Effect of a multifactorial, interdisciplinary intervention on risk factors for falls and fall rate in frail older people: a randomised controlled trial

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Abstract

Background: frail older people have a high risk of falling.
Objective: assess the effect of a frailty intervention on risk factors for falls and fall rates in frail older people.
Design: randomised controlled trial.
Participants: 241 community-dwelling people aged 70+ without severe cognitive impairment who met the Cardiovascular Health Study frailty definition.
Intervention: multifactorial, interdisciplinary intervention targeting frailty characteristics with an individualised home exercise programme prescribed in 10 home visits from a physiotherapist and interdisciplinary management of medical, psychological and social problems.
Measurements: risk factors for falls were measured using the Physiological Profile Assessment (PPA) and mobility measures at 12 months by a blinded assessor. Falls were monitored with calendars.
Results: participants had a mean (SD) age of 83.3 (5.9) years, 68% were women and 216 (90%) completed the study. After 12 months the intervention group had significantly better performance than the control group, after controlling for baseline values, in the PPA components of quadriceps strength (between-group difference 1.84 kg, 95% CI 0.17–3.51, \(P = 0.03\)) and body sway (−90.63 mm, 95% CI −168.6 to −12.6, \(P = 0.02\)), short physical performance battery (1.58, 95% CI 1.02–2.14, \(P \leq 0.001\)) and 4 m walk (0.06 m/s 95% CI −0.25 to 0.15, \(P = 0.02\)) with a trend toward a better total PPA score (−0.40, 95% CI −0.83–0.04, \(P = 0.07\)) but no difference in fall rates (incidence rate ratio 1.12, 95% CI 0.78–1.63, \(P = 0.53\)).
Conclusion: the intervention improved performance on risk factors for falls but did not reduce the rate of falls.
Trial registration: ACTRN12608000250336.

Keywords: exercise, falls, frail elderly, older people, randomised controlled trial

Introduction

One-third of community-dwelling people aged over 65 fall at least once per year [1], and the risk of falls is increased in older people who are frail [2–5]. Frail older adults are 1.16 [3] to 3.6 [4] times more likely to fall than those who are not frail. Falling can lead to loss of confidence [6], injury, functional decline [7], hospitalisation and admission to residential aged-care facilities [8]. As the proportion of older people rises globally, falls in frail older people will have an increasing impact on the healthcare system.

Frailty is recognised as a distinct syndrome whereby decline in multiple physiologic processes leads to vulnerability to adverse health outcomes [3, 9]. Frailty is an independent risk factor for falls [2–5], fall-related fracture [2] and reduced mobility [3]. While there is strong evidence that multifactorial
Interventions and exercise interventions prevent falls in older people residing in the community [7], the effect of interventions on falls and risk factors for falls in frail older people is unclear.

In a randomised controlled trial, we found that frailty was significantly reduced with a multifactorial interdisciplinary intervention targeting degree of frailty in older people who were defined as frail using the Cardiovascular Health Study (CHS) Frailty Phenotype [3, 10]. The intervention also addressed known risk factors for falls such as impaired balance and strength, home hazards and sub-optimal medication use [11]. The aim of this paper is to evaluate the effect of this intervention on risk factors for falls and fall rate.

**Methods**

**Trial design**

The Frailty Intervention Trial, a prospective, parallel-group, assessor-blind, randomised controlled trial, was conducted among 241 frail community-dwelling older people from January 2008 to June 2011. Ethical approval was obtained from Northern Sydney & Central Coast Health Human Research Ethics Committee. The study protocol was registered with the Australian New Zealand Clinical Trials Registry (ANZCTRN 12608000250336) and has been published [12]. The primary outcomes of the trial are reported elsewhere [10]. This paper reports the outcomes relating to fall risk factors and fall rate.

**Participants**

Potential participants were identified from older people being discharged from the Division of Rehabilitation and Aged Care Services at Hornsby Ku-ring-gai Health Service (Sydney, Australia). Eligible participants were 70 years or older; frail (met specified cut-offs for three or more of the CHS frailty criteria: slow gait, weak grip, exhaustion, low energy expenditure and weight loss) [3], did not live in a residential aged-care facility, had a Mini-Mental State Examination [13] score >18 and life expectancy of at least 12 months (a modified Implicit Illness Severity Scale score ≤3) [14].

**Randomisation**

Following baseline assessment, research staff randomised participants to the intervention or control group, with stratification by degree of frailty (three frailty criteria versus four or five frailty criteria). The group allocation schedule was generated and managed by an investigator independent of participant recruitment [15], using a computer-generated random number schedule with varying block sizes.

