Fall Prevention in Residential Care: A Cluster, Randomized, Controlled Trial

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OBJECTIVES: To establish the effectiveness of a fall-prevention program in reducing falls and injurious falls in older residential care residents.

DESIGN: Cluster, randomized, controlled trial.

SETTING: Fourteen randomly selected residential care homes in Auckland, New Zealand.

PARTICIPANTS: All older residents (n = 628, 95% participation rate).

INTERVENTION: Residential care staff, using existing resources, implemented systematic individualized fall-risk management for all residents using a fall-risk assessment tool, high-risk logo, and strategies to address identified risks.

MEASUREMENTS: Number of residents sustaining a fall, falls, and injurious-falls incidence rates.

RESULTS: During 12 months of follow-up, 103 (43%) residents in the control group and 173 (56%) residents in the intervention group fell ($P<.018$). There was a significantly higher incidence rate of falls in intervention homes than in control homes (incident rate ratio = 1.34, 95% confidence interval = 1.06–1.72) during the intervention period after adjusting for dependency level (type of home), baseline fall rate, and clustering. There was no difference in the injurious fall incidence rate or incidence of serious injuries.

CONCLUSION: This fall-prevention intervention did not reduce falls or injury from falls. Low-intensity intervention may be worse than usual care. **J Am Geriatr Soc 52:524–531, 2004.**

Key words: fall prevention; residential care; cluster randomized controlled trial

Falls are a major health problem in residential care, with up to 50% of residents falling every year.[1–3] Injuries are a common consequence of falls in this disabled group, with hip fracture being the most worrisome. Although risk factors have been identified,[4–6] few successful interventions in residential care are available to practitioners.

Successful interventions in long-term care have been intensive, multidisciplinary, and consequently expensive or have targeted a selected residential care population.[7,8] Residential care is complex because staff and facility factors contribute to fall risk, and the population of interest has complex health and disability-related risks for falls.

From a literature review,[9] an evidence-based fall-prevention intervention was developed that aimed to change processes in residential care homes toward systematic individualized fall-risk management and increase awareness of the staff about falls. Available fall-prevention strategies were suggested, maximizing use of existing resources and evaluation skills of existing staff. The program was based on a risk-assessment tool, to identify those at high risk,[10–15] and use of a high-risk logo,[14,16] along with written suggested strategies for staff to follow with those identified to have a high risk of falls. This program was refined with groups of local experts, including medical, nursing, physical therapy, and occupational therapy, to improve usability and relevance in the residential care setting. The hypothesis was that this intervention would decrease fall incidence rates.

METHODS

Design

A cluster, randomized, controlled trial was used to test the effect of this fall-prevention intervention in a residential care population on falls and fall-related injuries. The trial

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had a 5-month surveillance period to establish baseline fall rates in enrolled individuals and is reported according to the CONSORT statement.[17]

Participants

All older people in residential care in Auckland, New Zealand, were eligible for this study. In New Zealand, older people living in residential care live in rest homes or low-level dependency homes, where they require assistance with most instrumental activities of daily living and at least two activities of daily living (ADLs) but can usually ambulate to some degree and feed themselves. The more-dependent level of residential care is private hospital care or high-level dependency homes, where residents are dependent in most ADLs, and daily nursing care is usually needed. These residents may be bed bound or ambulatory with walking aids, and assistance is frequently needed for toileting and possibly feeding.

The New Zealand Ministry of Health supplied a listing of all residential care homes (subsequently termed "homes") in Auckland, New Zealand. This was stratified by type of home (high- vs low-level dependency), and random numbers were used to select eight low-level dependency homes (rest homes or hostels), four high-level dependency homes (private hospitals or nursing homes), and two large complexes containing low-level units, high-level units, and secure dementia units. After invitation, informed consent was obtained from the owners and managers of the homes and from all residents and their family members or guardians. The Auckland ethics committee approved the study.

