TRIAL PROTOCOL

Full title: Does Occupational Therapist led home environmental assessment and modification reduce falls among high risk older people?

Authorised by

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Role: Chief Investigator

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ISRCTN number: ISRCTN22202133

REC number: TBC

Funder: NIHR HTA Programme Grant Number

Sponsor: The University of York

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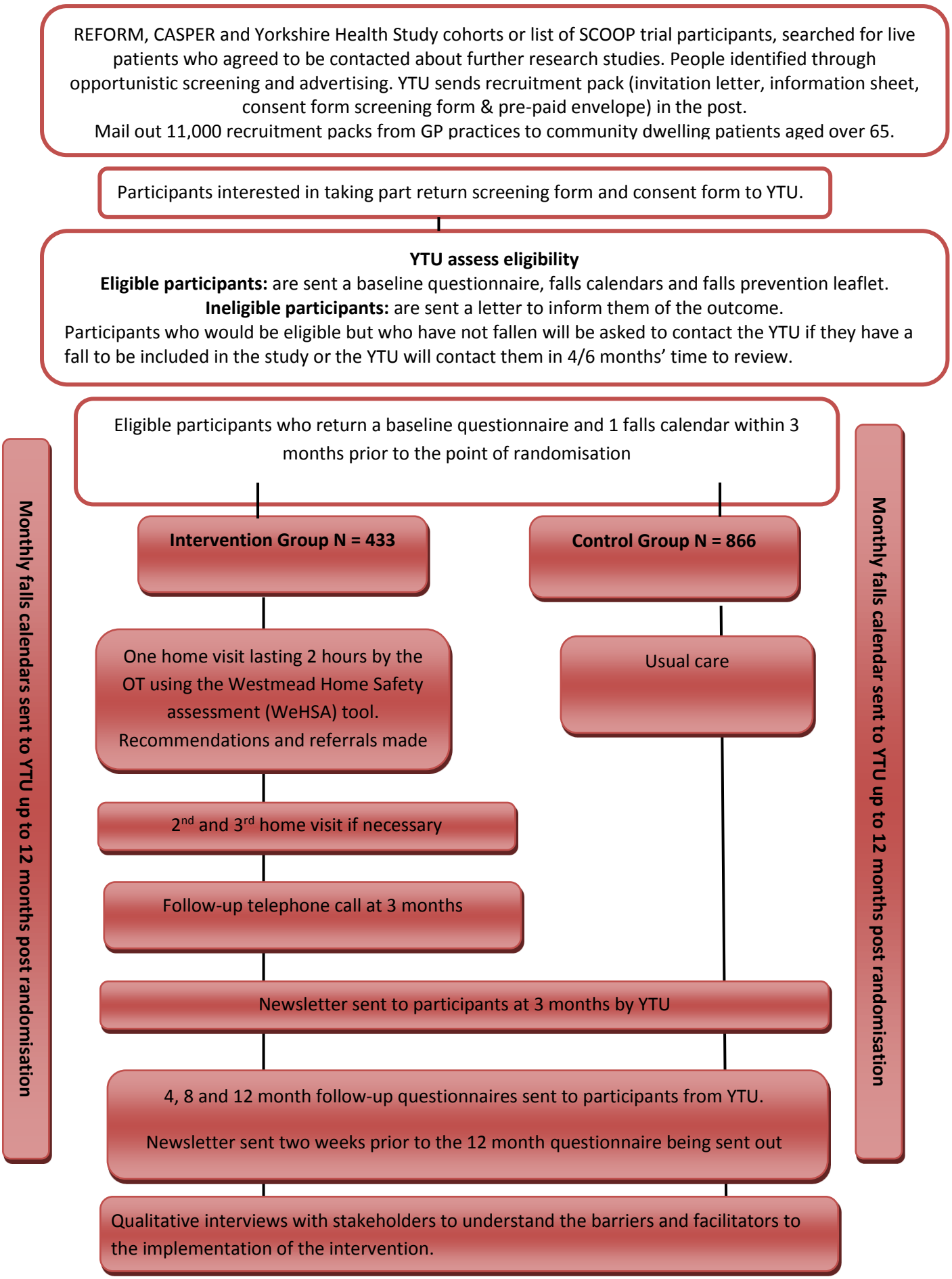
2. Trial summary

2.1 Summary Table

Acronym	OTIS (Occupational Therapist Intervention Study)
Long title	Does Occupational Therapist-led home environmental assessment and modification reduce falls among high risk older people?
Study design	A large pragmatic, individually randomised, controlled trial using unequal randomisation.
Setting	Participants' homes.
Target population	1,299 community dwelling men and women aged 65 years and over. Participants will be recruited from: the NIHR funded REFORM or CASPER trial cohorts; the Yorkshire Health Study cohort; the SCOOP trial cohort; or via GP practices.
Intervention	Environmental assessment and modification and intervention delivered by Occupational Therapists (OTs).
Primary outcome	The number of falls per participant over the 12 months from randomisation as measured by monthly falls calendars.
Secondary outcomes	EQ5D-5L, time to fall, proportion of single and multiple fallers, fear of falling, fall related injuries and costs.
Estimated recruitment period	June 2016 to August 2017.
Duration per patient	13 to 24 months approximately.
Estimate total trial duration	31 months 01.06.2016 to 31.01.2019
Planned trial sites	10
Number of participants	1,299; 433 to the intervention group and 866 to the control group.
Main eligibility criteria	Inclusion criteria • Aged 65 years and over • Willing to receive a home visit from an Occupational Therapist • Community dwelling • Have at least one risk factor for a fall in the next 12 months i.e., either one fall in the past 12 months or report a fear of falling on their screening questionnaire.

	<u>Exclusion criteria</u> • Unable to walk 10 feet today, with a walking aid if needed • Unable to give informed consent e.g., due to suffering from dementia or Alzheimer's disease • Living in residential or nursing home • Unable to read or speak English, and have no friend or relative who is able to translate/interpret for them. Have had an OT assessment for falls prevention in the past 12 months. • Are on a waiting list for an occupation therapy assessment • Have not completed one falls calendar in the three months prior to randomisation

2.2 STUDY FLOW CHART



2.3 ASSESSMENT SCHEDULE

	Screening form	Baseline	Randomisation (Eligible patients + BLQ + 1FC*)	Approx 2 weeks post randomisation	Approx 4/6 weeks post randomisation	Monthly data collection up to 12 months post randomisation	3 months post randomisation	4 months post randomisation	8 months post randomisation	12 months post randomisation
Eligibility screen by researchers at YTU	√									
Informed consent via the post	√									
Demographic questions: Date of birth, gender, dementia or Alzheimer's disease	√									
OT assessment for falls prevention in the past 12 months	√									
Falls history (number in last 12 months)	√									
Fear of falling	√							√	√	√
Able to walk 10m with walking aid	√									
On waiting list for OT										
Contact details, GP details	√									
Demographic questions: height, weights, taking >4 medications, comorbidities, ethnic group, living arrangements,		√								
Broken bones in last 10 years		√								
Difficulties with balance		√								
EQ5D-5L		√						√	√	√
Falls data						√		√	√	√
Economic evaluation		√						√	√	√
Randomisation			√							
OT home visit **				√						
Westmead Home Safety Assessment **				√						
Westmead Home Safety Report **				√	√					
OT telephone call **					√					
Adverse events				√	√	√		√	√	√
Newsletter update							√			√ (-2 weeks)
Level of adherence to recommendations										√

*BLQ – baseline questionnaire FC – falls calendar ** Intervention participants only

2.4 LAY SUMMARY

Falls and injuries caused by falls are common in older people and can cause serious health problems. Most falls happen when people are at home. Hazards in the home, such as slippery floors or poor lighting, are important causes. A review of the current research looked at the effect that home visits by an occupational therapist had on falls. This research was in people who had been treated in hospital for a fall. During the visit the occupational therapist would look at potential hazards that could lead to falls in the home and suggest changes to try to avoid them happening. This review of research found people who were visited by an occupational therapist had less falls. Some members of our research team did a small study and found that people in the community, who had not been admitted to hospital because of a fall, also had less falls when visited by an occupational therapist. To be more confident of these results, we wish to conduct a larger study to find out if people in the community would have less falls if they have a home hazard assessment by an occupational therapist. We also want to find out if this would be good value for money for the NHS.

We will ask 1299 people to take part in this study. We will ask people who have already been involved in three studies funded by the Department of Health and Medical Research Council that the research team have run, and people who are part of the Yorkshire Health Study cohort, if they would like to participate in this study. We will also invite patients from GP practices. All the participants in the study will have an increased risk of falling within the next 12 months as they will either have had at least one fall in the past 12 months or tell us that they worry about falling in their day-to-day lives. Once in the study participants will be asked, by filling in monthly falls calendars and postal questionnaires, if they've had a fall, about their quality of life and how often they use NHS services. Some participants will receive at least one home visit by a qualified occupational therapist to assess their home for dangers and make recommendations for changes. Four weeks later the therapist will ring them to find out if the recommendations made have been followed.

