

Fall and Injury Prevention in Older People Living in Residential Care Facilities

A Cluster Randomized Trial

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Background: Falls and resulting injuries are particularly common in older people living in residential care facilities, but knowledge about the prevention of falls is limited.

Objective: To investigate whether a multifactorial intervention program would reduce falls and fall-related injuries.

Design: A cluster randomized, controlled, nonblinded trial.

Setting: 9 residential care facilities located in a northern Swedish city.

Patients: 439 residents 65 years of age or older.

Intervention: An 11-week multidisciplinary program that included both general and resident-specific, tailored strategies. The strategies comprised educating staff, modifying the environment, implementing exercise programs, supplying and repairing aids, reviewing drug regimens, providing free hip protectors, having post-fall problem-solving conferences, and guiding staff.

Measurements: The primary outcomes were the number of res-

idents sustaining a fall, the number of falls, and the time to occurrence of the first fall. A secondary outcome was the number of injuries resulting from falls.

Results: During the 34-week follow-up period, 82 residents (44%) in the intervention program sustained a fall compared with 109 residents (56%) in the control group (risk ratio, 0.78 [95% CI, 0.64 to 0.96]). The adjusted odds ratio was 0.49 (CI, 0.37 to 0.65), and the adjusted incidence rate ratio of falls was 0.60 (CI, 0.50 to 0.73). Each of 3 residents in the intervention group and 12 in the control group had 1 femoral fracture (adjusted odds ratio, 0.23 [CI, 0.06 to 0.94]). Clustering was considered in all regression models.

Conclusion: An interdisciplinary and multifactorial prevention program targeting residents, staff, and the environment may reduce falls and femoral fractures.

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Falls are a major problem in older people (1, 2). Hip fractures resulting from falls are particularly common in elderly persons living in residential care facilities (3, 4); they account for a substantial proportion of dependency and mortality (5).

During the past decade, randomized, controlled trials studying fall prevention have shown both positive and negative results (6–8). Differences in target groups, interventions, and outcome measures may explain the inconsistent results. In residential care facilities and nursing homes, only one trial demonstrated that intervention programs may help prevent falls; however, this trial studied only people who fell repeatedly (9). Other trials have not shown reductions in falls or injuries (10–13) but have shown fewer hospital admissions (11) and improvements in mobility (12), visual acuity, and hypotension (13). The use of hip protectors has consistently proved effective in preventing hip fractures in selected high-risk populations (14).

Some trials that have included cognitively healthier older people in the community have shown reduced falls

and injuries when specific risk factors are targeted (15–18). However, evidence is lacking for older people living in institutions (19). We hypothesized that an intervention program that targeted multiple risk factors for falls in older people living in residential care facilities, in particular those with a high risk for falling, would reduce falls and fall-related injuries. We therefore conducted a cluster randomized trial for preventing falls in nine residential care facilities.

METHODS

Design

Study participants were older people living in residential care facilities located in Umeå, a city in northern Sweden. The selected facilities had to have more than 25 residents. The nine that met this criterion were divided into group A and group B. The distribution was based on the age and number of residents, type of setting (care and service offered as well as corridor or private home design), and record of previous falls as routinely reported to the local authority. To keep the groups dis-

Context

In frail older people living in residential care facilities, hip protectors reduce fall-related femoral and pelvic injuries.

In older people living in the community, prevention programs that target exercise and fall-related risk factors reduce falls and injuries.

In older people living in residential care facilities, fall prevention programs, other than the use of hip protectors, have had mixed results.

Contribution

This randomized trial shows that a multidisciplinary fall prevention program reduces falls and femoral fractures in older people living in residential care facilities. The program included general as well as resident-specific, tailored strategies.

Editors' Note

The Cochrane Library (Issue 3, 2001) has two systematic reviews that summarize randomized trial evidence about interventions to prevent falls.

—The Editors

tinct from one another, the physicians, registered nurses, physical therapists, and occupational therapists who were responsible for working with the residents in group A could not also work with group B residents. Group A consisted of four facilities that accommodated 224 residents; the facilities had 29 to 74 residents each, and the median age by facility ranged from 82 to 85 years. Group B consisted of five facilities with a total of 215 residents; there were 31 to 66 residents per facility, and the median age by facility ranged from 79 to 85 years. The number of falls reported to the local authorities in the 2.5 years preceding the trial was similar for both groups: 1.26 per resident per year for group A and 1.29 for group B.