Data Collection

Investigators (NK and MB) collected data about the residents' demographic information, previous falls and injuries, acute and chronic medical conditions, and medications using standardized forms from the residents' medical notes, care plans, and medication charts. The diagnosis of dementia, listed in the medical file, was used to establish cognitive impairment. To check for reliability, both researchers abstracted data from a small number of charts initially and discussed comparisons. Dependency levels were ascertained on a validated dependency questionnaire filled in by the registered nursing staff or the lead healthcare assistant.[18] This composite scale comprises three level scales. One scale, self-care (mobility, dressing, feeding, bathing, and toileting), was used to measure ADL function. Composite scales for mobility (transfers, mobility within the home, and ability on stairs) and behavior (needing night care, social behavior, memory, wandering, and awareness) were constructed and are termed mobility and behavioral score, respectively. Each scale is the summed score of its items, rating the resident as independent (3), able to with a little help (2), needing considerable help (1), or unable (0). This questionnaire has been found reliable and was used in the New Zealand Long-Term Care Survey.[19,20]

Randomization

After recruitment of all residential care homes and residents, these homes were stratified by type, and an independent researcher, not involved in the study, block randomized them into intervention or control group using computer-generated random numbers.

OUTCOMES

Falls

To establish the baseline fall rate for each enrolled resident, falls and fall-related injuries were monitored in all homes from December 1999 until April 28, 2000, when the intervention began. Falls and fall-related injury surveillance continued for another 12 months, until April 2001, to establish the intervention effect. All homes and staff were trained and given standard fall-reporting forms (circumstances, time, location, and any injuries sustained by the resident) to complete and send by facsimile to the study center. Research staff, blinded to group allocation of the home and resident, reviewed each form to decide whether a fall event had occurred using the definition "unintentionally coming to rest on a lower surface."[21] Falls from major medical events such as a seizure were excluded. All forms were audited monthly by comparison with the individual resident's chart and incident-reporting forms to crosscheck circumstances, duplication, and missed falls in all homes. All homes were visited the same number of times at the same intervals to audit falls surveillance. Records were screened to identify multiple reports of a single fall event.

Injury

Injury was defined as any sequelae relating from a fall, including bruising, skin tears, need for steri-strips, sutures, hematoma, sprains, joint dislocation, hip fracture, other fracture, the need to be transferred to an acute hospital for evaluation, the need for an urgent physician visit, or a radiological examination.

Serious Injury

Serious injury was defined as falls that resulted in sprains, joint dislocation, hip fracture, other fracture, the need to be transferred to an acute hospital for evaluation, the need for an urgent physician visit, or a radiological examination. All serious injuries were validated by contact with the health facility treating the resident or the resident's physician or by the radiology report.

Intervention Group Homes

The fall-prevention intervention consisted of a program of fall-risk management for all residents in the home, which used existing staff for evaluation and maximized use of existing resources. Specific program components included:

- Each home appointed a falls coordinator to undertake systematic fall-risk assessment of all residents, develop specific recommendations and care plans, coordinate with other healthcare professionals, and ensure that recommendations were followed.
- An evidence-based fall-risk assessment tool (see Figure 1).[22]
- For residents assessed as being at high risk, scoring higher than 8 out of 21, a high-risk logo (attractive laminated 5 inch by 5 inch picture of a flower with a leaf falling) including color-coded dots relating to tailored