The research team have a lot of experience in running large studies. They have a wide range of knowledge and include occupational therapists, clinical experts in the prevention of falls, trial methodologists, statisticians, qualitative researchers and health economists. We have also asked some patient representatives to give us advice about how to run the study and to help make sure the views of patients are taken into account. Many of the people in the team are recognised as

international experts in their area of work and are used to dealing with problems which are likely to happen when running a large study like this. We have designed the study to make it as efficient as possible and will only collect information that is vital to the running of the study. We will also interview some health care professionals to ask them their views about how we can roll out the treatment should we find it reduces falls.

3. Background

3.1 What is the problem to be addressed?

Falls in older people are highly prevalent 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 will occur in the home [3]. Fall related fractures are a serious cause of morbidity and cost to society [4]. A fifth of all falls are serious and require medical attention with 5% of falls leading to a fracture [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, who are more likely to sustain hip fractures due to slowed reflexes [1] [6]. This burden is likely to increase due to an ageing population and 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]. 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 [8]. Environmental hazards are implicated as a major contributor to falls amongst older people and are one of the most frequently cited causes of falls in the literature. One review described 'accident/environment related' factors as responsible for a mean of 31% (range 1-53%) of all falls (n=3,628) across twelve studies [6]. Similarly, a retrospective study by Talbot et al [9] observed 'accident/environment' factors to be the second most commonly perceived cause of falls by older people, specifically identifying wet and uneven surfaces, objects on floors, external forces and icy surfaces as key contributors.

The latest Cochrane review in this area (updated September 2012 [10]) found that environmental assessment and modification was an effective approach to reducing falls (relative risk of falling

0.88; 95% confidence interval 0.80 to 0.96). It also concluded that the effectiveness of an environmental intervention was increased if delivered by an Occupational Therapist (OT). Current NICE guidance suggests that "Older people who have received treatment in hospital following a fall should be offered a home hazard assessment and safety intervention/modifications by a suitably trained healthcare professional". However, there is currently no guidance with respect to environmental assessment for people living in the community who are at elevated risk of falling but have not yet received hospital treatment due to a fall. Indeed, there has only been one UK trial of environmental assessment by an OT, which is a pilot study conducted by the applicants [11]. Consequently, there is reasonable evidence to suggest occupational therapy delivered home hazard assessment and modification can lead to a reduction in falls. What is now needed is a large trial to confirm previous findings. This trial aims to address this issue. In this study we will undertake a randomised controlled trial to evaluate the clinical and cost effectiveness of an environmental assessment and modification intervention to reduce falls, among older people living in the community.

3.2 Aims

3.2.1 Primary aim

The primary aim of this study is to establish whether environmental assessment and modification by an Occupational Therapist (OT) will lead to a reduction in the number of falls among those at elevated risk of falling living in the community.

3.2.2 Secondary aims

Secondary aims include:

- To establish the cost effectiveness of OT delivered environmental assessment and modification
- To assess the impact of the intervention on participants' quality of life
- To explore the barriers and facilitators of implementing the trial's findings among the OT professionals and the wider community (e.g., commissioners of services)

4 Study design

4.1 Study design

OTIS is a pragmatic two arm, open randomised controlled trial, with unequal randomisation of 2:1 in favour of the control group.

4.2 Identification of sites

The trial will be undertaken in the same geographical locations as the REFORM, CASPER and SCOOP trials and the Yorkshire Health Study e.g., Yorkshire, Durham, Tyne and Wear, Northumberland and Lincolnshire. Sites may also be recruited from NHS Trusts where the co-applicants are based or from areas where the co-applicants or members of the study team have local contacts or via the Clinical Research Network. If additional sites are required, then a member of the study team will provide potential sites with information about the study and explain what participation would entail.

4.3 Identification of participants

We will recruit 1,299 men and women, aged 65 years and over to the trial. Potential participants will be identified from:

- A database of participants held at the York Trials Unit, who responded to an invitation to take part in either the NIHR funded REFORM [12] or CASPER [13] and agreed to be contacted about future studies
- The Yorkshire Health Study cohort [14]
- SCOOP trial participants [15]
- Direct mail out to patients on GP lists
- Opportunistic screening of family members or friends of people who receive a study information pack
- OTs may identify potential participants from referrals from other healthcare professionals or NHS services
- Radio, newspaper, online, television and other media advertisements
- Posters or flyers within the area of recruiting sites
- Events by YTU research staff
- Flyers placed in or stapled to pharmacy prescription bags

- Advertisements in organisations such as the University of the Third Age, Yorkshire Countrywomen, Womens Institute, Townswomens Guilds, the Rotary Club, Over Sixties clubs, faith organisations and institutions connected with the study

4.3.1 Identification of patients from the REFORM, CASPER and the Yorkshire Health Study and SCOOP trial to receive an invitation pack

A database search will be undertaken at the YTU to identify participants from the REFORM, SCOOP and CASPER cohorts who agreed to be contacted about future research studies. The research team at the YTU will liaise with the OTs delivering the intervention to ensure that patients are within their catchment area. The identified participants will be sent a study 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. Participants who either withdrew from the studies, moved out of the area, or who are known to spend large amounts of time outside of the UK will be excluded from the mail out.

A database search of the Yorkshire Health Study cohort or the PRE-FIT trial, will be undertaken by researchers on this study to identify patients living in the areas covered by this research who have agreed to be contacted about further research studies. Invitation packs will be mailed out by members of the Yorkshire Health Study team. The research team at the YTU will liaise with the OTs delivering the intervention to ensure that only those patients in the OT's catchment areas are mailed out to. The identified participants will be sent the study invitation pack. 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 study invitation pack may decline participation in the study, however, a family member or friend may be interested in taking part. In such cases, we will undertake opportunistic screening and ask the original recipient to pass on the research team's contact details, so that they can contact him/her in person.

4.3.2 Identification of participants via GP practices and other services

In order to increase the generalisability of the study's findings, we will also recruit participants by mailing out invitation packs to patients on GP practice lists. The GP practices will be identified following an introduction by the local Research Network and will be in either

- Geographical areas not covered by the REFORM, CASPER, SCOOP and Yorkshire Health Study cohorts but where the local trust and OTs have agreed to host the study

OR

- In geographical areas covered by the REFORM, CASPER, SCOOP and Yorkshire Health Study cohorts but where insufficient participants have been identified by the mail out from the YTU.

A database search will be undertaken to identify community dwelling men and women over the age of 65. Where possible, the database search will be refined to reduce the number of packs to be mailed out. For example, to include only patients who have fallen in the past 12 months; or exclude patients who are unable to walk 10 feet, with the use of a walking aid if needed. All patients who are identified as being potentially eligible will be sent an invitation pack. The pack will consist of a letter of invitation, participant information sheet, consent form, screening questionnaire and a pre-paid envelope. Participants who are unable to speak or read English will be allowed to participate in the study, if they have a family member or friend who is willing to translate/interpret for them.

In order to facilitate recruitment, where there is capacity, we will undertake opportunistic screening. Occupational therapists may give out/send an OTIS recruitment pack to patients who have been referred to them from other healthcare professionals (e.g GPs, Rapid Assessment Teams, COPD nurses, Heart Failure Nurses, Community Matrons), or NHS services (e.g.ambulance services, Neurology rehabilitation or virtual wards). Alternatively OTs may give out the study coordinator's contact details so that they can contact him/her in person. Other healthcare professionals (HCP) such as podiatrists, falls practitioners and physiotherapists may also support opportunistic recruitment and give out recruitment packs to potential participants. The trial coordinator or occupational therapist will provide the HCP with an eligibility check list and support if required.

Radio, newspaper, parish and other faith magazines, social media, websites or television advertisements may also be used to identify participants. Posters or flyers may also be placed within the area of recruiting sites to promote the study and asking for volunteers. These may be places in areas such as libraries, community centres, GP practices, public notice boards, Age Concern day centres, befriending services, hairdressers or supermarkets. Flyers may also be placed in or stapled to pharmacy prescription bags. Organisations such as the University of the Third Age, Yorkshire Country Women, the Womens Institute, Townswomens Guilds, the Rotary club, Over Sixties clubs, faith organisations and institutions connected with the study may be approached to advertise the study. Potential participants will be asked to ring the research team at the York Trials Unit for further information. NHS Trusts may also promote the trial by posting information on their Trust website, staff intranet, or on electronic noticeboards, within NHS premises in recruiting Trusts. A brief description of the project (based on information in the participant information sheet) and an invitation to individuals that are interested in taking part to phone or email the study coordinator for further details, will be given. For individuals ringing the study coordinator, a check will be made to ensure the potential participants fulfil the inclusion criteria.

