Fall and Injury Prevention in Residential Care—Effects in Residents with Higher and Lower Levels of Cognition

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OBJECTIVES: To evaluate the effectiveness of a multifactorial fall and injury prevention program in older people with higher and lower levels of cognition.

DESIGN: A preplanned subgroup comparison of the effectiveness of a cluster-randomized, nonblinded, usual-care, controlled trial.

SETTING: Nine residential facilities in Umeå, Sweden.

PARTICIPANTS: All consenting residents living in the facilities, aged 65 and older, who could be assessed using the Mini-Mental State Examination (MMSE; n = 378). An MMSE score of 19 was used to divide the sample into one group with lower and one with higher level of cognition. The lower MMSE group was older (mean ± standard deviation = 83.9 ± 5.8 vs 82.2 ± 7.5) and more functionally impaired (Barthel Index, median (interquartile range) 11 (6–15) vs 17 (13–18)) and had a higher risk of falling (64% vs 36%) than the higher MMSE group.

INTERVENTION: A multifactorial fall prevention program comprising staff education, environmental adjustment, exercise, drug review, aids, hip protectors, and post-fall problem-solving conferences.

MEASUREMENTS: The number of falls, time to first fall, and number of injuries were evaluated and compared by study group (intervention vs control) and by MMSE group.

RESULTS: A significant intervention effect on falls appeared in the higher MMSE group but not in the lower MMSE group (adjusted incidence rates ratio of falls $P = .016$ and $P = .121$ and adjusted hazard ratio $P < .001$ and $P = .420$, respectively). In the lower MMSE group, 10 femoral fractures were found, all of which occurred in the control group ($P = .006$).

CONCLUSION: The higher MMSE group experienced fewer falls after this multifactorial intervention program, whereas the lower MMSE group did not respond as well to the intervention, but femoral fractures were reduced in the lower MMSE group. **J Am Geriatr Soc 51:627–635, 2003.**

Key words: accidental falls; prevention and control; femoral fractures; cognition; dementia

The prevention of falls and injuries in older people with cognitive impairment is an important concern in public health. The risk of falls[1–4] resulting in serious consequences[5,6] and hip fractures[7–9] is high, as is the risk of institutionalization and mortality after a hip fracture[10,11] Thus, it is of vital interest to investigate whether older people with significant cognitive impairment would benefit from fall-prevention strategies.

Controlled trials in the prevention of falls have shown promising results in older people in the community when multifactorial[12,13] and single-factor intervention programs have been used (e.g., physical exercise[14] and drug withdrawal[15]). In residential care facilities and nursing homes, only one trial demonstrated that intervention programs help prevent falls.[16] This study used a falls consultation service. Other fall interventions directed toward elderly persons living in care facilities have used combined forms of exercise[17–19] and assessment with treatment recommendations,[18,20] and have resulted in fewer hospital admissions,[20] improvements in mobility,[17] and reductions in fall risk factors[18] but not in reductions in falls themselves.

To provide optimal conditions for the implementation of a fall-intervention program, some trials have excluded participants who were not able to cooperate,[19,20] and other interventions included only participants with mental status examination scores above specific but varying levels.[12,13,15,17,18] Only one trial was directed toward the entire nursing home sample but did not present the results with respect to level of cognition.[16]

Thus, it is not known whether older people with significant cognitive impairment benefit differently from fall prevention strategies from those who are nonimpaired or

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mildly impaired. It is also not known whether the effects of hip protectors vary with different levels of cognitive impairment in older people. However, hip protectors do appear to reduce hip fractures in the cognitively and physically heterogeneous group of older people who live in institutions or in their own homes with medical support.[21]

Recently, a multifactorial fall prevention program that reduced the number of people falling, falls, and femoral fractures among older people in residential care was presented.[22] The purpose of the present study was to analyze the effectiveness of this program in residents with a higher or lower level of cognition. Therefore, the authors conducted a preplanned analysis comparing the subgroups.