Score as Indicated	Score	Fall-Risk Management Strategies Identified and highlighted by colored flags
General Risk Factors 1. age ≥80 2. ≥1 falls in the past year 3. fear of falling 4. current acute illness	 1 3 2 1	• use of the high fall-risk logo if total score >8 • prompts in doctors' notes for medical review • staggered tea and meal breaks for staff • environmental assessment for room and surroundings • safe and supervised increase in mobility
Mobility Impairments 5. requires assistance to stand/transfer/mobilize 6. walks with cane/walking frame/wheelchair 7. has poor balance and coordination (sways/steps unevenly/looks unsteady) 8. hemiplegia	 1 1 2 1	Red Flag strategies • referral to the physician for strength and balance assessment • physical therapist assessment for strength and balance training • occupational therapist assessment for aides and safety review • specific caregiver instructions
Mental Impairments 9. has dementia or is currently confused/agitated/disorientated	 2	Blue Flag strategies • specific caregiver instructions regarding supervision and strategies for dementia care
Medications 10. sedatives/tranquilizers/antidepressants 11. diuretics/antihypertensives	 3 1	Purple Flag strategies • referral to physician for medication review, especially psychotropic, multiple medication
Continence 12. requires frequent toileting 13. changes noted in urgency/frequency/nocturia	 1 1	Yellow Flag strategies • implement toileting policy • consistently accompany the resident to the toilet
Sensory Impairments 14. vision/hearing impaired to the extent that everyday function is impaired	 1	Green Flag strategies • referral to ophthalmologist for cataract extraction as appropriate • referral to otolaryngologist for hearing assessment • specific caregiver instructions relating to visual or hearing impairments
High Fall-Risk Score	≥8/21	• high-fall-risk logo on the wall of the room • color coded dots on logo • commence appropriate fall-risk management care plan(s)

Caregiver means nursing assistant–level staff.

Figure 1. High-fall-risk assessment tool and examples of intervention strategies for the Falls and Injury Prevention Pilot Study intervention.

fall-prevention strategies based on the individual's fall risk, was attached to the wall of the resident's room.

- Information about specific fall-prevention strategies, including nursing strategies for fall prevention; indications for physical therapy, occupational therapy, medical, and specialist referral; and forms for care plans and tracking progress were provided. An environmental assessment for identification of potential falling hazards in a resident's room and public spaces inside the home and its immediate surrounding was provided. Using this information, staff in the home constructed color-coded nursing care plans for each category of risk identified on the risk assessment tool. (For examples, see Figure 1.) Matching color-coded care strategies were provided for caregivers (nursing assistants).
- A Falls and Injury Prevention Pilot Study manual containing the risk assessment form, information for strategies, high-risk fall logos, all forms, and educational information for nurses, doctors, physical therapists, and occupational therapists supported the program.

The program was implemented with two 1-hour educational sessions in each home, one for registered nurses and one for assistant staff, concerning fall-risk management and use of the program. Primary care physicians and management staff attended an evening educational session. Research staff (MB) spent between 2 and 4 hours training the falls coordinator in each home and continued to support implementation of the program with visits to intervention homes and telephone follow-up as needed for 6 months. The visits were to ensure that the falls coordinator understood the process of risk assessment, followed by fall-risk-management care planning and implementation of the care plan. Research staff did not assess any residents, although some suggestions for intervention strategies were made about individuals during training. The risk-assessment tools and examples of specific suggestions are presented in Figure 1. The examples represent a brief summary of more-extensive information from the manual.

Intervention homes sent falls-risk assessment forms by facsimile to the research center, and after 5 months all records of enrolled residents who had been assessed were audited to establish compliance with the recommendations resulting from the program.

Control Group Homes

Control homes continued their usual care and participated in fall surveillance. They were visited monthly to audit fall surveillance.

Blinding and Follow-Up

Baseline data and baseline fall-rate ascertainment were gathered before randomization. A blinded researcher completed judgment of falls forms, and blinded researchers conducted data input and outcome analysis. The homes and residents were not blinded to group allocation.

