

# Prevention of Fall Injury Trial

<b>Submission date</b> 02/02/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 13/04/2010	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 03/10/2023	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Falls and fractures are common and serious health problems for older people. A large study is needed to find out which types of treatments are most effective at preventing falls; whether they reduce fractures as well as falls; whether the treatments have effects on other problems that occur alongside or are linked to falls; and whether the treatments work best in people who are fitter or those who are frail. Because falls are a very common problem, we need to find out how acceptable the treatments are, and if people will naturally be more attracted to some types of treatments than others. We have designed a study that is able to answer these questions.

### Who can participate?

Patients aged over 70 who are living in the community including sheltered or supported accommodation

### What does the study involve?

Participating practices are randomly allocated to deliver one of following three falls prevention interventions to their patients: either advice only, advice with exercise, or advice with multifactorial falls prevention (MFFP). Patients are followed up for 18 months.

### What are the possible benefits and risks of participating?

None

### Where is the study run from?

The University of Warwick (UK)

### When is the study starting and how long is it expected to run for?

June 2010 to February 2019

### Who is funding the study?

NIHR Health Technology Assessment Programme - HTA (UK)

### Who is the main contact?

Prof Sarah Lamb

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# Contact information

## Type(s)

Scientific

## Contact name

Prof Sarah Lamb

## Contact details

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# Additional identifiers

## Protocol serial number

HTA 08/14/41

# Study information

## Scientific Title

Prevention of Fall Injury Trial: a parallel group cluster randomised controlled trial and economic evaluation

## Acronym

Pre-FIT

## Study objectives

Current study hypothesis as of 18/04/2018:

The primary objective is to determine the comparative effectiveness of advice, exercise and a multi-factorial fall prevention (MFFP) programme on fractures among older people living in the community.

Previous study hypothesis:

The primary objective is to determine the comparative effectiveness of advice, exercise and a multi-factorial fall prevention (MFFP) programme on peripheral fractures among older people living in the community.

Further details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/081441>

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 29/04/2010, Derbyshire Research Ethics Committee (1 Standard Court, Park Row, Nottingham NG1 6GN, UK; +44 (0)115 8839461; lisa.gregory@nottspct.nhs.uk), REC ref: 10 /H0401/36

## **Study design**

Three-arm cluster-randomised controlled trial and economic evaluation

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

## **Health condition(s) or problem(s) studied**

Fall-related injuries

## **Interventions**

Current interventions as of 18/04/2018:

Three arms:

1. Written advice
2. Written advice plus structured exercise
3. Written advice plus multi-factorial fall prevention (MFFP)

The total duration of follow-up for all trial arms is 18 months (updated 13/08/2015: was previously 12 months). The total duration of treatment varies across trial arms as follows:

1. Advice: Age Concern Staying Steady Advice Leaflet
2. Exercise: Age Concern Staying Steady Advice Leaflet together with upto 6 months of a physiotherapist supported home exercise programme
3. MFFP: Age Concern Staying Steady Advice Leaflet together with a single Multi-Factorial Falls Prevention Assessment, with onwards referral as necessary

Previous interventions:

Three arms:

1. Written advice
2. Written advice plus structured exercise
3. Written advice plus multi-factorial fall prevention (MFFP)

The total duration of follow-up for all trial arms is 18 months (updated 13/08/2015: was previously 12 months). The total duration of treatment varies across trial arms as follows:

1. Advice: 30 minutes
2. Exercise: 12 weeks (two 1-hour sessions per week)
3. MFFP: 8 weeks (depending on individual risk factors, but typically six 30-minute sessions over 8 weeks)

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Current primary outcome measures as of 18/04/2018:

Fracture, data will be collected at 4, 8, 12 and 18 (updated 13/08/2015: was previously 12) months

Previous primary outcome measures:

Peripheral fracture, data will be collected at 4, 8 and 18 (updated 13/08/2015: was previously 12) months.

### **Key secondary outcome(s)**

Current secondary outcome measures as of 18/04/2018:

1. Falls rate per person years of observation
2. Health related quality of life
3. Mortality

Data will be collected at 4, 8, 12 and 18 (updated 13/08/2015: was previously 12) months.

Previous secondary outcome measures:

1. Time to first fracture
2. Falls rate per person years of observation
3. Health related quality of life
4. Mortality

Data will be collected at 4, 8 and 18 (updated 13/08/2015: was previously 12) months.

### **Completion date**

28/02/2019

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 18/04/2018:

1. Registered with a collaborating practice
2. Aged over 70 years
3. Living in the community, including living in sheltered or supported accommodation
4. Able to provide informed written consent

Previous inclusion criteria:

1. Registered with a collaborating practice
2. Aged over 70 years, either sex
3. Living in the community, either alone, or with family/relative, friend or carer, or in sheltered accommodation

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Senior

### **Sex**

All

### **Total final enrolment**

9803

## **Key exclusion criteria**

Current exclusion criteria as of 18/04/2018:

1. Patients living in residential nursing/care homes
2. Limited life expectancy (<6 months)
3. Anything that in the GP's opinion would place the patient at an increased risk or preclude full compliance or completion of the study

Previous exclusion criteria:

Patients living in residential nursing/care homes

## **Date of first enrolment**

01/06/2010

## **Date of final enrolment**

30/06/2014

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

**The University of Warwick**

Coventry

United Kingdom

CV4 7AL

## **Sponsor information**

### **Organisation**

University of Warwick (UK)

### **ROR**

<https://ror.org/01a77tt86>

## **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

Not provided at time of registration

## IPD sharing plan summary

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	data collection method SWAT results	01/02/2019	20/01/2020	Yes	No
<a href="#">Results article</a>	baseline results	15/01/2020	12/11/2020	Yes	No
<a href="#">Results article</a>	results	05/11/2020	26/11/2020	Yes	No
<a href="#">Results article</a>		01/05/2021	03/06/2021	Yes	No
<a href="#">Results article</a>		23/01/2023	24/01/2023	Yes	No
<a href="#">Results article</a>		02/10/2023	03/10/2023	Yes	No
<a href="#">Protocol article</a>	protocol	18/01/2016		Yes	No