

# The Whitehorse NoFalls trial: effects on fall rates and injurious fall rates

MICHAEL P. FITZHARRIS<sup>1,2</sup>, LESLEY DAY<sup>1</sup>, STEPHEN R. LORD<sup>3</sup>, IAN GORDON<sup>4</sup>, BRIAN FILDES<sup>1,5</sup>

<sup>1</sup>Accident Research Centre, Monash University, Victoria 3800, Australia

<sup>2</sup>Injury Prevention and Safety Promotion Research Node, Monash South Africa, Johannesburg, South Africa

<sup>3</sup>Prince of Wales Medical Research Institute, University of New South Wales, Randwick, New South Wales, Australia

<sup>4</sup>Statistical Consulting Centre, The University of Melbourne, Melbourne, Victoria 3010, Australia

<sup>5</sup>Accident Research Centre, Monash University, Prato, Italy

Address correspondence to: M. P. Fitzharris. Tel: (+61) 428 522 784; Fax: (+61) 399 054 363.  
Email: michael.fitzharris@monash.edu

## Abstract

**Background:** the burden of falls and fall-related injuries among older adults is well established. Contention surrounds the effectiveness, and hence value, of multi-component fall prevention interventions delivered in the community.

**Objective:** using consensus-based analytic guidelines rather than time-to-first fall as the primary endpoint, the objective was to examine the effectiveness of the Whitehorse NoFalls trial on all falls, falls resulting in injury and falls requiring medical care to be sought.

**Design, setting and participants:** the study was a community-based randomised controlled trial, with 1,090 participants assigned to one of eight groups, these being a combination of one or more of exercise, vision and or home hazard reduction or alternatively assignment to the control group.

**Methods:** using negative binomial regression, the incidence of all falls, falls resulting in injury and those requiring medical care in the intervention groups were examined. Falls were reported using a monthly return calendar.

**Results:** exercise alone and in combination with vision and/or home hazard reduction was associated with fewer falls. For falls resulting in injury and the subset requiring medical care, the vision plus exercise intervention was associated with fewer falls.

**Conclusions:** the findings confirm the effectiveness of exercise in preventing falls among community-dwelling older adults and supports contention that multi-component interventions do not prevent more falls than a single intervention. The results highlight the effectiveness of vision plus exercise in preventing more serious falls, a finding which warrants further consideration.

**Keywords:** *alls, aged, home, wounds and injuries, randomized controlled trial, elderly*

## Introduction

The burden of falls and fall-related injuries to older community dwellers is well established. Early fall prevention trials demonstrated the efficacy of a range of interventions [1], and consequently, current guidelines support the implementation of multi-component prevention programmes [2–4]. In contrast, recent reviews suggest that there is limited evidence for the implementation of targeted multi-factorial intervention programmes [1, 5], with Gates *et al.* [5] also noting that there are few trials that report the effect of intervention programs on injurious falls. Additionally, a recent review by Campbell and Robertson [6] reported that single interventions delivered to community-dwelling older adults have proved to be

as effective in reducing falls as programmes with multiple interventions.

The ‘Whitehorse NoFalls’ randomised controlled trial remains one of the few multi-component falls prevention programs with a full factorial design [7]. The initial publication in 2002 reported ‘time-to-first’ fall as the primary outcome and demonstrated that an exercise program delivered alone or in combination with vision and/or home hazard reduction was effective. The vision and home hazard reduction interventions had no significant effect on falls when delivered alone.

However, as these results were published prior to the emergence of consensus recommendations regarding the analysis and reporting of falls trials [8, 9], the reporting

format can preclude inclusion in systematic reviews, comparison with later trials and enduring contribution to the field.

Consequently, we have undertaken a re-analysis of the Whitehorse NoFalls trial using the recommended negative binomial regression model and present the results consistent with contemporary reporting and analysis recommendations. In addition, we also report previously unexamined results of the impact of the interventions on injurious falls and of those necessitating medical treatment.

## Method

As this trial has been reported in detail previously [7], we provide a summary of the most pertinent aspects.

