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Prevention of Fall Injury Trial

Submission date	Recruitment status	[X] Prospectively registered
02/02/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/10/2023	Injury, Occupational Diseases, Poisoning	

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?
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Contact information

Type(s)
Scientific

Contact name
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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

Primary study design
Interventional

Study design
Three-arm cluster-randomised controlled trial and economic evaluation

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 provided 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 accomodation

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?
Results article	data collection method SWAT results	01/02/2019	20/01/2020	Yes	No
Results article	baseline results	15/01/2020	12/11/2020	Yes	No
Results article	results	05/11/2020	26/11/2020	Yes	No
Results article		01/05/2021	03/06/2021	Yes	No
Results article		23/01/2023	24/01/2023	Yes	No
Results article		02/10/2023	03/10/2023	Yes	No
Protocol article	protocol	18/01/2016		Yes	No