The study co-ordinator may also give out/send recruitment packs to people who request them at events aimed at people over 65 years old.

4.3.3 Pen sub-study

We will undertake an embedded randomised controlled trial in order to evaluate the effectiveness of including a pen with the trial invitation pack on recruitment of participants to the OTIS study. Participants allocated to the intervention group will receive a pen with the York Trials Unit logo/details on it whilst control participants will receive no pen. Participants will be randomised using block randomisation in a 2:1 ratio in favour of the control group in order to reduce costs.

Inclusion criteria

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.

Exclusion criteria

Participants in the REFORM, CASPER and Yorkshire Health Study cohorts and the SCOOP study have already consented to be contacted about other research studies and are therefore a different population to those who have not been approached about participating in research. They will therefore be excluded from this sub-study.

Outcome measures

The primary outcome will be the proportion of participants who go on to be randomised to the OTIS trial. Secondary outcomes include:

1. proportion of participants who return a screening form
2. time to return screening form
3. proportion of participants who are 'pending' in terms of their eligibility i.e. fulfil the eligibility criteria apart from the criterion relating to falls within past 12 months or fear of falling
4. proportion of participant who are eligible for randomisation
5. proportion of participants who remain in the trial at three months post randomisation (defined as returning at least the first three months' worth of falls calendars from the date of randomisation)

4.3.4 Text sub-study

We will undertake an embedded randomised controlled trial to evaluate the effectiveness of a personalised text compared with a standard text on postal questionnaire response rates. Participants will be randomised in a 1:1 ratio to receive either a personalised text or the York Trials Unit standard text with their four month follow-up questionnaire. The wording for the personalised text 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 wording on the YTU standard text 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".* Participants will be sent the text messages at the same time as they are expected to receive their postal follow-up questionnaire (i.e., two to four days after the questionnaire is sent). Text messages are likely to be sent using secure UK-based text message gateway software such as that provided by Intelli Software (**https://www.intellisoftware.co.uk/**). In the event that a message is not delivered, the sender will receive a notification, which will be used to classify the text message as "delivered" or "not delivered". The findings of this sub-study will be implemented during the course of this study.

Once the results of this sub-study become available, participants will receive the text which demonstrated the highest questionnaire response rate, at following time points.

Inclusion criteria

Participants who provide a mobile phone number and consent to be contact by this method, and who are due to be sent their four month follow-up questionnaire.

Exclusion criteria

Participants who withdraw from follow-up before their four month questionnaire is due.

Outcome measures

The primary outcome will be the proportion of participants in each group who return the questionnaire. Secondary outcomes will include time to response, completeness of response, whether a reminder notice is required and cost-effectiveness..

4.3.5 Invitation letter sub-study

We will undertake an embedded randomised controlled trial 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 randomised in a 1:1 ratio to receive either an invitation letter with their name written on either by hand or printed. Once the results of this sub-study become available, participants will receive the format of the letter which elicits the highest response rate.

Inclusion criteria

Participants who are due to be mailed out an invitation pack about the OTIS trial by the Yorkshire Health Study.

Exclusion criteria

We will exclude participants who have not agreed to be contacted about future studies.

Outcome measures

The primary outcome will be the proportion of participants who go on to be randomised to the OTIS trial. Secondary outcomes include:

1. proportion of participants who return a screening form

2. time to return screening form

3. proportion of participants who are 'pending' in terms of their eligibility i.e. fulfil the eligibility criteria apart from the criterion relating to falls within past 12 months or fear of falling

4. proportion of participant who are eligible for randomisation

5. proportion of participants who remain in the trial at three months post randomisation (defined as returning at least the first three months' worth of falls calendars from the date of randomisation)

4.4 Declining participation in the study

Participation in the OTIS trial is voluntary. People who do not wish to take part in the study will not have to return any forms to the YTU. However, if they are willing to provide some demographic information they may complete the screening questionnaire and send it back to the YTU. People who do not respond to the invitation mail out will not receive any further correspondence from the YTU about the study.

4.5 People who wish to take part in the study

People wishing to take part in the study will be asked to return their completed consent form and screening questionnaire by post to the YTU.

4.5.1 Assessment of eligibility

Researchers at the York Trials Unit will assess the returned screening forms for participant eligibility for the study according to the criteria in section 5.

If a person is found to be ineligible for the study, for example they are unable to walk 10 feet with the use of a walking aid if needed, they will be informed in writing. No further correspondence will be sent from the YTU.

If the respondent is assessed as being ineligible because they have not had a fall within the past 12 months and do not report a fear of falling, but otherwise fulfil the eligibility criteria then they will be informed about the reason in writing. They will be given the option to take part in the study at

a future date if they subsequently have a fall and, therefore, meet the inclusion criteria. If the respondent consents to being contacted again, the research team at the University of York may telephone, write to or email them (according to their preference) approximately every four to six months to ask if they are still interested in taking part in the study and whether they have had a fall. Respondents who have fallen since completing their initial screening form and who still wish to take part in the study will then be asked to complete and return a second screening questionnaire (either over the phone or a paper copy) to confirm eligibility. Respondents will then be sent a baseline questionnaire and a batch of monthly falls calendars.

4.5.2 Informed consent and completion of the consent form

If respondents require any further information about the study prior to giving their consent they will be able to contact members of the research team based at the York Trials Unit (YTU), who will have undertaken Good Clinical Practice (GCP) Training. If the respondent prefers, a family member, friend, carer or other nominated person may contact the YTU on their behalf. Respondents will be given at least 24 hours to consider participation in the study. Participation in the study is voluntary. People who wish to take part in the study will be asked to write their name, sign and date the consent form. They will also initial each of the statements to indicate they agree with them. If, however, a participant mistakenly places a tick or a cross in the boxes, these shall be taken as an indication of consent. Nevertheless, all due care will be taken to ensure that the participant provides consent to take part in the study. If the study team at the YTU has any doubts about whether a person wishes to take part in the study they will telephone them to confirm. Patients may nominate a family member or friend to talk to the trial team on their behalf. This will be documented on the consent form.

Copies of the consent forms will be stored at the YTU in a locked cabinet in a locked room and in accordance with the YTU Standard Operating Procedures. A copy of the completed consent form will be sent back to the participant.

4.5.3 Completion of the baseline questionnaire

All eligible, consenting participants will be sent a baseline questionnaire and a batch of monthly falls calendars by post. Participants who return a valid baseline questionnaire and at least one

falls calendar within the three months prior to the point of randomisation will be randomised into the trial.

5 Eligibility criteria for the OTIS trial

5.1 Inclusion criteria

Potential participants will be eligible for the trial if they fulfil the following criteria:

- Aged 65 years and over
- Willing to receive a home visit from an Occupational Therapist
- Community dwelling
- Have at least one risk factor for a fall in the next 12 months i.e., either one fall in the past 12 months or report a fear of falling on their screening questionnaire

5.2 Exclusion criteria

Potential participants will be excluded if they fulfil any of the following criteria:

- Unable to walk 10 feet today, with the use of a walking aid if needed
- Unable to give informed consent, for example, due to Alzheimer's disease or dementia
- Live in residential or nursing home
- Unable to read or speak English and have no friend or relative who is able to translate/interpret for them
- Have had an OT assessment for falls prevention in the past 12 months
- Are on a waiting list for an occupation therapy assessment
- Have not completed at least one falls calendar in the three months prior to randomisation

5.3 Primary outcome

The primary outcome is the number of falls experienced in the 12 months following randomisation, where a fall is defined as "an unexpected event in which the participant comes to rest on the ground, floor, or lower level".

5.4 Data collection for the primary outcome for the trial

Participants will be asked on monthly falls calendars if, in the past month, they had any falls including a slip or trip in which they lost their balance and landed on the floor or ground or lower

level. An explanation of what the researchers consider to be a fall will be included in the participant information sheet and on the falls calendar. 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. Data will be collected via participant self-reported monthly falls calendars in the 12 months following randomisation. Falls calendars will be sent to participants in the post along with their baseline questionnaire. If they had a fall that month participants will be asked to mark on the calendar the number of falls they had on each day and return their monthly falls calendar to the YTU via FREEPOST. Participants who do not return their falls calendar within 10 days of the due date will be telephoned, emailed or sent a reminder in the post by the YTU, to collect this information.

Participants will also be given the YTU free phone number to ring during office hours to report any fall they have as soon as it is safe and convenient to ring.

The YTU personnel will follow up every reported fall to collect information on cause/reason for fall, consequence of fall e.g., superficial wound (bruising, sprain, cut, abrasions), fractures (including type of fracture) and hospital admissions.