**Intervention**

The intervention has been described in detail previously [12]. Briefly, the 12-month multifactorial intervention was delivered by an interdisciplinary team comprising two physiotherapists, a geriatrician, rehabilitation physician, dietician and nurse and was coordinated via regular case conferences and case management. It was tailored to each participant based on baseline CHS frailty criteria and issues identified during comprehensive geriatric evaluation.

Ten physiotherapy visits in the 12-month study period focussed on exercise. A home programme of balance and lower limb strength training was performed in standing, tailored to the individuals’ physical impairments and prescribed for 20–30 min three to five times per week for 1 year. Full details of the weight-bearing exercise for Better Balance programme are available at www.webb.org.au. The physiotherapists assessed the home environment, provided safety advice, recommended mobility aids and organised simple modifications to enhance safety.

Medical management included medication review and management of chronic health conditions. Participants with significant urinary incontinence were referred to a continence clinic. Participants who met the weight loss CHS frailty criterion (unintentional weight loss exceeding 4.5 kg in the past year) underwent nutritional assessment and management. Participants were referred to an occupational therapist for home safety interventions when the environment presented a high fall risk.

The intervention and control groups received the usual care available to older residents of the Hornsby Ku-ring-gai area from community services and their general practitioner, such as medical management of health conditions, delivery of care requirements and allied health involvement.

**Outcomes**

The outcomes of interest were risk factors for falling and fall rate.

Risk factors for falls were assessed using performance-based tests in participants’ homes by assessors masked to group allocation at baseline and 3 months and 12 months after randomisation. The tests were: (i) the Physiological Profile Assessment (PPA) which includes five measures of physiological functioning (postural sway, knee extension strength, reaction time, lower limb proprioception and visual contrast sensitivity) and has been found to be predictive of falls and reliable [16]; (ii) two measures of mobility as mobility impairments are strongly associated with future falls [17], the short physical performance battery (SPPB) [18] and the 4-m walk test.

Fall rate was assessed using monthly calendars and follow-up telephone calls as required. A fall was defined as ‘unintentionally coming to the ground or some lower level other than as a consequence of sustaining a violent blow, loss of consciousness, sudden onset of paralysis as in stroke or an epileptic seizure’ [19].

The treating physiotherapists estimated a global level of adherence to the multifactorial intervention in five categories: 0, 1–24, 25–49, 50–74 and 75–100%.

**Sample size**

The sample size of 240 participants was designed to provide 80% power to detect a 15% between-group difference in the
lower extremity continuous summary performance score version of the SPPB [20], a primary outcome of the Frailty Intervention Trial.

Statistical analysis
The analyses were by intention to treat [21] using Stata version 12 (College Station, TX, USA). If participants could not perform tests due to physical limitations, we allocated a score of 0 for measures where a low score reflected poor performance and assigned a score of the mean +3 SD for measures where a high score indicated poor performance.

The effects of group allocation on continuously scored outcome measures were estimated with longitudinal mixed models that incorporated intervention group, time as a discrete variable (baseline, 3 and 12 months) and the interaction between group and time using the ‘xtmixed’ procedure in Stata [22]. We analysed the number of falls per person-year using negative binomial regression to estimate the difference in fall rates between the two groups adjusted for length of follow-up [23].

We tested for evidence of interactions between group and frailty severity (grouped by number of CHS criteria met, three versus more than three) and walking speed (as a continuous variable) [24].

We compared outcomes in the 51 ‘adherers’ (intervention group participants who adhered to >50% of the home exercise sessions) with the control group and then with the 69 ‘non-adherers’ (intervention group participants who adhered to 50% or less of the home exercise sessions). We adjusted for factors known to predict falls [25]: age, gender, Geriatric Depression Scale score, cognition, comorbidities and mobility and baseline score on the variable examined.

Results
Baseline characteristics
Table 1 shows the baseline characteristics of the 241 participants. The groups were similar at baseline, although the control group (n = 121) had slightly better SPPB test scores. Figure 1 shows participant flow through the study.

Interventions
The median level of adherence to the multifactorial intervention programme was in the 25–49% range. Adherence was 0% for 16 participants (13%).

Physiotherapists delivered the WEBB program to 93% of intervention group participants, with a median of eight sessions; targeted self-selected mobility goals in 61 participants (51%) and provided or advised on equipment for 48 (40%). The median number of face-to-face sessions with a physiotherapist was 10 (range 0–24), with the high end of the range reflecting the case management required by some participants. The dietician provided assessment and intervention to 60 (50%) participants, 29 (24%) were reviewed by a geriatrician or rehabilitation physician and 49 (41%) were referred to specialist aged-care services. Vitamin D supplements were recommended to 25 (21%) participants and 36 (30%) received advice regarding medication. Further details of the intervention as implemented are available from the authors on request.