After baseline assessment of all residents, groups A and B were randomly assigned by lots to an intervention or a control group (Figure 1). The random allocation was conducted by a person with no knowledge of the study. Two sealed, dark envelopes were used. In each envelope, a letter specified one of the groups. Before the lot was drawn, the first envelope drawn was designated as the intervention group. The local authorities, residents, staff of the nine facilities, and the research group were then informed of the results of the randomization.

All residents in the study received written and oral information. All participants (or the relatives and guardians of participants with severe cognitive dysfunction) gave informed consent. The administrators and staff of the nine facilities involved also received information about the study and agreed to participate. The Ethics Committee of the Medical Faculty of Umeå University approved the study.

Definition of a Fall and an Injury

A fall was defined as an event in which the resident unintentionally came to rest on the ground or floor, regardless of whether an injury was sustained. Thus, this definition also includes falls that resulted from acute illness or epileptic seizure and incidents that resulted in a resident's falling and being found on the floor by staff or another resident.

An injury was defined according to the Abbreviated Injury Scale (20). Classifications were *minor* for injuries limited to superficial wounds and bruises; *moderate* for intermediate-level injuries, such as vertebral and wrist fractures; and *serious* for major fractures, such as hip fractures and other femoral fractures.

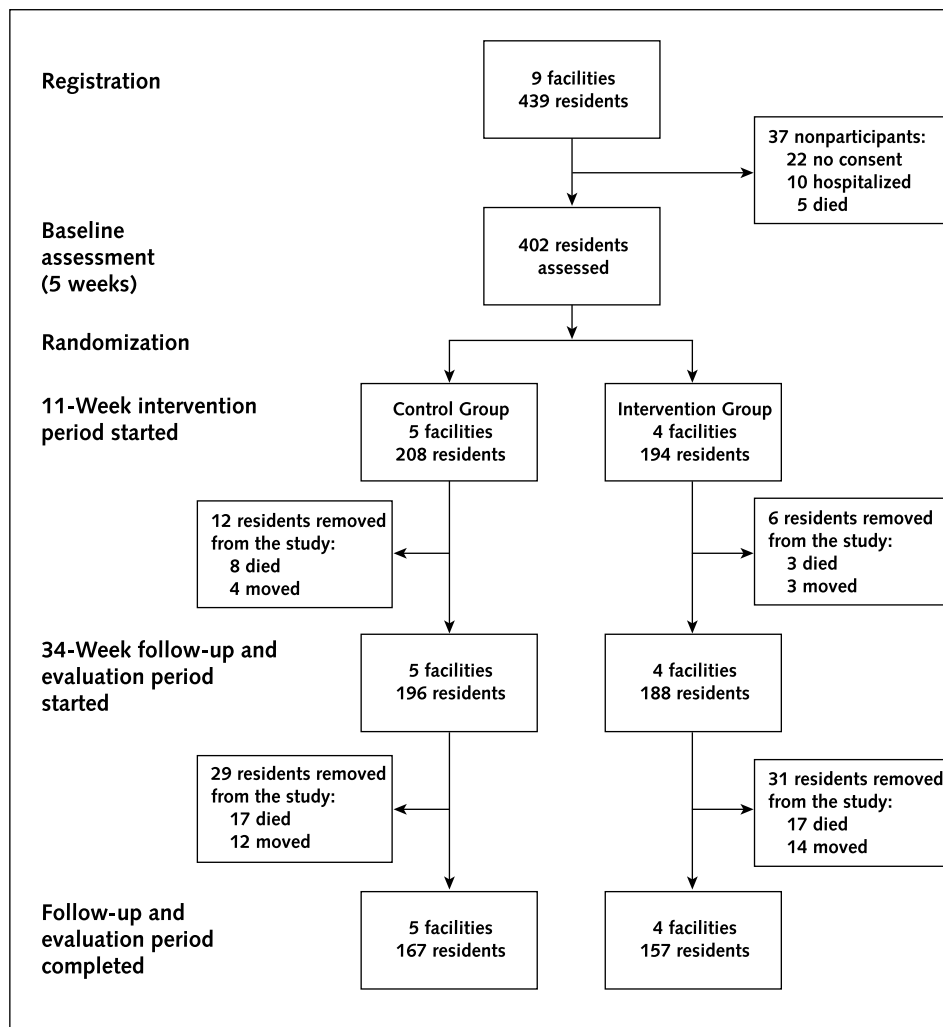
Participants and Settings

All residents in the nine facilities who were 65 years of age or older were selected in a cross-sectional manner. Thirty-seven of these residents declined to participate, were admitted to hospitals, or died before randomization. Sex and age of the 37 nonparticipants were similar to those of the remaining 402 residents.

