCOOP study. . *Osteoporosis International* 2012;23(10):2507-15.
19. Mitchell N, Hewitt C, Adamson J, Parrott S, Torgerson D, Ekers D, et al. A randomised evaluation of Collaborative care and active surveillance for Screen-Positive ElDeRs with sub-threshold depression (CASPER): study protocol for a randomized controlled trial. *Trials*. 2011;12(225):6215-12.
20. Relton C, Bissell P, Smith C, Blackburn J, Cooper CL, Nicholl J, et al. South Yorkshire Cohort: a cohort trials facility study of health and weight-Protocol for the recruitment phase. *BMC Public Health*. 2011;11(1):640.
21. Clemson L. A guide to identifying fall hazards in the homes of elderly people and an accompaniment to the assessment Tool, the Westmead Home Safety Assessment (WeHSA): . West Brunswick VAC-oP, editor 1997.
22. Lamb S, Jorstad-Stein E, Hauer K, Becker C. Development of a common outcome data set for fall injury prevention trials: the Prevention of Falls Network Europe consensus. . *J Am Geriatr Soc* 2005;53(9):1618-22.
23. Kind P. The EuroQoL instrument: an index of health-related quality of life. *Quality of life and pharmacoeconomics in clinical trials*. 1996;2:191-201.
24. May CR MF, Finch T, et al. . Development of a theory of implementation and integration: Normalization Process Theory. *Implementation Science* 2009;4(1):29.
25. Silverman D. *Interpreting Qualitative Data: Methods for Analyzing Talk, Text and Interaction*.: London: Sage 1993
26. National Institute for Health and Care Excellence. *Guide to the methods of technology appraisal*. London: NICE: 2013.
27. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation*. 2011;20(10):1727-36. Epub 2011/04/12. doi: 10.1007/s11136-011-9903-x. PubMed PMID: 21479777; PubMed Central PMCID: PMC3220807.
28. Matthews JN, Altman DG, Campbell MJ, Royston P. Analysis of serial measurements in medical research. *BMJ (Clinical research ed)*. 1990;300(6719):230-5. Epub 1990/01/27. PubMed PMID: 2106931; PubMed Central PMCID: PMC1662068.
29. Billingham L, Abrams KR, Jones DR. Methods for the analysis of quality-of-life and survival data in health technology assessment. *Health Technol Assess*. 1998;3(10):1-152.
30. Department of Health. *NHS Reference Costs 2013/14*  
<https://www.gov.uk/government/publications/nhs-reference-costs-2013-to-20142014>.
31. Curtis L. *Unit Costs of Health and Social Care 2014*. University of Kent: Personal Social Services Research Unit; 2014. Available from: <http://www.pssru.ac.uk>.

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32. Stinnett AA, Mullahy J. Net health benefits: a new framework for the analysis of uncertainty in cost-effectiveness analysis. *Medical decision making : an international journal of the Society for Medical Decision Making*. 1998;18(2 Suppl):S68-80. Epub 1998/05/05. PubMed PMID: 9566468.
33. Manca A, Palmer S. Handling missing data in patient-level cost-effectiveness analysis alongside randomised clinical trials. *Appl Health Econ Health Policy*. 2005;4(2):65-75. Epub 2005/09/16. PubMed PMID: 16162026.
34. Fenwick E, O'Brien BJ, Briggs A. Cost-effectiveness acceptability curves--facts, fallacies and frequently asked questions. *Health economics*. 2004;13(5):405-15. Epub 2004/05/06. doi: 10.1002/hec.903. PubMed PMID: 15127421.
35. Briggs A, Claxton K, Sculpher M, Briggs A, Claxton K, Sculpher M. *Decision modelling for health economic evaluation*: Oxford University Press; 2006.
36. Cockayne S, Adamson J, Martin BC, Fairhurst C, Hewitt C, Hicks K, et al. The REFORM study protocol: a cohort randomised controlled trial of a multifaceted podiatry intervention for the prevention of falls in older people. *BMJ open*. 2014;4(12):e006977.

Figure 1 Flow chart of participants through the OTIS trial





SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	Addressed on page number
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	3, 23, 1, 4, 11, 9,6, 13, 22,
Protocol version	3	Date and version identifier	24
Funding	4	Sources and types of financial, material, and other support	23
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1 & 23
	5b	Name and contact information for the trial sponsor	23
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	23
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	17 & 23

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## Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4 - 5
	6b	Explanation for choice of comparators	10- 12
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6

## Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	11 & 12
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	13
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9, 13

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3	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
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5	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
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### 8 **Methods: Assignment of interventions (for controlled trials)**

#### 9 Allocation:

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12	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	9
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17	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9
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21	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9
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24	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10
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27		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
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### 31 **Methods: Data collection, management, and analysis**

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33	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8
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38		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11
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3	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	24
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7	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15-17
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10		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16
11				
12		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
13				
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15	<b>Methods: Monitoring</b>			
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17	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	23
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22		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
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25	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	17
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28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	17
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32	<b>Ethics and dissemination</b>			
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34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	3, 22 & 23
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37	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	3, 23
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3	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
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6		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	12
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8	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	7, 8
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11	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	23
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14	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	24
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17	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
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20	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	3
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25		31b	Authorship eligibility guidelines and any intended use of professional writers	23
26				
27		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	24
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29	<b>Appendices</b>			
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31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Attached as supplementary file
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34	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A
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37 \*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.  
 38 Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons  
 39 "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.  
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# BMJ Open

## Can Occupational Therapist led home environmental assessment prevent falls in older people? A modified cohort randomised controlled trial protocol.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-022488.R1
Article Type:	Protocol
Date Submitted by the Author:	08-Jun-2018
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<b>Primary Subject Heading</b>:	Occupational and environmental medicine
Secondary Subject Heading:	Evidence based practice, Geriatric medicine, Health economics
Keywords:	Falls prevention, Home environmental assessment and modification, Modified Cohort randomised controlled trial, Occupational therapist

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Manuscripts

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3 Can Occupational Therapist led home environmental assessment prevent falls in older people? A  
4 modified cohort randomised controlled trial protocol.  
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9 Sarah Cockayne<sup>1</sup>§, Alison Pighills<sup>2</sup>, Joy Adamson<sup>3</sup>, Caroline Fairhurst<sup>1</sup>, Avril Drummond<sup>4</sup>, Catherine  
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11 Simon Gilbody<sup>1</sup>, Clare Relton<sup>8</sup>, and David J Torgerson<sup>1</sup> on behalf of the OTIS study  
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14 **Key words**

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16 Modified Cohort randomised controlled trial, home environmental assessment and modification,  
17 prevention of falls.  
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21 **Word count** 7679  
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ABSTRACT

**Introduction:** Falls and fall-related injuries are a serious cause of morbidity and cost to society. Environmental hazards are implicated as a major contributor to falls amongst older people. A recent Cochrane review found an environmental assessment, undertaken by an Occupational Therapist, to be an effective approach to reducing falls. However, none of the trials included a cost-effectiveness evaluation in the UK setting. This protocol describes a large multicentre trial investigating the clinical and cost-effectiveness of environmental assessment and modification within the home with the aim of preventing falls in older people.

**Methods and analysis:** A two arm, modified cohort, randomised controlled trial, conducted within England, with 1299 community dwelling participants aged 65 and above, who are at an increased risk of falls. Participants will be randomised 2:1 to receive either usual care or home assessment and modification. The primary outcome is rate of falls (falls/person/time) over 12 months assessed by monthly patient self-report falls calendars. Secondary self-reported outcome measures include: the proportion of single and multiple fallers, time to first fall over a 12-month period; quality of life (EuroQoL EQ-5D-5L), and health service utilisation at 4, 8 and 12 months. A nested qualitative study will examine the feasibility of providing the intervention, and explore barriers, facilitators, workload implications and readiness to employ these interventions into routine practice. An economic evaluation will assess value for money in terms of cost per fall averted.

