

The Screening and Intervention to Prevent Falls and Fractures in Older People Randomised Controlled Trial: Overview and Commentary

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The Prevention of Fall Injury Trial (PreFIT) was commissioned by the UK National Institute of Health Research Health Technology Assessment programme. This large multicentre pragmatic cluster randomised controlled trial aimed to evaluate the clinical and cost-effectiveness of three alternative primary care interventions for preventing falls and fractures in community dwelling older adults. The three primary care interventions consisted of a) advice only, b) screening, advice and exercise and c) screening, advice and multifactorial falls prevention.

Study design and outcomes

This trial involved 63 urban and rural general practices across South-West, Central and Northern England that were supported by Primary Care Research Networks and Comprehensive Local Research Networks. General practices were eligible to participate if they were in an English region with infrastructure to support the trial, agreed to adhere to a predetermined treatment pathway and had the technical capacity to undertake electronic searching to identify a suitable sample. Recruited general practices were enlisted in blocks of three from the same local health district with one practice assigned to each intervention.

Participants were eligible if they were 70 years of age or older and were living in the community or in sheltered housing. Participants were excluded if they were residing in long-term residential or nursing care, had a terminal illness or had an expected shortened lifespan (estimated to be less than 6 months by the general practitioner).

The primary outcome for the trial was peripheral fracture, expressed as the fracture rate per 100 person-years over 18 months after randomisation of the general practice. Peripheral fracture included any fracture to the appendicular skeleton, i.e. limbs, shoulder and pelvic girdle, skull and facial bones. Compression fractures within the vertebral column were excluded. Secondary outcomes included number of patients with at least one fracture, falls, mortality, health-related quality of life and resource use.

Recruited general practices using their electronic databases identified a random sample of 400 adults aged 70 years and above. After removal of excluded participants, they mailed an invitation package containing an advice booklet on preventing falls, baseline questionnaire and consent form. The initial aim was to recruit 150-200 participants from each general practice; however, this was broadened to 300-400 participants per practice during the trial. Prior to the recruitment protocol change, once 150-250 participants from each practice returned the survey and a signed consent form, enrolment was closed.

Nine thousand and three participants were recruited and underwent randomisation. Across the groups, the mean age was 78 years, 53% were female. Baseline characteristics of the randomised participants between the three groups were similar with regard to age, sex, race, education, coexisting conditions, fall risk, reported falls in previous year, reported fracture in previous year, frailty, cognitive impairment and body-mass index.

Intervention and its implementation

Upon reaching the required number of participants at three general practices from a local health district, each was randomly assigned to one of the intervention groups. All participants received an advice booklet on preventing falls. This booklet contained information on improving strength and balance, eyesight, hearing, medications, home safety and advice on fear of falling. It also contained contact information and a list of websites for national help organisations. Participants in the practices in the advice only intervention received no further intervention or screening.

Practices in the exercise or multifactorial fall prevention interventions provided participants with an additional screening questionnaire about the risk of falls. Participants whose responses indicated an increased risk of falls (36.9% for exercise and 37.5% for multi-factorial fall prevention interventions) were then provided an exercise or multifactorial fall prevention intervention dependent on their random assignment.

Exercise Intervention – Otago Exercise Program

Participants who were screened as being at risk of falls (36.9%) initially underwent a 1-hour individual baseline assessment. This consisted of a brief medical history followed by a Chair Stand Test and the Four Test Balance Scale assessment. The results of these tests determined the starting level of exercise prescription.

1. The Chair Test measures a participant's ability to stand up and sit down as quickly as possible from a chair 5 times with arms crossed. A maximum time of 2 minutes was given and use of arms was allowed if needed. If this were the case, the participant would then start at Level 1 for strength exercises.
2. The Four Test Balance Scale involves the participant completing and progressing through 4 increasingly difficult balance tests: feet together stand, semi-tandem stand, tandem stand and single leg stand. Progression through the test continues if a stance is held for 10 seconds.
3. Walking frequency was documented and safe ways to increase walking duration was discussed and if safe a target of 30 minutes twice a week was set.

