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# Occupational therapist home assessment and modification for prevention of falls

**Submission date**
20/06/2016

**Recruitment status**
No longer recruiting

**Registration date**
21/06/2016

**Overall study status**
Completed

**Last Edited**
04/06/2025

**Condition category**
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
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 involved 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 fewer 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 fewer 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 fewer 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.

Who can participate?
Community-dwelling men and women aged 65 years and over who are at an increased risk of falling (i.e., who have either had at least one fall in the past 12 months or tell us that they worry about falling in their day-to-day lives) will be eligible to participate. Participants who are unable to walk 10 feet (with or without a walking aid), are unable to give informed consent (e.g. due to Alzheimer's disease or dementia), live in a residential or nursing home, are 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 previous 12 months, and/or are on a waiting list for an occupational therapy assessment or who have not completed one falls calendar in the three months prior to randomisation will be excluded.

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives usual care from their GP or other healthcare professional and a falls prevention leaflet. In addition to usual care and a falls prevention leaflet, the other group receives a home environmental assessment by an occupational therapist to assess their home for dangers and make recommendations for changes. Four weeks after the home visit the therapist, or a member of the research team, rings

the participant to find out if the recommendations made have been followed. Participants are asked, by filling in monthly falls calendars and postal questionnaires, if they've had a fall and if so how many, about their quality of life and how often they use NHS services. Within the main trial, four sub-studies are embedded to investigate whether i) the inclusion of a pen in recruitment packs increases the likelihood of participants taking part in the trial; ii) receiving an invitation letter with a hand-written name increases the likelihood of participants taking part in the trial relative to a letter with a printed name; and iii) receiving a personalised text message around the same time as the 4-month questionnaire increases response rates relative to receiving a non-personalised text message at the same time and iv) whether including a pen, a cover letter with social incentive text (i.e. inclusion of text and a table summarising previous questionnaires returned), both interventions or neither intervention with the 12-month questionnaire, on the 12-month postal questionnaire affects response rates of participants to the OTIS study.

What are the possible benefits and risks of participating?
We cannot promise that taking part in the study will help participants personally. However, it may help us find out how to reduce the number of falls older people have. We are not aware of any known risks to participants as the aim of the intervention being tested is to reduce falls.

Where is the study run from?
University of York, Department of Health Sciences, York Trials Unit (UK)

When is the study starting and how long is it expected to run for?
July 2016 to December 2019

Who is funding the study?
National Institute for Health Research - Health Technology Assessment Programme (UK)

Who is the main contact?
Caroline Fairhurst, caroline.fairhurst@york.ac.uk

### Study website
https://www.york.ac.uk/healthsciences/research/trials/research/trials/otis/#tab-3

# Contact information

### Type(s)
Scientific

### Contact name
Ms Caroline Fairhurst

### ORCID ID
https://orcid.org/0000-0003-0547-462X

### Contact details
York Trials Unit
Department of Health Sciences
Faculty of Sciences
Ground Floor ARRC Building
University of York

Heslington
York
United Kingdom
YO10 5DD
+44 (0)1904 321513
caroline.fairhurst@york.ac.uk

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
HTA 14/49/149; 1.0

# Study information

### Scientific Title
Does occupational therapist led home environmental assessment and modification reduce falls among high-risk older people?

### Acronym
OTIS

### Study objectives
Current hypothesis as of 14/02/2018:
Main OTIS trial hypothesis: The null hypothesis is that there is no difference in the number of falls people over the age of 65 years who are of high risk of falling, have in the 12 months post randomisation between the two trial groups. The intervention group will receive an occupational therapist led home environmental assessment and modification, and a falls prevention leaflet as well as usual care from their GP and/or other healthcare professionals. The control group will receive the falls prevention leaflet and usual care from their GP and/or other healthcare professionals.

Pen sub-study hypothesis: The null hypothesis is that there is no difference in the proportion of participants allocated to receive a pen with their trial invitation pack who go on to be randomised to the main OTIS trial, than in the group who do not receive a pen.

Invitation letter sub-study hypothesis: The null hypothesis is that there is no difference in the proportion of participants who are randomised for the OTIS study between those who receive an invitation letter with their name handwritten on compared with a printed name.

Text sub-study hypothesis: The null hypothesis is that there is no difference in the proportion of participants returning their 4-month questionnaire between the group that receive a personalised text message when their questionnaire is due and those that receive a non-personalised text message.

Added 12/06/2020: Social incentive cover letter and/or pen sub-study hypothesis: The null hypothesis is that there is no difference in postal response rates between participants in the main OTIS trial who received either a pen alone, a pen and cover letter containing social incentive text, no pen and a standard cover letter or a social incentive cover letter alone.