Analysis

Because falls and injury from falls were of interest, power calculations were conducted for both these outcomes. One hundred three people were needed to detect a difference of 20% in the proportion of participants sustaining falls between two groups, assuming that the nonintervention group had a proportion of 50%.[1] To adjust for the clustered design of the trial, the sample size was inflated.[2,3] Inflating this number by a design effect of 2 (estimated), 206 residents were needed in each arm of the randomized trial (power = 0.8, alpha = 0.05). To detect a difference of 15% in the proportion of participants sustaining injury between two groups, assuming that the nonintervention group had a rate of injury of 30%, 134 residents were needed. Inflating this by a design effect of 1.5 (estimated), 201 residents were needed in each group (power = 0.8, alpha = 0.05). Allowing for an attrition rate of 15%, a participation rate of 80% (from previous work with older people in homes) and with an average facility size of 40, 460 residents from 14 homes would be sufficient to show meaningful change in falls and that fall-related injury outcomes were not due to chance alone.

SPSS (version 11.0, SPSS Inc., Chicago, IL) and STATA (version 7.0, Stata Corp., College Station, TX) were used for descriptive statistics and analyses. The number of days each resident was in the study was calculated by tracking dates of admission, transfer, and death. Baseline falls rates (before the intervention started) and fall-incidence rates (outcome variable) were calculated as the number of falls or injuries per resident year. Residents' data were excluded if a resident was enrolled in the study for less than 2 days and sustained more than two falls in one of those days. A negative binomial regression model was fitted to determine the incidence rate ratio (IRR) for the intervention group

compared with the control group for falls and fall-related injuries. Because level of dependency and previous falls are strong predictors of falls, baseline fall-incidence rates of each individual and level of dependency (type of home) were controlled for, and the models were adjusted for clustering. An exposure term was included in the models: the variable indicating follow-up time in days for each individual in the trial. Next, the model was performed adding possible confounding variables such as sex, mobility level, behavioral score, and age. These models are not reported as the final model if the IRRs in the adjusted and unadjusted model did not vary by more than 10%.[24] Results are expressed as IRRs and 95% confidence intervals (CIs).

RESULTS

Figure 2 shows the flow of homes and residents through the trial. Fourteen homes (93% response rate) and 628 older people (95% response rate) were successfully enrolled and randomized. Table 1 shows the baseline characteristics of the residents at the beginning of the intervention period. There were more low-level-dependency residents and residents from dementia-specific secure units in the intervention group than the control group. Staffing ratios for registered and nursing assistant staff on all three shifts were similar in homes in both groups ($P = .37$). Characteristics of residents were equally distributed between the groups. No statistically significant differences between variables were detected. The average length of time enrolled in the study ± standard deviation for intervention and control group residents was 313 ± 107 days and 321 ± 99 days, respectively.

After received by facsimile, fall forms were matched to resident chart audit and homes incident forms in 83% of falls. Information on an additional 17% was recorded from the chart or incident form. All falls, regardless of source of information, were included in the analysis. Falls for the 5 months before the intervention period occurred at an equivalent incidence rate in control and intervention group homes (IRR = 1.38, 95% CI = 0.81–2.33).

Intervention Implementation

In five of the seven intervention homes, the falls coordinator was a registered nurse. The other two homes used lead nursing assistants to coordinate the program. Most homes were able to incorporate the intervention forms and processes into their usual routine. Five of the seven homes had high compliance rates with the program, assessing 48% to 85% of all residents. The two remaining homes, termed noncompliant homes, assessed 0% and 35% of residents and were the homes where lead nursing assistants coordinated the program and management engagement in the enrollment and implementation process was low. Overall, 49% of residents underwent individualized assessment, but when the two noncompliant homes were excluded, on average, 68% of residents were assessed. One hundred one of 150 residents who were assessed (67%) subsequently fell.

Five to seven months after the intervention began, all homes were audited to establish completion of recommendations generated on the fall care plans. When a fall-risk assessment was completed and an individualized care plan was generated (n = 123), there was 98% compliance in implementing the recommended strategies. Eighty-three percent of residents assessed as needing physician review (45% of assessed residents) had this review completed and had a medication change. Each resident had an average of 10 individual fall-prevention strategies recommended. Taken together, 1,272 fall-prevention care-planning actions and strategies were recommended in intervention homes. At the 5-month audit, 1,151 had been undertaken (98.4%), showing compliance with the Falls and Injury Prevention Pilot Study fall-risk management. Including the two noncompliant homes, 78% of all residents involved in the program had fall-prevention strategies applied.