5.5 Secondary outcomes

Secondary outcomes in this study are:

- Health related Quality of Life as measured by the EQ5D-5L
- 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
- Fear of falling
- Fall related injuries and costs
- Patient self-reported fractures

5.6 Participant withdrawal

Participants can withdraw from the trial at any point during the course of the study by directly contacting the trial coordinator at the York Trials Unit or informing a member of the research team delivering the intervention. If a participant indicates that they wish to withdraw from the study, they will be asked whether they wish to withdraw from the intervention only (i.e., withdrawal from treatment) or withdraw fully from the study. Where withdrawal is only from the intervention then follow-up data will continue to be collected. The reason for the participant wishing to withdraw from the study will not have to be stated, however, if the participant indicates the reason this will be recorded. Data provided by participants who withdraw will be retained for analysis.

5.7 Randomisation

Participants who fulfil the eligibility criteria and who have provided written consent to take part in the study will be eligible for randomisation. Participants will be randomly allocated using the York Trials Unit secure web-based randomisation system designed and maintained by an independent data systems manager at the York Trials Unit, who is not involved in the recruitment of participants. Participants will be randomised by site using single large blocks Up to 12 participants can be randomised in a single block at any one time. The number of participants chosen to be randomised will depend on the availability of Occupational Therapy appointment slots. The randomisation system allows the use of allocation ratios between 2:1 and 3:1 in favour of the intervention (). For example, if a site has availability to see three participants, then 9, 10 or 11 eligible participant from that site may be randomised (in an allocation ratio of 6:3 (i.e., 2:1), 7:3, or 8:3, respectively). The ratio of 2:1 will be used wherever possible; however, in the situation where 11 participants have been awaiting randomisation for some time and the likelihood of more participants becoming eligible to be randomised in the near future is unlikely, then all 11 participants may be randomised. The YTU will write to the intervention participants informing them of their group allocation and that the OT will be in contact with them to arrange a home visit(s). The OT delivering the intervention will be notified that a new participant has been randomised to the intervention group via email, telephone call or letter. The OT will receive participant details (name, address, GP contact details and copy of consent form) using their NHS Trust approved method of encrypted email or by using the secure University of York Dropoff system and will arrange the required appointments for that participant. It is anticipated that the first home visit will take place within two weeks of randomisation. If necessary, the OT may

review intervention participants' medical notes and/or contact the GP prior to or after their home environmental assessment. This is to obtain information needed for the consultation and/or to liaise with the GP regarding any actions required as a result of the home environmental assessment or any concerns about the participants' health.

The York Trials Unit (YTU) will write to the participants' GPs informing them about their participation in the study.

Randomisation to the pen sub- study

Block randomisation will be used to allocate participants being mailed a recruitment pack from GP practices to either the intervention group or the control group 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.

Randomisation to the text sub-study

Block randomisation will be used to allocate participants who provide a mobile telephone number in a 1:1 ratio to either the intervention group or the control group. 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.

Randomisation to the invitation letter sub-study

Block randomisation will be used to allocate participants being mailed a recruitment pack from the Yorkshire Health Study to either the 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.

5.8 Blinding

Blinding of participants to group allocation will not be feasible, nor is blinding of the members of the study team who are actively involved in the administration of the study, the statistician or health economist. Data entry staff will be blind to group allocation.

5.9 Usual care group

All participants will receive usual care from their General Practitioner and other health care professionals which may include referrals to a falls clinic. They will also be sent a falls prevention advice leaflet produced by Age UK in the post with their baseline questionnaire. The current version of the falls prevention leaflet is called "Staying steady, Keep active and reduce your risk of falling". Participants will receive a group specific newsletter at three months post randomisation and two weeks before their 12 month follow up questionnaire is due, to inform them about progress with the study.

5.10 Intervention

In addition to the usual care and falls prevention leaflet described above, the intervention participants will receive at least one environmental assessment to identify personal fall related hazards. The assessment will be undertaken by a Health and Care Professions Council registered Occupational Therapist (OT) and will take approximately two hours to conduct. If the assessment is too demanding for the participant, the appointment can be split into two visits. The OT or other delegated person within the trust or the York Trials Unit will telephone the participant in order to arrange a convenient date and time for an appointment. Written confirmation of the appointment will be sent to the participant in the post.

The environmental assessment will begin with an initial discussion about the participant's history of falling, lifestyle, patterns of usage of areas in the home, risk taking behaviour, strategies already adopted to reduce falls, environmental changes made and functional vision. This will then be followed by the Timed Up and Go (TUG) and the environmental assessment using the Westmead Home Safety (WeHSA) tool [17] see Appendix 1. The WeHSA was developed in Australia in 1997 for older adults and consists of a 72 item checklist of fall hazards in the following areas: internal/ external traffic ways, general/ indoors, living area, seating, bedroom, bathroom, kitchen, laundry, footwear, medication management. The OT and the participant will move through the house together and a functional evaluation will be made. Items on the checklist will be rated as either relevant (i.e., deemed to be a hazard) or not relevant (i.e., not deemed to be a hazard). The OT will discuss any potential falls hazards identified during the assessment and possible solutions with the participant and a list of recommendations will be agreed. If possible any identified hazards will be removed. The OT may carry a resource bag containing small aids such as easy reaches, anti-slip

bath mats, adhesive carpet tape, walking aid parking devices, ferrules, carpet glue and reflective anti-slip tape. The actual content of the bag will vary, and will be in line with normal trust policy. This will allow them to deal with minor safety issues during the visit and avert the necessity for further visits. If required, the OT will make referrals to other agencies for equipment or a handy man for other minor modifications. They may also make recommendations for equipment that cannot be provided by Social Services, such as lightweight step ladders with handles and height adjustable rotary washing lines. In such cases the OT will liaise with the client or a family member regarding purchase of such equipment. The OT will make a clinical judgement whether an additional home visit is required. A written summary of the OT's recommendations will be sent to the participant and the York Trials Unit (YTU). A copy of the Westmead Home Safety Assessment will be sent to the YTU.

Four weeks after the assessment the OT will telephone the participant to check adherence to the recommendations and provide further advice if necessary. In the pilot study [11] approximately 20% of participants required two or more home visits. If further visits are required, the OT and participant will agree their content, frequency, duration and total number of sessions to be provided. The content of the further visits will be informed by the potential hazards identified in the initial assessment. If a participant is identified as being at particular risk during functional activities, then the further contact will include the participant undertaking those activities under supervision, using a different functional approach, or using equipment to make the task safer. Alternatively if a participant indicated they were concerned about falling whilst undertaking a certain task, the further visits would focus on discussing ways of making the task safer, and practising the task to increase skill and self-confidence.

In order to assess the treatment fidelity, we will undertake some observational work. An OT who was involved in teaching the delivery of the intervention will shadow OTs whilst they deliver the intervention. We will purposely sample OTs to ensure we select a sample of OTs who attended the different training sessions. Approximately 15 OTs will be observed. Consent for a second OT to attend the home visit will be obtained from the participant. Verbal consent will be obtained during the initial phone call, to arrange a home visit. At this point the purpose of the attendance and the fact that the focus will be on the OT delivering the intervention and not the participant will be reiterated. Written consent will then be obtained at the beginning of the home visit.

Participants will be able to decline the second OT attending the visit at any point during the process, and will still be able to have a home visit.

5.10.1 Training for the OT

The OTs will attend a one-day, face-to-face training session on how to conduct the assessment which will be delivered by one of the grant co-applicants. The OTs will be given the accompanying Westmead Home Safety manual or will access the on-line training package which is based on the same manual. There is no pre-course reading for the training session. However, there is an online training resource about slips and trips which OTs may find beneficial to do either before or after the training session. The web link for this training is

http://www.hse.gov.uk/slips/step/health/advanced/8E7F777B-3B84-49FE-A3D6-D0324E25A801/HSLCourseTemplate/28531/slidetype2_101866.htm

In addition, the grant applicants with a background in occupational therapy will be available to discuss any specific issues that arise during the course of the study.

Relevant training in day-to-day trial management related activities will be provided to OTs by the trial manager.

6 Data collection

6.1 Quantitative data collection

Participants will be asked to return monthly falls calendars for 12 months following randomisation. Participants will be asked to complete follow-up questionnaires sent in the post at four, eight and 12 months post randomisation. A reminder to return any outstanding falls calendars will be included with the follow-up questionnaires. Participants who provide an email address or a mobile phone number, and consent to be contacted by these methods, will be sent either a pre-notification email or text on the day their follow-up questionnaire is due. This email/text will alert participants that they will soon receive a follow-up questionnaire. The personalised vs non-personalised text sub-study will be embedded into the trial at the four month follow-up.

Participants who do not return their follow-up questionnaire within three weeks will be sent one reminder by post followed by a telephone call two weeks later.

All participants will be sent a newsletter about the trial progress at three months post randomisation and two weeks before their 12 month questionnaire is due to be sent out. They will also be sent a pen and an unconditional £5 with the 12 month questionnaire in recognition of their commitment to the study and to cover any expenses incurred in completing the questionnaires. Members of the research team may also contact participants or their delegated contact as documented on the consent form, by telephone, post, email or text regarding any queries they may have in relation to the follow-up questionnaires or falls calendars.