Previous hypothesis:
Main OTIS trial hypothesis: The null hypothesis is that there is no difference in the number of falls people over the age of 65 years who are of high risk of falling, have in the 12 months post randomisation between the two trial groups. The intervention group will receive an occupational therapist led home environmental assessment and modification, and a falls prevention leaflet. The control group will receive the falls prevention leaflet and usual care from their GP and/or other healthcare professionals.

Pen sub-study hypothesis: The null hypothesis is that there is no difference in the proportion of participants allocated to receive a pen with their trial invitation pack who go on to be randomised to the main OTIS trial, than in the group who do not receive a pen.

Text sub-study hypothesis: The null hypothesis is that there is no difference in the proportion of participants returning their 4-month questionnaire between the group that receive a personalised text message when their questionnaire is due and those that receive a standard text message.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. West of Scotland REC 3 committee, 08/08/2016, ref: 16/WS/0154
2. University of York, Department of Health Sciences Research Governance Committee, 20/05/2016
Added 14/02/2018: 3. West of Scotland REC 3 committee approved the invitation letter sub-study on 20/03/2017

## Study design
Current study design as of 12/06/2020:
Multicentre open modified cohort randomised controlled trial with an embedded qualitative study, economic evaluation and four studies within a trial (SWATs).

Previous study design as of 14/02/2018:
Multicentre open modified cohort randomised controlled trial with an embedded qualitative study, economic evaluation and three studies within a trial (SWATs)

Previous study design:
Multicentre open randomised controlled trial with an embedded qualitative study, economic evaluation and two studies within a trial (SWATs)

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Community

## Study type(s)
Prevention

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Falls prevention

## Interventions
Current interventions as of 14/02/2018:
Main OTIS trial: Participants will be randomly allocated 2:1 in favour of the control group to receive either:

1. Usual care from their GP or other healthcare professional and a falls prevention leaflet; or

2. One home environmental assessment and modification to identify personal fall related hazards by an occupational therapist, in addition to usual care and a falls prevention leaflet.

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 assessments.

Pen sub-study: Participants will be randomised in a 2:1 ratio in favour of the control group to receive no pen or to receive a pen with their trial invitation pack.

Invitation letter sub-study: Participants due to be sent an invitation pack in the first mail out from the Yorkshire Health Study will be randomised 1:1 to receive either an invitation letter with their name handwritten on or an invitation letter with their name printed.

Text sub-study: Trial participants will be randomised 1:1 to receive either a personalised text message or a non-personalised text message from the York Trials Unit at the time their four month follow-up questionnaire is due to be received.

Added 12/06/2020: Social incentive sub-study: Participants will be randomised in a 1:1:1:1 ratio to receive either a pen alone, a pen and cover letter containing social incentive text, no pen and a standard cover letter or a social incentive cover letter alone.

Previous interventions:
Main OTIS trial: Participants will be randomly allocated 2:1 in favour of the control group to either:
1. Usual care from their GP or other healthcare professional and a falls prevention leaflet
2. In addition to usual care and a falls prevention leaflet, the intervention group will receive one home environmental assessment and modification to identify personal fall related hazards by an occupational therapist.

Pen sub-study: Participants will be randomised in a 2:1 ratio in favour of the control group to receive either no pen or to receive a pen with their trial invitation pack.

Text sub-study: Trial participants will be randomised in a 1:1 ratio to receive either a personalised text or a standard text from the York Trials Unit at the time their four month follow-up questionnaire is due to be received.

## Intervention Type
Other

## Primary outcome measure
Current primary outcome measures as of 14/02/2018:
Main OTIS trial: 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”, as collected prospectively via participant-reported monthly falls calendars.

Pen sub-study: The proportion of participants who go on to be randomised into the main OTIS trial.

Invitation letter sub-study: The proportion of participants who go on to be randomised to the main OTIS trial.

Text sub-study: The proportion of four-month questionnaires returned to the York Trials Unit.

Added 12/06/2020: Social incentive cover letter and/or pen sub-study hypothesis: The primary outcome was response rate, defined as the proportion of participants in each group who returned the 12-month questionnaire.

Previous primary outcome measures:
Main OTIS trial: 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”, as collected prospectively via participant-reported monthly falls calendars.

Pen sub-study: The proportion of participants sent a trial invitation pack who go on to be randomised into the main OTIS trial.

Text sub-study: The proportion of four-month questionnaires returned to the York Trials Unit.