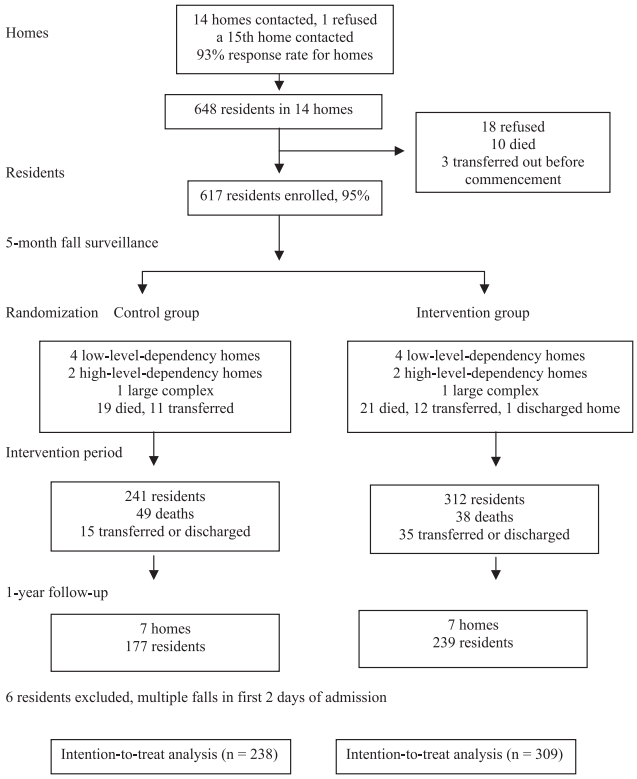

Figure 2. Overview of a clustered, randomized trial of a fall prevention intervention.

Falls and Injurious Falls

During the intervention period, 276 residents (50.5% of residents) sustained 1,290 falls (Table 2). The majority of falling residents fell once or twice. Significantly more residents fell in the intervention group ($P < .018$), and there were more multiple fallers in the intervention group than in the control group during the intervention period, although this difference did not reach statistical significance ($P = .078$). Figure 3 shows the distribution of fall rates and injurious fall rates throughout the study period.

One hundred ninety-nine residents (26% of residents, 72% of fallers) sustained injurious falls, with 47 residents sustaining serious injury from a fall (9% of residents, 17% of fallers). Thirty-four serious injuries occurred in the intervention group and 20 in the control group (five residents had more than one serious injury).

Table 1. Baseline Characteristics of Control and Intervention Group Residents in a Trial of a Falls Prevention Intervention

Characteristic	Control Group n = 238	Intervention Group n = 309	Total n = 547
High-level dependency residents, n (%)	118 (49.5)	74 (23.9)	192 (35.1)
Dementia specific secure residents, n (%)	10 (4.2)	46 (14.9)	56 (10.2)
Low-level dependency residents, n (%)	110 (46.2)	189 (61.2)	299 (54.7)
Age, mean ± SD	83.6 ± 12.5	83.0 ± 8.9	83.2 ± 10.6
Male, n (%)	56 (23.5)	96 (31.0)	152 (27.8)
Self-care score, 1–24,* mean ± SD	8.0 ± 4.7	10.3 ± 4.6	9.3 ± 4.8
Mobility score 1–12,* mean ± SD	5.2 ± 3.6	7.2 ± 3.5	6.3 ± 3.7
Behavioral score 1–20,* mean ± SD	13.6 ± 6.0	15.0 ± 5.5	14.4 ± 5.8
Total medications, n (%)	5.3 (2.8)	5.8 (3.2)	5.6 (3.1)
Total diagnoses, n (%)†	4.8 (2.1)	4.8 (2.1)	5.6 (3.1)
Parkinson's disease, n (%)†	15 (5.8)	21 (6.4)	32 (5.8)
Diagnosis of dementia, n (%)†	113 (47.0)	165 (53.0)	278 (50.0)

Note: No statistically significant differences were detected comparing intervention and control groups on resident baseline variables.
* Self-care, mobility, and behavioral scores were calculated from subscales of the dependency questionnaire; higher score means higher level of function.
† Diagnoses established from the summary sheet in the medical record.
SD = standard deviation.