**Ethics and dissemination:** This study protocol (including the original application and subsequent amendments) received a favourable ethical opinion from NHS West of Scotland REC 3. The trial results will be published in peer-reviewed journals and at conference presentations. A summary of the findings will be sent to participants.

**Trial registration:** Current Controlled Trials ISRCTN22202133 assigned 21/06/2016 assigned 21.06.2016.

## Article Summary

### Strengths and limitations of this study

- The largest randomised controlled trial in an English setting to assess the clinical and cost effectiveness of a home environmental assessment and modification for falls prevention.
- Investigates the feasibility of recruiting participants from databases of participants previously assembled whilst conducting cohort, falls prevention randomised controlled trials.
- Hosts three 'Studies within a Trial', which will add to the evidence base about recruitment strategies and ways to minimise missing data within trials.
- Results will be generalisable to a community dwelling population of older people within England.
- Uses an unblinded, patient self-report primary outcome measure, therefore, there is a possibility of reporting bias.

### Introduction

Falls in older people are common and can have serious consequences. Approximately 30% of people over the age of 65 years living in the community will have a fall each year [1, 2]. Around 85% of falls occur in the home [3]. A fifth of all falls are serious and require medical attention with 5% leading to a fracture [4]. Fall related fractures are a serious cause of morbidity and cost to society [5]. Repeated falls commonly precipitate admission to institutional care, and tend to be experienced by frail people in the older age range of 75 years and over. [1] [6]. The number of falls is likely to increase due to an ageing population and will have a major impact on health care resource use, primarily due to hip fractures resulting from a fall. The importance of fall related injuries has been recognised in the National Service Framework (NSF) for Older People [7] and in the NICE Guidelines [8]. The NSF calls for health improvement plans to be devised that will reduce the burden of fall related injuries.

It is well recognised that many falls result from an interaction between environmental hazards and a broad array of medical conditions and physiological impairments [9]. Environmental hazards are attributed by older people as primary factors in their falls and, thus, frequently cited in the literature as major contributors to falls. 'Accident/environment' related factors were identified as the primary cause of just under one third of falls in a review of twelve studies (mean of 31%, range 1-53%, n=3,628) [6]. Talbot et al [10] conducted a retrospective study and identified that

1 'accident/environment' related factors were perceived by older people as the second most  
2 common cause of falls, with key environmental contributors identified as objects on floors,  
3 external forces and wet, uneven and icy surfaces.  
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9 The theoretical approach underpinning environmental assessment and modification is the person-  
10 environment-occupation (PEO) conceptual model of Occupational Therapy practice [11]. This  
11 model posits that the person, environment and task being performed continually interact in ways  
12 that enhance or diminish a person's occupational performance and that environmental hazards  
13 are dynamic entities which occur through the interaction between these three elements. The PEO  
14 model underpins occupational therapy practice which aims to maintain, restore or create a  
15 balance between these elements [12].  
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23 The latest Cochrane review in this area (updated September 2012) [13] found that environmental  
24 assessment and modification was an effective approach to reducing falls (relative risk of falling  
25 0.88; 95% confidence interval 0.80 to 0.96). It also concluded that the effectiveness of an  
26 environmental intervention was increased if delivered by an Occupational Therapist (OT). Current  
27 National Institute for Health and Care Excellence (NICE) guidance suggests that "older people who  
28 have received treatment in hospital following a fall should be offered a home hazard assessment  
29 and safety intervention/modifications by a suitably trained healthcare professional". However, at  
30 the time of setting up the study there was no guidance with respect to environmental assessment  
31 for people living in the community who are at elevated risk of falling but have not yet received  
32 hospital treatment due to a fall. Indeed, there has only been one UK trial of environmental  
33 assessment by an OT, which was a pilot study conducted by some of the authors [14]. Whilst this  
34 study showed no evidence of a difference between the randomised groups on the primary  
35 outcome of fear of falling, a statistically significant reduction was observed in the number of falls  
36 (a secondary outcome). Consequently there is reasonable evidence to suggest occupational  
37 therapist delivered home hazard assessment and modification can lead to a reduction in falls. This  
38 large, multicentre trial builds on this previous work, and aims to undertake a high quality,  
39 adequately powered trial to evaluate the clinical and cost effectiveness of an environmental  
40 assessment and modification, delivered by an OT, for the prevention of falls.  
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## 56 Methods and analysis

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## Trial design

The OTIS (Occupational Therapist Intervention Study) study is a modified cohort [15] pragmatic, two arm, open, randomised controlled trial (RCT) with an economic evaluation and nested qualitative study. The cohort randomised controlled trial (cRCT) design was chosen to avoid some of the key potential biases that can occur in a pragmatic trial, namely: high attrition and patient preference effects. In a cRCT patients are recruited initially into a cohort and there is usually an outcome run-in period. Given that outcome attrition occurs largely at the first follow-up time point, this attrition is largely avoided if an eligibility criterion for the randomised phase is completion of outcomes during the run-in period[16]. With respect to preference effects, although the control group are aware of the possibility of being offered an intervention (in this case Occupational Therapy) they are unaware of when the actual randomisation occurs: this might avoid those biases, due to patient preference effects, which relate to timing of the offer of the intervention. In this study the cmRCT design was modified in that both intervention and control groups were told about the intervention prior to randomisation and that which group they would be in, would be decided by chance/ randomisation. In the cmRCT design, the process of obtaining patient information and consent aims to replicate that in real world routine health care, where patients are never told prospectively that their care options will be decided by chance. This approach partly replicates routine care in that the participant is not aware of when randomisation takes place and those in the control group are not aware of when they were formally allocated to be in the comparison group. Similarly the intervention group are offered the intervention without having to face the possibility that once an offer has been made that randomisation would withdraw the offer.

## OTIS main study aim

The main aim is to establish whether environmental assessment and modification delivered by an OT will lead to a reduction in the number of falls among those at elevated risk of falling living in the community.

## OTIS secondary aims include:

1. Establishing the cost-effectiveness of OT delivered environmental assessment and modification.
2. Assessing the impact of the intervention on participants' quality of life.
3. Exploring the barriers and facilitators of implementing the trial's findings among OT professionals and the wider community (e.g., commissioners of services).

## Participants

### *Participant recruitment*

One thousand two hundred and ninety-nine participants will be recruited by one of the following methods (see Figure 1):

1. Database search of existing cohorts held by the York Trials Unit (YTU) and the Yorkshire Health Study

The YTU has assembled a cohort of participants who originally participated in either the REFORM [17], SCOOP [18] or CASPER[19] trials and agreed to be contacted about future research studies run by the YTU. These studies recruited participants aged 65 years and over, from either routine NHS podiatry clinics or GP practices. A database search of these cohorts and the Yorkshire Health Study cohort to identify participants over the age of 65 years [20] will be undertaken to identify participants living in the OTs' catchment area (Yorkshire and North Lincolnshire), who will be eligible for an invitation mailing. Participants known to live in a residential or nursing home will be excluded from the mail out. Potentially eligible participants will be sent an invitation pack asking if they would like to participate in the study. The pack will contain an invitation letter, participant information sheet, consent form, screening questionnaire and a pre-paid envelope. In some cases, the person receiving the invitation pack may decline participation in the study but a family member or friend may be interested in taking part. In such cases the original recipient will be asked to pass on the research team's contact details, so that the interested person can contact the study team.