### Setting and participants

Participants were community-dwelling people aged 70 and older living in the City of Whitehorse local government area in metropolitan Melbourne. Eligibility criteria included living in one's own home or apartment or leasing similar accommodation and permitted to make modifications. Potential participants with severe disability, mobility or cognitive limitations were excluded [7, 10]. Recruitment involved mailing 11,120 invitation letters to all residents 70 years and over and registered on the Australian electoral roll; follow-up telephone calls to those receiving the letter of invitation were also made. The invitation letter included a statement explaining the study as well as eligibility and exclusion criteria. Local publicity and recruitment by general practitioners supported the primary recruitment strategy. A total of 1,967 individuals expressed interest in the study by contacting the study office, and of these, 1,107 enrolled into the study.

### Design

The targeted risk factors were strength and balance, poor vision, and the presence of home hazards. A factorial design was used with eight groups defined according to the presence or absence of each of the three interventions. Intervention groups received at least one intervention or combinations thereof. A control group, receiving a deferred intervention, was also included. Random assignment to study arm occurred after baseline assessment.

### Interventions

The exercise intervention was a weekly strength and balance exercise class of 1 h for 15 weeks, supplemented by daily home exercises. The home hazard intervention involved the removal or modification of hazards, both inside the home and at the entry points, identified in the initial risk factor assessment. Home hazard reduction was undertaken either by the participants or via the City of Whitehorse's home maintenance service. The vision intervention involved

referral to the participant's usual eye-care provider, general practitioner or local optometrist, if their vision tested below predetermined criteria. Full details of the interventions and their uptake are described elsewhere [7].

### Falls outcome measures

Participants reported falls for up to 18 months using a monthly post-card calendar system. Falls were defined as 'injurious' where the following self-reported outcome occurred: a cut, scrape, gash, bruise or fracture was sustained; a head injury resulted or where the fall resulted in hospitalisation.

### Analyses

The primary endpoint was all falls experienced by participants across their surveillance period, commencing from the date of assessment and enrolment into the study and continuing until participants withdrew, had died or were lost to follow-up. Secondary endpoints were injurious falls and falls necessitating medical attention.

Negative binomial regression was used to analyse the primary and secondary endpoints [11]. Model fitting involved entering the three interventions as dichotomous variables with surveillance period—expressed in days, being the offset variable. Over-dispersion in the model was assessed using the likelihood ratio test of  $a=0$  against a standard Poisson model; a  $P \leq 0.05$  indicated over-dispersion and hence appropriate use of the negative binomial model. Upon fitting the main-effects model, higher-order interactions were assessed and there were none evident in the models ( $P \geq 0.05$ ). Additive combinations were used to assess the combined impact of intervention combinations on falls outcome. This results in the derivation of incidence rate ratios (IRRs) of the singular and additive *average* effect of receiving one or more of the interventions, relative to not receiving that intervention; this adjusts for the effect of other interventions and is the main-effects analysis. Analyses were performed in STATA SE Version 10 [12]. All analyses were performed on an intention-to-treat basis.

### Results

A total of 1107 participants were randomised with 1090 remaining in the trial after group allocation. Demographic characteristics and baseline risk factors were similar across the eight groups [7].

Table 1 presents the total number of falls, injurious falls and falls requiring medical care. The proportion of fallers and the fall rate (per 100 person-years) for the total number of falls was lower for those receiving the exercise and vision intervention compared with those that did not. Table 2 further disaggregates the main-effects model into the eight study arms, including the control (deferred

**Table 1.** Incidence of falls and follow-up times for participants by allocation to the Whitehorse NoFalls study interventions (main-effects model)

	Exercise intervention		Vision intervention		Home hazard management (HHM) intervention	
	In exercise	Not in exercise	In vision	Not in vision	In HHM	Not in HHM
Number participants	541	549	547	543	543	547
Number of falls	619	829	691	757	719	729
Number (% of total) of injurious falls	358 (57.8)	446 (53.8)	374 (54.1)	430 (56.8)	403 (56.1)	401 (55.0)
Number of (% of total) falls for which medical care sought	51 (8.2)	73 (8.8)	49 (7.1)	75 (9.9)	66 (9.2)	58 (7.9)
Number of (%) persons with at least one fall	279 (51.6)	327 (59.6)	291 (53.2)	315 (58.0)	285 (52.5)	321 (58.7)
Number of (%) persons with two or more falls	125 (23.1)	173 (31.5)	139 (25.4)	159 (29.3)	136 (25.0)	162 (29.6)
Number of (%) persons with three or more falls	84 (15.5)	93 (16.9)	88 (16.1)	89 (16.4)	70 (12.9)	107 (19.6)
Number of (%) persons with 10 or more falls	5 (0.9)	7 (1.3)	3 (0.5)	9 (1.7%)	2 (0.4)	10 (1.8)
Surveillance period as total person-years	682.81	725.47	706.27	702.00	704.32	703.96
Falls per 100 person-years	90.65	114.27	97.84	107.83	102.08	103.56
Injurious falls per 100 person-years	52.43	61.48	52.95	61.25	57.22	56.96
Falls requiring medical care per 100 person-years	7.47	10.06	6.94	10.68	9.37	8.24

