Randomised controlled trial of prevention of falls in people aged ≥75 with severe visual impairment: the VIP trial

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Abstract

Objectives To assess the efficacy and cost effectiveness of a home safety programme and a home exercise programme to reduce falls and injuries in older people with low vision.
Design Randomised controlled trial.
Setting Dunedin and Auckland, New Zealand.
Participants 391 women and men aged ≥75 with visual acuity of 6/24 or worse who were living in the community; 92% (361 of 391) completed one year of follow-up.
Interventions Participants received a home safety assessment and modification programme delivered by an occupational therapist (n=100), an exercise programme prescribed at home by a physiotherapist plus vitamin D supplementation (n=97), both interventions (n=98), or social visits (n=96).
Main outcome measures Numbers of falls and injuries resulting from falls, costs of implementing the home safety programme.
Results Fewer falls occurred in people randomised to the home safety programme but not in those randomised to the exercise programme (incidence rate ratios 0.59 (95% confidence interval 0.42 to 0.83) and 1.15 (0.82 to 1.61), respectively). However, within the exercise programme, stricter adherence was associated with fewer falls (P=0.001). A conservative analysis showed neither intervention was effective in reducing injuries from falls. Delivering the home safety programme cost $NZ650 (£234; $432; €344) (at 2004 prices) per fall prevented.
Conclusion The home safety programme reduced falls and was more cost effective than an exercise programme in this group of elderly people with poor vision. The Otago exercise programme with vitamin D supplementation was not effective in reducing falls or injuries in this group, possibly due to low levels of adherence.
Trial registration number ISRCTN15342873.

Introduction

Multiple factors contribute to most falls in older people.[1 2] A landmark study by Tinetti and colleagues[3] and subsequent studies in specific populations have shown that multiple interventions can prevent falls. Many guidelines now recommend such strategies.[4–6] The problem with this approach is that not all components of multiple intervention programmes are effective.[7] Also, intervention programmes are not effective in certain groups, such as those with dementia.[8] Importantly, in selected populations, trials using single interventions such as strength and balance retraining[9] or withdrawal of psychotropic drugs[10] have been as successful as those using multiple interventions.

People with visual impairment fall more frequently than those with normal sight.[11] They may exercise less with consequent loss of strength and balance and may venture outside less, resulting in low vitamin D concentrations. We carried out a randomised controlled trial to investigate the effectiveness of two home based strategies to prevent falls in elderly people with impaired vision—a programme to address safety in the home environment and a programme of strength and balance retraining plus vitamin D supplements.

Methods

From potential participants who were living in the community we identified those aged ≥75 years with poor vision, defined as visual acuity of 6/24 or worse in the better eye. We excluded those who could not walk around their own residence, who were receiving physiotherapy at the time of recruitment, or could not understand the trial requirements. Full details of the trial design can be found on bmj.com.

Interventions

The two occupational therapists and three physiotherapists delivering the interventions and the two independent assessors attended a two day training course.

Home safety programme—The home safety assessment and modification programme was specifically designed for people with severe visual impairments. The occupational therapist (one in each centre) visited the person at home, identified hazards, and discussed with the participant any items, behaviour, or lack of equipment that could lead to falls.[12] The therapist listed any recommendations in a follow-up letter to the participant—such as, removing or changing loose floor mats, painting the edge of steps, reducing glare, install-