Process data, including the Westmead Home Assessment form collected by the Occupational Therapist, will be collected at the participant's initial and follow-up home or telephone contact.

6.2 Qualitative data collection

6.2.1 Qualitative sample

In order to inform potential large-scale implementation of Occupational Therapy environmental assessment, qualitative interviews will take place with key stakeholder groups involved in intervention delivery (Occupational Therapists, those who are clinical leads/practitioner roles for falls prevention services). It is essential that we are confident that the intervention is acceptable and feasible to both older people and service providers. Our previous pilot study has indicated that the intervention is acceptable to service users. Therefore, semi-structured interviews will be conducted with a sample of the Occupational Therapists delivering the intervention in the trial (n = 15), and clinical leads who run falls prevention services/care of older people services (sampled from services involved in the trial (n=10) and services external to the trial (n=5)).

6.2.2 Qualitative analysis

Data will be collected on the feasibility of providing this intervention on a regular basis, identification of the barriers and facilitators, workload implications and readiness to employ this intervention into their regular falls prevention practice. We will use Normalisation Process Theory (NPT)[17] to guide data collection and to frame the analysis to understand how easy it is to implement these interventions into routine practice. NPT conceives making changes in established routines as a complex and dynamic enterprise, and proposes a model which explains the way in which new practices are adopted and absorbed by individuals into existing behavioural conventions and routines. It has been suggested that this can help identify whether interventions are likely to become embedded and integrated as part of routine practice or not [18].

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. To introduce transparency and a systematic approach we will engage in: detailed familiarisation; identification and indexing of key themes; contextualising these themes in relation to the broader dataset; and interpreting them, within the context of theoretical themes relevant to the interview material (using NPT). During the analysis, regular meetings will be held between the research team to discuss the emergent themes from the fieldwork material. Throughout the process of analysis we will maintain a sharp focus on the relevance of any findings in order to develop an implementation policy for Occupational Therapy falls environmental assessment, if this is found to be an effective and cost-effective intervention. Therefore, we will specifically construct a series of themes selected purposively to engage with our understanding of how we would best implement this intervention within a broader organisational and policy perspective.

7 Statistical considerations

7.1 Sample size

We will recruit and randomise 1299 participants. Up to 12 participants from a particular site will be randomised at a time in a single block. The blocks of participants will mostly be randomised 2:1 in favour of the control group (to reduce costs). However, the allocation ratio used may go up to 3:1 in a block if the OTs have capacity to see *n* intervention participants but there are (up to) *3n* participants eligible to be randomised. Randomising 1299 participants in a 2:1 ratio (i.e., 866 to

usual care and 433 to intervention) allows for 10% attrition and gives us 90% power (using two-sided significance at the 5% level) to show a difference in the proportion of participants who experience at least one fall in the 12 months following randomisation from 60% in the control group to 50% in the intervention group. If the final ratio was 3:1 (i.e., 974 to the usual care and 325 to the intervention) we would have 85% power under the same conditions. This should be a conservative sample size for the primary analysis of the number of falls per participant over 12 months.

7.1.1 Sample size for the pen sub-study

As is usual with an embedded trial within a trial, no formal power calculation will be undertaken for the study, as the sample size will be constrained by the number of participants available to mail out to.

7.1.2. Sample size for the text sub-study

The OTIS trial is a host study for the Personalised versus standard text message prompts for increasing trial participant response to postal questionnaires (PROMPTS) study. The primary outcome for PROMPTS is the proportion of questionnaires returned by participants. To provide a sample size estimation, it is assumed that there will be a base response rate of approximately 85%. We define a significant improvement in response rate as an increase in response of 5%. If individual patients are randomized (i.e., to standard text message or to personalised text message), 700 participants per arm (total 1400 participants) would be required to provide 80% power to detect a 5% difference (5% two sided significance). For the OTIS text sub-studies, no formal power calculation will be undertaken for these embedded trials as the sample size will be constrained by the number of participants available to send a text to.

7.1.3 Sample size for the invitation letter sub-study

We will randomise 314 participants who are due to be mailed out an invitation pack about the OTIS trial by the Yorkshire. 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.

7.2 Statistical analysis for the main OTIS trial

There will be one single analysis at the end of the trial. All analyses will be conducted in STATA v13 or later (StataCorp, 4905 Lakeway Drive, College Station, Texas 77845 USA). Analyses will be described in detail in a Statistical Analysis Plan drafted by the study statisticians and reviewed by the Trial Steering Committee. It will be signed by the Chief Investigator and the study statisticians prior to the analysis being undertaken. The main planned analyses are summarised below.

This trial will be reported according to the CONSORT guidelines for clinical trials (Consolidated Standards Of Reporting Trials statement (http://www.consort-statement.org/). Baseline data (sex, age, diagnosis distributions, etc.) will be summarised descriptively and presented in tabular form. No formal statistical comparisons will be undertaken at baseline. Continuous measures will be reported as means and standard deviations whilst the categorical data will be reported as counts and percentages. Analyses will be conducted following the principles of intention-to-treat with participant's outcomes analysed according to their original, randomised group, where data are available, irrespective of deviations based on non-compliance.

7.3 Primary outcome for the main OTIS trial

The number of falls per person will be analysed using a Poisson regression model (or negative binomial regression model, as appropriate) adjusting for gender, age, history of falling and the allocation ratio used to randomise the batch of participants which included the participant, to estimate the difference in fall rate between the groups. The model will include an exposure variable for the number of months that the participant returned a monthly falls calendar. Point estimates and in the form of an incidence rate ratio and their associated 95% confidence intervals will be provided.

7.4 Sensitivity analysis for the primary outcome

Given the trial design, we may have clustering by OT in the intervention group. The success of the intervention may depend on the skill/experience of the OT and their relationship with the participant. To account for this variation between OTs, a sensitivity analysis will be conducted in which every participant whether allocated to the intervention or control group will be associated with an OT: for intervention participants, this is the OT delivering their intervention; whereas for control participants, we will assign them a counterfactual therapist; i.e., one that they could have seen had they been randomised to the intervention group. Each OT will then have their own

cluster of control and intervention patients. Therapist will then be included as a random effect in the primary analysis model.

7.5 Secondary Outcomes for the main OTIS trial

The following outcomes will be analysed by logistic regression adjusted as for 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. Odds ratios and their associated 95% confidence intervals will be provided.

Fear of falling will also be analysed in its continuous form using a covariance pattern model incorporating all post randomisation time points 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. Different covariance structures for the repeated measurements, that are available as part of Stata v13 (or later), will be explored and the most appropriate pattern will be used for the final model. Diagnostics including Akaike's information criterion [10] will be compared for each model (smaller values are preferred). Participants are included in the model if they have full data for the baseline covariates and outcome data for at least one post-randomisation time point (four, eight or 12 months). Estimates of the difference between treatment groups in the outcome will be derived at all time points with 95% confidence intervals and p-values.

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 from the participant's falls calendar. 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. Hazard ratios and their associated 95% confidence intervals will be provided. The proportional hazards assumption will be evaluated using Schoenfeld residuals.

7.6 Sub-group analysis

We shall repeat the primary analysis including an interaction of the treatment allocation with a variable to indicate whether or not the 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.

7.7 Missing data

We anticipate that missing data will be relatively small. In our pilot trial we had falls data on 94% of the trial participants and in the REFORM trial we had falls data on 98% of participants. The amount of missing data will be reported for each randomised arm, and we will also compare the baseline characteristics of participants who are included in the primary analysis to ensure that any attrition has not produced any imbalance in the groups in important covariates. To account for any possible selection bias, a logistic regression will be run 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 this affects the parameter estimates.

7.8 Intervention adherence

A Complier Average Causal Effect (CACE) analysis to assess the impact of compliance on treatment estimates will be undertaken. CACE analysis allows an unbiased treatment estimate of, in this case, Occupational Therapy in the presence of non-compliance. It is less prone to biased estimates than the more commonly used approaches of per protocol or 'on treatment' analysis as it preserves the original randomisation and uses the randomisation status as an instrumental variable to account for the non-compliance.

7.9 Economic Analysis

The trial Health Economist will write a detailed analysis plan prior to any analysis being conducted. This will be signed by the Chief Investigators and the Health Economist.

The health economic evaluation will aim 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 individual patient level data on an intention to treat basis. The analytical approach will take the form of cost-effectiveness and cost-utility analyses. The cost-effectiveness approach will assess value for money in terms of cost per fall averted, and the cost-utility analysis will assess cost per quality adjusted life-year (QALY) gained. The perspective for both analyses will be that of the UK NHS and personal social services, as well as secondary analyses undertaken from a societal perspective. Discounting for future cost and health benefit will not be undertaken given the time frame for the trial is 12 months after randomisation. The year of pricing will be set as the mid-year of the trial.

