

Effectiveness of a Falls-and-Fracture Nurse Coordinator to Reduce Falls: A Randomized, Controlled Trial of At-Risk Older Adults

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(See editorial comments by Dr. Mary Tinetti on pp 1563–1565)

OBJECTIVES: To assess the effectiveness of a community-based falls-and-fracture nurse coordinator and multifactorial intervention in reducing falls in older people.

DESIGN: Randomized, controlled trial.

SETTING: Screening for previous falls in family practice followed by community-based intervention.

PARTICIPANTS: Three hundred twelve community-living people aged 75 and older who had fallen in the previous year.

INTERVENTION: Home-based nurse assessment of falls-and-fracture risk factors and home hazards, referral to appropriate community interventions, and strength and balance exercise program. Control group received usual care and social visits.

MEASUREMENTS: Primary outcome was rate of falls over 12 months. Secondary outcomes were muscle strength and balance, falls efficacy, activities of daily living, self-reported physical activity level, and quality of life (Medical Outcomes Study 36-item Short Form Questionnaire).

RESULTS: Of the 3,434 older adults screened for falls, 312 (9%) from 19 family practices were enrolled and randomized. The average age was 81 ± 5 , and 69% (215/312) were women. The incidence rate ratio for falls for the intervention group compared with the control group was 0.96 (95% confidence interval = 0.70–1.34). There were no significant differences in secondary outcomes between the two groups.

CONCLUSION: This nurse-led intervention was not effective in reducing falls in older people who had fallen previously. Implementation and adherence to the fall-prevention measures was dependent on referral to other health professionals working in their usual clinical practice. This may have limited the effectiveness of the interventions. *J Am Geriatr Soc* 56:1383–1389, 2008.

Key words: falls prevention; elderly people; randomized controlled trial; multifactorial intervention

Fall-prevention strategies work for people who are elderly and at risk. There is substantial evidence from randomized, controlled trials that multifactorial and single-factor interventions decrease falls in trial populations.^{1,2} There is now considerable public investment in fall prevention because of the consequences of falling, the cost to the community, and the evidence that this is a partially preventable problem, although important questions remain about how best to deliver fall and fracture prevention programs to meet the current guidelines.³

There are reasons why a multifactorial intervention program using a falls-and-fracture nurse coordinator working with family physicians may be highly effective. Family physicians are in an ideal position to identify those at risk and are influential for recruitment and adherence.^{4–6} Most falls result from multiple risk factors, and multifactorial intervention trials in other settings have reduced falls.^{7,8} Fractures are the most serious and frequent consequences of falls, and through family physicians, measures to improve bone strength could be coupled with fall-prevention strategies.

However, trial evidence does not always translate into gains in real-life health care. There is also some evidence that multiple interventions may interact so that each intervention is less effective than when used singly.⁹ Further

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research is needed in the “real world” setting to clarify the most efficient strategy for widespread dissemination.

This randomized, controlled trial was designed to determine whether a falls-and-fracture nurse coordinator working with family physicians could reduce falls by assessing and referring at-risk older adults to appropriate interventions using existing health services.

METHODS

Trial Design

This was a randomized, controlled trial with 1 year of follow-up conducted in the Hutt Valley, Wellington, New Zealand, between March 2005 and February 2007. All family practices from two large primary care organizations in the area and a Maori health provider were invited to participate. Further details of the trial design, recruitment process, and multifactorial intervention are available.¹⁰ The Wellington Ethics Committee approved the study, and the trial was registered with the Australia New Zealand Clinical Trials Register (ID number: 12605000054617).

Participants and Recruitment

Women and men aged 75 and older (≥ 55 for Maori, the indigenous people of New Zealand, and Pacific people, as is recommended practice in New Zealand) who had fallen in the previous 12 months were recruited through participating family physicians. A screening form was used that described the study and asked whether the person had a fall or trip in the previous 12 months. Two methods of recruitment were used; forms were mailed to all those in the age group on patient registers, with completed forms sent back to the research center, and reception staff handed forms to all those in the age group as they entered practice waiting rooms. Research staff on the premises explained the project to eligible participants who expressed interest and invited them to participate. Exclusion criteria were inability to understand study information and consent processes, unstable or progressive medical condition, severe physical disability, and dementia.