**Table 2.** Incidence of falls and follow up times by allocation to single and combined Whitehorse NoFalls study interventions

	No intervention	Exercise	Vision	HHM	Exercise + Vision	Exercise + HHM	Vision + HHM	Exercise + Vision + HHM
Number participants	137	135	139	136	136	135	137	135
Number of falls	211	181	214	212	123	153	192	162
Number (%) of injurious falls	115 (54.5)	101 (55.8)	116 (54.2)	114 (53.8)	69 (56.1)	100 (65.4)	101 (52.6)	88 (54.3)
Number of (%) falls for which medical care sought	18 (8.5)	16 (8.8)	17 (7.9)	27 (12.7)	7 (5.7)	14 (9.2)	11 (5.7)	14 (8.6)
At least one fall, N (%)	87 (63.5)	76 (56.3)	84 (60.4)	78 (57.4)	66 (48.5)	72 (53.3)	78 (56.9)	65 (48.1)
Two or more falls, N (%)	45 (32.8)	40 (29.6)	45 (32.4)	42 (30.9)	24 (17.6)	30 (22.2)	41 (29.9)	31 (23.7)
Three or more falls, N (%)	25 (18.2)	30 (22.2)	26 (18.7)	18 (13.2)	18 (13.2)	14 (10.4)	24 (17.5)	22 (16.3)
10 or more falls, N (%)	3 (2.2)	1 (0.7)	1 (0.7)	2 (1.5)	—	1 (0.7)	1 (0.7)	3 (2.2)
Surveillance period as total person-years	175.96	172.64	188.34	179.52	167.03	173.88	181.65	169.26
Falls per 100 person-years	119.9	104.8	113.6	118.1	73.6	88.0	105.7	95.7
Injurious falls per 100 person-years	65.4	58.5	61.6	63.5	41.3	57.5	55.6	52.0
Falls requiring medical care per 100 person-years	10.2	9.3	9.0	15.0	4.2	8.1	6.1	8.3

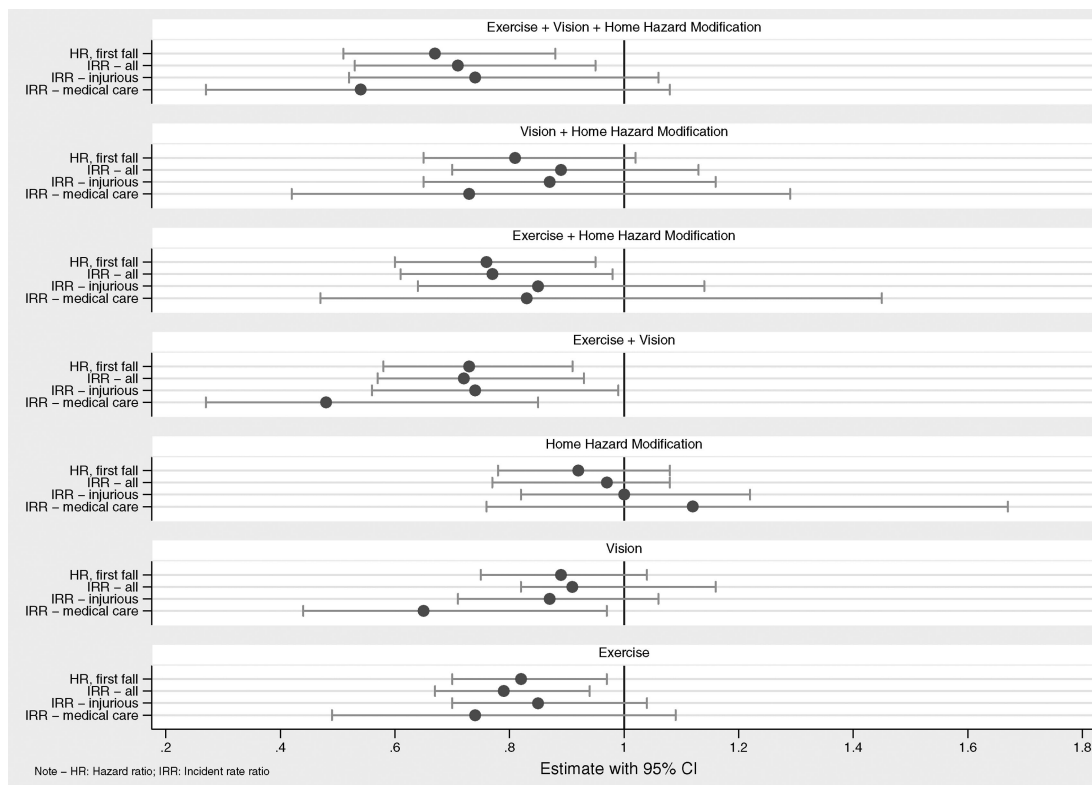
intervention) group and provides complementary information with regard to fall rates in groups who received single and multiple interventions.