Outcomes
Fall risk factors
Table 2 shows the scores for the continuously measured outcomes. In the intervention group, PPA fall risk decreased in the first 3 months then returned to baseline levels; a post hoc test of trend showed a significant quadratic trend (P = 0.008). The control group showed a significant linear trend (P < 0.001) with an overall increase in fall risk. After 12 months, the intervention group had better performance on the PPA than the control group, but this was not statistically significant (between-group difference 0.40, 95% CI −0.83–0.04, P = 0.07). There were statistically significant between-group differences for the quadriceps strength and sway components of the PPA, with significant group by time interactions at 12 months but not 3 months, and a significant effect of treatment overall. The intervention had no significant effect on the reaction time, contrast sensitivity or proprioception components of the PPA.

The SPPB and gait speed measures of mobility showed significant group by time interactions at 12 months, but not 3 months, and there was a significant effect of treatment overall (Table 2).
Effect of multifactorial intervention on risk factors for falls in frail older people

There was a greater effect of the intervention on gait speed in the more frail participants. This was not significant at 3 months (interaction term $P = 0.97$) but was significant at 12 months (interaction term $P = 0.03$) with a between-group difference of $0.14 \text{ m/s} \ (95\% \text{ CI } 0.06–0.22, n = 76)$ in the more frail participants and $0.02 \text{ m/s} \ (95\% \text{ CI } -0.04–0.07, n = 140)$ in the less frail. There was no significant differential effect of the intervention on SPPB or PPA components based on baseline degree of frailty or walking speed.

Compared with the control group, adherers had a lower PPA fall risk than the control group at 12 months (IRR 0.70; 95% CI 0.41–1.19, $P = 0.19$). The intervention reduced fall risk factors, with significant improvements in mobility, strength and balance measures and a trend toward a better total PPA score. However, no effect of the intervention on fall rate was evident.

The intervention benefited quadriceps strength and sway, two of the five PPA fall risk score components—findings consistent with other studies that have shown weight-bearing exercise can benefit these measures [27, 28]. Previous studies have also reported exercise can improve reaction time [28]; however, we found no treatment effect, perhaps due to insufficient challenge during unsupervised home-based exercise sessions. The effect of the intervention on mobility is consistent with previous studies in frail older people, which indicate regular multi-component training over a prolonged period can improve composite activity measures and gait speed [29]. Importantly, the between-group differences in SPPB and gait speed found here are considered clinically significant in older people [30].

Greater impacts on PPA scores and falls may have been achieved from a higher dose of intervention. The median adherence of 25–50% totalled <1 h of exercise per week. This level falls significantly below systematic review evidence which indicates at least 2 h of exercise per week for at least 6 months results in larger falls prevention effects [31]. Fall risk outcomes were significantly better in the participants who

Adverse events

Two intervention group participants experienced back pain consistent with the study definition of an adverse event: a medical event or injury that restricted activities of daily living for more than 2 days or resulted in medical attention [26]. Both participants recommenced exercise following modification of the exercise program.

Discussion

To our knowledge, this is the first study to evaluate the effect of an intervention targeting frailty on fall risk factors and falls in older people defined as frail using a validated measure of frailty. Fifty-eight percent of participants fell in the follow-up year, and 60% had PPA scores of >2, confirming frail older people are at markedly increased risk of falls based on normative data [16]. The 12-month multifactorial intervention reduced fall risk factors, with significant improvements in mobility, strength and balance measures and a trend toward a better total PPA score. However, no effect of the intervention on fall rate was evident.

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Table 2. Mean (SD) of intervention and control groups, and mean (95% CI) difference between groups for continuous outcomes