Health benefits associated with the treatments will be measured in terms of both estimates of the mean number of falls, corresponding to the main outcome of the trial, and mean QALYs, which is defined as a year lived with full health. In line with NICE recommendations [19], the EuroQol EQ-5D [20] will be used to elicit patient utility values at different points in time and used to calculate QALYs for each patient using the area under the curve approach [21,22]. These utility values are used as 'quality adjustment' for each patient's survival time. Specifically, the EQ-5D-5L will be used; the value sets for the EQ-5D-5L health states are currently being derived and in the interim EuroQol is providing a crosswalk between the EQ-5D-3L value sets and the new EQ-5D-5L descriptive system, resulting in crosswalk value sets for the EQ-5D. If the value sets for the EQ-5D-5L are not delivered by the time of the analysis then these crosswalk value sets will be used, in line with the most recent EuroQol guidance [23].

Cost data will be collected for each patient regarding health care resource use; specifically within primary care and the community (i.e., GP, nurse, physiotherapist, occupational therapist visits) and the hospital setting (i.e., outpatient attendances, day cases, inpatient stays and accident and emergency attendances). Unit costs will then be applied to estimate the total cost per patient. Additional information will be collected regarding intervention costs and private/personal expenses that feed into the societal perspective analysis (e.g., Activities of Daily Living equipment,

travel costs for health care attendances). Unit costs will be obtained from established costing sources such as NHS Reference Costs [24] and PSSRU Unit Costs of Health and Social Care [25]. Data on the cost and utility measures will be collected prospectively at baseline, four, eight and 12 months via self-reported questionnaires.

Mean within-trial estimates of cost and health benefits will be estimated using regression methods, allowing for the correlation between costs and effects, as well as adjusting for covariates. The results will be presented as incremental cost-effectiveness ratios (ICERs), where the difference in mean cost estimates between the two arms is divided by the difference in mean health benefit between the two arms. Findings will also be presented in terms of net health benefit [26]. Multiple imputation methods will be used to handle missing data where needed [27].

The uncertainty surrounding the decision to accept a treatment as the most cost-effective will be explored in cost-effectiveness acceptability curves (CEACs) [28]. These curves depict the probability of accepting a treatment as being cost-effective for a large range of willingness to pay values for an extra unit of health benefit. Sensitivity analysis will be conducted to explore the impact of underlying assumptions of the analysis and the range of unit costs on the cost-effectiveness results.

The main outcome of the trial, falls reduction, is associated with a reduction in fractures. However, due to the restriction in the length of follow-up, the long term effect in terms of the decreasing number of fractures might not be observed in the current trial. Therefore a further analysis will explore the possible long term impact of the trial assuming that a falls reduction should also lead to a fracture reduction. A decision analytic model approach will be adopted to perform such a task. The perspective will be the UK NHS and personal social services, with a lifetime time horizon whereby every participant in a hypothetical cohort is followed up until the last participant dies. The hypothetical cohort will be constructed, based on the characteristics of the trial population, to estimate the QALY yield and cost saving of the long term effect of the intervention. The model parameters which are not collected in the trial will be extracted from the existing literature.

The model outputs will be the estimated expected mean costs, effectiveness, and QALYs associated with each alternative treatment. Estimated total costs and outcomes will be discounted according to the latest health technology appraisal guidance [19]. Uncertainty regarding cost-effectiveness will be evaluated using probabilistic sensitivity analysis, where inputs into the analysis are defined as probability distributions which reflect uncertainty [29]. The uncertainty surrounding the decision to adopt a given treatment option as a cost-effective treatment at different levels of willingness to pay will be represented in CEACs. The impact of assumptions undertaken in the analysis regarding the evidence over parameters or relating to the decision model (such as extrapolation) will be evaluated in sensitivity analysis, if possible.

7.10 Sub-studies analysis

Pen and invitation letter sub studies analysis

Categorical data will be compared using logistic regression and time to response by a Cox proportional hazards model.

Text substudy analysis

Categorical data will be compared using logistic regression and time to response by a Cox proportional hazards model. All models will adjust for main trial allocation.

To determine the cost-effectiveness of the text message intervention, a cost per response will be calculated by dividing the total cost by the number of respondents in the control and intervention groups. Research staff costs will not be calculated as the follow-up of participants will be undertaken during the normal time on the host trial.

7.11 Definition of the end of the trial

The end of the study is defined as the date when the last randomised participant is due to return their 12 month follow up questionnaire. The trial will be stopped prematurely if:

- Funding for the trial ceases
- Following recommendation from the Trial Steering Committee
- Mandated by the Research Ethics Committee

The Research Ethics Committee will be notified in writing if the trial has been concluded or terminated early.

8. Adverse Event Reporting

8.1 Adverse Events (AEs)

The most common Adverse Event likely to occur within the study relates to falls, which are being recorded (in patient self-reported falls calendars and follow up questionnaires) as part of the trial. If a participant has a fall, an AE form will only be completed if the event fulfils the reporting criteria listed below.

Serious Adverse Events (SAE) will be collected. Non-serious adverse events will not be recorded or reported for this study unless they are related to being in the study or are related to the intervention. This study will record and report only details of any serious adverse events (SAEs) that are required to be reported to the Health Research Authority (HRA) i.e., events which are related to taking part in the study and are unexpected.

Details of any SAEs reported to the York Trials Unit either directly by the participant or by OT will be recorded using a trial adverse event form. Events reported by the OT will be reported to the YTU within 48 hours of becoming aware of the event. A follow-up report will be completed if additional information becomes available.

8.2 Definition of Serious Adverse Events

For this trial a Serious Adverse Event (SAE) is defined as any untoward occurrence that:

(a) Results in death
(b) Is life threatening
(c) Requires hospitalisation or prolongation of existing hospitalisation
(d) Consists of a congenital anomaly or birth defect; or
(e) Is otherwise considered medically significant by the investigator

8.3 Expected Events

Incidents of hospitalisations, disabling / incapacitating / life-threatening conditions, aging-associated diseases (such as cancer, cardiovascular disease, diabetes, arthritis, osteoporosis, dementia) other common illnesses such as depression, falls and deaths are expected in the study population due to the age of the cohort. Similarly, any hospitalisation that was planned prior to entry into the study or cannot be attributed to taking part in the study or prolongation of an existing hospitalisation due to social reasons will not be recorded as a SAE. A pre-existing condition (i.e., a disorder present at the start of the study) is not to be reported as an AE.

In the context of this study, SAEs will only be reported if they appear to be related to an aspect of taking part in the study and it is an unexpected occurrence.

8.4 Definition of a related event

An event is defined as 'related' if the event was due to the administration of any research procedure. Whereas an 'unexpected event' is defined as a type of event not listed in the protocol as an expected occurrence. The relatedness of an event will be reviewed by the Chief Investigator and the Trial Steering Committee.

8.5 Reporting adverse events

The AE reporting period for this trial begins as soon as the participant consents to be in the study and ends twelve months after they are randomised. For those participants who are not randomised, then the reporting period will end once the participant is informed that their participation in the study has ended.

9 Trial monitoring

9.1 Site monitoring

Site monitoring visits for this study will not be undertaken on behalf of the sponsors since:

(a) the eligibility for the study is undertaken by review of potential participant's self-reported data by researchers based at the York Trials Unit
(b) consent is taken via the post
(c) the majority of source data for this study is patient self-reported data, provided participants who complete either questionnaires or falls calendars
(d) data on adverse events will mainly be collected via participant self-report data sent to the York Trials Unit. However, if an OT becomes aware that an adverse event has occurred, then they will report this to the York Trials Unit using an Adverse Event Form.

Participating sites may be asked to assist in trial related monitoring when required for example audits, ethics committee review and regulatory inspections.

9.2 Standard Operating Procedures

The study will be run in accordance with the University of York, Dpt Health Sciences, York Trials Unit's Standard Operating Procedures.

10 Service User Involvement

We will establish a patient reference group (PRG). The PRG will be recruited from the REFORM, CASPER, SCOOP or Yorkshire Heath Study cohorts and through contact with patient groups (e. g. Age Concern). It will comprise of approximately four people and will meet regularly during the research process. The PRG meeting will be attended by either, the Chief Investigator, the Trial Manager or the Trial coordinator or Trial Support Officer. A member of the PRG will be asked to co-chair the meeting and will be supported by a member of the study team. This will help to ensure that there is a two way communication between the PRG and the research team.

The PRG will be asked to provide input to all elements of the research study, including the design of questionnaires and finalisation of the trial methods. In particular, the PRG will be essential in assisting with the production of and reviewing all patient information, including the participant information sheet, informed consent forms, newsletters and any dissemination activity that results from the study.