The Otago Exercise Program consisted of a warmup, five lower limb strength exercises and twelve dynamic balance exercises with the therapist tailoring the exercises and starting levels to a difficulty appropriate for the participant. Sessions lasted approximately 30 minutes and participants were instructed to complete the program at least 3 times per week with a rest day in between each session. Participants were encouraged to use exercise activity calendars and SMART (Specific, Measurable, Achievable, Relevant and Timely) goals were used to help with compliance.

The exercise intervention ran for 6 months and included a minimum of three face-to-face appointments, either individually or in a group setting and three telephone appointments. An exercise log was taken at each appointment and exercises were progressed as needed. At the

conclusion of the exercise program participants were encouraged to continue with their exercise programme and a 'staying active' leaflet, designed specifically for the trial, was given to each participant. This provided information on the ongoing benefits of exercise, purchasing of equipment and local exercise groups.

All therapists who ran this intervention received an initial 4-hour structured training session from a physiotherapist qualified as an Otago Exercise Program leader. Training included a background to the problem of falls, current fall prevention evidence, rationale for the trial and both theoretical and practical sessions on the Otago Exercise Program and PreFIT administrative procedures. Each therapist underwent at least one structured observation by a research physiotherapist to assess whether they delivered the exercise in accordance with the specified protocol. Therapists were graded (satisfactory, minor concerns or serious concerns) on correct exercise prescription in response to initial assessment, effective and safe delivery including progression, adherence to protocol and completion of paperwork. Therapists consisted of 58% Physiotherapists, 10% Occupational Therapists, 17% Therapy Assistants and 15% Exercise Specialists.

Multifactorial Fall Prevention Intervention

The Multifactorial Fall Assessments were conducted by a practice nurse or equivalent registered healthcare professional, or by a community or hospital-based falls team. This was performed within the general practice, home or community or general hospital. Participants who were screened as being at risk of falls (37.5%) undertook a 1-hour assessment including a detailed falls history, followed by assessments of balance and gait, vision, medication, a cardiac screen, a feet and footwear screen and a home environment assessment. Every participant referred for a multifactorial fall prevention intervention had each of the above risk factors assessed. Recommendations and further referral were then provided.

The initial assessment included seven components:

1. Falls history interview: The purpose of the fall history interview was to identify any predisposing factors leading to a fall, to determine the context and consequences of previous falls or near falls and to elucidate clues about causation.
Intervention: The assessor was trained in systematic enquiry about falls, including symptoms and contextual factors before, during and after any fall-related event and aimed to identify 'red flags' that may require referral to a GP or medical specialist.
2. Balance and gait assessment: The Timed Up-and-Go (TUGT) was used as an assessment of the participants balance and gait.
Intervention: A 14 second cut-point was used as a predictor of falls and generated a referral to PreFIT physiotherapy for strength and balance retraining (Otago Exercise Programme).
3. Cardiac screening: Participants were asked whether they experience dizziness or light-headedness when standing up quickly or first thing in the morning getting out of bed. Lying and standing blood pressure measures were taken on all participants and the radial pulse was measured for 1 minute with an electrocardiogram taken if the participant had an irregular pulse, bradycardia or tachycardia. Participants were asked to report the presence of dizziness or light-headedness during the standing phase.

Intervention: Symptomatic participants were provided with a leaflet on advice about changing position, fluid intake and strategies to reduce chance of light-headedness. A referral was made to a GP or consultant-led falls clinic if a cardiac problem was suspected.

4. Medication review: Two different medication reviews were conducted. A visual medication screen of all prescribed drugs combined with a face-to-face discussion with the patient on their use. The aim of this screen was to search for psychotropics and culprit medication such as anti-hypertensives, antiarrhythmics, diuretics, vestibular suppressants, analgesics, anticonvulsants, anti-Parkinsonians and vasodilators.

