ISRCTN16949845 https://doi.org/10.1186/ISRCTN16949845

Falls prevention in the visually impaired

Submission date 20/05/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/05/2015	**Overall study status** Completed	
Last Edited 14/06/2023	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Falls and fear of falling have a big impact on older people's lives. Many people stop going out altogether, or reduce their activity so that they are much less active than they used to be. This in turn has a negative impact on their social life and general well-being. Research has shown that exercise programmes can help with this, by building up a person's confidence as well as their physical strength and stamina. This can help make them less likely to fall, more likely to keep active and more likely to have a better quality of life. However, there are a lot of older people who are visually impaired or blind and cannot easily access or participate in these kinds of exercise programmes. The aim of this study is to work with a group of older people with vision problems to adapt an existing exercise programme designed to help prevent falls so that it can also be used by people who are visually impaired. To do this, a group of older, visually impaired people will work alongside health and exercise professionals to adapt the programme and agree on ways of measuring how well it works (e.g. measuring confidence, number of falls, fear of falling and general health) for those with sight loss. The main focus of this small study will be to see if older people with sight loss in Newcastle and Glasgow are prepared to join in and stick with the exercise programme and complete the assessments. The results of this study will be used to see whether a larger study could be carried out.

Who can participate?
Adults aged 60 and over with visual impairment.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) take part in a 12-week exercise programme. Those in group 2 (control group) are given standard primary health care advice. Measurements, including confidence, fear of falling, number of falls etc. are taken at the start of the trial, at the end of the exercise programme, and again 6 months later.

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

Where is the study run from?
University of Newcastle upon Tyne (UK)

When is the study starting and how long is it expected to run for?
May 2015 to May 2016

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

Who is the main contact?
Ms R Lampitt

Contact information

Type(s)
Scientific

Contact name
Ms Rosy Lampitt

Contact details
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United Kingdom
NE2 4AE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18789

Study information

Scientific Title
Visually Impaired OLder people’s Exercise programme for falls prevention (VIOLET): a feasibility study

Acronym
VIOLET

Study objectives
This study will assess the feasibility and acceptability of, and adherence to, an exercise programme aimed to increase fitness in older people with sight loss. The exercise programme aims to decrease physical injury from falls and increase confidence in participants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ref: 15/NE/0057

Study design
Randomised interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life

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
Fitness of visually impaired older people

Interventions
1. Treatment group takes part in an adapted exercise programme designed for older, visually impaired people for 12 weeks
2. Control group receives standard care

Intervention Type
Behavioural

Primary outcome measure
Fear of falling measured using Short Falls Efficacy Scale – International (FES-I) at baseline, 12 weeks and 24 weeks.

Secondary outcome measures
Not available at time of registration

Overall study start date
01/05/2015

Completion date
23/05/2016

Eligibility

Key inclusion criteria
1. Age >60 years
2. Attend a low vision clinic and/or are members of organisations for the visually impaired such as NSBP in Newcastle or Visibility in Glasgow
3. Live in their own home
4. Can walk indoors without the help of another person but may use a walking aid such as a stick
5. Can walk outdoors but may need the help of another and/or walking aid
6. Physically able to take part in a group exercise class
7. Participant has given informed consent (as appropriate to each older person with visual impairment) to participate in the study prior to any study-specific procedures

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
UK Sample Size: 80

Key exclusion criteria
1. Unable to comprehend or follow simple movement instructions in English (to an extent of being unable to follow simple movement instructions)
2. Acute or uncontrolled medical problems which the participant's General Practitioner considers would exclude then from undertaking the exercise programme (e.g. uncontrolled heart disease, poorly controlled diabetes, acute systemic illness, neurological problems, severe chronic obstructive pulmonary disease (COPD)) in addition to visual impairment
3. Conditions requiring a specialist exercise programme e.g. uncontrolled epilepsy, severe neurological disease or impairment, unable to maintain a seated upright position or unable to move independently indoors
4. Current involvement in other falls prevention exercise programmes (but not excluding walking programmes), investigational studies or trials

Date of first enrolment
01/05/2015

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Newcastle upon Tyne
Neurosurgical Trials Unit
3-4 Claremont Terrace
Newcastle University
Newcastle upon Tyne
United Kingdom
NE2 4AE

Sponsor information

Organisation
University of Northumbria at Newcastle

Sponsor details
Psychology
Queen Victoria Road
Newcastle Upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/049e6bc10

Funder(s)

Funder type
Government

Funder Name
Public Health Research Programme

Alternative Name(s)
NIHR Public Health Research Programme, PHR

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?
Results article	results	12/12/2018		Yes	No
Protocol article		02/08/2016	14/06/2023	Yes	No
Results article		01/02/2019	14/06/2023	Yes	No
HRA research summary			28/06/2023	No	No