Minutes of the PRG meetings will be forwarded to the Trial Steering/Data Monitoring and Ethics Committee. At least one member of the PRG will be asked to join the Trial Steering Committee. Members of the research team will provide support for the PRG members to attend these meetings.

11 Ethical issues

We are aware that some older people may represent a vulnerable group. However, we do not anticipate any major ethical issues with this study. Participation in the study is voluntary. Participants will not be denied any form of care that is currently available in the NHS by participating in the trial, subject to local provision of services. Participants will be able to withdraw from the study at any point without prejudice by contacting the trial coordinator or the OT delivering the intervention.

11.1 Obtaining consent

Participation in the study will be entirely voluntary. Potential participants will receive an information pack about the trial in the post. The pack will contain an invitation letter, participant information sheet, a consent form, screening questionnaire and pre-paid envelope. Potential participants will be given the trial coordinator's or trial support officer's telephone number to phone if they have any queries about taking part in the study. The qualitative researcher will obtain informed consent from the participant for the qualitative part of the study.

Due to the nature of the intervention of the pen and text sub-studies it will not be possible to ask participants to give their informed consent to enter these sub-studies. However, we do not consider this to be a major ethical issue. For the pen sub-study some participants will receive a pen and all those who are enrolled in the main study will receive a pen with their 12 month questionnaire. For the text sub-study all participants have agreed to be in the OTIS study, and consented to receive text messages, it is just the wording of the text that will be slightly different.

11.2 Anticipated risks and benefits

This study does not involve any invasive/potentially harmful procedures and is therefore considered low risk for participants. The trial intervention consists of a home hazard assessment

and environmental modification by an Occupational Therapist. This intervention was used without incident in a pilot trial [11].

11.3 Informing participants of anticipated risks and benefits

The participant information sheet will provide information about the possible benefits and anticipated risks of taking part in the study. Participants will be given the opportunity to discuss participation with the trial manger or trial support officer prior to consenting to participate. Participants will be informed of any new information which comes to light that may affect their willingness to participate in the study.

11.4 Retention of study documentation

All data will be stored for a minimum of five years after the end of the main analysis of the trial in accordance with the current York Trials Unit's Standard Operating Procedures. All paper records will be stored in secure storage facilities. Personal identifiable paper records will be stored separately from anonymised paper records. All electronic records will be stored on a password protected server within the York Trials Unit.

12 Sponsorship

The University of York will act as the sponsor for the study.

12.1 Indemnity

NHS Indemnity covers NHS staff delivering the intervention and will apply for patients treated within the NHS sites. The University of York will provide legal liability cover for their employed staff. Non negligent harm will not be covered.

12.2 Funding

Research funding has been secured from the National Institute of Health Research – Health Technology Assessment Programme reference 14/49/149.

12.3 Independent Steering Committee

Due to the low risk nature of this study, approval will be sought from the funders to set up one Independent Steering and Monitoring Committee to undertake the roles traditionally undertaken by the TSC and the DMEC. This committee will comprise of an Independent Chair who will be a clinician with expertise in falls prevention, a statistician, an Occupational Therapist, a member of the Patient Reference Group, the Chief Investigator and Trial Coordinator/Manager. Other study collaborators may also attend the meeting. The independent members of the committee will be allowed to see unblinded data. The role of this committee will include the review of all serious adverse events which are thought to be treatment related and unexpected. The committee will meet at least annually or more frequently if the committee requests.

If however, the funders to not agree to one committee being set up, then separate TSC and DMEC committees will be set up. The TSC will include an Independent Chair and at least two other independent members along with the Chief Investigator and the Trial Coordinator/Manager and other study collaborators. The DMEC will comprise of an Independent Chair, a statistician and an Occupational Therapist. Both committees will meet annually. The role of the DMEC will be to immediately see all serious adverse events which are thought to be related to the intervention or being in the study and unexpected.

12.4 Trial Management Group (TMG)

A TMG will be set up. It will consist of the Chief Investigator (who will be in overall charge of the study), the trial manager (who will be in charge of the day-to-day management of the study); the study's grant co-applicants and the Principal Investigators or delegated person at sites delivering the intervention. Regular meetings will be held according to the needs of the trial. Trial progress will also be reviewed at the York Trials Unit, Trial coordinator meetings. These meetings are held by the Director of the York Trials Unit approximately every two months.

13 Publication policy

The study will provide evidence on the role of the OT in falls prevention to inform the service delivery model. It is intended that the results of the study will be reported and disseminated in

high impact peer-reviewed scientific journals. The funders, the NIHR HTA currently publish all monographs on their website http://www.hta.ac.uk/project/hta[ibs.asp and it is anticipated that the full trial report will be available approximately one year after the final report is submitted. We will also aim to publish in Occupational Therapy specific journals and newsletters for example OT News to ensure that clinical healthcare professionals have prompt access to the study's findings.

The results of the study will be submitted to the Annual Conference of the College of Occupational Therapists and Occupational Therapy Australia and to the College of Occupational Therapists Specialist Sections for Older People and for Housing to ensure maximum dissemination among the Occupational Therapy community. We will also disseminate our results to the wider Allied Health Professional Community through, for example the national Physiotherapy Congress and the Society for Research in Rehabilitation.

We will produce a short summary of the results of the study which will be distributed to all trial participants.

List of abbreviations

Abbreviation	Explanation
AE	Adverse event
CEAC	Cost-effectiveness acceptability curve
CONSORT	Consolidated Standards of Reporting Trials
EQ-5D	European Quality of Life-5 Dimensions
GP	General Practitioner
ICER	Incremental cost-effectiveness ratio
NICE	National Institute for Health and Care Excellence
OT	Occupational Therapist
QALY	Quality-adjusted life year
SAE	Serious Adverse Event
TMG	Trial Management Group
TSC	Trial Steering Committee
YTU	York Trials Unit

FALLS PREVENTION
HOME AND COMMUNITY SAFETY

WESTMEAD HOME SAFETY ASSESSMENT LONG FORM

Participant trial ID number ☐☐ ☐☐☐☐☐

Name of THERAPIST: _____ DATE OF VISIT: ____ / ____ / _____

TYPE OF RESIDENCE: _____ OWNERSHIP: _____

DIAGNOSIS: _____ AGE: _____

No. FALLS PAST YEAR: _____ FUNCTIONAL VISION: _____

MOBILITY: _____

FUNCTIONAL COGNITION: _____

HOME & COMMUNITY SUPPORTS/ASSISTANCE: _____

Timed up and go -- ☐☐☐ seconds

SUMMARY AND ACTION PLAN

_____

_____

_____

_____

_____

_____

_____

_____

EXTERNAL TRAFFICWAYS

GATES

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Difficult to open/close
- ☐ Slippery surface near gate
- ☐ Uneven surfaces near gate
- ☐ Deep steps near gate
- ☐ Poor visibility at steps near gate
- ☐ Other:

PATHWAYS / DRIVEWAYS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Slippery surfaces
- ☐ Uneven/loose surfaces
- ☐ Narrow
- ☐ Steep gradient
- ☐ Obstructions on pathways
- ☐ Poor visibility
- ☐ Other:

STEPS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Slippery surfaces
- ☐ Uneven surfaces
- ☐ Steps too high/uneven heights
- ☐ Deep tread
- ☐ Narrow stairway
- ☐ Obstacles
- ☐ Poor visibility
- ☐ Other:

RAMPS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Irregular ground surfaces
- ☐ Obstructions
- ☐ Slippery surfaces
- ☐ Unstable
- ☐ Poor visibility
- ☐ Steep gradient
- ☐ Other:

HAND RAILS – ACCESS (external steps and ramps)

	Not relevant	No hazard		Not present	Inadequate position	Inadequate angle	Inadequate diameter	Inadequate length	Not secure	Poor condition	Other:
Steps											
Ramps											

ICE / SNOW ON WALKWAYS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Slippery
- ☐ Difficulty to see / manoeuvre
- ☐ Footwear inadequate grip

LAWNS / GARDENS / GROUNDS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Irregular ground surfaces
- ☐ Obstacles
- ☐ Slippery surfaces
- ☐ Irregular lawn surface
- ☐ Steep gradient or lawn
- ☐ Large lawn
- ☐ Access to equipment
- ☐ Tools hard to use
- ☐ Other:

GARAGE

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Poor access
- ☐ Untidy
- ☐ Inadequate lighting
- ☐ Access to car
- ☐ Other:

DOORMAT

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Curled edges
- ☐ Worn areas
- ☐ Slippery
- ☐ Other:

DOOR OPENING

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ No landing for outward opening doors
- ☐ Stiff/ heavy doors
- ☐ High lock
- ☐ Multiple locks/difficult door handle
- ☐ Threshold
- ☐ Other:

NIGHTLIGHTING

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Not present
- ☐ Steps/pathways not illuminated
- ☐ Does not eliminate dark, shadowy areas
- ☐ Other:

