

## The OTIS study:

A research study about falls

### *Can you help?*



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### We invite you to take part in a study

- Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully and decide whether or not you wish to take part.
- It's up to you to decide if you take part or not. Ask us if there is anything that is not clear or if you would like more information. Talk to others about the study if you wish.
- If you have any questions, please contact us.
- Thank you for reading this information sheet.

### Contact details

If you require further information about this study, you can contact the study co-ordinator at York Trials Unit:

[insert contact name]

Telephone: [insert number]

### Why are we doing this study?

Falling is a common problem among older people. In fact, up to half of people over 80 may fall each year with most falls happening in the home. Unfortunately some falls cause serious injuries, such as broken bones. People often think that falls are part of getting old and that little can be done to stop them. However, there are many different ways to reduce falls such as changing footwear, checking your eyesight or reviewing the medications you take. Reducing hazards in the home, such as slippery floors and poor lighting, may also prevent falls. This study aims to find out if a home visit by an occupational therapist to assess and tackle these possible hazards can reduce the number of falls people have.

### Why am I being asked to take part?

The University of York is working together with NHS occupational therapy services across the UK to help conduct this study. People over the age of 65 are being asked if they would like to take part. We have sent you this invitation as you have previously taken part in the **REFORM study / CASPER study / SCOOP study/ Yorkshire Health Study {delete as appropriate}** and agreed to be contacted about further studies.

If you are interested in taking part after reading this information sheet we would be happy to hear from you. However, unfortunately on this occasion we are unable to include the following people who:

- Are unable to walk 10 feet today, with a walking aid if needed
- Live in a residential or nursing home
- Suffer from Alzheimer's disease or dementia
- Have had a visit by an Occupational Therapist within the past 12 months because they have fallen

## 1 What happens in this study?

People in this study will have either:

- A. At least one home visit from an occupational therapist
- or
- B. Normal care from the GP and other health professionals

### A. Visit from an occupational therapist

If you are offered a home visit by an occupational therapist we will contact you to arrange this. The visit will last around 2 hours. The occupational therapist may visit your home for a second or third time, if necessary.

At the home visit an occupational therapist will work with you to identify potential hazards that could lead to falls. You will be asked to show how you do everyday tasks such as getting in and out of the chair and on and off your bed. The occupational therapist will then work with you to identify safer ways of carrying out the tasks that are acceptable to you. The occupational therapist may recommend equipment to make the tasks safer. The equipment may be provided free of charge. It is entirely up to you if you accept the offer of equipment.

After four weeks either the Occupational Therapist who visited you or a member of the research team based at the University of York, York Trials Unit will call you to check how you are doing with any changes.

The occupational therapist may look at your medical records or contact your GP for information about you that they need in order to help them deliver the intervention.

## 2 What will I need to do if I take part ?

### B. Normal care from your GP and other health professionals

If you are offered normal care from your GP and other health professionals, your healthcare will continue as usual. We will also send you some advice about how to prevent falls.

If you agree to take part, we would first ask you to fill in some short questionnaires about yourself and return them to us.

We would then send you a calendar, which we would ask you to complete and return to us each month. It records whether or not you have fallen during that month. If you prefer, you can choose to call us on a free phone number to let us know if you have fallen.

After 4, 8 and 12 months we will send you some questionnaires to fill in. We expect they will take you about 20 minutes to fill in on each occasion. We will provide stamped addressed envelopes so it will not cost you anything to return the questionnaire.

If you do have a fall at any time, we would ask you to ring the researchers at the University of York, who will ask you some questions about it. If you prefer, a family member or a friend can contact us on your behalf.

If you agree to take part in the study, we would ask for your help for no more than 18 to 24 months in total. The information you provide will allow us to follow your health and see if it changes over time.

### 3 What are the possible benefits and disadvantages of taking part in the study?

- We cannot promise that taking part will help you personally. However it may help us find out how to reduce the number of falls older people have.
- Taking part in this study will involve some of your time to complete questionnaires.
- If you are offered a visit from an occupational therapist they will need to visit your home.
- Unfortunately we cannot offer any expenses or payments to people who take part in this study.