## Secondary outcome measures
Current secondary outcome measures as of 14/02/2018:
Main OTIS trial:
1. Health-related Quality of Life as measured by the EQ5D-5L at 4, 8 and 12 months
2. Proportion of participants reporting at least one fall in the 12 months from randomisation
3. Proportion of participants reporting multiple (2 or more) falls in the 12 months from randomisation
4. Time to first fall from date of randomisation, with censoring at date of withdrawal, death or end of 12 month follow-up
5. Fear of falling at 4, 8 and 12 months
6. Fall-related injuries and costs over the 12 months post randomisation
7. Patient self-reported fractures over the 12 months post randomisation

Pen sub-study:
1. The proportion of participants who return a screening form
2. Time to return screening form
3. The proportion of participants who fulfil the eligibility criteria apart from the criterion relating to falls within the past 12 months or fear of falling
4. The proportion of participants eligible for randomisation
5. The proportion of participants who remain in the trial for 3 months post randomisation.

Invitation letter sub-study:
1. The proportion of participants who return a screening form
2. Time to return screening form
3. The proportion of participants who fulfil the eligibility criteria apart from the criterion relating to falls within past 12 months or fear of falling
4. The proportion of participants who are eligible for randomisation
5. The proportion of participants who remain in the trial for 3 months post randomisation.

Text message sub-study:
1. Time to response i.e. number of days between the questionnaire being mailed out to the participant and the questionnaire recorded as being returned to York Trials Unit
2. The proportion of participants requiring a reminder
3. Completeness of questionnaires
4. Cost effectiveness of the text message intervention

Added 12/06/2020: Social incentive cover letter and/or pen sub-study:
1. Time to return 12-month questionnaire
2. The completeness of the 12-month questionnaire
3. The requirement for a reminder letter to be sent
4. Cost effectiveness

Previous secondary outcome measures:
Main OTIS trial:
1. Health-related Quality of Life as measured by the EQ5D-5L at 4, 8 and 12 months
2. Proportion of participants reporting at least one fall in the 12 months from randomisation
3. Proportion of participants reporting multiple (2 or more) falls in the 12 months from randomisation
4. Time to first fall from date of randomisation, with censoring at date of withdrawal, death or end of 12 month follow-up
5. Fear of falling at 4, 8 and 12 months
6. Fall-related injuries and costs over the 12 months post randomisation
7. Patient self-reported fractures over the 12 months post randomisation

Pen sub-study:
1. Proportion of patients retained in the trial at 3 months post randomisation defined as returning at least the first 3 months' worth of falls calendars from the date of randomisation
2. Number of ineligible participants

Text sub-study:
1. Time to response i.e. number of days between the questionnaire being mailed out to the participant and the questionnaire recorded as being returned to York Trials Unit
2. The proportion of participants requiring a reminder
3. Completeness of questionnaires
4. Cost effectiveness of the text message intervention

### Overall study start date
01/07/2016

### Completion date
31/12/2019

# Eligibility

### Key inclusion criteria
Current participant inclusion criteria as of 14/02/2018:
Main OTIS study:
1. Aged 65 years and over
2. Willing to receive a home visit from an Occupational Therapist
3. Community dwelling
4. 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
If a respondent is initially 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 and consent to being re-contacted, they will be rescreened at a later date and given the opportunity to take part in the study if they subsequently have a fall or report a fear of falling and therefore, meet the inclusion criteria.

OTIS qualitative study: Occupational Therapists delivering the OTIS intervention, clinical leads who run falls prevention services/care of older people services and services external to the trial will be eligible to be involved in the qualitative study.

Pen sub-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.

Invitation letter sub-study: Participants who are due to be mailed out an invitation pack about the OTIS trial in the first mailout by the Yorkshire Health Study will be entered into the invitation latter sub-study.

Text sub-study: Participants who provide a mobile phone number and consent to be contacted by this method, and who are due to be sent their four month follow-up questionnaire, will be included in this sub-study.

Added 12/06/2020: Social incentive cover letter and/or pen sub-study: Any participant due to receive their 12-month questionnaire

Previous inclusion criteria:
Main OTIS study:
1. Aged 65 years and over
2. Willing to receive a home visit from an Occupational Therapist
3. Community dwelling
4. 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 or be a former REFORM trial participant

OTIS qualitative study: Occupational Therapists delivering the OTIS intervention, clinical leads who run falls prevention services/care of older people services and services external to the trial.

Pen sub-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.

Text sub-study: Participants who provide a mobile phone number and consent to be contacted by this method, and who are due to be sent their four month follow-up questionnaire will be included in this sub-study.