In Sweden, older people living in residential care facilities are disabled by cognitive or physical impairment and thus require supervision, functional support, or nursing care. In this study, some residents lived in private apartments and others had private rooms but shared dining and living rooms. In all facilities, residents had 24-hour daily access to assistance with activities of daily living, household issues, and medical care. The median age was 83 years (range, 65 to 100 years), and most residents were female (72%). Few residents could walk outdoors without a walking aid (14%) or shower without assistance (18%); few were nonambulatory (19%) or entirely dependent when eating (8%). Additional baseline characteristics are presented in the Table.

All members of the permanent staff, regardless of

Figure 1. Study design.



profession, participated in the study. In addition, eight physiotherapists were employed part-time (a total of 200 h/wk) until the end of the intervention period, and three physiotherapists were employed part-time (a total of 10 h/wk) during the follow-up period. A total of 273 nurses' aides or licensed practical nurses and 20 registered nurses worked at the nine facilities.

Baseline Assessment

Each resident's physician completed a questionnaire regarding clinical characteristics and drugs prescribed. A registered nurse reported delirium episodes (Table).

Physiotherapists interviewed and assessed all residents. Hearing was rated as impaired if the resident

could not hear normal speech from a distance of 1 meter or used a hearing aid. Vision was rated as impaired when the resident, with or without glasses, could not read a word written in 5-mm capital letters at reading distance. Global cognitive function was screened by using the Mini-Mental State Examination (MMSE) (21). Licensed practical nurses or nurses' aides were interviewed to determine the number of falls that had occurred during the 6 months preceding the study and the extent of use of physical restraints. Activities of daily living were assessed according to the Barthel index (22, 23).

All residents were screened for the risk for falling. First, by using the Mobility Interaction Fall Chart (24), a resident was classified to be at higher risk for falling if

Table. Baseline Characteristics of the 402 Residents Participating in the Study

Characteristic	Intervention Group (n = 194)	Control Group (n = 208)
Median age (range), y	83 (65–97)	84 (65–100)
Women, n (%)	137 (71)	151 (73)
History of falls, n (%)*	80 (42)	81 (39)
Screened as having high risk for falls, n (%)	89 (46)	98 (47)
Measures of function		
Median Mini-Mental State Examination score (range)†	20 (0–30)	18 (0–30)
Median Barthel index score (range)	15 (0–20)	14 (0–20)
Independent walking (with or without aids)	136 (70)	139 (67)
Physical restraint (belt), n (%)	2 (1)	11 (5)
Physical characteristics, n (%)‡		
Hearing impaired	62 (32)	59 (29)
Vision impaired§	48 (26)	48 (25)
Dementia	69 (36)	74 (36)
Depression	66 (34)	59 (29)
Delirium episodes (during the past month)	62 (32)	44 (22)
Heart disease	114 (59)	107 (52)
Previous stroke or transient ischemic attack	61 (32)	70 (34)
Parkinson disease	8 (4)	4 (2)
Urinary incontinence	62 (32)	65 (31)
Fractures (previous year)	27 (14)	19 (9)
Prescribed drugs		
Digitalis, n (%)	34 (15)	31 (18)
Diuretics, n (%)	100 (52)	108 (52)
Analgesics, n (%)	132 (68)	133 (64)
Benzodiazepines, n (%)	51 (26)	69 (33)
Antidepressants, n (%)	60 (34)	70 (31)
Neuroleptics, n (%)	47 (24)	64 (31)
Median drugs (range), n	6 (0–15)	6 (0–16)

* 6 months preceding the study.