2. GP practices and other services

To increase the generalisability of the study's findings, participants will be recruited through GP practices in primary care. GP practices will be recruited to the study after a member of the study team or the local Clinical Research Network has contacted the practice and explained the study and the participants' involvement. A database search will be undertaken to identify community dwelling men and women over the age of 65 who will be sent a recruitment pack. Patients known to have dementia or Alzheimer's disease, or who live in a residential or nursing home will be excluded from the mail out, by the use of Read Codes (which are a coded thesaurus of clinical terms) and review of the patient's address.

3. Opportunistic screening

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2 Where there is capacity, opportunistic screening by other healthcare professionals (e.g. GPs, Rapid  
3 Assessment Teams, chronic obstructive pulmonary disease nurses, Heart Failure Nurses,  
4 Community Matrons, or NHS services (e.g. ambulance services) will take place. Potential  
5 participants will be given an invitation pack.  
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#### 10 4. Advertising for participants

11 Radio, newspaper, faith magazine, social media, or television advertisements may also be used to  
12 publicise the study and encourage potential participants to get in touch with the researchers.  
13 Additionally, posters or flyers may be placed within the geographical area of recruiting sites in  
14 places such as supermarkets, libraries, and community centres.  
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20 Individuals identified via any of the four approaches described above who wish to take part in the  
21 study will be asked to return their completed consent form and screening questionnaire by post to  
22 the YTU. Researchers will assess the screening form for participant eligibility according to the  
23 study eligibility criteria. Participants deemed to be ineligible will be informed in writing. If the  
24 respondent is assessed as being ineligible because they have not had a fall within the past 12  
25 months or do not report a fear of falling, but otherwise fulfil the eligibility criteria, they will be  
26 given the option to be re-screened in four to six months' time.  
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34 All eligible, consenting participants will be asked to complete a baseline questionnaire and  
35 monthly falls calendars by post. Participants who return a valid baseline questionnaire and at  
36 least one falls calendar will be randomised into the trial. Participants can withdraw from the study  
37 at any point. The reason for withdrawal will not have to be declared; however, if provided, this will  
38 be recorded. Participants who do not wish to take part in the main study are not required to  
39 return any forms to the YTU.  
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#### 46 Inclusion criteria

47 Participants will be eligible for the OTIS trial if they:

- 48 1. Are aged 65 years or over
- 49 2. Are willing to receive a home visit from an Occupational Therapist
- 50 3. Are community dwelling
- 51 4. Have at least one of the following risk factors for a fall in the next 12 months: either one  
52 fall in the past 12 months; or report a fear of falling on their screening questionnaire  
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### Exclusion criteria

Participants will be ineligible for the OTIS trial if they:

1. Are unable to walk 10 feet today (3.05 metres) even with the use of a walking aid
2. Are unable to give informed consent, for example, due to Alzheimer's disease or dementia
3. Live in a residential or nursing home
4. Are unable to read or speak English and have no friend or relative to translate/interpret for them
5. Have had an OT assessment for falls prevention in the previous 12 months
6. Are on a waiting list for an occupational therapy assessment
7. Have not returned at least one completed falls calendar in the three months prior to randomisation.

### Randomisation

Participants will be enrolled into the study if they fulfil the eligibility criteria and provide written consent to take part in the study; they will then be randomised to either the intervention or control arm when they have returned a valid baseline questionnaire and at least one falls calendar within three months prior to the point of randomisation. Randomisation will be carried out using the YTU secure web-based computer randomisation service based on an allocation sequence generated by an independent data systems manager, who is not involved in the recruitment of participants. Participants will be randomly allocated to either the control group or the intervention group in a 2:1 ratio in favour of the control group (to reduce costs). Up to 12 participants from a particular site will be randomised at a time in a single block according to when sites state they have capacity to undertake intervention appointments and for how many participants. The allocation ratio used may go up to 3:1 in a block if the OTs have reduced capacity to carry out the assessment. The YTU will write to the participant's GP informing them of study participation and to participants who are allocated to the intervention group.

### Sample size

We propose to recruit and randomise 1299 participants to the OTIS trial in a 2:1 ratio (i.e., 866 to usual care and 433 to intervention). This number allows for 10% attrition and provides 90% power (using two-sided significance at the 5% level) to show a difference in the percentage of

1 participants who experience at least one fall in the 12 months following randomisation from 60%  
2 in the control group to 50% in the intervention group, accounting for the unequal randomisation  
3 (StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP.). In the  
4 REFORM trial, previously conducted by some of the authors, an absolute difference of 5% was  
5 observed in the percentage of participants experiencing a fall (Intervention group 50%; Control  
6 group 55%), with a lower confidence limit of 13%; therefore, the decision was made to power this  
7 trial for a 10% absolute difference. In the event that sites are struggling with capacity to  
8 undertake assessments, we will consider using an allocation ratio of 3:1 (usual care to  
9 intervention) to reduce the number of participants they would have to see. If the final ratio was  
10 3:1 (i.e., 974 to the usual care and 325 to the intervention) we would have 85% power under the  
11 same conditions. The primary outcome is actually a count variable (number of falls, whilst  
12 proportion of participants experiencing at least one fall over the 12 months is a key secondary  
13 outcome); however, powering a trial for count data is more complex and requires greater  
14 assumptions and so a binary approach to the sample size calculation has been taken here.

#### 28 Blinding

29 Control participants will be blind to when the intervention takes place; however, due to the nature  
30 of the intervention participants in the intervention group will not be blind. It is also not possible to  
31 blind members of the research team who are actively involved in the administration of the study,  
32 the statistician or health economist. Data entry staff will be blind to group allocation.

#### 38 Trial Intervention

##### 40 OTIS trial usual care group

41 Participants will receive usual care from their General Practitioner and other health care  
42 professionals which may include referrals to a falls clinic. Participants will receive a falls  
43 prevention advice leaflet produced by Age UK ('Staying steady' published in June 2015) with their  
44 baseline questionnaire in the post. A group specific newsletter will be sent to participants at three  
45 months post randomisation and two weeks before their 12 month follow up questionnaire is due,  
46 informing them about study progress. All participants will receive a pen and £5 with their 12  
47 month follow-up questionnaire in recognition of their participation and to offset any incidental  
48 expenses associated with completing the questionnaires.

##### 57 OTIS trial intervention group

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3 In addition to the usual care and falls prevention leaflet described above, participants allocated to  
4 the intervention arm will be offered a home environmental assessment to identify personal fall  
5 related hazards and behaviours. The assessment will be undertaken by a Health and Care  
6 Professions Council registered OT and will take approximately two hours to conduct. If the  
7 assessment is too demanding for the participant, the appointment may be split over two visits.  
8 OTs will attend a one-day face-to-face training session on how to conduct the assessment. This  
9 will be provided by either the researcher who carried out the pilot trial (AP) or two of the OT  
10 researchers (SCr and AD) who will be trained by AP to deliver the training in a standardised way.  
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18 The environmental assessment will begin with an initial discussion about the participant's history  
19 of falling, lifestyle, patterns of usage of areas in the home, risk taking behaviour, strategies already  
20 adopted to reduce falls, environmental changes already in place prior to the assessment and  
21 functional vision. This will then be followed by the Timed Up and Go (TUG) test and an  
22 environmental assessment using the Westmead Home Safety (WeHSA) tool [21]. The WeHSA was  
23 developed in Australia in 1997 for older adults and consists of a 57 item standardised, valid and  
24 reliable checklist of fall hazards in the following domains: internal/ external traffic ways, general/  
25 indoors, living area, seating, bedroom, toilet, bathroom, kitchen, laundry, mobility aid, footwear,  
26 pets, medication management and safety call systems. The OT and the participant will move  
27 through the house together and a functional assessment will be completed. Items on the checklist  
28 will be rated as either relevant (i.e., deemed to be a hazard) or not relevant (i.e., not deemed to be  
29 a hazard or not present). The OT will discuss any potential falls hazards identified by either the  
30 participant or the OT during the assessment and problem solve with the participant to engage  
31 them in identifying possible solutions. A list of recommendations will be agreed. If possible, any  
32 identified hazards will be removed. If required, the OT will make referrals to other agencies for  
33 equipment or a handyman for other minor modifications. They may also make recommendations  
34 for equipment that cannot be provided by Social Services, such as lightweight step ladders with  
35 handles and height adjustable rotary washing lines. In such cases the OT will liaise with the client  
36 or a family member regarding purchase of such equipment. The OT will make a clinical judgement  
37 whether an additional home visit is required. Four weeks after the assessment the OT or member  
38 of the OTIS research team will telephone the participant to check adherence to the  
39 recommendations.  
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## Treatment Fidelity

Treatment fidelity will be assessed using the following combination of strategies.

