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Multifaceted podiatry intervention for fall prevention in patients over 65 years of age

Submission date
30/06/2011

Recruitment status
No longer recruiting

Registration date
01/07/2011

Overall study status
Completed

Last Edited
23/04/2020

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Main REFORM study

Background and study aims
Falling is a common problem among people over the age of 65 years. People often think that falls are an unavoidable result of getting older and that little can be done to stop them. It may not be possible to prevent falls completely, however, there are many different ways to help reduce the number of falls someone has. This study is looking to see if a newly developed package of care from a podiatrist can help reduce the number of falls people over 65 years of age.

Who can participate?
Men and women aged 65 and over who have fallen and live in the community

What does the study involve?
Participants are asked to complete a screening questionnaire and send it to the University of York's Trials Unit. Researchers then look at the answers to determine if they are eligible for the study. If they are eligible for the study they are asked to complete some additional questionnaires and monthly falls calendars. If they fall during the study the participants contact the researchers and tell them what happened. Participants are randomly allocated to one of two groups: either the package of podiatry care group or the usual care group. If they are allocated to the podiatrist package of care group, they are asked to see a podiatrist at their local podiatry clinic on two occasions. The podiatrist assesses their footwear, measures their feet and fits an orthotic device (a type of insole which is worn in the shoe). They are then shown some foot and ankle exercises and asked to do these at home three times a week. If they are allocated to the usual care group, GP care continues as usual. If participants are already seeing a podiatrist for treatment which is not related to the study, they continue to see them as usual. If they are not currently receiving treatment from a podiatrist, they are not be invited to attend the podiatry clinic.

What are the possible benefits and risks of participating?
Whilst it cannot promised that taking part in this study will help the participants, the information obtained may help find out how to improve balance and reduce the number of falls people have. No additional risks are expected.

Where is the study run from?
Podiatry clinics in England, in the Harrogate, Leeds, Scarborough, Sheffield and York areas (UK)

When is the study starting and how long is it expected to run for?
October 2011 to April 2015

Who is funding the study?
NIHR Health Technology Assessment Programme (HTA) (UK)

Who is the main contact?
Mrs Sarah Cockayne
sarah.cockayne@york.ac.uk

What are the effects of a re-designed Participant Information Sheet? A randomised controlled trial sub-study

Background and study aims
It has been suggested that patients can be put off from taking part in research studies because the written information they are given is too long and difficult to understand. This study is looking to see if the information given to patients can be improved.

Who can participate?
Anyone who is approached to take part in the REFORM study

What does the study involve?
Potential participants are sent one of three information sheets and are sked to fill in a questionnaire about the information they received.

What are the possible benefits and risks of participating?
Whilst it cannot be promised that taking part in this study will help the participants, the information obtained may help to provide better information to potential study participants. No additional risks are expected.

Where is the study run from?
Podiatry clinics in England, in the Harrogate, Leeds, Scarborough, Sheffield and North Yorkshire areas (UK)

When is the study starting and how long is it expected to run for?
Spring 2013 to Autumn 2013

Who is funding the study?
NIHR Health Technology Assessment Programme (HTA) (UK)

Who is the main contact?
Mrs Sarah Cockayne
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A nested randomised controlled trial of a leaflet containing information on research to increase recruitment rates of potential REFORM trial participants

Background and study aims
Many trials find it difficult to recruit patients. It has been suggested that people would be more willing to take part in a study if they were better informed. It is possible to increase the number of questionnaires returned in the post, by sending information before the questionnaire is sent out. This study aims to find out if the number of people who agree to take part in the REFORM study can be increased by sending them a leaflet about the importance of research in the NHS, before theyre invited to take part in the study.

Who can participate?
Anyone who is approached to take part in the REFORM study

What does the study involve?
Some people are sent a leaflet to read before they are sent information about taking part in the REFORM study.

What are the possible benefits and risks of participating?
Whilst it cannot be promised that taking part in this study will help the participants, the information obtained may help to find how to increase the number of people taking part in research studies. No additional risks are expected.

Where is the study run from?
Podiatry clinics in North Yorkshire (UK)

When is the study starting and how long is it expected to run for?
Spring 2013 to Autumn 2013

Who is funding the study?
NIHR Health Technology Assessment Programme (HTA) (UK)

Who is the main contact?
Mrs Sarah Cockayne
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 09/77/01

Study information

Scientific Title
Randomised trial of a multifaceted podiatry intervention for fall prevention in patients over 65 years of age

Acronym
REFORM

Study objectives
1. To develop a multifaceted podiatry intervention for fall prevention.
2. To test the feasibility of conducting a successful trial of the multifaceted podiatry intervention for fall prevention.
3. To establish the clinical effectiveness of the multifaceted podiatry intervention for fall prevention.
4. To examine the cost effectiveness of the multifaceted podiatry intervention for fall prevention.

Added 21/08/2013:

What are the effects of a re-designed Participant Information Sheet? A randomised controlled trial sub-study
1. To establish if the number of patients recruited to the REFORM study is improved by using a user-tested participant information sheet (PIS) and covering letter, or a PIS developed using a user-tested PIS template.
2. To explore whether changes to the design of the PIS/covering letter improves retention in the REFORM study.
3. To explore whether the quality of informed consent given by patients is affected by the type of PIS they initially receive.
Study design: nested randomised controlled trial.

A nested randomised controlled trial of a leaflet containing information on research to increase recruitment rates of potential REFORM trial participants.
1. To evaluate the effectiveness of a pre-notification leaflet (providing information on and detailing the importance of taking part in research) on improving participation in the REFORM study.
Study design: nested randomised controlled trial.