GENERAL INDOORS

LIGHTING

☐ *Not relevant* ☐ *No hazard*

Hazards: Time observed:
- ☐ A.M
- ☐ P.M

	OT observation	Client self-report
Dark / dim		
Shadowy		
Abrupt changes		
Glare		
Other:		

TIDINESS / CLEANLINESS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Clutter
- ☐ Spills on floor
- ☐ Other:

CLEANING EQUIPMENT

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Access
- ☐ Ease of use
- ☐ Other:

IRONING AREA

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Difficulty setting up ironing board
- ☐ Other:

TELEPHONE

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Access
- ☐ No sitting area
- ☐ Access to phone books
- ☐ Other:

HEATERS / FANS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Access
- ☐ Difficulty switching on/off
- ☐ Inadequate heating
- ☐ Other:

COMMONLY OPENED WINDOWS/CURTAINS/SHADES

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Difficult to open/close
- ☐ Access
- ☐ Other:

REACHING FOR HIGH PLACES

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Unsafe when reaching
- ☐ Inaccessible storage of used items
- ☐ Unsafe when climbing
- ☐ Unstable furniture / equipment used
- ☐ Other:

INTERNAL TRAFFICWAYS

FLOORS & FLOOR COVERINGS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Slipperiness
- ☐ Slippery when wet
- ☐ Worn/loose areas or edges
- ☐ Changes in patterns & textures
- ☐ Other:

FLOOR MATS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Small & lightweight
- ☐ Slippery
- ☐ Loose
- ☐ Curled edges
- ☐ Other:

LIGHT SWITCHES / POWER POINTS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Access
- ☐ Cords across trafficways
- ☐ Other:

SPACE

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Obstacles in trafficways (furnishings)
- ☐ Obstacles in trafficways (objects)
- ☐ Unstable objects used for support
- ☐ Objects reducing space for mobility & manoeuvrability
- ☐ Proximity of walking aid when not in use
- ☐ Lack of colour contrasts
- ☐ Cords across trafficways
- ☐ Other:

DOORWAYS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Access
- ☐ Difficult to open/close
- ☐ Other:

RAMPS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Poor condition of material
- ☐ Steep gradient
- ☐ Slippery
- ☐ Unstable
- ☐ Poor visibility
- ☐ Other:

STAIRS / ELEVATORS APPROACH / DISEMBARKATION

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Access
- ☐ Obstacles
- ☐ Visibility
- ☐ Other:

STEPS / STAIRS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Slippery/loose surfaces
- ☐ Uneven coverings
- ☐ Tread coverings
- ☐ Deep tread
- ☐ Steps too high/uneven heights
- ☐ Step overhang
- ☐ Narrow stairway
- ☐ Obstacles
- ☐ Poor visibility
- ☐ Step contrasts/visual surrounds
- ☐ Other:

HANDRAILS – INTERNAL STEPS / STAIRS

	Not relevant	No hazards		Not present	Inadequate position	Inadequate angle	Inadequate diameter	Not secure	Poor condition	Other:
Steps										
Ramps										

MOBILITY AID

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Aid not appropriate
- ☐ Poor condition
- ☐ Other:

PETS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Small
- ☐ Large
- ☐ Many dogs/cats
- ☐ Playful/boisterous
- ☐ Other:

LIVING AREA

FURNITURE

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Unstable
- ☐ Other:

LAMPS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Access
- ☐ Other:

SEATING

☐ *Not relevant* ☐ *No hazard*

Indicate relevant area (e.g. lounge, kitchen)

	Tow low	Too high	Too soft	No arms	Back too sloped	unstable	Poor access	Splayed legs	Cushions	Other:
1.										
2.										
3.										

MEDICATION MANAGEMENT

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Access to medications
- ☐ Difficulty to open / close containers
- ☐ Reminder aid not in place
- ☐ Instructions not readable/understandable
- ☐ Other:

SAFETY CALL SYSTEM

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ No alarm system / plan of action
- ☐ Other:

BEDROOM

BED

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Too low
- ☐ Too high
- ☐ Too soft
- ☐ Worn mattress
- ☐ Unstable
- ☐ Poor access
- ☐ Difficulty transferring
- ☐ Unstable furniture used for transferring
- ☐ Other:

WARDROBES / CUPBOARDS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Difficult to open/close
- ☐ Poor access
- ☐ Difficulty reaching daily clothing
- ☐ Other:

CURTAINS / BED COVERS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Trailing in trafficways
- ☐ Other:

BED LIGHTING

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Not present
- ☐ Poor access
- ☐ Other:

BEDSIDE TELEPHONE

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Poor access
- ☐ Other:

COMMODE

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Poor access
- ☐ Inadequate height
- ☐ Other:

FOOTWEAR

☐ *Not relevant* ☐ *No hazard*

(E.g. Indoors/outdoors, special occasions, slippers, etc.)

	Improper fit	Open/worn down heel	Slippery heel/sole	High heel	Thickness of soles	Narrow heel	Stocking feet	Other:
1.								
2.								
3.								

BATHROOM

LOCATION

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Poor proximity
- ☐ Hazardous trafficways en route
- ☐ Other:

FLOOR SURFACE

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Slippery when wet
- ☐ Slippery when dry
- ☐ Slippery mats or curled edges
- ☐ Worn floor covering
- ☐ Raised or loose tiles
- ☐ Other:

SHOWER RECESS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Poor access
- ☐ Narrow doorway
- ☐ High hob / sill
- ☐ Slippery floor in recess
- ☐ Slippery shower mat
- ☐ Uneven floor surface
- ☐ Difficulty reaching toiletries
- ☐ Difficulty reaching taps
- ☐ Unstable shower chair or stool
- ☐ Other:

BATH / OVERHEAD SHOWER

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Unstable bathseat
- ☐ Narrow bathseat
- ☐ High sides
- ☐ Poor access
- ☐ Slippery bath
- ☐ Slippery bathmat
- ☐ Difficulty reaching taps
- ☐ Difficulty turning water heater on/off
- ☐ Other:

TOILET AREA

LOCATION

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Poor proximity
- ☐ Hazardous trafficways en route
- ☐ Inadequate night lighting
- ☐ Other:

FLOOR COVERINGS

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Slippery when wet
- ☐ Slippery when dry
- ☐ Slippery mats or curled edges
- ☐ Worn floor covering
- ☐ Uneven floor surface
- ☐ Other:

TOILET

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Poor access
- ☐ Too low
- ☐ Too high
- ☐ Difficulty reaching toilet roll
- ☐ Difficulty reaching flush
- ☐ Inadequate lighting in room
- ☐ Other:

GRABRAILS – BATHROOM / TOILET

	Not relevant	No hazard		Not present	Inadequate position	Inadequate angle	Inadequate diameter	Inadequate length	Not secure	Poor condition	Other:
Bath											
Shower											
Toilet											

KITCHEN

USAGE

- ☐ Not relevant
- ☐ Drink only
- ☐ Light meals
- ☐ All meals

PROXIMITY OF KITCHEN TO EATING AREA

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Not directly adjacent to each other
- ☐ Steps en route
- ☐ Other:

KITCHEN WORK AREAS / EQUIPMENT

	Not relevant	No hazard		Poor access	untidy	Working height
Workplace						
Commonly used items						
Power points						
Sink						
Jug/Kettle						
Fridge						
Freezer						
Oven						
Grill						
Hot plates						
Microwave						
Dishwasher						
Other						

GARBAGE

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Kitchen tidy access
- ☐ Taking garbage to bin
- ☐ Garbage bin access
- ☐ Garbage bin to street
- ☐ Other:

LAUNDRY

LOCATION

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Trafficway from house to laundry
- ☐ Trafficway from laundry to drying area
- ☐ Poor proximity to house
- ☐ Poor proximity to drying area
- ☐ Other:

WASHING MACHINE

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Poor access
- ☐ Other:

DRIER

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Poor access
- ☐ Other:

CLOTHES LINE

☐ *Not relevant* ☐ *No hazard*

Hazards:
- ☐ Taking washing to line
- ☐ Poor access
- ☐ Difficult to set up
- ☐ Access to pegs
- ☐ Other:

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Protocol changes:

Protocol version 2 [21.12.16]

The following changes were made to the original version of the protocol:

- Opportunistic screening of family members, friends, referrals from other HCP or NHS services, radio, newspaper or TV advertisement, YTU research staff events.
- OTs many carry a 'grab bag', contents within normal trust policy
- End of recruitment date updated
- Update to when questionnaire reminders are sent to participants

Protocol version 3 [20.02.17]

- Clarification to recruitment methods
- Information included about an additional sub-study about hand written name on an invitation letter to improve response rates to uptake to the study

Protocol version 4 [23.5.17]

- Clarification to recruitment methods

Protocol version 5[23.5.17]

- Clarification to recruitment methods

Protocol version 6 [31.07.17]

- Clarification to recruitment methods