### 1. Provider Training

A standard face-to-face training package will be used to standardise provider training. Training sessions will be recorded where possible. A checklist will be used to document whether all aspects of the training are covered when provided by different facilitators. Occupational Therapists will have the option to additionally undertake an on-line training course.

### 2. Delivery of treatment

An observational study will be undertaken over the course of the trial to assess how the treatment was delivered. An OT who delivered the intervention training will shadow OTs whilst they visit participants. A checklist will be used to record which elements of the intervention are delivered. We will purposively sample OTs for shadowing to ensure we select a sample of OTs who attended different training sessions and who delivered either several or few assessments. Approximately 10 OTs will be observed. Whilst this is a small number of observations involving approximately half of the OTs delivering the intervention, if a greater number were undertaken, then the observation itself would become part of the intervention. Consent for an additional, observing OT to attend the home visit will be obtained from the participant. Participants will be able to decline the second OT attending the visit at any point during the process, and will still be able to receive a home visit. Elements of fidelity will also be included in the qualitative interviews. A similar sampling strategy to that detailed above will be used.

### 3. Demonstration of adherence

In order to demonstrate adherence, completion rates of the individual items on the WeHSA will be summarised. In addition to this an OT who was involved in teaching the delivery of the intervention, will review the WeHSA data collected by the OT for each participant. Delivery of the treatment is tailored to individual participant's clinical need, therefore assessment and recommendations will not be the same for all participants. However, a checklist will be used to document whether the key elements had been covered during each of the consultations.

## Outcome measures

#### Primary outcome measure for the OTIS trial

The primary outcome is the number of falls per participant over the 12 months from randomisation. A fall is defined as ‘an unexpected event in which the participant comes to rest on the ground, floor or lower level’ [22]. Data will be collected via participant self-reported monthly falls calendars, on which participants will be asked to mark the number of falls they have on each day, or indicate that they have had no falls that month. An explanation of what the researchers consider to be a fall will be included in the participant information sheet and on the falls calendars. If a participant is uncertain as to whether an event is classed as a fall, then they will be encouraged to ring the research team at the YTU to discuss. Participants who do not return their falls calendar within ten days of the due date will be either telephoned or sent a letter by the YTU to obtain missing data. Participants will be given a Freephone number to ring during office hours to report any falls as soon as possible after the event and when it is safe and convenient to do so. Participants who ring to report a fall will be asked for further details. Participants who indicate on their falls calendar that they have sustained a fall will be telephoned by the research team for further information. Information collected during the telephone call will include: cause/reason for fall, consequence of fall e.g., superficial wound (bruising, sprain, cut, abrasions), fractures (including type of fracture) and hospital admissions. Data collected from the 4, 8 and 12 month follow-ups questionnaires will include falls data and will be used for those participants who do not return their monthly falls calendars.

#### OTIS trial secondary outcomes

All secondary outcomes will be self-reported by the participant and collected via questionnaires at baseline, 4, 8 and 12 months, or by monthly falls calendars. They include: proportion of participants reporting at least one fall in the 12 months from randomisation; proportion of participants reporting multiple (2 or more) falls in the 12 months from randomisation; time to first fall from date of randomisation; health-related quality of life as measured by the EQ-5D-5L [23]; fracture rate; fear of falling as measured by the question “During the past 4 weeks have you worried about having a fall?”; and health service utilisation.

#### Nested qualitative study

To inform potential large-scale implementation of Occupational Therapy environmental assessment, qualitative interviews will take place with key stakeholder groups involved in



1  
2 intervention delivery (Occupational Therapists, those who have clinical lead/practitioner roles for  
3 falls prevention services). Data will be collected on the feasibility of routinely providing this  
4 intervention, barriers and facilitators to implementation, workload implications and readiness to  
5 employ this intervention into their regular falls prevention practice. Normalisation Process Theory  
6 [24] will be used to guide data collection, and to frame the analysis, to understand how easy it is  
7 to implement these interventions into routine practice.  
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13 Fifteen OTs delivering the intervention in the trial and ten clinical leads who run falls prevention  
14 services/care of older people services from organisations involved in the trial and five external to  
15 the trial will be purposively selected. Participants will be invited to attend a telephone interview.  
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### 20 Adverse events

21 This study will record and report details of any adverse events (AEs) that are required to be  
22 reported to the Health Research Authority (HRA) i.e., events which are related to taking part in the  
23 study and are unexpected. The AE reporting period begins as soon as the participant consents to  
24 be in the study and ends twelve months after they are randomised.  
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30 Details of any adverse events will be recorded using a trial adverse event form. Serious adverse  
31 events reported by the OT should be reported within 48 hours of the OT becoming aware of the  
32 event or within 14 days for non-serious events. A follow-up report will be completed if additional  
33 information becomes available.  
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39 For this trial a Serious Adverse Event (SAE) is defined as any untoward occurrence that:  
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- 42 (a) Results in death
  - 43 (b) Is life threatening
  - 44 (c) Requires hospitalisation or prolongation of existing hospitalisation
  - 45 (d) Consists of a congenital anomaly or birth defect; or
  - 46 (e) Is otherwise considered medically significant by the investigator
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53 An event is defined as 'related' if the event was due to the administration of any research  
54 procedure. Whereas an 'unexpected event' is defined as a type of event not listed in the protocol  
55 as an expected occurrence.  
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3 The relatedness of an event will be reviewed by the Chief Investigator and the Trial Steering  
4 Committee. Incidents of hospitalisations, disabling / incapacitating / life-threatening conditions,  
5 aging-associated diseases (such as cancer, cardiovascular disease, diabetes, arthritis, osteoporosis,  
6 dementia), other common illnesses such as depression, falls and deaths are expected in the study  
7 population due to the age of the cohort. Similarly, any hospitalisation that was planned prior to  
8 entry into the study or cannot be attributed to taking part in the study or prolongation of an  
9 existing hospitalisation due to social reasons will not be recorded as a SAE.  
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### 16 17 Statistical analysis

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19 There are no planned interim analyses, therefore, the statistical analysis will be undertaken at the  
20 end of the trial and will be conducted using STATA version 15 or later (StataCorp, 4905 Lakeway  
21 Drive, College Station, Texas 77845, USA). All analyses will be conducted on an intention-to-treat  
22 (ITT) basis, including all randomised patients in the groups to which they were originally allocated.  
23 Participant baseline data will be summarised descriptively by group, for all those who have been  
24 randomised and for all those who are included in the primary outcome analysis by randomised  
25 arm. No formal statistical comparisons will be undertaken. Continuous measures will be reported  
26 as means and standard deviations while the categorical data will be reported as counts and  
27 percentages.  
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### 36 Statistical analysis of the OTIS primary outcome

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38 The number of falls per person will be analysed using Poisson regression (or negative binomial  
39 regression, as appropriate) adjusting for gender, age, history of falling and the allocation ratio  
40 used to randomise the participant as fixed effects. The model will include an exposure variable for  
41 the number of months that the participant returned a monthly falls calendar. A sensitivity analysis  
42 will be conducted to account for potential clustering effects by the OT by assigning every  
43 randomised participant an OT irrespective of group allocation. For intervention participants, this  
44 will be the OT delivering their intervention; whereas for control participants, a counterfactual  
45 therapist i.e., one that they could have seen had they been randomised to the intervention group,  
46 will be randomly assigned to them. Therapist will then be included as a random effect in the  
47 primary analysis model. Additionally, a Complier Average Causal Effect (CACE) analysis to assess  
48 the impact of compliance on treatment estimates will be undertaken for the primary analysis.  
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## Secondary analysis

The following outcomes will be analysed by logistic regression adjusted for the same covariates as the primary analysis model: the proportion of participants who fall at least once over the 12 month period from the date of randomisation; the proportion of multiple fallers (2 or more falls in the 12 months from randomisation); the proportion of participants having at least one fracture over the 12 month follow-up; the proportion of patients obtaining multiple fractures (from different events, if this occurs a sufficient number of times); and the proportion of participants who report that they are worried about falling at 12 months post-randomisation.