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Groups</th>
<th>Difference between groups</th>
<th>Overall treatment effect</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Intervention Month 0 (n = 120) / Month 3 (n = 109) / Month 12 (n = 107)</td>
<td>Intervention minus control</td>
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<tr>
<td></td>
<td>Control Month 0 (n = 121) / Month 3 (n = 117) / Month 12 (n = 109)</td>
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<td>Month 3 adjusted for Month 0</td>
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<td>Month 12 adjusted for Month 0</td>
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<td>Fall risk:</td>
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<tr>
<td>PPA Falls Risk Score³</td>
<td>2.79 (1.75) / 2.38 (1.70) / 2.79 (1.93)</td>
<td>-0.25 (−0.68 to 0.17, P = 0.24)</td>
<td>-0.40 (−0.83 to 0.04, P = 0.07)</td>
</tr>
<tr>
<td>Visual contrast sensitivity (score)³</td>
<td>16.6 (3.94) / 16.86 (4.27) / 16.35 (4.56)</td>
<td>-0.40 (−0.83 to 0.04, P = 0.07)</td>
<td>P = 0.87</td>
</tr>
<tr>
<td>Postural sway on foam total length (mm)³</td>
<td>361.08 (273.26) / 388.78 (304.66) / 388.78 (304.66)</td>
<td>-9.82 (−86.7 to 67.0, P = 0.80)</td>
<td>-90.63 (−168.6 to −12.6, P = 0.02)</td>
</tr>
<tr>
<td>Knee extension strength (kg)³</td>
<td>14.07 (5.58) / 12.04 (5.47) / 11.76 (5.65)</td>
<td>-0.13 (−1.77 to 1.51, P = 0.88)</td>
<td>1.84 (0.17–3.51, P = 0.03)</td>
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<tr>
<td>Lower limb proprioception (degrees)³</td>
<td>2.98 (2.02) / 3.38 (2.14) / 4.22 (2.33)</td>
<td>0.11 (−0.55 to 0.78, P = 0.74)</td>
<td>0.07 (−0.60 to 0.75, P = 0.83)</td>
</tr>
<tr>
<td>Hand reaction time (s)³</td>
<td>349.44 (121.40) / 293.32 (86.01) / 309.01 (110.51)</td>
<td>1.58 (0.60–2.14, P &lt; 0.001)</td>
<td>P &lt; 0.001</td>
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<tr>
<td>Mobility</td>
<td></td>
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<tr>
<td>SPPB, 0–12³</td>
<td>5.21 (1.89) / 5.40 (2.32) / 5.83 (2.82)</td>
<td>0.17 (−0.38 to 0.73, P = 0.55)</td>
<td>1.58 (1.02–2.14, P &lt; 0.001)</td>
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<tr>
<td>Gait speed (m/s)³</td>
<td>0.48 (0.18) / 0.50 (0.21) / 0.55 (0.24)</td>
<td>0 (−0.04 to 0.05, P = 0.81)</td>
<td>0.06 (0.01–0.10, P = 0.02)</td>
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P-values of <0.05 are in bold.

³Lower scores reflect better performance.

³Higher scores reflect better performance.

adhered to >50% of the intervention, a finding that stresses the need for identifying improved strategies for maximising adherence in rehabilitation.

Our study was not powered for falls (power calculations indicate we would have needed 520 people to detect a 30% reduction in falls), but there was no indication the intervention reduced falls. Previous trials have included samples that are probably frail, for example people living in aged-care facilities [32], recently sustaining hip fractures [33–35], and meeting specified clinical predictors of frailty [26, 36, 37] and the results of these trials are inconsistent [7, 32]. Further studies should address the specific needs of frail older people. For example, multifactorial interventions specifically targeting falls may be more effective than the present intervention which primarily targeted frailty itself. However, multifactorial fall prevention interventions may also be too intensive or confusing for frail older people so single interventions should also be explored as they may be equally effective and more easily implemented than multifactorial interventions [38]; intervention effects may be greater with increased supervision during exercise (to increase adherence and challenge to balance); and additional interventions addressing risk factors such as urinary incontinence, impaired cognition, low mood and vitamin D deficiency could be considered.

The strengths of our trial were the inclusion of participants who met a commonly accepted definition of frailty, robust trial design, adherence to the published study protocol and small losses to follow-up. It is feasible to generalise the findings to community-dwelling frail older people and the intervention resembles that deliverable in existing health services in urban Australia. The study is not without limitations. Outcome assessors were inadvertently unblinded to group status by 123 participants (51%) at the 12-month follow-up. As there was no frequency-matched social intervention for the control group, the positive impact of contact with staff providing the intervention cannot be excluded.

**Conclusion**

For frail older people residing in the community, a 12-month multifactorial intervention improved performance on risk factors for falls but had no effect on the rate of falling itself. Further investigation is required to determine optimal falls prevention interventions in frail older people.

**Key points**

- A multifactorial intervention led to improved performance on risk factors for falls in older people who are frail.
- There were significant improvements in strength, balance and mobility. There was no detectible effect on rate of falling.
- Future research is needed to determine whether these gains translate into reduced fall and injury risk in frail older people.

**Conflict of interest**

None declared.

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**Supplementary data**

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

**References**

The list of references supporting this paper has meant that only the most important are listed here and are represented by bold type throughout the text. The full list of references is available as Supplemental data available in *Age and Ageing* online, Appendix 2.


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