Intervention: Participants with one or more of these medications then underwent a comprehensive GP-led clinical medication review.

5. Visual Acuity: A visual acuity screen was performed using a standard 3 metre Snellen chart. This was used in conjunction with questions on last eye check, changes in eyesight and visual problems.

Intervention: Participants identified with corrected visual acuity worse than 6/6 for either eye were referred to an optician for a full eye test.

6. Foot problems: Participants were screened for any foot problems including pain, numbness, diabetes and regular attendance at chiropody/podiatry. Visual examinations for bunions, hammertoes, calluses or nails that cause pain or gait disturbances were completed. Proprioception was measured by matching big toes with eyes closed. Sensation was measured by brushing cotton wool lightly across both feet.

Intervention: Footwear was assessed, and advice provided on proper fitting shoes.

7. Home environment: A home assessment was conducted if a participant expressed concerns about their home environment or safety whilst performing activities, or if concerns are raised during the falls interview. Screening questions included asking about the use of furniture while walking, difficulty getting out of chairs or rising from the toilet, stairs or steps located at home and coping with stairs and the use of walking aids.

Intervention: Referrals were then made to Occupational Therapists or social services. A home safety sheet was provided to anyone considered to benefit from simple advice on home safety.

Main findings

Although not statistically significant, the greatest number of fractures occurred among persons assigned to the multifactorial fall-prevention strategy, and the fewest number occurred in the group that received advice by mail only. There was no significant difference in fracture rates (number of fractures per 100 person-years) between the exercise group and the advice-by-mail group (adjusted rate ratio for fracture, 1.20; 95% CI, 0.91 to 1.59; P=0.19) or between the multifactorial fall-prevention group and the advice-by-mail group (adjusted rate ratio, 1.30; 95% CI, 0.99 to 1.71; P=0.06).

Regarding secondary outcomes, there was a reduction in the fall rate in the exercise group compared to the advice group in the 4–8-month timepoint (adjusted rate ratio for falls, 0.79; 95% CI, 0.62-1.08), but this difference in fall rates were not sustained over 18 months. There were no differences in the Short-Form General Health Survey (SF-12) or Strawbridge Frailty Index scores among the groups and no subgroup or adherence effects.

A nested analysis was conducted of participants who were at an increased risk for falls as determined from a fall risk screening questionnaire (4192 of 9803 participants). The fracture rate was 3.70 per 100 person-years in the exercise group (adjusted rate ratio in the comparison with advice-by-mail group, 0.94; 95% CI, 0.65 to 1.35), 5.12 per 100 person-years in the multifactorial fall-prevention group (adjusted rate ratio in the comparison with advice-by-mail group, 1.26; 95% CI, 0.89 to 1.78), and 4.28 per 100 person-years in the advice-by-mail group.

The exercise strategy was the most cost effective compared to the mail alone and multifactorial fall prevention strategies in terms of producing higher QALYs at a lower expected cost. However, the practical differences between the quality of life and costs estimated between treatment choices are modest and driven largely by a higher QALY gain for exercise, particularly as compared with multifactorial fall prevention. The probability that exercise is cost-effective at the £20,000 (AUD\$36,000) threshold is 70%.

Authors' interpretations of the findings

The authors acknowledge several limitations of the study. Due to the large sample size, the main method of measuring falls was retrospective reporting over survey intervals. This method may have underestimated the incidence of falls as compared with reporting from diaries. This was confirmed in a study within the trial. Participants were invited to self-complete 4 monthly falls diaries. Included participants were randomly assigned to complete the 4 monthly falls diaries at either baseline to 4 months; 5-8 months; and 9-12 months. Adjusted analyses summarised for the whole year of follow-up suggested a 32% difference in falls rate between prospective and retrospective data collection methods. However, under-reporting of falls was consistent across groups and the authors did not believe this affected the estimates of the intervention effect. The authors also reported that participants who were likely to be at greatest risk of falling (older age, poorer physical and mental health, poor cognitive function, frail or with a history of falling) were less likely to return a monthly falls calendar.