† Mini-Mental State Examination score could not be assessed in 8 residents in the intervention group and 16 residents in the control group because of aphasia or other medical reasons. Two residents moved out of the facilities before the start of follow-up and were not included in the analysis.

‡ Physical characteristics were not determined for 2 to 8 residents.

§ Vision could not be assessed in 9 residents in the intervention group and 12 residents in the control group because of cognitive impairment.

he or she stopped walking when talking to an accompanying person (25), walked more slowly when carrying a glass of water (26), or had impaired vision or difficulty concentrating. Second, a physiotherapist globally rated the fall risk as higher if the resident showed risk-taking behavior considered to jeopardize balance. If the residents were not classified to be at higher risk for falling by any of these described measures, they were considered to be at lower risk for falling.

Residents at higher risk were likely to be older than those at lower risk (median age, 84 years [range, 65 to 98 years] vs. 83 years [range, 65 to 100 years]), to have

lower MMSE scores (median score, 17 [range, 0 to 30] vs. 21 [range, 0 to 30]), and to have more medical diagnoses (median, 4 vs. 3).

The main areas of each facility were also screened according to a checklist for environmental hazards, such as lighting, flooring, obstacles inside the facility, and dangerous areas outside the facility (for example, icy areas).

Twelve residents in the control group and six in the intervention group died or moved during the 11-week intervention period (Figure 1).

Intervention Program

The intervention program comprised strategies that targeted both general and resident-specific risk factors for falling. The strategies were designed to be meaningful to the residents without compromising mobility. The 89 residents screened as being at higher risk as well as the 19 residents at lower risk who fell during the 11-week intervention period were the focus of the individualized intervention program. Increasing the staff's knowledge about fall prevention was believed to be the starting point of a process that would produce long-term results.

Staff Education

All staff were invited to a 4-hour educational session, and more than half attended. The sessions were led by a physician and a physiotherapist and covered risk factors for falls and intervention strategies. To stimulate the adoption of a problem-solving strategy, specific cases of falls were discussed.

Environmental Modification

Environmental hazards in common areas were reduced, for example, by rearranging furniture that posed a risk for falling, quickly wiping wet areas on the floor, and clearing snow from the entrance to the facility.

Staff and study physiotherapists made adjustments in the residents' accommodations. Adjustments entailed removal of loose carpets and repair of doorsteps ($n = 18$); provision of grip bars, new beds, and firm mattresses in the bedroom and bathroom ($n = 15$); furniture changes ($n = 6$); and improved lighting ($n = 3$).

Exercise

Resident-specific training to improve physical function targeted several areas: strength, balance, gait, and safe transfer. Strength and balance exercises focused on moderate-intensity to high-intensity training that progressively challenged each resident's capacity. Exercises to improve safe movement focused on finding solutions to the specific resident's problems. Supervised exercise was suggested to 80 residents. Of these, 70 performed the exercises; 59 did them two to three times weekly and 11 exercised less frequently, for a mean (\pm SD) period of 9.1 ± 2.5 weeks.

Supply or Repair of Aids

Twenty-nine residents received various types of aids or the repair of aids already owned. Overall, study physiotherapists carried out 40 measures of supply and repair of aids; this represented 93% of suggested measures. The most frequent measures concerned supply, adjustment, or repair of mobility-related aids ($n = 34$); 24 of these 34 measures were for walkers, wheelchairs, and belts for assisted walking and 10 were for fitted footwear.

Change in Medication

During the 11-week intervention period, medication was adjusted for 21 residents because suspected side effects were believed to increase the risk for falling. The drugs adjusted were benzodiazepines in 8 residents, antidepressants in 8, neuroleptics in 2, eye drops prescribed for glaucoma in 2, diuretics in 1, and dopamine in 1.

In addition, pharmacologic treatment was initiated or adjusted in 26 residents because of medical conditions believed to pose a particular risk for falling. These conditions included anemia, heart disease, infection, pain, and depression. Seventeen residents were referred to other specialists, such as an eye or ear specialist or an optician.

Hip Protectors

Of the 47 residents who were considered particularly prone to sustaining a fall-related hip fracture and who were therefore offered free hip protectors, 34 agreed to use them. Common risk factors for fractures were considered in this decision (for example, known or suspected osteoporosis, impaired balance, risk-taking be-

havior, low body mass index, a previous fracture, and poor response to the fall prevention measures).