## Participant type(s)
Mixed

## Age group
Senior

## Lower age limit
65 Years

## Sex
Both

## Target number of participants
Main OTIS trial: 1299 (n=433 Intervention group; n=866 Usual Care group); OTIS qualitative study n=30; SWATs: Added 14/02/2018: targets for pen and text sub studies constrained by number of participants mailed out to via GP mail outs and those remaining in the trial at 4 months post randomisation; and those remaining in the trial at 12 months, respectively. 314 participants will be included in the invitation letter sub-study. Added 12/06/2020: 779 participants will be included in the social incentive cover letter and/or pen sub-study

## Total final enrolment
1331

## Key exclusion criteria
Current exclusion criteria as of 14/02/2018:
Main OTIS trial:
1. Unable to walk 10 feet today, even with a walking aid if needed
2. Unable to give informed consent e.g., due to suffering from dementia or Alzheimer's disease
3. Living in residential or nursing home
4. Unable to read or speak English and have no friend or relative who is able to translate /interpret for them
5. Had an OT assessment for falls prevention in the previous 12 months
6. Are on a waiting list for an occupation therapy assessment
7. Have not returned one completed falls calendar in the 3 months prior to randomisation

Pen sub-study: Participants in the REFORM, CASPER and Yorkshire Health Study cohorts and the SCOOP study will be excluded from the sub-study.

Text sub-study: Participants who withdraw from the OTIS main trial follow-up before their 4-month questionnaire is due will be excluded from this sub-study.

Invitation letter sub-study: Participants who have not agreed to be contacted about future studies.

Previous exclusion criteria:
Main OTIS trial:
1. Unable to walk 10 feet today, with a walking aid if needed
2. Unable to give informed consent e.g., due to suffering from dementia or Alzheimer's disease
3. Living in residential or nursing home
4. Do not speak English
5. Had a home assessment in the previous 12 months as a result of falling
6. Are on a waiting list for an occupation therapy assessment
7. Have not completed one falls calendar in the 3 months prior to randomisation

Pen sub-study: Participants in the REFORM, CASPER and Yorkshire Health Study cohorts and the SCOOP study will be excluded from the sub-study.

Text sub-study: Participants who withdraw from the OTIS main trial follow-up before their 4-month questionnaire is due will be excluded from the mail out.

### Date of first enrolment
01/08/2016

### Date of final enrolment
02/08/2018

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
### Sheffield Teaching Hospitals NHS Foundation Trust
Sheffield
United Kingdom
S10 2JF

### Study participating centre
### Harrogate Hospital
Harrogate
United Kingdom
HG2 7SX

### Study participating centre

**NHS Humber**
Hull
United Kingdom
HU10 6ED

**Study participating centre**
**East Sussex Healthcare NHS Trust**
Seaford
United Kingdom
BN25 1DH

**Study participating centre**
**East Coast Community Healthcare**
Lowestoft
United Kingdom
NR32 1DE

**Study participating centre**
**North Lincolnshire and Goole NHS Foundation Trust**
Scunthorpe
United Kingdom
DN15 7BH

**Study participating centre**
**Leeds Community Healthcare NHS Trust**
Leeds
United Kingdom
LS12 5SG

**Study participating centre**
**York Teaching Hospital NHS Foundation Trust**
York
United Kingdom
YO31 8HE

# Sponsor information

### Organisation
University of York (UK)

### Sponsor details
Contracts and Sponsorship Manager
Research and Enterprise
University of York
Innovation Centre
York Science Park
York
England
United Kingdom
YO10 5DG
+44 (0)1904 435154
michael.barber@york.ac.uk

### Sponsor type
University/education

### ROR
https://ror.org/04m01e293

## Funder(s)

### Funder type
Government

### Funder Name
Health Technology Assessment Programme

### Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

## Results and Publications

### Publication and dissemination plan

The main trial results and study protocol will form the basis of academic papers in peer-reviewed journals.
The outcomes of the trial will be presented as a conference paper on completion of the trial.

## Intention to publish date
14/01/2020

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary
Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | invitation letter sub-study results | 14/05/2019 | 02/06/2020 | Yes | No |
| Results article | pen sub-study results | 21/03/2019 | 02/06/2020 | Yes | No |
| Protocol article | protocol | 10/09/2018 | 15/01/2021 | Yes | No |
| Results article | text message sub-study results | 26/02/2020 | 15/01/2021 | Yes | No |
| Results article | | 01/07/2021 | 14/07/2021 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Results article | pen and/or cover letter sub-study results | 17/06/2020 | 10/07/2023 | Yes | No |