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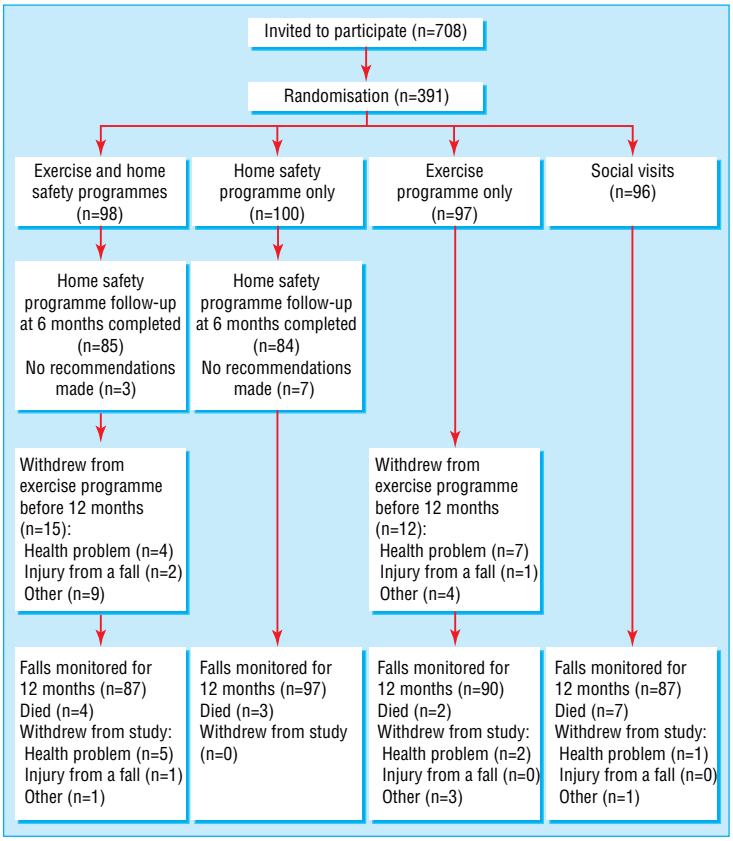

Flow of participants through the trial

ing grab bars and stair rails, removing clutter, and improving lighting. She facilitated provision of equipment and payment. She evaluated adherence to the home safety programme during a telephone interview six months after study entry. The participant reported whether each recommendation had been acted on, partially acted on, or not carried out.

Exercise programme—The one year exercise intervention consisted of the Otago exercise programme,[13] modified for those with severe visual acuity loss, with vitamin D supplementation. The physiotherapist individually prescribed the exercises during five home visits. Audiotapes of the exercises in four different levels of difficulty were available for those who could not see the exercise instruction sheets. Participants were expected to exercise at least three times a week (about 30 minutes a session) and to walk, if walking outside could be done safely, at least twice a week for a year. The physiotherapist delivered vitamin D tablets. For the months with no scheduled home visit the physiotherapist telephoned to encourage the person to maintain motivation and discuss any problems. Adherence to the exercise programme was monitored for a year with monthly postcard calendars similar to those used to monitor falls.

Social visits—Research staff made two home visits lasting an hour each during the first six months of the trial to participants who were not randomised to either the exercise or home safety programmes.

Measurement of vision

We measured distance high contrast and low contrast (10%) visual acuity, a broad measure of peripheral field loss in four quadrants, and contrast sensitivity.[14]

Falls and injuries

Falls were defined as "unintentionally coming to rest on the ground, floor or lower level." Falls were monitored for one year for each person with participants using prepaid, addressed, tear-off monthly postcard calendars. The independent assessor in each centre telephoned participants to record the circumstances of the falls and any resulting injuries or use of resources.

Fall events were classified as resulting in serious injury if the fall resulted in a fracture or admission to hospital with an injury or if stitches were required; "moderate" injury if bruising, sprains, cuts, abrasions, or reduction in physical function for at least three days resulted, or if the participant sought medical help; and no injury. The circumstances of serious injuries were confirmed from hospital and general practice records.

Economic evaluation

We used cost effectiveness analysis to enable comparisons of efficiency among different interventions to prevent falls. We considered costs from the societal perspective and measured cost effectiveness as the incremental cost of delivering the programme per fall event prevented by the programme during the one year trial. One way sensitivity analyses were performed (see bmj.com).

Statistical analysis

Data were analysed on an intention to treat basis with Stata Release 7 and SPSS 11. We compared the number of falls in the intervention and control groups using negative binomial regression models.[15] We also used negative binomial regression models to test whether there was a difference between the fall rates inside and outside the home environment and to determine the fall rates at different levels of adherence to the exercise programme.

Results

Trial participants and follow-up

The figure shows the flow of participants through the trial. The mean age of participants was 83.6 (SD 4.8) years, and ages ranged from 75 to 96 years. The four groups seemed well balanced at baseline.

The occupational therapist completed a six month follow-up telephone call for those in the home safety group. Ninety per cent of participants (152/169) reported complying partially or completely with one or more of the recommendations.