Among participants reporting injurious falls ( $n = 428$ ), 31 sustained a fracture (5 had two separate falls resulting in a fracture) and 18 sustained an injury to the head. Overall, 104 participants sought medical care for 124 falls, and 22 participants attended hospital for 25 falls.

Results from the negative binomial model are shown in Figure 1 (see also Supplementary data available in *Age and Ageing* online). For purposes of comparison, our previously published results in which time to first fall was modelled using the Cox proportional hazards model are also shown [7]. The difference between these two analyses is that the negative binomial model includes the counts of all falls, whereas the Cox proportional hazards model is based on the time to the first fall only. Incidence rate ratios and hazard ratios are for each intervention group relative to those not receiving the intervention; owing to the factorial nature of the model all participants contribute to the analysis.

Those in the exercise intervention fell at a rate 21% lower than those not receiving the exercise intervention (IRR: 0.79, 95% CI 0.67–0.94). The effect of the vision and home hazard interventions individually was relatively small, although the wide confidence intervals preclude a definitive conclusion (Figure 1; Supplementary data available in *Age and Ageing* online). Among the groups receiving a combination of two interventions, the largest effect was observed for the exercise combinations. The fall reduction effect appeared greatest for those receiving all three interventions (IRR: 0.67, 95% CI 0.51–0.88). However, the wide confidence intervals indicate that the effect size of any of the combined interventions could be comparable. These results are similar to, and thus reinforce, our previously reported findings using the Cox proportional hazards model for the first fall only.

The effects on injurious falls were generally smaller, with the exception of the exercise plus vision, and all three combined groups. In contrast, some potentially large effects were observed for falls requiring medical care.



**Figure 1.** Hazard ratio (based on time to first fall) and IRR (based on all falls) for falls, injurious falls and falls necessitating medical care, by intervention (main-effects factorial model).

The exercise plus vision group fell at a rate 52% lower than those not receiving these two interventions together (IRR 0.48, 95% CI 0.27–0.85), whereas the vision only group fell at a rate 35% lower than participants not receiving the vision intervention (IRR 0.65, 95% CI 0.44–0.97). There may also be an important effect for the all three combined group (Figure 1).

## Discussion

The re-analysis of the Whitehorse NoFalls trial confirms our earlier reported findings of the efficacy of the exercise intervention delivered alone and in combination with the vision and/or home hazard intervention, despite using a different statistical analysis technique [7]. Our results for exercise and home modification interventions as single interventions are consistent with those of the recent Cochrane review [1].

Consistent with the observations of Campbell and Robertson [6], our results suggest that there is unlikely to be large differences in the falls reducing effect of multi-component interventions and a single intervention delivered in the community. Reduced compliance in the presence of multiple interventions could be one explanation, although our previously published preliminary results showed only slightly reduced compliance in all three interventions compared with exercise alone [9]. In addition, there was no evidence for an

adverse impact on fall rates due to multiple interventions as there were no statistical interactions evident. This is in contrast to the negative interaction between home safety and exercise interactions observed in a more frail study sample [6].

We reported a new finding of potentially important effects on injurious falls, particularly for the vision, and vision plus exercise interventions. It could be the case that the specific combination of improved vision and improved strength and balance may provide the ability to both see and respond quickly to hazards and hazardous situations resulting in fewer falls in high injury risk locations such as bathrooms and stairs. Alternatively, as multiple comparisons were made, there is the possibility that this result could be a chance finding.