Fear of falling will also be analysed in its continuous form using a covariance pattern model incorporating all post randomisation time points in the analysis and adjusting for baseline score, gender, age, history of falling, allocation ratio, treatment group, time and a treatment group-by-time interaction. The correlation of observations within patients over time will be modelled.

The time to the first fall will be derived as the number of days from randomisation until the patient reports having a fall as detailed in the participant's falls calendars. Time between any subsequent falls will also be calculated. Participants who have not had a fall will be treated as censored at their date of trial exit, or date of last available assessment or 365 days/trial cessation, as appropriate. The proportion of patients yet to experience a fall will be summarised by a Kaplan Meier survival curve for each group. Time to fall will be analysed using the Andersen and Gill method for analysing time to event data when the event can be repeated. The analysis treats each time to event or censoring as a separate observation. The data will be analysed by Cox Proportional Hazards regression using robust standard errors to account for dependent observations by participant, and adjusting for the same covariates as in the primary analysis model.

Adherence to the WeHSA and results of the TUG will also be summarised descriptively.

Sub-group analysis: The primary analysis will be repeated including an interaction term between the treatment allocation and whether or not a patient received care in a hospital (outpatient appointment, day case, A&E presentation, or hospital admission) as a result of a fall in the 4 months prior to completion of the baseline questionnaire.

### Missing data

The amount of missing data will be reported by trial arm. A comparison of the baseline characteristics of participants who are included in the primary analysis will be undertaken to ensure that any attrition has not produced imbalance in the groups in important baseline covariates. A logistic regression model will be used to predict non-response (no falls data received post-randomisation) including all variables collected prior to randomisation. The primary analysis will then be repeated, including as covariates all variables found to be significantly predictive of non-response, to determine if these affect the parameter estimates and study conclusions.

### Qualitative analysis

All interviews will be audio recorded digitally and transcribed verbatim.. Initially, following familiarisation with the data , the interview material will be organised according to analytical headings using a constant comparison approach [25]. Key themes will be identified which will then be contextualised in relation to the broader dataset and will be used to assist the interpretation of the trial result. For example, if the intervention is shown to be effective, we will use a NPT framework to facilitate the development of an implementation plan for integration of Occupational Therapy falls environmental assessment into routine practice. During the analysis, regular meetings will be held between the qualitative research team and project steering group to discuss emergent themes.

### Adverse event data

Adverse event data will be summarised descriptively by randomised arm.

### Trial monitoring

A Trial Steering Committee and Data Monitoring and Ethics Committee will monitor the trial at least every 12 months, or more frequently if the committee requests. The role of this committee will include the review of all serious adverse events which are thought to be treatment related and unexpected.

### Economic evaluation

The health economic evaluation aims to establish the cost-effectiveness of OT delivered environmental assessment and modification in terms of preventing falls, and assess the impact of the intervention on participants' quality of life. The economic analysis will be performed using

1 individual patient level data on an ITT basis. The analytical approach will take the form of cost-  
2 effectiveness and cost-utility analyses. The cost-effectiveness approach will assess value for  
3 money in terms of cost per fall averted, and the cost-utility analysis will assess cost per quality  
4 adjusted life-year (QALY) gained. The perspective for both analyses will be that of the UK NHS and  
5 personal social services, as well as secondary analyses undertaken from a societal perspective.  
6 Discounting for future cost and health benefit will not be undertaken given the time frame for the  
7 trial is 12 months after randomisation. The year of pricing will be set as the mid-year of the trial.  
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10 Health benefits associated with the treatments will be measured in terms of both estimates of the  
11 mean number of falls, corresponding to the main outcome of the trial, and mean QALYs, defined  
12 as a year lived with full health. In line with NICE recommendations [26], the EuroQol EQ-5D [27]  
13 will be used to elicit patient utility values at different points in time and used to calculate QALYs  
14 for each patient, using the area under the curve approach [28, 29]. These utility values are used as  
15 'quality adjustment' for each patient's survival time. Specifically, the EQ-5D-5L will be used.  
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18 Cost data will be collected for each patient regarding health care resource use; specifically within  
19 primary care and the community (i.e., GP, nurse, physiotherapist, occupational therapist visits)  
20 and the hospital setting (i.e., outpatient attendances, day cases, inpatient stays and accident and  
21 emergency attendances). Unit costs will then be applied to estimate the total cost per patient.  
22 Additional information will be collected regarding intervention costs and private/personal  
23 expenses that feed into the societal perspective analysis (e.g., activities of daily living equipment,  
24 travel costs for health care attendances). Unit costs will be obtained from established costing  
25 sources such as NHS Reference Costs [30] and PSSRU Unit Costs of Health and Social Care [31].  
26 Data on the cost and utility measures will be collected prospectively at baseline, four, eight and 12  
27 months via self-reported questionnaires.  
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30 Mean within-trial estimates of cost and health benefits will be estimated using regression  
31 methods, allowing for the correlation between costs and effects, as well as adjusting for  
32 covariates. The results will be presented as incremental cost-effectiveness ratios (ICERs), where  
33 the difference in mean cost estimates between the two arms is divided by the difference in mean  
34 health benefit between the two arms. Findings will also be presented in terms of net health  
35 benefit [32]. Multiple imputation methods will be used to handle missing data where needed  
36 [33].  
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3 The uncertainty surrounding the decision to accept a treatment as the most cost-effective will be  
4 explored in cost-effectiveness acceptability curves (CEACs) [34]. These curves depict the  
5 probability of accepting a treatment as being cost-effective for a large range of willingness to pay  
6 values for an extra unit of health benefit. Sensitivity analysis will be conducted to explore the  
7 impact of underlying assumptions of the analysis and the range of unit costs on the cost-  
8 effectiveness results.  
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15 The main outcome of the trial, falls reduction, is associated with a reduction in fractures.  
16 However, due to the restriction in the length of follow-up, the long term effect in terms of the  
17 decreasing number of fractures might not be observed in the current trial. Therefore, a further  
18 analysis will explore the possible long term impact of the trial, assuming that a falls reduction  
19 should also lead to a fracture reduction. A decision analytic model approach will be adopted to  
20 perform this task. The perspective will be the UK NHS and personal social services, with a lifetime  
21 time horizon whereby every participant in a hypothetical cohort is followed up until the last  
22 participant dies. The hypothetical cohort will be constructed, based on the characteristics of the  
23 trial population, to estimate the QALY yield and cost saving of the long term effect of the  
24 intervention. The model parameters which are not collected in the trial will be extracted from the  
25 existing literature.  
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36 The model outputs will be the estimated expected mean costs, effectiveness, and QALYs  
37 associated with each alternative treatment. Estimated total costs and outcomes will be  
38 discounted according to the latest health technology appraisal guidance [26]. Uncertainty  
39 regarding cost-effectiveness will be evaluated using probabilistic sensitivity analysis, where inputs  
40 into the analysis are defined as probability distributions which reflect uncertainty [35]. The  
41 uncertainty surrounding the decision to adopt a given treatment option as a cost-effective  
42 treatment at different levels of willingness to pay will be represented in CEACs. The impact of  
43 assumptions undertaken in the analysis regarding the evidence over parameters or relating to the  
44 decision model (such as extrapolation) will be evaluated in sensitivity analysis, if possible.  
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### 53 Patient and Public Involvement statement