A trained nurse completed baseline assessments on consenting participants using standardized procedures. After completion of baseline assessments, an independent researcher at a distant site randomly allocated participants to the intervention or control group using a computer-based schedule generated by a statistician.

Measures

The primary outcome was rate of falls over the 12 months of follow-up. A fall was defined as “an unexpected event in which the participants come to rest on the ground, floor, or other lower level.”¹¹ Participants recorded their falls prospectively using postcard calendars, completed daily and posted monthly to the research team. A follow-up telephone interview by a research staff member blind to group allocation established the circumstances and consequences of the fall, including injury and hospital admission. Injuries as a result of a fall were classified as serious (a fracture, hospital admission, or sutures) or moderate (bruising, sprains, cuts, abrasions, seeking medical attention, or a decrease in physical function for a period of 3 days or more).¹² Partic-

ipants not returning the falls calendars were telephoned within 4 weeks to ask about falls in that month.

Secondary outcome measures were assessed in a single follow-up visit at 12 months in the person’s home and included muscle strength and balance (Timed Up and Go Test,¹³ 30-second chair stand test,¹⁴ four-test balance scale,¹⁵ and 7.5-cm block step test¹⁶), fear of falling (Modified Falls Efficacy Scale¹⁷), activities of daily living (Nottingham Extended Activities of Daily Living Profile¹⁸), level of physical activity (Auckland Heart Study physical activity questionnaire¹⁹), and quality of life (Medical Outcomes Study 36-item Short Form Questionnaire).²⁰

The research nurses who recorded the demographic, clinical, and outcome measures at baseline and after 1 year, remained blind to group allocation. To assess one source of contamination of the intervention, all participants were asked after follow-up if they had participated in any exercise programs apart from the study intervention.

Delivery of Interventions

A falls-and-fracture nurse coordinator with substantial gerontological experience was trained by the clinical investigators and at an established community-based fall-prevention program in Australia (2 days). She visited intervention participants at home and used a standardized health assessment and an evidence-based algorithm to assess risk of falls and refer participants to their family physician, an optometrist, podiatrist, physical therapist, or occupational therapist and to receive a home-based exercise program to address identified risks:¹⁰

1. *Health assessment*: history of circumstances of the fall, medications, previous cardiovascular or neurological illness, continence, vision, postural blood pressure, balance and gait, cardiovascular screen (syncope, arrhythmia).
2. *Home hazards assessment*: an audit for environmental safety.^{7,21}
3. *Bone health assessment*: a brief osteoporosis risk screen, recommendation for family physician assessment to consider vitamin D and calcium supplementation,²² dual energy X-ray absorptiometry (DEXA) measurement of bone density, and bisphosphonates where indicated.²³
4. *The Otago Exercise Programme* delivered by a trained health practitioner or physical therapist for 1 year during home visits at Weeks 1, 2, 4, and 8 and after 6 months.²⁴ Participants were given monthly calendars to fill in and return to researchers recording daily adherence to exercises and a walking plan. Exclusion criteria for the Otago Exercise Programme were a Timed Up and Go Test score longer than 30 seconds or marked neurological impairment. The falls-and-fracture nurse coordinator could refer those excluded to a community physical therapist who tailored an alternative exercise program.