These findings add to what has been described as the limited evidence base [5] of fall prevention programmes being effective in reducing both injurious falls and those resulting in medical treatment [7]. Our findings are consistent with the study by Harwood *et al.* [13] who reported that enhancing vision via expedited cataract surgery was effective in reducing falls and fall-related fractures but inconsistent with those of Cumming *et al.* [14] who reported an increased rate of falls and a trend towards increased fracture rate for a similar vision intervention and study sample.

Our findings confirm previously reported trial results using the current recommended analytic and reporting approaches [8, 15]. The no falls interventions reduced both the risk and rate of falling. The results support the

contention that multi-component interventions do not prevent more falls than single interventions. However, the new finding of benefit for injurious falls and for falls necessitating medical treatment for the combined vision plus exercise intervention adds another dimension to the debate on the value of multi-component programmes [16]. Further examination of intervention compliance, the impact of compliance on the findings reported here, the characteristics of compliers and ultimately methods to ensure high levels of compliance with community-based falls prevention programmes is required.

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## Key points

- Confirms the effectiveness of exercise in preventing falls among community dwelling older adults.
  - Supports the contention that multi-component interventions do not prevent more falls than a single intervention.
  - For injurious falls and falls necessitating medical care, the vision intervention was associated with fewer falls, especially when combined with exercise.
  - Further research on methods to ensure intervention compliance is required.
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## Supplementary data

Supplementary data mentioned in the text is available to subscribers in *Age and Ageing* online.

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## Contributors

All authors were involved in study conception or design, interpreting the results and drafting and revising the paper.

M.F. undertook the analysis. M.F. and L.D. are the guarantors.

## Conflicts of interest

None declared.

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# Investigating age-related changes in taste and affects on sensory perceptions of oral nutritional supplements

ORLA KENNEDY<sup>1</sup>, CLARA LAW<sup>1</sup>, LISA METHVEN<sup>1</sup>, DONALD MOTTRAM<sup>1</sup>, MARGOT GOSNEY<sup>2</sup>

<sup>1</sup>Food and Nutritional Sciences, Reading University, Reading, UK

<sup>2</sup>Clinical Health Sciences, Reading University, Reading, UK

Address correspondence to: O. Kennedy. Tel: (+44) 118 378 7709; Fax: (+44) 118 378 7586; Email: o.b.kennedy@reading.ac.uk

## Abstract

**Background:** sip feeds are oral nutritional supplements (ONSs) that are commonly prescribed to malnourished patients to improve their nutritional and clinical status. However, ONSs are poorly consumed and frequently wasted, with sweetness being identified as one of the factors leading to patients' dislike of ONSs.

**Objectives:** to investigate if age affects sweetness thresholds and if this impacts upon perceived sweetness intensity, hedonic (sweetness and overall) and ranked preference of ONS products.

**Design:** prospective, observational.

**Subjects:** thirty-six young adults (18–33 years) and 48 healthy older adults (63–85 years).

**Setting:** Department of Food and Nutritional Sciences and the Clinical Health Sciences at the University of Reading.

**Methods:** detection and recognition threshold levels, basic taste identification and 'just about right' level of sweetness were examined. Three ONSs (chocolate, vanilla, strawberry) and sucrose solutions were evaluated for hedonic sweetness, overall hedonic liking, sweetness intensity and rank preference.

**Results:** significant differences were found in both sweetness detection and recognition thresholds ( $P = 0.0001$ ) between young and older adults, with older adults more likely to incorrectly identify the taste ( $P = 0.0001$ ). Despite the deterioration in sweetness sensitivity among the older adults, there were no significant differences found in sweetness intensity perceived for the ONS products presented ( $P > 0.05$ ) when compared with the young adults. However, across both groups sweetness intensity was found to be correlated with overall product dislike across all flavour variants tested ( $R = 0.398$ ,  $P = 0.0001$ ).

**Conclusions:** sweetness appears to be one of many factors contributing to the dislike of ONSs. Manufacturers are encouraged to reconsider the formulations of these products so that beneficial effects of ONSs can be delivered in a more palatable and acceptable form and wastage reduced.

**Keywords:** oral nutritional supplement, taste, acceptability, preference, elderly