54 Our patient representatives were identified from the cohort of participants who have taken part in  
55 previous studies run the members of the study team. They helped develop the design and  
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1 conduct of the study by providing feedback on the grant application submitted to the funder. We  
2 have set up a Patient Involvement Group. This group gives advice to the trial team on the design  
3 and conduct of the trial. This included providing input into case report forms, information sheets,  
4 participant newsletters and recruitment strategies. They have agreed to help us disseminate our  
5 research findings by providing assistance with writing the plain language summaries and the  
6 research study findings letter we will send to participants, who request it. A member of the group  
7 is also a member of the Trial Steering/Data Monitoring and Ethics Committee, where PPI is a  
8 standing item.  
9

### 17 Studies within trials

20 In addition to the main OTIS study, three 'Studies within a Trial' (SWATS) are being conducted.

### 24 Pen sub-study

25 The aim of this sub study is to evaluate the effectiveness of including a pen with the trial invitation  
26 pack on recruitment of participants to the OTIS study. Any patient identified in the GP mail out as  
27 eligible to receive an OTIS trial invitation pack will be entered into the pen sub-study. Block  
28 randomisation will be used to allocate participants in a 2:1 ratio in favour of the control group.  
29 Generation of the allocation sequence will be undertaken independently by a researcher not  
30 involved with the production of the recruitment packs. A single block the size of the number of  
31 participants from each GP practice will be used. The intervention group will receive a pen with the  
32 York Trials Unit logo/details on it; the control group will not receive a pen at the point of being  
33 invited to take part in the study. The primary outcome is the proportion of participants who go on  
34 to be randomised to the OTIS trial. Secondary outcomes include: the proportion of participants  
35 who return a screening form; time to return screening form; the proportion of participants who  
36 fulfil the eligibility criteria apart from the criterion relating to falls within past 12 months or fear of  
37 falling; the proportion of participants who are eligible for randomisation; and the proportion of  
38 participants who remain in the trial at three months post randomisation. Categorical data will be  
39 compared using logistic regression and time to response via a Cox proportional hazards model.  
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### 53 Invitation letter sub-study

54 The aim of this sub study is to evaluate the effectiveness of writing the potential participant's name by  
55 hand on the invitation letter, versus printing their name, on the recruitment rate to the study.  
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Participants will be eligible for this sub-study if are they due to be sent an invitation pack about the OTIS trial in the first mail out undertaken by the Yorkshire Health Study. Block randomisation will be used to allocate participants in a 1:1 ratio to receive either a hand written name on the invitation letter (intervention group) or printed name on the invitation letter (control group). Generation of the allocation sequence will be undertaken independently by a researcher not involved with the production of the recruitment packs. The primary outcome is the proportion of participants who go on to be randomised to the OTIS trial. Secondary outcomes include: the proportion of participants who return a screening form; time to return screening form; the proportion of participants who fulfil the eligibility criteria apart from the criterion relating to falls within past 12 months or fear of falling; the proportion of participants who are eligible for randomisation; and the proportion of participants who remain in the trial at three months post randomisation. Categorical data will be compared using logistic regression and time to response via a Cox proportional hazards model.

#### Text message sub-study

The aim of this sub study is to evaluate the effectiveness of a personalised text message compared with a standard text message on postal questionnaire response rates. Participants who are due to be sent their four month follow-up questionnaire and who have provided a mobile phone number and consented to be contacted by text message will be randomised. Block randomisation will be used to allocate participants in a 1:1 ratio, to receive either a personalised (intervention group) or a standard text message (control group) at the same time as they are due to receive their postal follow-up questionnaire (i.e., two to four days after the questionnaire is sent). The randomisation will be stratified by main trial allocation. Generation of the allocation sequence will be undertaken independently by a researcher not involved with the delivery of the text messages.

The personalised text message will read *"OTIS Trial: [Title, surname of participant] you should have received a questionnaire in the post by now. Your answers are important; so please help by returning it as soon as you can. Thanks."*

The standard text message will read *"OTIS Trial: you should have received a questionnaire in the post by now. Your answers are important; so please help by returning it as soon as you can. Thanks"*. The primary outcome is the proportion of participants in each group who return the questionnaire. Secondary outcomes include time to response, completeness of response, whether a reminder notice is required and cost-effectiveness. Categorical data will be compared



1 using logistic regression and time to response via a Cox proportional hazards model. All models  
2 will adjust for main trial allocation.  
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### 6 Sample size for the SWATs

7 As is usual with an embedded trial within a trial, no formal power calculation will be undertaken  
8 for the pen and text message sub-studies, as the sample size will be constrained by the number of  
9 participants available to either mail out to, or contact. We will, however, randomise 314  
10 participants, who are due to be mailed out by the Yorkshire Health Study an invitation pack about  
11 the OTIS trial. This sample size will allow us to detect a 10% difference in the percentage of  
12 participants who go on to be randomised (from 10 to 20%) between the two groups at 80% power  
13 and a two-sided alpha level of 0.1.  
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### 23 Ethics and dissemination

#### 24 Ethics

25 All participants will give written informed consent prior to entry to the study. Further consent will  
26 be obtained for the qualitative interviews and fidelity observations. This study protocol (version 7,  
27 19.10.2017) including the original application and subsequent amendments received a favourable  
28 ethical opinion from NHS West of Scotland REC 3, the University of York, Department of Health  
29 Sciences Research Governance and NHS Trust Research and Development approval at recruiting  
30 sites.  
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#### 41 Dissemination

42 The results of the study will be disseminated through high impact peer-reviewed journals, through  
43 national and international research conferences and Occupational Therapy specific journals and  
44 newsletters. A short summary of the results will be sent to participants who request this at the  
45 end of the trial.  
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#### 51 Discussion

52 This study uses a modified cohort randomised controlled (cRCT) design. The authors have  
53 previously conducted three cRCT [36]. Participants in these trials were recruited from either routine  
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1 NHS podiatry clinics [17] or from General Practices [18, 19]. All were aged at least 65 years and over  
2 and therefore had an elevated risk of falling. One key feature of the cRCT design is the capacity to  
3 undertake multiple randomised controlled trials over time. A strength to this trial is that during the  
4 recruitment phase of the OTIS study, we will be able to test the feasibility of recruiting participants  
5 from these cohorts and determine whether it is a quick and cost-effective means to recruit  
6 participants. A further strength lies in the fact that in addition to the main OTIS trial, we have taken  
7 the opportunity to undertake three SWATs. The results of these studies will add a significant  
8 contribution to the body of evidence about strategies to improve recruitment to trials and minimise  
9 the amount of missing data.  
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19 One potential limitation to the study is that some participants with mild dementia and cognitive  
20 impairment may be included in the study. These participants may have a higher risk of falling. We  
21 have tried to exclude this group of participants at screening by collecting data on participant's  
22 medical history. In addition, if the study team have any concerns about the ability of a participant  
23 to provide informed consent or outcome data during the course of the study, then this is discussed  
24 with either the participant, a family member (if the participant consents) or with the participant's  
25 General Practitioner. Nevertheless it is still possible that some participants with mild dementia and  
26 cognitive impairment, may be included in the study that we are unaware of. Further limitations  
27 include the fact that the study uses unblinded, patient self-report primary outcome measure, so  
28 there is the possibility of reporting bias being introduced. Also the results of the study will be results  
29 will be generalisable to a community dwelling population of older people within England only.  
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41 Falls in older people are a major health problem. A recent Cochrane review found environmental  
42 assessment, undertaken by an Occupational Therapist, to be an effective approach to reducing falls  
43 in older people. As far as we are aware, none of the trials included a cost effectiveness evaluation  
44 within a UK setting. The OTIS protocol aims to evaluate the clinical and cost-effectiveness of an  
45 environmental assessment and modification for preventing falls in older people, and will be the  
46 largest trial to evaluate this intervention in isolation. If the results of this study are found to be  
47 positive, then further research could be conducted to investigate whether or not the intervention  
48 could be delivered equally effectively by trained assessors. Alternatively, further research into the  
49 intensity of the intervention, i.e. whether more home visits are more effective, could be  
50 undertaken.  
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### Trial status