After completion of the assessment, the nurse made the referrals and followed up to ensure that contact was made with the Otago Exercise Programme exercise instructor. The nurse instigated a referral to the regional occupational therapy service if a need for modification was detected using the standard home assessment. The nurse conducted small alterations such as lightbulb replacement, nonslip bath

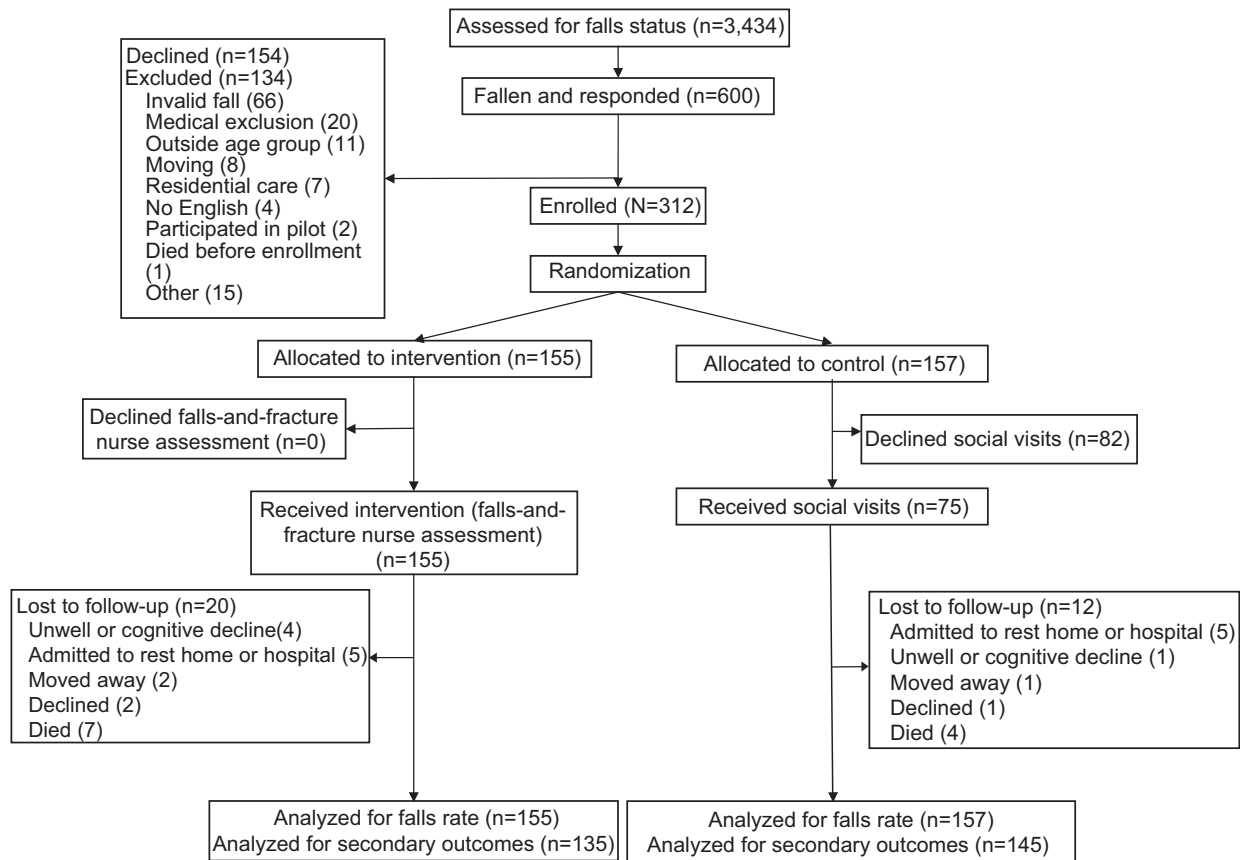


Figure 1. Flow of participants through the trial.

mates, and coordinating family or community volunteers to paint the edge of outdoor steps with white paint to improve visibility.

The intervention assessment was usually undertaken at one visit. The nurse telephoned 2 to 4 weeks later to ensure that referral consultations had taken place.

Control group participants received usual care and were offered two social visits from an accredited provider for older people, a nursing student, or a medical student. All study participants received a pamphlet produced by the New Zealand Accident Compensation Corporation about prevention of falls in older adults, which is current recommended practice after a fall. All family physicians in the area were invited to an evening educational session about falls prevention, osteoporosis, and fracture prevention as part of regular regional continuing education. This ensured that the physicians had basic background when referrals were made to them for identified falls risk factors.