Post-Fall Problem-Solving Conferences

The registered nurse followed up on falls on the same day, and the physiotherapist followed up within 3 days. A team comprising a physician, nurse, physiotherapist, and sometimes other staff members met weekly to discuss fall reports. The team determined and addressed the most plausible explanation for the fall. Physical restraints were not suggested for any resident who fell.

Staff Guidance

Staff and study researchers held ongoing discussions about safety issues pertaining to 90 fall-prone residents. The most significant measure adopted was enhancing safe mobility by providing individualized supervision, improving the transfer technique, and supplying bed alarms.

Usual Care

The residents assigned to the control group received usual care. The tasks of the physiotherapist were not changed, and no hip protectors were provided. There were no systematic fall-related problem-solving conferences or major fall-related environmental modifications. The only change in routine was that all reports of falls were collected weekly during the intervention and follow-up periods.

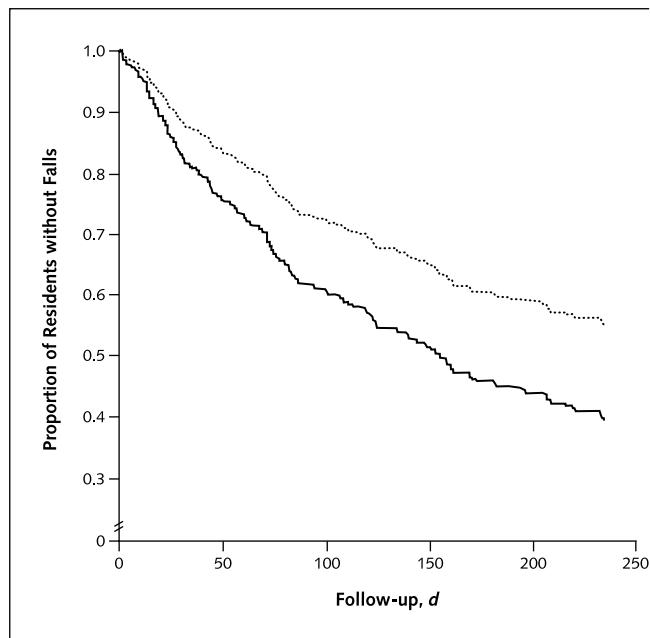
Outcomes

The primary outcomes were the number of residents sustaining a fall, the number of falls, and time to occurrence of the first fall. A secondary outcome was the number of injuries resulting from the falls.

The follow-up period was preplanned to last 34 weeks (**Figure 1**) and included post-fall problem-solving conferences in the intervention group. Nurses' aides and licensed practical nurses registered each fall that they personally witnessed or that was reported to them. The falls were documented on a structured report form specifically designed for this study. When the fall resulted in injury, such as a suspected fracture, the responsible physician assessed the resident on the same day as the fall.

To further improve reporting of falls, the residents'

Figure 2. Survival curves for time to first fall in residents in the intervention and control groups.



Survival curves were determined by using the multiple Cox regression method with adjustment for baseline factors, unadjusted for clustering (hazard ratio, 0.66 [95% CI, 0.48 to 0.89]). The dotted line denotes the intervention group; the solid line denotes the control group.

regular charts were reviewed at the end of the study. Staff were required to report falls on these charts. Of the 619 falls recorded on the regular charts, 33 (5%) had not been registered on the structured report of falls (2% in the intervention group and 8% in the control group). These falls were included in the overall analysis.

Statistical Analyses

The sample size was calculated to detect a 12% difference in falling between the intervention and control groups at a significance level of 0.05. To calculate the incidence rates, observation days were counted from the beginning to the end of the follow-up period or until the resident moved or died. For the analysis of hazard rates, observation days were counted to the day on which the first fall occurred. Days spent outside the facility, if more than 3, were subtracted.

In all statistical analyses using logistic regression, Poisson regression, and Cox regression, standard errors were adjusted for clustering (Stata software, version 7, Stata Corp., College Station, Texas) because the resi-

dents in the nine facilities might not be individually independent (27). The main explanatory variable was “treatment” (binary data). The following baseline factors were also adjusted for and entered into the models: MMSE score (ordinal data, 0 to 30), Barthel index score (ordinal data, 0 to 20), physical restraints and delirium, sex and history of falls (binary data), and age (continuous data). Adjustments for clustering were made in all analyses, both with and without the adjustment for baseline factors. A multiple imputation was performed because of 22 missing values for the MMSE.