There was no interaction between type of home (low-dependency home, high-dependency home, or secure unit) and intervention ($P < .195$), so all homes' data were analyzed together to test for an intervention effect using the preplanned analysis, adjusting for baseline fall rate, clustering, and dependency level (type of home).

There was a significantly higher incidence rate of falls in intervention homes than in control homes (IRR = 1.34, 95% CI = 1.06–1.72) during the intervention period. Potential confounding variables (sex, mobility score, self-care score, behavioral score, age, and diagnosis of dementia) did not alter the result when entered into the model one at a time.

There was no statistically significant difference in the injurious fall incidence rate between the two groups (IRR = 1.12, 95% CI = 0.85–1.47), adjusting for dependency level (type of home), baseline fall rate, and clustering. Similarly, this intervention did not affect the incidence rate of serious injury (IRR = 1.14, 95% CI = 0.61–2.13), adjusting for dependency level (type of home), baseline fall rate, and clustering.

Post hoc analyses were conducted to see whether the two noncompliant homes mediated the apparent increase in falls. Excluding the two noncompliant homes from the analysis did not alter the result for falls (IRR = 1.33, 95% CI = 1.02 –1.73) or injurious falls (IRR = 1.02, 95% CI = 0.75–1.39).

Table 2. Results of a Randomized Trial of a Fall Intervention in Residential Care

Parameter	Control n = 238	Intervention n = 309	Total n = 547
Baseline period 5 months			
Rate of falls (falls/resident year mean ± SD)	2.3 ± 7.8	2.9 ± 7.1	2.6 ± 7.4
Rate of injurious falls (injurious falls/resident year mean ± SD)	1.0 ± 3.8	1.3 ± 4.1	1.1 ± 4.0
Intervention period 12 months			
Residents who fell, n (%)	103 (43.3)	173 (56.0)	276 (50.5)
1–2 falls	59 (24.8)	96 (31.1)	155 (28.3)
3–15 falls	40 (16.7)	68 (22.0)	108 (19.7)
>15 falls	4 (1.7)	9 (2.9)	13 (2.4)
Falls, n	436	863	1290
Residents who sustained injurious falls, n (% of residents)	103 (43.3)	173 (56.0)	276 (50.5)
1 injurious falls	42 (17.7)	64 (20.7)	106 (19.4)
2–5 injurious falls	29 (12.2)	48 (15.5)	77 (14.1)
>6 injurious falls	5 (2.1)	11 (3.6)	16 (2.9)
Injurious falls, n	184	339	523
Rate of falls (falls/resident year)*	2.3 ± 7.1	4.1 ± 13.2	3.3 ± 11.0
Rate of injurious falls (injurious falls/resident year)†	1.0 ± 3.0	1.6 ± 5.4	1.4 ± 4.5
Rate of serious injury (serious injury/10 resident years)‡	1.8 ± 12.1	0.9 ± 3.6	1.3 ± 9.1

* Incidence rate ratio (IRR) = 1.34, 95% confidence interval (CI) = 1.06–1.72; † IRR = 1.12, CI = 0.85–1.47; and ‡ IRR = 1.14, CI = 0.61–2.13, controlling for dependency level (type of home) and baseline fall rate and adjusted for clustering.
SD = standard deviation.