Sample Size Calculation

Based on previous falls rates and attrition rates during a similar falls prevention trial, the proportions of the control group and intervention group who would fall during a 1-year period were predicted to be 52% and 32%, respectively.⁷ To detect this as statistically significant ($\alpha = 0.05$, power = 0.80), 105 participants were required in each group. An attrition rate of 30% over the 12 months was assumed given a sample size of 300 (150 in each of the control and intervention groups).

Statistical Analysis

Baseline characteristics were described for the intervention and control groups to assess balance and adequacy of randomization. The rate of falls for all participants in the two groups during the 1-year trial was compared with a negative binomial regression model using STATA 9.1 (Stata Corp., College Station, TX).²⁵ Where secondary outcome measures were not normally distributed, they were log-transformed or converted to categorical variables for analysis. Linear and ordinal logistic regression models controlling for baseline values were then used to compare changes in secondary outcomes in the two groups at 12-month follow-up.

RESULTS

Twenty-four family care practices were invited to participate, of which 19 (80%) agreed (54 family physicians). Figure 1 shows the recruitment and flow of participants through the study. Of the 3,434 older adults screened for falls, 312 (9%) were eligible and willing to participate. Six people classified themselves as Maori (age range 61–75) and three as Pacific (age range 64–72); five Maori or Pacific people were in the intervention group and four in the control group. The average age \pm standard deviation of all participants was 81 ± 5 , and 215 (69%) were women. Baseline characteristics were balanced between the two groups (Table 1). All control participants were offered social visits, and 75 of 157 (48%) accepted.

The incidence rate ratio for all falls for the intervention group compared with the control group during the

Table 1. Characteristics of Study Participants at Baseline

Characteristic	Intervention Group (n = 155)	Control Group (n = 157)	Total (N = 312)
Age, mean ± SD	80.4 ± 4.8	81.1 ± 5.3	80.8 ± 5.0
Female, n (%)	105 (68)	110 (70)	215 (69)
Number of medical conditions, mean ± SD*	6.9 ± 2.8	7.2 ± 2.9	7.0 ± 2.9
Total number of medications, mean ± SD	5.3 ± 3.4	5.6 ± 3.2	5.5 ± 3.3
Psychotropic medication(s), n (%) [†]	48 (31)	41 (26)	89 (29)
Bone-sparing medication(s), n (%) [‡]	39 (25)	48 (31)	87 (28)
Bisphosphonate, n (%)	14 (9)	13 (8)	27 (9)
Vitamin D supplement, n (%)	7 (5)	8 (5)	15 (5)
Calcium supplement, n (%)	12 (8)	25 (16)	37 (12)
Multivitamin, n (%)	19 (12)	20 (13)	39 (13)
Previous cerebrovascular accident, n (%)	28 (18)	48 (31)	76 (24)
Previous fracture, n (%) [§]	60 (39)	47 (30)	107 (34)
Previous hip fracture, n (%) [§]	2 (1)	6 (4)	8 (3)
Systolic blood pressure, mmHg, mean ± SD	148.4 ± 24.2	149.9 ± 21.7	149.2 ± 22.9
Diastolic blood pressure, mmHg, mean ± SD	71.6 ± 11.9	72.2 ± 11.4	71.9 ± 11.6
Body mass index, kg/m ² , mean ± SD	27.0 ± 6.0	27.4 ± 4.7	27.2 ± 5.4
Number of falls in previous year, median (interquartile range)	2 (1–3)	2 (1–4)	2 (1–3)

* Self-reported from a list of 27 medical conditions such as Parkinson's disease, arthritis, epilepsy, ischemic heart disease, hypertension, congestive heart failure, stroke, and other neurological condition (e.g., multiple sclerosis).

[†] Taking benzodiazepine or other sedative, other psychotropic medication, major tranquilizer, or antidepressant.

[‡] Includes bisphosphonate, vitamin D supplement, calcium supplement, and multivitamin.

[§] Fracture at any age in the past.

