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Interventions to prevent falls and injury in elderly people with impaired vision

Submission date	Recruitment status
02/03/2005	No longer recruiting
Registration date	**Overall study status**
07/03/2005	Completed
Last Edited	**Condition category**
20/12/2007	Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
02/265

Study information

Scientific Title

Acronym
VIP Falls Prevention Trial

Study objectives
Study objectives:
1. To demonstrate the efficacy of two interventions:
1.1. A strength and balance retraining programme and vitamin D supplements
1.2. A home safety programme, in preventing falls and injuries in people living in the community aged 75 years and over with visual impairment (visual acuity 6/24 or less)
2. To demonstrate the efficacy of the two programmes in improving independence, level of physical activity and quality of life
3. To determine the cost effectiveness of the two interventions in comparison with other falls prevention strategies
4. To determine the vitamin D status in a sample of people 75 years and over with visual impairment and compare this with an age and sex matched control group drawn from the same general practices at the same time

Summary of study design:
We will assess the effectiveness and cost effectiveness of two falls prevention programmes in a randomised controlled trial with one year of follow up. The two interventions will be individually delivered at home:
1. An exercise programme for one year consisting of a set of leg muscle strengthening and balance retraining exercises and a walking plan, modified for use by visually impaired people and individually prescribed by a physiotherapist. Participants in this intervention arm will also receive vitamin D (Calciferol) supplements.
2. An injury prevention programme of home safety assessment and modification designed specifically for visually impaired people and delivered by an occupational therapist.

We will recruit 400 men and women living in the community and aged 75 years and older with visual acuity of 6/24 metres or less. Potential participants will be recruited from low vision clinics at two city hospitals and one university department and from those registered with the Royal New Zealand Foundation for the Blind.

The trial has a two by two factorial design. There will be 100 people randomly allocated to each of four groups:
1. The home exercise programme and vitamin D supplements, plus the home safety programme
2. The home exercise programme and vitamin D supplements
3. The home safety programme
4. A control group with no falls prevention intervention who will receive their usual care and health services, plus social visits.

Falls, injuries and healthcare resource use as a result of falls will be monitored for one year.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from Otago and Auckland Ethics Committees.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Falls in elderly people

Interventions
1. Home environment programme
2. Home exercise programme
3. Both home environment and exercise programmes
4. Social visits

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Falls and injuries resulting from falls.

Secondary outcome measures
1. Self perceived health status (36-item short form health survey [SF-36])
2. Fear of falling
3. Physical activity level (human activity profile)
4. Visual disability (VF-14)
5. Mobility and physical independence (Nottingham extended activities of daily living [ADL])
6. Muscle strength and balance (4-test balance scale, chair stand test)
7. Use of health care resources as a result of falls and injuries
8. The incremental costs and cost effectiveness of delivering each intervention (if the intervention is effective in reducing falls)

Overall study start date
01/10/2002

Completion date
31/10/2004

Eligibility

Key inclusion criteria
1. Community living women and men aged 75 years and older
2. Visual acuity 6/24 metres or less

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
391

Key exclusion criteria
1. Cannot walk around their own residence
2. Receiving physiotherapy at the time of recruitment
3. Cannot understand the trial requirements

Date of first enrolment
01/10/2002

Date of final enrolment
31/10/2004

Locations

Countries of recruitment
New Zealand

Study participating centre
Department of Medical and Surgical Sciences
Dunedin
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9001

Sponsor information

Organisation
Health Research Council of New Zealand (New Zealand)

Sponsor details
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Sponsor type
Research council

Website
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ROR
https://ror.org/00zbf3d93

Funder(s)

Funder type
Research council

Funder Name
Health Research Council of New Zealand (New Zealand) (ref: 02/265)

Alternative Name(s)
HRCNewZealand, HRC New Zealand, HRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
New Zealand

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	08/10/2005		Yes	No