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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
06/07/2026

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

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

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)

Study type(s)
Prevention

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(s)
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.

Key secondary outcome(s)

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

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.

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 Years

Upper age limit
100 Years

Sex
All

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
United Kingdom

England

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
England
S5 7AU

Study participating centre
Harrogate District Hospital
Lancaster Park Road
Harrogate
England
HG2 7SX

Study participating centre
NHS Humber
-
Hull
England
HU10 6ED

Study participating centre
East Sussex Healthcare NHS Trust
-
Seaford
England
BN25 1DH

Study participating centre
East Coast Community Healthcare C.i.c
Hamilton House
Battery Green Road
Lowestoft
England
NR32 1DE

Study participating centre
North Lincolnshire and Goole NHS Foundation Trust
-
Scunthorpe
England
DN15 7BH

Study participating centre
Leeds Community Healthcare NHS Trust
-
Leeds
England
LS12 5SG

Study participating centre
York and Scarborough Teaching Hospitals NHS Foundation Trust
York Hospital
Wigginton Road
York
England
YO31 8HE

Sponsor information

Organisation
University of York (UK)

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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		01/07/2021	14/07/2021	Yes	No
Protocol article		10/09/2018	15/01/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Invitation letter sub-study results	14/05/2019	02/06/2020	Yes	No
Other publications	Pen sub-study results	21/03/2019	02/06/2020	Yes	No
Other publications	Text message sub-study results	26/02/2020	15/01/2021	Yes	No
Other publications	Pen and/or cover letter sub-study results	17/06/2020	10/07/2023	Yes	No
Other publications		22/10/2024	06/07/2026	Yes	No
Study website		11/11/2025	11/11/2025	No	Yes