SD = standard deviation.

12-month follow-up was 0.96 (95% confidence interval = 0.70–1.34) (Table 2). There were also no significant differences in secondary outcomes between the two groups (Table 3).

Table 2. Incidence of Fall Events and Follow-Up Times

Measure	Intervention Group (n = 155)	Control Group (n = 157)
Number of falls during 12-month study*	285	299
Falls per person-year during study, mean (95% CI) [†]	1.91 (1.70–2.16)	2.01 (1.79–2.25)
Falls, n (%)		
≥1	106 (68.4)	98 (62.4)
≥2	69 (44.5)	54 (34.4)
Injurious fall, n		
Moderate injury [‡]	156	149
Serious injury [§]	14	7
Injurious falls per person-year		
Moderate injury [‡]	1.05	1.00
Serious injury [§]	0.09	0.05
Follow-up, days, mean ± standard deviation	349.8 ± 50.9	346.1 ± 72.2
Total follow-up time, person-years	148.53	148.85

* Incident rate ratio for falls in intervention versus control group: 0.96 (95% confidence interval (CI) = 0.70–1.34).

[†] CIs were calculated taking into account the Poisson type distribution.

[‡] Fall resulting in bruising, sprains, cuts, abrasions, seeking medical attention, or a decrease in physical function for 3 days or longer.

[§] Fall resulting in a fracture, hospital admission, or sutures.

Referrals made by the falls-and-fracture nurse after assessment of intervention participants are listed in Table 4. Just under two-thirds were referred to their family physician with a letter outlining risk factors that could be addressed. Consideration of a DEXA scan was suggested to the family physician for nearly one-third of participants. A referral was sent to an occupational therapist to address one or more identified home hazards in one-quarter of cases. One hundred twenty-three of 155 (79%) were eligible and accepted the exercise intervention (Otago Exercise Programme), but adherence was variable (Table 5). At Month 10, only 30 of 123 (24%) returned exercise adherence calendars and reported that they were still doing the exercises three times per week as instructed.

There was no difference at follow-up in the number of participants taking psychotropic medications in the intervention and control groups (29/135 (21%) vs 27/145 (19%), $P = .67$ after adjusting for taking these medications at baseline). Similarly, there was no difference between the intervention and control groups in the number taking a bone-sparing medication (44 (33%) vs 45 (31%), $P = .65$ after adjusting for taking ≥ 1 of these medications at baseline). There was no difference in the number of participants who reported participating in an exercise program other than the programs delivered as part of the intervention (10/135 (7.4%) intervention group vs 18/145 (12.4%) control group, $P = .23$).

DISCUSSION

This community-based falls-and-fracture nurse assessment and multifactorial falls prevention referral intervention was

Table 3. Secondary Outcome Measures at Baseline and 12-Month Follow-Up for Participants Who Completed Follow-Up

Measures	Intervention Group (n = 135)		Control Group (n = 145)		P-Value*
	Baseline	Follow-Up	Baseline	Follow-Up	
	Median (Interquartile Range)				
Frailty and Injuries: Cooperative Studies of Intervention Techniques four-test balance score (range 0–5) ^{†,§}	3.0 (3.0–4.0)	4.0 (3.0–5.0)	3.0 (3.0–4.0)	4.0 (3.0–5.0)	.48
Step test, number of steps [†]	8.5 (5.5–11.5)	8.8 (6.0–12.0)	8.5 (5.5–11.0)	8.5 (5.5–11.0)	.38
Timed Up and Go, seconds ^{‡#}	12.0 (10.0–16.0)	11.2 (10.0–14.6)	12.0 (1.0–17.4)	12.0 (10.0–17.5)	.72
30-second chair stand test, number of stands ^{†**}	9.0 (6.0–12.0)	10.0 (7.0–12.0)	9.0 (5.0–11.0)	9.0 (5.0–11.0)	.09
Nottingham Extended Activities of Daily Living score (range 0–22) ^{†††}	19.0 (18.0–21.0)	18.0 (17.0–20.0)	19.0 (16.0–2.0)	19.0 (17.0–20.0)	.43
Modified Falls Efficacy, score (range 0–10) ^{†%}	8.5 (7.0–9.5)	8.4 (6.9–9.4)	8.6 (7.1–9.5)	8.1 (6.0–9.4)	.49
Leisure activity or walking, min/wk	130 (30–270)	149 (70–300)	120 (4–210)	150 (44–280)	.11
Medical Outcomes Study 36-item Short Form Questionnaire (range 0–100) ^{††}					
Physical component summary score	35.4 (29.4–43.8)	39.4 (29.9–46.0)	36.5 (29.7–43.9)	37.2 (29.0–45.4)	.25
Mental component summary score	57.5 (50.1–61.8)	56.7 (48.8–61.3)	58.7 (53.1–62.5)	57.7 (49.4–61.9)	.40