Eighteen per cent of participants (36/195) in the exercise groups carried out their prescribed set of exercises three or more times a week for one year; 70 (36%) completed their exercises at least twice a week during their time in the trial. A total of 44% (85 of 195) walked at least twice a week during the year. Of those prescribed vitamin D supplements at trial entry, 100/145 continued taking the tablets for a year (for details see bmj.com).

Falls and fall related injuries

There was a significant interaction between the two interventions for falls ($P = 0.016$) (table 1).[16] We have reported the more conservative results of the combined group comparisons as the main outcomes of the trial. With this approach, the number of falls resulting in severe and moderate injuries or falls requiring medical care did not differ between the intervention groups.

Table 1 Incidence of fall events and follow-up times

	Separate intervention groups				Combined intervention groups			
	Home safety + exercise programmes (n=98)	Home safety programme alone (n=100)	Exercise programme alone (n=97)	Social visits alone (n=96)	Home safety programme (n=198)	No home safety programme (n=193)	Exercise programme (n=195)	No exercise programme (n=196)
No of falls	108	64	120	151	172	271	228	215
Falls per person year	1.17	0.65	1.30	1.65	0.90	1.47	1.23	1.13
No (% of group) with ≥1 fall(s)	47 (48)	36 (36)	47 (48)	59 (61)	83 (42)	106 (55)	94 (48)	95 (48)
No (% of group) with ≥2 falls	24 (24)	16 (16)	27 (28)	29 (30)	40 (20)	56 (29)	51 (26)	45 (23)
No of injurious falls:								
Any	61	39	53	65	100	118	114	104
Serious	11	10	4	4	21	8	15	14
Moderate	50	29	49	61	79	110	99	90
Injurious falls per person year:								
Any	0.66	0.40	0.57	0.71	0.53	0.64	0.62	0.55
Serious	0.12	0.10	0.04	0.04	0.11	0.04	0.08	0.07
Moderate	0.54	0.30	0.53	0.67	0.42	0.60	0.54	0.48
No (%) of falls for which medical care sought	30 (28)	19 (30)	32 (27)	32 (21)	49 (28)	64 (24)	62 (27)	51 (24)
Mean (SD) follow-up (months)	11.30 (2.27)	11.77 (1.29)	11.46 (2.17)	11.41 (2.08)	11.54 (1.85)	11.44 (2.12)	11.38 (2.22)	11.60 (1.73)
Total follow-up (person years)	92.24	98.12	92.63	91.31	190.36	183.94	184.87	189.43

Home safety programme

There were 41% fewer falls in the participants of the home safety programme compared with those who did not receive this programme (incidence rate ratio 0.59, 95% confidence interval 0.42 to 0.83). There was no significant difference in the reduction of falls at home compared with those away from the home environment (ratio of incidence rate ratios 0.60, 0.31 to 1.17). No adverse events were reported as a result of this intervention.

Exercise programme

There were 15% more falls during the trial in participants randomised to the exercise programme compared with those who did not receive this programme (incidence rate ratio 1.15, 0.82 to 1.61). There was one moderate injury but no falls while the person was exercising according to instructions.

As the fall rate was higher in the exercise programme groups, we tested whether the exercise programme was safe to deliver to this sample of older people by investigating the relation between falls and the number of exercise sessions completed during the trial. We found that higher levels of adherence were associated with lower fall rates. The rate of falls was 77% lower in those who exercised at least three times a week during their time in the trial compared with those exercising less than once a week.

Economic evaluation

As we did not find that the exercise programme was effective in reducing falls, we report only the cost effectiveness of the home safety programme. The programme cost $NZ64 337 to deliver to the 198 participants in the two centres, or $NZ325 (SD $NZ292) per person. Table 2 shows the cost effectiveness ratios we calculated to indicate the incremental cost of implementing the home safety programme per fall prevented and the results of the sensitivity analyses.

Discussion

We have shown that in community based programmes for prevention of falls one size does not fit all. Different elderly populations require specifically selected programmes. Any organisation seeking to reduce falls in elderly people with severe visual impairment would do best by investing in a proved programme of assessment and modification of home safety delivered by an occupational therapist.