Recruitment and follow-up are in progress. Recruitment to the study began in October 2015 and will continue until approximately summer 2018. Participants will continue to be followed-up until winter 2019.

### Acknowledgments

The research team would like to thank the independent members of the Trial Steering/Data Monitoring and Ethics Committee: Professor Roger Francis, Dr Ranjit Lall, Dr Claire Ballinger, Professor Lindy Clemson and Mrs Margaret McCabe for their advice, overseeing the study and reviewing adverse event data. The authors also extend very grateful thanks to the Patient Involvement Group, the study participants, Occupational Therapists for delivering the intervention and to the CRN for assistance with the GP mail out of recruitment packs.

### Author's Contributions

DT and AP wrote the original protocol. JA, SB, SC, SCr, AD, CF, SG, CH, SL, AP, CR, SR, SJR, DT were either applicants on the NIHR HTA funding application or helped to refine the protocol. SC wrote the first draft of this article with input from CF. All authors read and approved the final manuscript.

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### Competing Interest

Catherine Hewitt declares membership of the HTA Commissioning board, and Sarah Lamb declares membership of the HTA Prioritisation board. No other competing interests are declared.

### Peer review

This study was peer reviewed for ethical and funding approval prior to submission.

### Data sharing statement

Requests to access OTIS data can be made to the corresponding author, and will be considered on a case-by-case basis by the Trial Management Group. All data requests will be managed according to York Trials Unit, University of York processes and procedures.

### REFERENCES

1. Morris M, Osborne D, Hill K, Kendig H, Lundgren-Lindquist B, Browning C, et al. Predisposing factors for occasional and multiple falls in older Australians who live at home. *Australian journal of physiotherapy*. 2004;50(3):153-9.
2. Campbell AJ, Borrie MJ, Spears GF, Jackson SL, Brown JS, Fitzgerald JL. Circumstances and consequences of falls experienced by a community population 70 years and over during a prospective study. *Age and ageing*. 1990;19(2):136-41.
3. Tideiksaar R. Fall prevention in the home. *Topics in Geriatric Rehabilitation*. 1987;3(1):57-64. PubMed PMID: 00013614-198710000-00010.
4. Vetter NJ LP, Ford D. . Can health visitors prevent fractures in elderly people? . *British Medical Journal* 1992;304(6831):888-9.
5. Iglesias C, Manca A, Torgerson D. The health-related quality of life and cost implications of falls in elderly women *Osteoporos Int* (2009) (20):869–78 DOI 10.1007/s00198-008-0753-5.
6. L R. Falls in older people: epidemiology, risk factors and strategies for prevention. *Age and Ageing* 2006;35-S2:ii37-ii41.
7. (DH). DoH. National service framework for older people. <https://www.gov.uk/government/publications/quality-standards-for-care-services-for-older-people> (accessed 20 Oct 2014).2001.
8. National, Institute, for, Health, and, Care, et al. Falls in older people: assessing risk and prevention. NICE Guideline (CG161)2013.
9. Lord S, Sherrington C, Menz H, Close J. Falls in older people: risk factors and strategies for prevention: Cambridge University Press, Cambridge; 2007.
10. Talbot LA MR, Witham EK, Metter EJ. . Falls in young, middle-aged and older community dwelling adults: perceived cause, environmental factors and injury. . *BMC Public Health* 2005;5(1):1
11. Law M CB, Strong S, Stewart D, Rigby P, Letts L. The Person-Environment-Occupation Model: A Transactive Approach to Occupational Performance *Canadian Journal of Occupational Therapy* 1996;63(1):9-23.
12. Todd CJ, Ballinger C, Whitehead S. A global report on falls prevention: reviews of socio-demographic factors related to falls and environmental interventions to prevent falls amongst older people living in the community. World Health Organization. 2007.
13. Gillespie L, Robertson M, Gillespie W, Lamb S, Gates S, Cumming R, et al. Interventions for preventing falls in older people living in the community. *Cochrane Database Syst Rev* 2009;2:CD007146.
14. Pighills AC, Torgerson DJ, Sheldon TA, Drummond AE, Bland JM. Environmental assessment and modification to prevent falls in older people. *Journal of the American Geriatrics Society*. 2011;59(1):26-33.
15. Relton C, Torgerson D, O'Cathain A, J N. Rethinking pragmatic randomised controlled trials: introducing the "cohort multiple randomised controlled trial" design. *BMJ*. 2010;340:Mar 19;340:c1066. doi: 10.1136/bmj.c.1066.