More details can be found at: https://www.journalslibrary.nihr.ac.uk/programmes/hta/097701/#/

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. NRES committee - East of England - Cambridge East, 09/11/2011
2. NRES committee - East of England - Cambridge East approved the Participant Information Sheet sub-study on 21/02/2013
3. NRES committee - East of England - Cambridge East approved the nested randomised controlled trial of a leaflet containing information on research to increase recruitment rates of potential REFORM trial participants on 28/03/2013

Study design
Main REFORM study: Cohort randomised controlled trial including prospective economic evaluation and a qualitative sub-study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Falls prevention in older people

Interventions
The multifaceted podiatry intervention will consist of:
1. Footwear assessment and advice and financial assistance in purchasing more appropriate footwear if required.
2. Routine podiatry care
3. Foot orthoses

4. Home-based foot and ankle exercises
5. Falls prevention leaflet based on National Institute for Health and Clinical Excellence (NICE) guidance

Control group will receive:
Falls prevention leaflet based on NICE guidance

Added 21/08/2013:

REFORM sub-study: What are the effects of a re-designed Participant Information Sheet? A randomised controlled trial.

The intervention group will receive either a user-tested revised participant information sheet (PIS) and covering letter or a PIS written using a PIS user-tested template.

The control group will receive PIS written in accordance with NRES guidance.

REFORM sub-study: A nested randomised controlled trial of a leaflet containing information on research to increase recruitment rates of potential REFORM trial participants.

The intervention group will be sent a leaflet providing information on, and detailing the importance of, taking part in research. The leaflet will be sent to them approximately two weeks prior to the REFORM recruitment pack being mailed out.

The control group will receive no literature.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
REFORM main study
Rate of falls i.e. falls/person/time over a 12-month period

Added 21/08/2013:

REFORM sub-study: What are the effects of a re-designed Participant Information Sheet? A randomised controlled trial.
The recruitment rate, which is defined as the proportion of patients recruited to the REFORM trial.

REFORM sub-study: A nested randomised controlled trial of a leaflet containing information on research to increase recruitment rates of potential REFORM trial participants.
The recruitment rate, which is defined as the proportion of people who are randomised into the REFORM trial.

Secondary outcome measures
1. Proportion of fallers over a 12-month period
2. Proportion of multiple fallers over a 12-month period
3. Patient reported time to first fall during follow-up to 12 months

4. Health related quality of life EQ5D measured at baseline, 6 and 12 months
5. Short falls efficacy scale measured at baseline, 6 and 12 months
6. Fear of falling measured at baseline, 6 and 12 months
7. Activity of Daily Living measured at baseline, 6 and 12 months
8. Fracture rate over a 12-month period

Added 21/08/2013:

REFORM sub-study: What are the effects of a re-designed Participant Information Sheet? A randomised controlled trial.
1. The proportion of patients recruited to the REFORM cohort.
2. The proportion of recruited patients who are retained to the end of the REFORM study (trial and cohort) or the number remaining in the study six months prior to the end of the MRC START programme.
3. The number of ineligible patients in each intervention group.

REFORM sub-study: A nested randomised controlled trial of a leaflet containing information on research to increase recruitment rates of potential REFORM trial participants.
1. Time to response i.e. the number of days elapsed between the recruitment pack being sent and returned to the York Trials Unit.
2. Rate of retention in the study.
3. Recruitment rate to the cohort, which can be defined as the proportion of eligible people who agree to take part in the REFORM study.

Overall study start date
01/10/2011

Completion date
01/04/2015

Eligibility

Key inclusion criteria
Main REFORM cohort:
Community dwelling men and women over 65 years of age

Main REFORM trial:
Community dwelling men and women over 65 years of age who have had one fall within the past 12 months or one fall which required hospital attention

Added 21/08/2013:

What are the effects of re-designed Participant Information Sheets (PIS)? A randomised controlled trial:
All patients identified as potentially eligible for the REFORM study

A nested randomised controlled trial of a leaflet containing information on research to increase recruitment rates of potential REFORM trial participants:
The same as the main REFORM cohort

Participant type(s)

Patient

Age group
Senior

Sex
Both

Target number of participants
Main REFORM study: 1700 in the cohort and 890 in the randomised controlled trial; REFORM sub-study: What are the effects of a re-designed Participant Information Sheets? A randomised controlled trial: 2247; REFORM sub-study: A nested randomised controlled trial of a leaflet containing information on research to increase recruitment rates of potential REFORM trial participants: 3300

Key exclusion criteria
Main REFORM cohort and trial:
1. Are known to have neuropathy
2. Are known to have a neurodegenerative disorder
3. Are known to have dementia
4. Are unable to walk household distances (10 m)
5. Have had a lower limb amputation
6. Do not complete baseline or run-in data collection instruments adequately
7. Have footwear which has been adapted in such a way which would not allow an orthotic to be fitted
8. Are unable to read or speak English

Added 21/08/2013:

What are the effects of re-designed Participant Information Sheets (PIS)? A randomised controlled trial:
There are no further exclusion criteria

A nested randomised controlled trial of a leaflet containing information on research to increase recruitment rates of potential REFORM trial participants:
The same as the main REFORM cohort and trial

Date of first enrolment
01/10/2011

Date of final enrolment
01/04/2015

Locations

Countries of recruitment
Ireland

United Kingdom

Study participating centre
University of York
York
United Kingdom
YO10 5 DD

Sponsor information

Organisation
University of York (UK)

Sponsor details
Research Innovation Office
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England
United Kingdom
YO10 5DG
+44 (0)190 443 5154
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Sponsor type
University/education

Website
http://www.york.ac.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, HTA

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/12/2014		Yes	No
Results article	results	20/01/2017		Yes	No
Results article	results	28/03/2017		Yes	No
Results article	results	01/04/2017		Yes	No
Results article	qualitative results	21/04/2020	23/04/2020	Yes	No