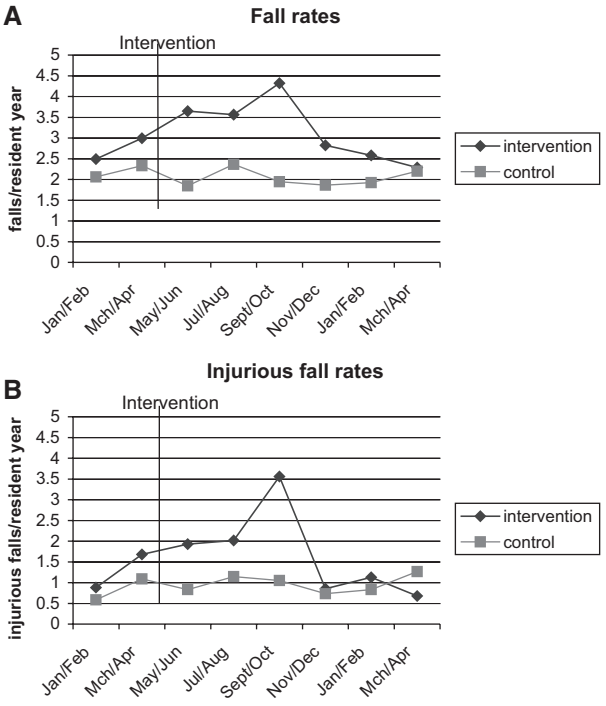

Figure 3. Graph of the effect of a fall-prevention intervention, bimonthly comparison of (A) fall and (B) injurious fall rates.

DISCUSSION

Contrary to the hypothesis, the intervention program was associated with an increase in the incidence rate of falls in intervention group homes. These results are troublesome, because this program is similar to quality assurance programs active in many long-term care settings in the United States, Australia, and the United Kingdom.

This intervention was not successful in reducing falls and may have resulted in an increase in falls in this residential care population. The intervention was designed to be implemented by existing staff in homes without significant input from outside experts or additional resources beyond staff training for implementation, as is currently the case in existing long-term care quality improvement programs. The work of the falls coordinator was time consuming and, if attentively completed, may have taken that staff member away from his of her other roles, potentially decreasing staff available for usual activities. Because compliance was high in the majority of homes, this could have stressed existing staffing levels. Therefore, this would have affected intervention homes more because the staffing ratios in control and intervention group homes were equivalent at baseline.

Perhaps this low-intensity intervention was worse than no intervention at all. Preventing falls in frail older populations is difficult, and other trials in residential care have reported no improvement in falls as a result of well-planned higher-intensity interventions.[25–29] This intervention provided little training for the falls coordinator or staff, did not provide outside expertise for assessment of residents, and provided no additional staff. It was designed this way as a test of the efficacy of a low-intensity intervention.

Understanding that research is difficult in residential care settings, compliance with the program was high in most of the homes. In two homes (91 residents) most of the residents were not assessed. Excluding these homes from the analysis did not affect the result, but additional staff training and follow-up, use of registered nursing staff for the coordination of the program, and more-active engagement of management may have increased adherence and affected the overall result. It is encouraging that, once residents were assessed, almost all recommendations were followed up and completed. To ensure program implementation, adequate resources and training must be made available.

Intervention materials emphasized safe increases in activity within the home and physical therapy assessment with treatment of gait and balance impairment. Perhaps increasing activity levels of residents explained the observed increase in falls. Change in level of activity was not measured during the intervention period, but increased activity is associated with increased falls in frail older populations. Increased falls resulted from a well-intentioned brisk walking group intervention in the community[30] and less rigorous studies have suggested an increase in the number of falls as a result of multifaceted interventions in residential care.[14,31–33] The results of the current study, if due to increased activity, support one study's suggestion of a trade-off between mobility and falls.[32]

All residents were included in the current study, rather than targeting the intervention to a selected group, and there is a potential for case mix to have diluted any intervention effect, because a significant proportion of this population has complex risk profiles potentially not amenable to any intervention. Intensive fall-prevention interventions specifically designed for those with dementia have not been successful,[34] and 50% of the sample had a diagnosis of dementia. Individual standardized assessment of cognition on each resident was beyond the scope of this trial. The listing of diagnoses in summary sheets by the usual physicians may have been an imprecise measure, but controlling for the presence of dementia did not affect the result, and the intervention did not have any specific interaction effects in the secure units compared with the other levels of dependency. In future research, measurement of cognition is needed, and specific interventions for demented older residents need to be further developed.

