



## PARTICIPANT INFORMATION SHEET

We are inviting you to take part in a research study. Before you decide if you want to take part, please take time to read carefully the information in this leaflet. You can talk about the study with other people if you wish.

### **What is the purpose of the study?**

The study will investigate how NHS general practices can best help people aged over 70 to retain good balance and function, and avoid problems like falls and fractures. To do this, we will collect health information on 9,000 people from up to 60 practices in England. We will ask the practices to advise patients on approaches and treatments to help retain balance and function, and improve health. We will study people over 12 months. The results of this study will guide the government, doctors and other healthcare workers to know how best to support patients in the future.

### **Why have I been chosen?**

Your general practice has agreed to help us with this study. We are inviting a selection of 300 patients from your practice to provide information on their health and well-being for this study. You have been selected as one of these people. The selection is based on a lottery process i.e. it is determined by chance and not any other issues.

### **Do I have to take part in the study?**

No. It is up to you to decide if you want to take part. If you decide not to take part, the usual care you receive from your GP will not be affected in any way. If you agree to take part, you can withdraw from the study at any time without having to give a reason.

### **What will I be asked to do if I take part in the study?**

If you want to take part in the study you will need to initial and sign the enclosed consent form and return it in the freepost envelope provided. This consent form gives permission for us to look at some information from your medical records. This would include your GP and hospital records and the NHS Information Centre records. An NHS health professional or other authorised researcher would review your medical records to get the information we need. We do not wish to look at all information, only that which involves any fracture in the year before the study, and during the course of the study, a review of the prescriptions, general practice attendances and hospital attendances and admissions, for the same time period. In the first instance we would examine your records for a one year period only. If the treatments provided in the study are successful, we would study your records for up to 3 years in the same way so that we can study the long term effect.

You would be asked to complete 3 questionnaires which would be posted to you at four month intervals over the next 12 months. A freepost envelope will be provided for their return. Each questionnaire will take approximately 30 minutes to complete. We would also ask you at some point in the next 12 months to complete a diary recording if you have had any falls. This will involve writing the number of falls each day on the diary for four months, and we would ask you to return the diary every month. Writing this number in the diary takes a few seconds each day. The diary is returned by freepost. We may telephone you when we receive the diary, if you tell us you have had a fall, to collect some more information.

**What are the possible risks of taking part?**

We do not think there are any risks with taking part in this study. We are asking you to complete brief questionnaires and to let us to have information from the health care records held by your general practice and/or the NHS.

**What are the possible benefits of taking part?**

The findings of this study will help healthcare professionals, such as your GP, to know how they can best support older people to maintain their balance and function, and to avoid problems of falls and fractures.

**Who will know that I am taking part?**

The only people who will know that you are taking part will be members of the study team and your GP. You are free to tell anyone that you are taking part if you wish.

**Will my details be kept confidential?**

Yes. All information that is collected during the study will be kept confidential at all times and in compliance with the Data Protection Act 1998.

**How will records from the study be stored?**

All paper records from the study will be stored in a locked cabinet in a locked office and only members of the study team have access. All information stored on computer will be protected by a password that is known only to the study team.

**What happens when the research project stops?**

You will continue to be treated as usual by your GP.

**What will you do with the findings of the study?**

The findings of the study will be reported to the NHS and published in relevant medical journals. We will also present the findings to doctors, nurses and other health and social care professionals in the UK.

**Who is organising and paying for the study?**

The study is being co-ordinated by the University of Warwick, and is being led by Professor Sallie Lamb. The study is funded by the NHS, who have identified this study as an important piece of research for the NHS. The study has been reviewed by the Derbyshire Research Ethics Committee.

**What if I want to complain?**

If you wish to make a complaint, please contact: The University Secretary's Office, University House, University of Warwick, Coventry CV4 7AL (Tel: 024 7652 3523).

**How can I contact the study team?**

If you have any questions about the study, or your involvement in it, either now or in the future, do please contact the study team either by telephone Freephone: 0800 634 0439, email: [prefit@warwick.ac.uk](mailto:prefit@warwick.ac.uk) or in writing:

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