* P-value associated with group comparison at 12 months controlling for baseline value.

† One person in each group did not complete these measures at follow-up.

‡ Two participants in the intervention group and six in the control group were not able to do this test.

§ Higher scores indicate better balance.

More steps indicate better performance.

|| Shorter times indicate better performance.

** More stands indicate better performance.

†† Higher scores indicate better performance.

% Higher scores indicate more confidence.

†† Higher scores indicate better health status.

not effective in reducing falls in older people who were living in the community and had fallen previously. Also, there were no benefits in strength and balance, functional, physical activity, or quality-of-life outcome measures after 1 year.

Current guidelines recommend an individualized, multifactorial approach to reduce falls. The first successful falls prevention trial used a multifactorial intervention.⁸ An intervention using referral to appropriate services was successful in preventing falls in those who presented to an emergency department after a fall.⁷ Meta-analyses have shown that multifactorial interventions reduce the number of falls,^{2,26} yet a recent meta-analysis showed that multifactorial interventions did not significantly reduce the num-

ber of people having at least one fall.²⁷ A number of trials of multifactorial interventions targeting community-dwelling fallers or those with fall risk factors have reported no significant effect on the number of falls or participants falling.^{28–30}

Questions Raised by the Trial Results

The lack of effectiveness of this trial and the mixed results from other trials raise three questions that need answering when considering public investment in community-based fall-prevention programs. Are there trial-design problems with this study that would have predisposed to a null result? Are the practical difficulties of introducing fall-prevention strategies into routine healthcare practice so great that the potential benefit of proven interventions is lost? Do multiple components in an intervention lessen the effectiveness of the individual components?

Table 4. Intervention Component Referral and Uptake

Referrals from Falls-and-Fracture Nurse (n = 155 Participants):	Referred n (%)	Attended or Commenced n (% of Those Referred)
Family physician	98 (63)	90 (92)
Dual-energy X-ray absorptiometry measurement of bone density	45 (29)	39 (87)
Occupational therapist	39 (25)	35 (90)
Optometrist	22 (14)	21 (95)
Podiatrist	21 (14)	16 (76)
Physical therapist	14 (9)	9 (64)
Continence nurse	5 (3)	3 (60)
Otago Exercise Programme	123 (79)	123 (100)

Table 5. Exercise Intervention Component Adherence

Adherence to Otago Exercise Programme (n = 123 Participants)	Month 2	Month 6	Month 10
	n (%)		
Returned exercise calendars	110 (89)	90 (73)	68 (55)
Exercised, times/wk			
≥3*	69 (56)	45 (37)	30 (24)
≥2 [†]	93 (76)	65 (53)	42 (34)
Walked ≥2 times/wk [†]	67 (54)	52 (42)	35 (28)

* Minimum of 12 times per month.

† Minimum of 8 times per month.