The Otago exercise programme, previously shown to be of benefit in those aged ≥ 80,[17–19] was not successful in this population. This may be a frailer population than we have studied before and more participants were unable to participate fully in the strength and balance retraining. Adherence rates were considerably lower than in our previous trials.[17–19]

Table 2 Incidence rate ratios for fall events for home safety and exercise programmes*

	Incidence rate ratio (95% CI)
Effect on falls	
Home safety programme:	
All receiving home safety programme (n=198) *v* all not receiving home safety programme (n=193)	0.59 (0.42 to 0.83)
Home safety programme only group (n=100) *v* social visits group (n=96)	0.39 (0.24 to 0.62)
Exercise programme:	
All receiving exercise programme (n=195) *v* all not receiving exercise programme (n=196)	1.15 (0.82 to 1.61)
Exercise programme only group (n=97) *v* social visits group (n=96)	0.79 (0.48 to 1.28)
Effect on injurious falls	
Home safety programme:	
All receiving home safety programme (n=198) *v* all not receiving home safety programme (n=193)	0.81 (0.56 to 1.16)
Home safety programme only group (n=100) *v* social visits group (n=96)	0.56 (0.36 to 0.87)
Exercise programme:	
All receiving exercise programme (n=195) *v* all not receiving exercise programme (n=196)	1.15 (0.80 to 1.65)
Exercise programme only group (n=97) *v* social visits group (n=96)	0.82 (0.48 to 1.40)

*Interaction ratios for falls and injurious falls were 2.28 (1.17 to 4.45) and 2.05 (0.99 to 4.23), respectively.

What is already known on this topic

Older people with poor vision are at increased risk of falling

Home safety assessment and modification programmes can be effective in reducing falls in those who have fallen previously

A home based strength and balance retraining programme (the Otago exercise programme) is effective in reducing falls in older people with normal sight living in the community

What this study adds

Community based programmes for prevention of falls should be targeted at particular population groups

Older people with severe visual impairment can benefit from a specially developed programme of home safety assessment and modification

A home exercise programme was not effective in reducing falls in this sample with visual impairment, possibly due to lower levels of adherence

The home safety programme we adapted for older people with severe vision loss is currently the only successful falls prevention programme reported for this group, although earlier cataract removal was associated with fewer falls and fractures in elderly women on the waiting list for cataract surgery.[20]

Our home safety programme cost less per person to implement than the Otago exercise programme delivered to people aged ≥75 with normal sight ($NZ484 per person at 2004 prices).[17] When we considered savings in hospital costs resulting from a reduction in serious injuries, however, the Otago exercise programme in the previous trial was more cost effective to deliver than the home safety programme in the current trial.[17]

Limitations of the study

We had not expected any interaction between the two interventions and have no convincing explanation for the fact that the home safety programme seemed less effective when the person was also receiving the exercise programme. It may simply be a chance effect. We feel that the conservative estimates for the combined group rate ratio are more likely to indicate the efficacy of the interventions (see bmj.com).

Participants were recruited through the Royal New Zealand Foundation of the Blind and through low vision clinics. They were not selected for their ability to participate in an exercise programme. A population screened through primary care for their ability to participate in an exercise programme may benefit. Many of those who were registered with the Foundation of the Blind had already undertaken an orientation and mobility programme and this may have lessened the benefit from the home safety programme.

The duration of visual impairment varied considerably, as did the causes of blindness. There were too few participants to determine if particular groups, such as those who had lost their sight recently, benefited more from the home safety programme.

Future directions

Falls result in loss of confidence, injuries, admission to an institution, fractures, and death.[5] They can be prevented at a cost. Careful targeting of the programme to specific population groups and avoidance of programmes in groups who will not benefit can reduce that cost. There is now sufficient evidence from trials to design community programmes to prevent falls so that the specific interventions are used only in the particular populations known to benefit.

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Contributors: All authors contributed to the study or protocol design, or both, interpreted the data, and wrote the paper. AJC directed the project, interpreted the data, and wrote the paper. MCR managed the project and the data gathering, analysed and interpreted the data, and wrote the paper. MCR and NMK supervised the research staff. SJLaG developed the home safety programme. GFS, RJJ, and DMS advised on vision measures and recruited participants. LAH supervised the physiotherapists. AJC and MCR are guarantors.

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