16. Dascanio VB, Yvonne; Clark, Laura Kate; Fairhurst, Caroline; MacPherson, Hugh; Torgerson, David J. Randomized cohort trial was shown to be feasible for evaluating treatments in low back pain. *Journal of Clinical Epidemiology*. 2014;67(No. 8): 940-6.
17. Cockayne S AJ, Clarke A, Corbacho B, Fairhurst C, Green L et al. . Cohort Randomised Controlled Trial of a Multifaceted Podiatry Intervention for the Prevention of Falls in Older People (The REFORM Trial). *PLoS One* 2017 12(1).
18. Shepstone L FR, Lenaghan E, et al. . A pragmatic randomised controlled trial of the effectiveness and cost-effectiveness of screening older women for the prevention of fractures: rationale, design and methods for the SCOOP study. . *Osteoporosis International* 2012;23(10):2507-15.
19. Mitchell N, Hewitt C, Adamson J, Parrott S, Torgerson D, Ekers D, et al. A randomised evaluation of Collaborative care and active surveillance for Screen-Positive ElDeRs with sub-threshold depression (CASPER): study protocol for a randomized controlled trial. *Trials*. 2011;12(225):6215-12.
20. Relton C, Bissell P, Smith C, Blackburn J, Cooper CL, Nicholl J, et al. South Yorkshire Cohort: a cohort trials facility study of health and weight-Protocol for the recruitment phase. *BMC Public Health*. 2011;11(1):640.
21. Clemson L. A guide to identifying fall hazards in the homes of elderly people and an accompaniment to the assessment Tool, the Westmead Home Safety Assessment (WeHSA): . West Brunswick VAC-oP, editor 1997.
22. Lamb S, Jorstad-Stein E, Hauer K, Becker C. Development of a common outcome data set for fall injury prevention trials: the Prevention of Falls Network Europe consensus. . *J Am Geriatr Soc* 2005;53(9):1618-22.
23. Kind P. The EuroQoL instrument: an index of health-related quality of life. *Quality of life and pharmacoeconomics in clinical trials*. 1996;2:191-201.
24. May CR MF, Finch T, et al. . Development of a theory of implementation and integration: Normalization Process Theory. *Implementation Science* 2009;4(1):29.
25. Silverman D. *Interpreting Qualitative Data: Methods for Analyzing Talk, Text and Interaction.*: London: Sage 1993
26. National Institute for Health and Care Excellence. *Guide to the methods of technology appraisal*. London: NICE: 2013.
27. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation*. 2011;20(10):1727-36. Epub 2011/04/12. doi: 10.1007/s11136-011-9903-x. PubMed PMID: 21479777; PubMed Central PMCID: PMC3220807.
28. Matthews JN, Altman DG, Campbell MJ, Royston P. Analysis of serial measurements in medical research. *BMJ (Clinical research ed)*. 1990;300(6719):230-5. Epub 1990/01/27. PubMed PMID: 2106931; PubMed Central PMCID: PMC321662068.
29. Billingham L, Abrams KR, Jones DR. Methods for the analysis of quality-of-life and survival data in health technology assessment. *Health Technol Assess*. 1998;3(10):1-152.
30. Department of Health. *NHS Reference Costs 2013/14*  
<https://www.gov.uk/government/publications/nhs-reference-costs-2013-to-20142014>.
31. Curtis L. *Unit Costs of Health and Social Care 2014*. University of Kent: Personal Social Services Research Unit; 2014. Available from: <http://www.pssru.ac.uk>.
32. Stinnett AA, Mullahy J. Net health benefits: a new framework for the analysis of uncertainty in cost-effectiveness analysis. *Medical decision making : an international journal of the Society for Medical Decision Making*. 1998;18(2 Suppl):S68-80. Epub 1998/05/05. PubMed PMID: 9566468.
33. Manca A, Palmer S. Handling missing data in patient-level cost-effectiveness analysis alongside randomised clinical trials. *Appl Health Econ Health Policy*. 2005;4(2):65-75. Epub 2005/09/16. PubMed PMID: 16162026.
34. Fenwick E, O'Brien BJ, Briggs A. Cost-effectiveness acceptability curves--facts, fallacies and frequently asked questions. *Health economics*. 2004;13(5):405-15. Epub 2004/05/06. doi: 10.1002/hec.903. PubMed PMID: 15127421.
35. Briggs A, Claxton K, Sculpher M, Briggs A, Claxton K, Sculpher M. *Decision modelling for health economic evaluation*: Oxford University Press; 2006.

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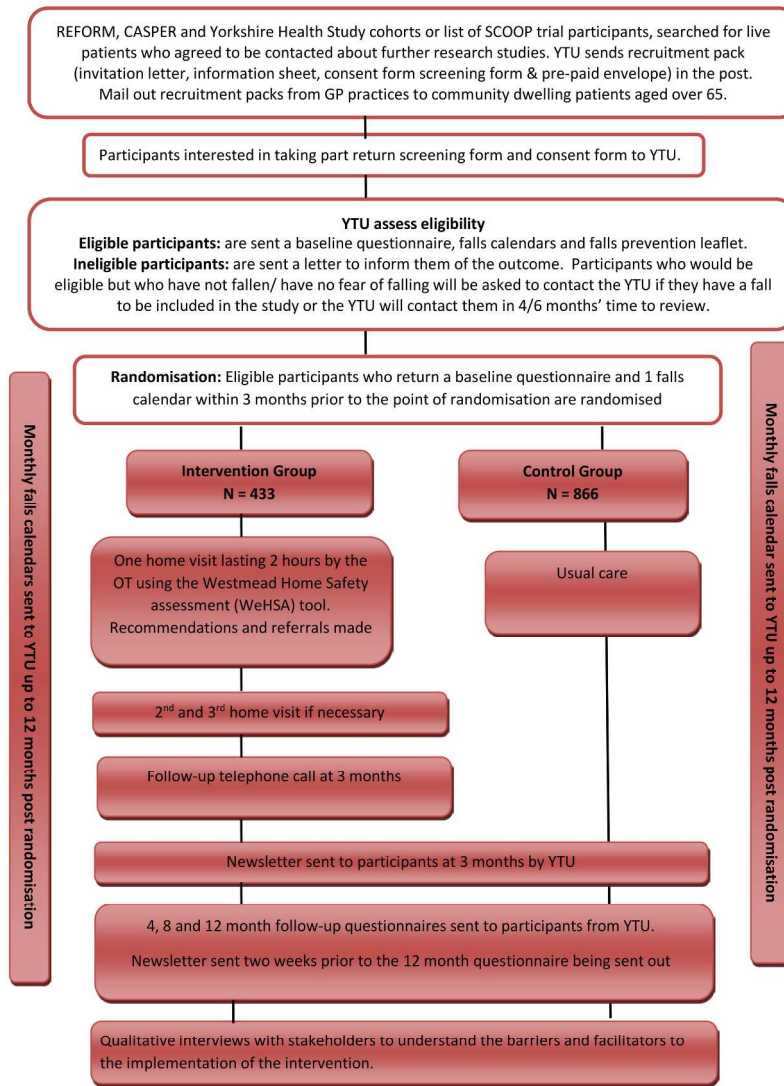
36. Cockayne S, Adamson J, Martin BC, Fairhurst C, Hewitt C, Hicks K, et al. The REFORM study protocol: a cohort randomised controlled trial of a multifaceted podiatry intervention for the prevention of falls in older people. *BMJ open*. 2014;4(12):e006977.

Figure Legends

Figure 1: Flow chart of participants through the OTIS trial

For peer review only

Figure 1 Flow chart of participants through the OTIS trial



OTIS protocol for BMJ Open Figure 1

182x276mm (300 x 300 DPI)



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	Addressed on page number
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	3, 23, 1, 4, 11, 9,6, 13, 22,
Protocol version	3	Date and version identifier	24
Funding	4	Sources and types of financial, material, and other support	23
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1 & 23
	5b	Name and contact information for the trial sponsor	23
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	23
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	17 & 23



## Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4 - 5
	6b	Explanation for choice of comparators	10- 12
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6

## Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	11 & 12
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	13
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9, 13

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3 Sample size 14 Estimated number of participants needed to achieve study objectives and how it was determined, including 10  
4 clinical and statistical assumptions supporting any sample size calculations

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6 Recruitment 15 Strategies for achieving adequate participant enrolment to reach target sample size 7  
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8 **Methods: Assignment of interventions (for controlled trials)**  
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10 Allocation:

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12 Sequence generation 16a Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any 9  
13 factors for stratification. To reduce predictability of a random sequence, details of any planned restriction  
14 (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants  
15 or assign interventions  
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17 Allocation concealment mechanism 16b Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, 9  
18 opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned  
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21 Implementation 16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to 9  
22 interventions  
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24 Blinding (masking) 17a Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome 10  
25 assessors, data analysts), and how  
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27 17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's 11  
28 allocated intervention during the trial  
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31 **Methods: Data collection, management, and analysis**  
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33 Data collection methods 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related 8  
34 processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of  
35 study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known.  
36 Reference to where data collection forms can be found, if not in the protocol  
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38 18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be 11  
39 collected for participants who discontinue or deviate from intervention protocols  
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3	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	24
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7	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15-17
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10		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16
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12		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
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15	<b>Methods: Monitoring</b>			
16				
17	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	23
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22		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
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25	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	17
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28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	17
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32	<b>Ethics and dissemination</b>			
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34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	3, 22 & 23
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37	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	3, 23
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3	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
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6		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	12
7				
8	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	7, 8
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11	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	23
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14	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	24
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17	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
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20	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	3
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25		31b	Authorship eligibility guidelines and any intended use of professional writers	23
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27		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	24
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29	<b>Appendices</b>			
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31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Attached as supplementary file
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34	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A
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37 \*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.  
 38 Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons  
 39 "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.  
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