Robustness of the Trial

The trial design (randomization, falls and participation monitoring, use of assessors blind to group allocation, and the analyses) was robust and based on the research group's previous successful fall-prevention trials. The trial had a high level of participation from family practice, with 80% of family practices in the area invited to participate doing so. The participation rate of older patients was less than ideal, with 9% of the sample eligible and willing. Between 40% and 58% of those eligible agreed to participate.¹⁰

Internal contamination is possible, because all participating family physicians managed intervention and control participants. They attended an educational session about falls prevention and received information from the assessment nurse, potentially changing their practice of fall-prevention for all participants. The control group also received the falls prevention pamphlet. Control participants improved their level of physical activity, and every strength and balance measure was maintained or improved, suggesting that participation in the trial, even in the control group, may have had benefit. When planning, it was not considered that a cluster randomized design based on the family practices would have lessened the risk of contamination. The interventions were well known and established and available through existing health services, and the interventions were delivered to the participants in their own homes.

The two social visits adequately controlled for the attention received from the intervention nurse, although those who were referred to the Otago Exercise Programme received more attention than those in the control group. However, this bias would have been more likely to overestimate the benefit of the intervention, not underestimate it.

Trial Benefits in Clinical Practice

There are difficulties in translating successful strategies from research trials into everyday clinical practice. Research teams have a single purpose; they are encouraging, enthusiastic, highly skilled, and motivated. Encouragement from those delivering the intervention components in a usual healthcare setting may be less than from a research team.

Uptake of the components of the program was high, with 70% of the intervention group being referred to and commencing the Otago Exercise Programme. Adherence to the exercises was lower than that reported in previous pragmatic trial reports, in which 70% were exercising at 1 year, and falls were significantly reduced.^{4,5} In the current study, only 34% of 123 originally referred reported that they were undertaking two or more exercise sessions per week 10 months after the program commenced.

The falls-and-fracture nurse intervention involved referral to other health practitioners. Not all participants who were referred attended. In the family practices, the fall-prevention program was just one of many prevention initiatives, and the recommendations from the falls-and-fracture nurse was just one of the many sources of advice. Rehabilitation services would also have been managing many other patients and were not focused on one preventive program.

Other multiple intervention trials successful in reducing falls have documented higher levels of adherence to program components.^{8,31} The lower adherence in the

current trial may have been an important factor in the failure to reduce falls.

This trial was a true effectiveness trial asking usual practitioners to deliver proven falls prevention strategies in the "real world." Either this combination of interventions was not successful in the high-risk group targeted in this primary care setting, or greater attention to adherence to program components was needed. Alternatively, the intensity of the intervention may have been inadequate to produce an effect. This program was of low intensity, with one assessment visit, low-level education, and no formal behavior modification process. The exercise intervention was of moderate intensity and has been shown in single trials and meta-analysis to be effective,³² but adherence in the present trial was low. Greater resources would have been needed for better adherence and follow-up, but it was desired to test a process that is feasible within current health structures. In a pragmatic trial, such as this, each intervention is subject to adherence risks at each step of the referrer-family physician-therapist-participant chain.

Multiple or Single Interventions

This trial adds to the debate about whether single or multifactorial fall-prevention strategies are more effective.^{2,9,26} In the present study, multiple interventions were suggested to the participants. It is possible that, with such an approach, participants may choose to comply only with the intervention that appeals to them. They may be unclear about the many different pieces of advice offered. This may result in lower adherence to the individual components of the program.

The falls-and-fracture nurse also addressed fracture risk. The study was not powered to determine the effect on fractures. Uptake of bone-protective investigations and medications was the same in the intervention and control groups. Coupling fall- and fracture-prevention strategies may appear logical and efficient, but it adds to the complexity of the intervention and the advice. It may lessen the effect of advice on falls reduction.³³

CONCLUSION

Falls in older people are common, and widely available, community-based, proven interventions are needed for the many older people at risk. It has now been shown that a falls-and-fracture nurse completing a detailed assessment and advising on the use of multiple, previously successful fall-prevention strategies, did not reduce the fall rate.

This pragmatic trial failed to give the promising results shown in the efficacy trials. Greater attention to adherence to the components of the nurse-led program may have improved the outcome. Alternatively, attention to specific population subgroups with use of proven, effective, single interventions applied vigorously may improve success in falls prevention.

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