We presented, by study group, the number of residents sustaining at least one fall, sustaining more than one fall, and having a femur fracture; logistic regression analysis was used to determine odds ratios with adjustment for clustering by using the “logic” command in Stata software.

The occurrence of falls is presented as incidence rates and incidence rate ratios with 95% CIs. Incidence rate ratios were calculated by Poisson regression analysis to account for overdispersion of falling minus the possibility of multiple falls per resident by using the “nbg” command in Stata software.

Time to first fall was analyzed by means of Cox regression analysis (28) by using the “Cox” command in Stata software, and the effect of treatment was expressed as a hazard ratio. A subgroup interaction analysis was also performed to calculate the intervention effect for time to first fall in residents rated as higher and lower risk, respectively. For this purpose, a variable of four categories was formed by combining risk groups (low and high) and study groups (intervention and control).

The number of residents needed to treat for one person to benefit was obtained by calculating the reciprocal of the absolute risk reduction. The confidence limits were estimated by using a substitution method (29).

In the analyses, 95% CIs were used. For the inferential statistical analyses, we used Stata software, version 7.0. **Figure 2** was generated by using SPSS software, version 6.1 (SPSS Inc., Chicago, Illinois).

Role of the Funding Sources

The funding sources had no role in the collection, analysis, or interpretation of the data or in the decision to submit the manuscript for publication.

RESULTS

Fewer residents in the intervention group than in the control group fell: 82 of 188 (44%) compared with 109 of 196 (56%); this represents a risk ratio of 0.78 (CI, 0.64 to 0.96). Falls per resident ranged from 0 to 16 in the intervention group and 0 to 26 in the control group. In the logistic regression analysis, the odds ratio for falling for the intervention compared with the control group was 0.62 (CI, 0.42 to 0.91) unadjusted for baseline factors and 0.49 (CI, 0.37 to 0.65) adjusted for baseline factors.

Forty-eight of 188 residents in the intervention group (26%) sustained more than one fall compared with 64 of 196 (33%) in the control group. The corresponding odds ratio was 0.71 (CI, 0.37 to 1.34) unadjusted for baseline factors and 0.58 (CI, 0.38 to 0.89) adjusted for baseline factors.

A total of 273 falls occurred during 40 898 observation days in the intervention group, and 346 falls occurred during 41 590 observation days in the control group. The corresponding incidence of falls was 6.7 and 8.3 per 1000 person-days for the intervention and control groups, respectively. In a Poisson regression, the resulting incidence rate ratios were 0.75 (CI, 0.51 to 1.10) unadjusted for baseline factors and 0.60 (CI, 0.50 to 0.73) adjusted for baseline factors.

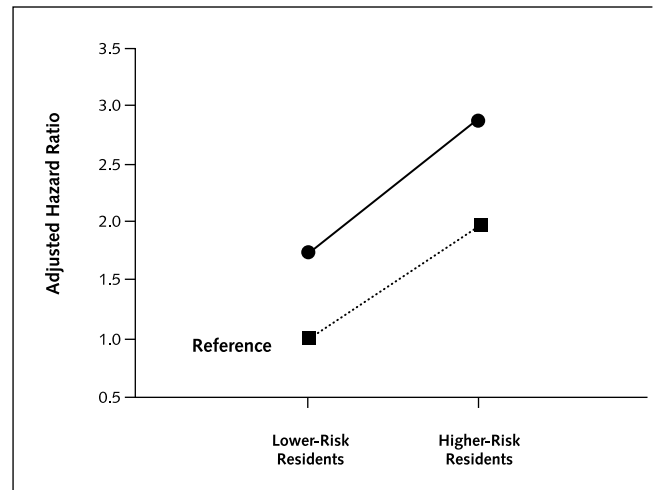
The time to first fall was longer for the intervention group than for the control group (unadjusted hazard ratio, 0.71 [CI, 0.54 to 0.94]; adjusted hazard ratio, 0.66 [CI, 0.54 to 0.79]) (Figure 2).