### 4 More information about taking part

#### Do I have to take part?

No, taking part is entirely voluntary. If you decide not to participate, it will not affect the treatment you receive now or in the future. If you do take part you can withdraw at any time without having to give a reason.

#### Will taking part in this study cost me anything, and will I be paid?

Participation in this study will not cost you anything but there will not be any payment for taking part.

#### Will my GP be notified of my participation in this study?

If you agree to take part we will inform your GP. We will also contact your GP if we have any concerns about your health during your participation. If you do have a fall we may ask if we can contact your GP to find out some further information.

#### Can I take part in the study if I have never fallen?

Even if you haven't fallen, you may still be able to take part in the study. If you are not eligible for the study we will write and let you know.

#### What is a fall?

For this study we are interested in any falls regardless of the reason. We would like to know about any fall you have including a slip or trip in which you lost your balance and landed on the floor or ground or lower level.

#### Who is running and funding the research?

This study is being organised by the University of York. The OTIS Study is funded by the National Institute for Health Research's Health Technology Assessment Programme. Before any research goes ahead it is looked at by an independent group of people called a Research Ethics Committee to protect your interests. This study has been reviewed and approved by the West of Scotland Research Ethics Committee. It has also been reviewed by your local hospital Trust Research and Development Committee.

All people who decide to take part will be sent a summary of the results. You can also request copies of any published information by contacting the study co-ordinator.

If you decide not to take part in the study but would like to receive a copy of the results you can contact [insert contact name] at the Trials Unit directly, at the University of York (see page 1).

#### Will my taking part in the study be kept confidential?

Any information you provide us with will be treated in confidence. At the beginning of the study we will record your name, address, telephone number and date of birth and keep a copy of your signed consent form. This information will be stored securely at the University of York in accordance with the Data Protection Act 1998. Your name will not be mentioned in any publications arising from the study and we will ensure that individuals cannot be identified from details in reports of the study results. If you agree to us contacting you about other studies, we will keep your personal data for a total of 10 years after the study has finished to allow us to do this. Researchers working at the University of York, York Trials Unit may have access to your details. If you withdraw from the study at any time, the information you have already provided will be used in anonymous form for the purposes of the study, unless you inform us otherwise.

If you agree to us sending a text message your mobile number will be stored on a secure management system at the University of York. Text messages will be sent using a secure UK based text messaging service managed by a third party organisation. The University of York and third party organisation will not use your mobile number for any other purposes and your information will not be shared with anyone else.

### What will happen to the data collected in the study?

The results of this study may be published or presented at scientific meetings and in journals so health professionals caring for similar populations can learn from your experience. The costs of treatment will also be explored to see if an occupational therapist home visit is a cost-effective way to prevent falls. Anonymised data that you provide may be used by authorised researchers studying other relevant research projects. Please let us know if you do not agree to this.

### What if there is a problem?

If you have concerns about any aspect of this study first of all please contact the OTIS study co-ordinator [insert name], who will do her best to answer your questions. Please see page 1 for her contact details. If you prefer you can contact the local principal investigator ([PI name and contact telephone]) or your local Patient Advice and Liaison Service <insert phone no.>

While we anticipate no harm or distress to anyone as a result of this study it is important to state that there are no special compensation arrangements. If you are harmed due to someone's negligence, then you have ground for legal action but you may have to pay for it. Regardless of this if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you.

The OTIS study is funded by the National Institute for Health Research's Health Technology Assessment Programme.

### How can I find out about the results of the study?

This study is due to finish in **XX 20XX**. Let us know if you would like the results of the study.

## 5

### What do I do now?

Having read the information you have the following options:

#### Yes I want to take part

If you want to take part in the study, please fill in and sign the **yellow** consent form and the background information form and return them in the envelope provided (no stamp needed). Please keep this information booklet.

If you need any help to complete the forms, please phone us and we will be happy to help.

We will then write to you in a few weeks to ask you to fill in a short questionnaire. We will write to you to confirm you are involved in the study and tell your GP.

#### No I do not want to take part

There is no need to do anything if you do not want to take part.

#### I am unsure and want more information

We would be pleased to answer any questions. Please contact the study co-ordinator [insert name] ([insert number]). If there is no answer please leave a message and we will contact you as soon as possible.

### Thank you for reading this information sheet

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