Two successful fall-prevention trials have targeted intervention efforts on selected residents. The first trial tested a multidisciplinary consultation service model, with experts evaluating high-risk fallers in seven highly selected homes in the United States, and showed a 10% reduction in the proportion of fallers in intervention group homes.[8] The second trial enrolled nine long-term care homes in one region of Sweden and implemented a multifaceted intervention for high-risk residents in a randomly selected region. The intervention included staff education, medication review, environmental assessment, individualized moderate- to high-intensity strength and balance training, hip protectors, and postfall conferences with staff guidance. Results showed a decrease in time to first fall, proportion of fallers, fall-incidence rates, and hip fractures.[7] Both of these interventions were intensive, with considerable input in

addition to the usual resources of long-term care. In contrast, the current study was designed specifically to use available resources in a different way, raising the awareness of fall risk and stimulating rational fall-risk management. It was not successful in reducing falls. Although reasons for this intervention's failure are unclear, the current residential care settings in New Zealand and overseas[35,36] are already considered to be understaffed and underfunded. Any intervention that asks for extra work and does not add extra staff is unlikely to have a positive effect.

Sources of bias that potentially affect the internal validity of this result include measurement bias and failure of randomization. The trial itself might have influenced this trial's outcome measurement because intervention home staff could have been primed to report falls that they otherwise would not have reported. Other investigators have observed this,[14] and the timing of the increase in falls in the current study began directly after the intervention implementation (Figure 2). Falls self-reported by residents were accepted in this trial, and residents may also have been primed to report falls they otherwise would not have reported, despite equal numbers of auditing visits by research staff to intervention and control homes and inclusion of incident form and chart information. Nevertheless, if this was so, one would reasonably have expected a rise in the proportion of noninjurious falls reported during the implementation, understanding that injuries are likely to be consistently reported on incident and accident forms in all homes in New Zealand. This was not the case. The proportion of injurious falls reported in control and intervention homes at baseline and after 6 months of intervention implementation was similar, suggesting that all falls increased or that injurious falls were underreported before the study.

Baseline characteristics of residents in the two groups of this trial had similar statistical distribution, but the sum of many small differences, all suggesting a more-mobile, less-disabled intervention group, may have led to confounding that was not adjusted for adequately in the analysis. The IRR resulting from the intervention period analysis (IRR = 1.34) was controlled for the baseline fall rate, the strongest predictor of subsequent falls, and therefore cannot be directly compared with the IRR resulting from the comparison before the trial started (IRR = 1.38). The two groups were not different in incidence rate initially, although it would have been interesting to observe baseline fall rates for a longer period.

Although there may be some uncertainty about whether this intervention caused harm, it is quite certain that it did not provide any benefit. This trial succeeded in recruiting a randomly selected group of homes with high response rates, whereas other trials have had overly restrictive selection criteria limiting generalizability.[8] The rigorous design and conduct of this research were likely to have accurately tested this plausible intervention strategy. If mobility was increased, then an increase in noninjurious falls may be acceptable. If this intervention is tested again, additional resources and training may aid implementation and effectiveness. Further research should build on proven fall-prevention success strategies[7,8] and evaluate mobility and functional status change to understand any potential tradeoff between falls and function. Further effort may be better placed on protection of frail residents from the consequences of falls because successful strategies such as hip-protective garments are easily applied to this population.[37]

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