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To promote adherence to two interventions to prevent falls in older people with visual impairment

Submission date	Recruitment status	[_] Prospectively registered
08/05/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/05/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/09/2016	Eye Diseases	

Plain English summary of protocol

Background and study aims
Visual impairment is identified as a risk factor for falls. Previous research in New Zealand has shown that home safety improvement and exercise programmes help people over 75 with visual impairment to reduce falls and falls related injuries. However, in the NZ study over half of the people made their homes as safe as possible and only 19% exercised for more than twice a week as directed. Compliance is required as those who did manage to complete the programme were shown to have fewer falls. The aims of this study are to assess the acceptability of the programme, the feasibility of carrying out a large scale study in the NHS, the uptake and long term use of two exercise programmes to reduce falls and falls-related injuries.

Who can participate?
Visually impaired people aged over 75 took part in this study.

What does the study involve?
The participants were randomly allocated to receive one of three treatments: usual care, home safety programme or home safety programme plus home exercise programme for six months. Falls and injuries related to fall were analysed.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The study was run from Manchester Royal Eye Hospital and Central Manchester University Hospitals NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
July 2011 to December 2012

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Heather Waterman
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10883

Study information

Scientific Title
A pilot study to promote adherence to two interventions to prevent falls in older people with visual impairment

Acronym
VIP2UK

Study objectives
To assess the acceptability of interventions to reduce the risk of falls and to assess the feasibility of carrying out a full scale randomised controlled trial (RCT) within the NHS
Objectives:
1. To adapt home safety and home based exercise programme for older people with sight impairment
2. To determine the willingness of clinicians to identify and introduce the study to potential participants, and the rate of recruitment and attrition

3. To monitor the response rate to follow-up assessments of primary and secondary outcomes measures
4. To estimate the variability of outcome measures and statistical parameters needed to calculate sample size in a definitive trial
5. To investigate adherence rate to the HS modifications and HE programmes
6. To explore the resource implications and costs of the interventions, and conduct a preliminary cost effectiveness analysis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lancaster Research Ethics Service; 29/03/2011; 11/NW/0038

Study design
Randomised; Interventional; Design type: Not specified, Prevention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Topic: Primary Care, Ophthalmology; Subtopic: Not Assigned, Eye (all Subtopics); Disease: All Diseases, Other

Interventions
Participants were randomly allocated to one of three groups:
1. (Control) received usual care and social visits from a volunteer lay person
2. (Experimental 1) received the Home Safety (HS) programme implemented by an Occupational Therapist
3. (Experimental 2) received the HS plus the home exercise programmes both implemented by the OT and supported by a volunteer peer mentor.

An amended version of the Westmead Home Safety Assessment for those with severe VI was used to assess the physical and environmental home hazards of participants.

The OTAGO exercise programme also amended for people with severe VI was employed comprising leg muscle strengthening and balance retraining exercises. A walking plan was also agreed, if walking was considered safe, undertaken for 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Falls recorded in Falls Calander over six months

Secondary outcome measures
Falls related injuries measured by Falls Calendar

Overall study start date
29/07/2011

Completion date
01/12/2012

Eligibility

Key inclusion criteria
Vision related inclusion criteria:
1. Binocular visual acuity less than 0.6 LogMAR (Snellen equivalent 6/24), stratified into (i) 0.61.0 LogMAR(1.0 LogMar = Snellens 6/60), (ii) less than 1.0 LogMAR and/or
2. Moderate visual field loss, defined as affecting more than 20% of the test location used in a binocular Estermann
test, stratified into (i) those missing 2050%
of the test locations, (ii) those missing >50% of the test locations.

Other inclusion criteria:
1. Aged 75 years and over
2. Independent community dwelling
3. Able to walk around their own residence
4. Cognitively able to participate in the programme
5. Able to understand the study requirements

Carers
To have a relative or friend who is 75 years or older and with a visual impairment and to have the baility to able to communicate in a group

Peer mentors
Planned inclusion/exclusion criteria for peer mentors:
1. Peer mentors must be physically active
2. 65 or older
3. Cognitively intact
4. Willing to have CRB/Disclosure
5. Willing to engage with 35 patients with visual impairment
6. Undertake home visits throughout ten months
7. They must be volunteers who live locally
8. Willing to travel to people's homes

9. Willing to be trained using the Senior Peer Mentor Physical Activity Programme for Older People.

Occupational therapists
Planned inclusion criteria:
1. To have experience of working with older patients with visual impairments
2. Be willing to go under a CRB check and to supervise peer mentors
3. To have excellent interpersonal skills
4. Ability to work within a team and independently
5. Willing to travel to people's homes

Participant type(s)
Mixed

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 193; UK Sample Size: 193

Key exclusion criteria
1. Receiving an OT or physiotherapist intervention or home assessment and modification or exercise intervention eg. Falls Clinic.
2. Cognitive impairment assessed by the Abbreviated Mental Test (26) which is a quick and reliable measure suitable for identifying patients who ought to be excluded from the study.
3. Carers, peer mentors and Ots Not meeting inclusion criteria above

Date of first enrolment
29/07/2011

Date of final enrolment
01/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Manchester
Manchester
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Sponsor information

Organisation
University of Manchester (UK)

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Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0909-20090; Thomas Pocklington Trust

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?
Results article	results	26/09/2016		Yes	No