A subgroup analysis of time to first fall was performed for residents at lower risk for falls (101 in the intervention group and 106 in the control group) and those at higher risk for falls (87 in the intervention group and 90 in the control group). Differences between the intervention and control groups were similar in the higher- and lower-risk groups (Figure 3).

Of 619 falls, 145 (23%) resulted in injuries. The severity of injury did not differ significantly between the groups: 51 minor injuries in the intervention group versus 61 in the control group and 11 moderate injuries in the intervention group versus 7 in the control group.

Three of 188 residents in the intervention group (1.6%) and 12 of 196 in the control group (6.1%) had a femoral fracture. In a logistic regression analysis, the unadjusted odds ratio for having a femoral fracture was

Figure 3. Interaction analysis by study group comparing the time to first fall of lower- and higher-risk residents.



The lower-risk intervention group is the reference group. Adjusted hazard ratios were as follows: lower-risk residents in the control group, 1.73 (95% CI, 1.17 to 2.55); higher-risk residents in the intervention group, 1.94 (CI, 1.15 to 3.30); and higher-risk residents in the control group, 2.87 (CI, 1.93 to 4.27). The dotted line denotes the intervention group; the solid line denotes the control group.

0.25 (CI, 0.05 to 1.13) and the adjusted odds ratio was 0.23 (CI, 0.06 to 0.94).

For a period of 34 weeks, 8 (CI, 4.6 to 48.5) residents needed to be treated to prevent 1 resident from falling, and 22 (CI, 12.0 to 138.5) needed to be treated to prevent 1 resident from sustaining a femoral fracture.

DISCUSSION

Our intervention program significantly reduced the number of residents who fell, total number of falls, time to first fall, and number of femoral fractures. To our knowledge, only one randomized, controlled trial in older people in nursing homes or residential care facilities has reported any positive effects on falls. This trial, however, dealt only with people who fell repeatedly (9).

Our intervention program combined several measures that targeted risk factors (30). Therefore, we could not estimate the effect of individual prevention measures (11, 16). However, the multifactorial approach may be considered successful because all residents (those at lower and higher risk for falling) benefited similarly from the program. Because both staff and residents were active participants, the assumption was that a positive process would develop among those involved. This as-

sumption is indirectly supported by the shape of the survival curves for time to first fall, which showed a growing gap during the follow-up period.

The analyses revealed a reduction in the number of femoral fractures, even when clustering was taken into account. Because no femoral fractures occurred in residents wearing hip protectors and the proportional reduction in hip fractures was greater than the proportional reduction in falls, the use of hip protectors may have contributed to the result. Previous trials in which hip protectors were used have reported positive results (31–33). In agreement with other studies done in similar target groups (9–13), the number of less serious injuries did not differ between the study groups. More research in this area is needed. However, results may be influenced by methods used. In our study, minor and moderate injuries may have been more carefully reported in the intervention group because staff members were involved in post-fall assessments and interventions during the follow-up period.

Our study has some limitations. Randomization of the facilities into groups was considered necessary to keep the groups distinct from one another. Because some staff members were responsible for several facilities, they and the facilities in which they worked had to be part of the same study group. In addition, the focus of the intervention programs on the staff and the environment in each facility made individual randomization inappropriate. However, the analyses adjusted for clustering of residents in the nine facilities. Of note, all facilities had the same management, staff administration, care policy, and criteria for admission to the facility; also, the study groups had the same reported frequency of previous falls at baseline.

The research team encouraged the reporting of all falls, but this probably did not occur. In the control group, it was found that more falls were registered in the regular medical charts (but not in the study's "fall reports") than were recorded for the intervention group (8% vs. 2%). Thus, more falls may have gone unreported in the control group. For the Frailty and Injuries: Cooperative Studies of Intervention Techniques trials, Buchner and colleagues evaluated the accuracy of the recording of falls on a "fall report" (34). These investigators found that even in institutions well attuned to the importance of reporting falls, 10% to 15% of the

falls were unreported. In our study, the reporting of falls was higher than in the trial by Buchner and colleagues.

Our intervention program affected all outcome measures, which strongly supports the validity of the results. We conclude that an interdisciplinary, multifactorial fall prevention program that avoids the use of physical restraints and that targets older people, staff, and the residential care environment may reduce the number of residents who fall, the total number of falls, and femoral fractures.

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