Falls were significantly reduced during the course of the six-month exercise programme, but this effect was not sustained over the 18 months of trial follow-up. Consistent with other studies, it appears exercise needs to be regular and maintained to be efficacious for fall prevention. Further, the provision of encouragement and a leaflet at the end of the exercise programme appears not to have been sufficient to maintain exercise participation, and in consequence resulted in a loss of a protection for falls. More intensive and prolonged exercise interventions with adequate adherence are required to definitively evaluate the role of exercise for fall prevention on fall injuries including fractures.

The proportion of participants who experienced a fracture was lower than anticipated for the calculation of the sample size. A between-group comparison of rate (number of fractures per 100 person-years) was used for the estimation of effect which provided more power in the analysis than a comparison of the proportion of participants.

A small number of people at increased fall risk may have been missed, as persons who did not respond to the initial fall risk screening mail were not recontacted.

Lead author Professor Sallie Lamb presented additional information on the treatment uptake and progress on 12/12/2020 at a webinar hosted by the Institute for Musculoskeletal Health and the Australian and New Zealand Falls Prevention Society. Professor Lamb mentioned that there was poor uptake of both the exercise and Multifactorial Fall Prevention interventions which may have contributed to the study's ineffectiveness. Sixty five percent of eligible and referred participants commenced the exercise intervention and 71% of eligible and referred participants commenced the multifactorial intervention. Participants who received the multifactorial assessments did not necessarily receive changes in management. Forty three percent of the participants were referred for medication review, however, the majority reported no changes to their medications. There was an increase in the total number of drugs prescribed over time, including a slight increase in the prescribing of psychotropic medications and bisphosphonates and an increase in mineral supplementation. Despite detailed training of clinicians, only 24% of participants were referred to exercise, with mostly older, frailer women being referred. There was also low use of Occupational Therapist home assessments, with most participants receiving advice leaflets instead. The ineffectiveness of the Multifactorial Fall Prevention intervention is in line with current evidence from a Cochrane review which found variable impacts of multifactorial interventions on falls and no reliable evidence about fractures.

Additional interpretations of the findings

The trial was designed so only participants who were at an increased risk of falling determined via responses to a questionnaire were eligible for an intervention. Of the 2929 participants assigned to the advice by mail, screening, and targeted exercise only 1079 (36.9%) were eligible for exercise and 350 of these did not attend. A similar result was found in the advice by mail, screening, and targeted multifactorial fall prevention. One thousand and seventy-four participants (37.5%) in this group were eligible for a multifactorial fall prevention program and 439 participants did not attend. Primary analyses included all participants enrolled from practices that underwent randomisation and this meant that many participants who did not receive an intervention were included in the fracture analyses.

A nested analysis was performed on participants who were at increased risk of falls (4192 of 9803 participants). The fracture rate was 3.70 per 100 person-years in the exercise group (adjusted rate ratio in the comparison with advice-by-mail group, 0.94; 95% CI, 0.65 to 1.35), 5.12 per 100 person-years in the multifactorial fall prevention group (adjusted rate ratio in the comparison with advice-by-mail group, 1.26; 95% CI, 0.89 to 1.78), and 4.28 per 100 person-years in the advice-by-mail group. This did not take into consideration those who, while eligible, did not undertake an intervention.

Conclusions

This study provides valuable insight into the challenges of delivering and evaluating fall-prevention interventions at scale. It is clear that using this model of screening and intervention delivery neither exercise nor multifactorial interventions prevented fractures. There were some positive impacts of exercise on falls.

Given the limitations in roll out of the intervention and the screening approach used it cannot be concluded that fall prevention interventions will never prevent fractures. Further investigations in

which interventions are comprehensively implemented are required to definitively determine whether fall prevention interventions can prevent fall related injuries.