METHODS

Participants and Settings

Study participants were people living in residential care facilities (n = 9) located in Umeå, a city in northern Sweden. The selected facilities had to have more than 25 residents. All residents, aged 65 and older (n = 439) living in the nine facilities were included in a cross-sectional manner (Figure 1). Thirty-seven of these residents declined to participate, were in the hospital, or died before randomization, and cognition could not be assessed in 24 residents, resulting in a sample of 378 residents (192 control and 186 intervention) at the start of the intervention period. The residents who dropped out or lacked cognition data (n = 61) were younger (median age = 80, interquartile range = 77–86 vs 84, 79–88; $P = .01$) but did not differ in sex from the remaining residents. During the intervention period, 16 residents moved or died; thus 362 residents were followed up and included in the analyses.

In Sweden, older people living in residential care facilities are disabled by cognitive or physical impairment and thus require supervision, functional support, or care. Dependency in walking and activities of daily living (ADLs) are particularly common in residents in this target group.[23] In this study, some residents lived in private apartments, and others had a private room but shared dining and living rooms. In all facilities, the residents had access to help with ADLs, household matters, and medical care around the clock, as required. Few residents were able to walk outdoors without a walking aid (15%) or to shower without assistance (19%). About one-fifth of the residents were nonambulatory, and 8% were entirely dependent with eating. Further baseline characteristics are presented by level of cognition in Table 1. Residents with Mini-Mental State Examination (MMSE) scores less than 19 were older, more functionally impaired, and at greater risk of falling than those with higher MMSE scores. Characteristics are compared by study group (intervention vs control) in Table 2.

All members of the permanent staff, regardless of profession, participated in the intervention. 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. Two hundred seventy-three nurses' aides or licensed practical nurses and 20 registered nurses worked at the nine facilities.

Design

The nine residential care facilities were divided into two groups, A and B. The distribution was based on the age and number of residents, type of setting (care and service offered and corridor or private home design), and previous falls as routinely reported to the local authority. To keep the groups distinct from one another, the distribution was also based on the principle that the physicians, registered nurses, physical therapists, and occupational therapists who were responsible for working with the residents in Group A should not also work with Group B residents. Group A included four facilities with a total of 224 residents. Group B included five facilities with a total of 215 residents. The number of falls reported to the local authorities in the previous 2.5 years was similar for the two groups: 1.26 (A) and 1.29 (B) falls per resident and year.

After baseline assessment of all residents, a person with no knowledge of the study conducted the random allocation into an intervention or a control group by lot (Figure 1). Two dark envelopes were used. In each envelope a letter specified one of the groups, A or B. Before the lot was drawn, it was decided that the first envelope chosen would determine the intervention group.

All residents included were given written and oral information. All of those who participated, or the relatives or guardians of the residents with severe cognitive dysfunction, consented orally to participate in the study. The administrators and staff of the nine facilities involved also received information, 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

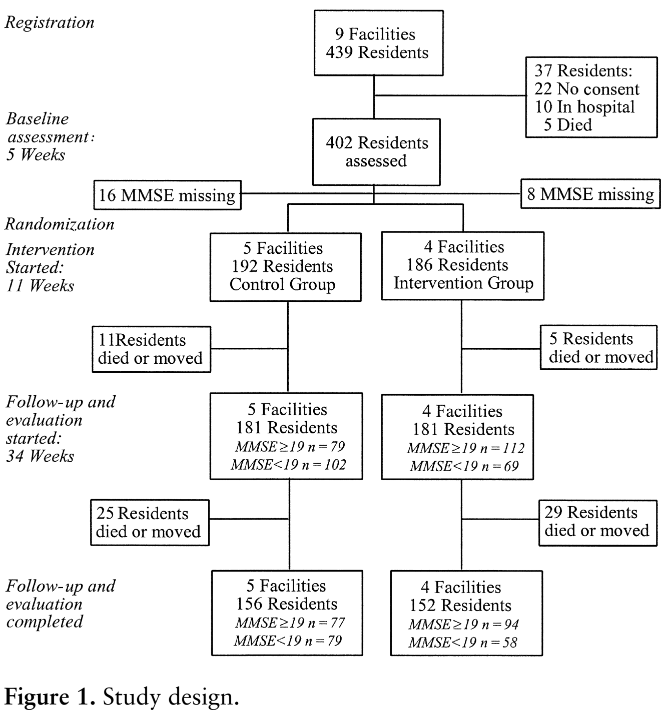

Figure 1. Study design.

Table 1. Baseline Characteristics of the 378 Residents by Level of Cognition

Characteristic	MMSE ≥19 n = 199	MMSE <19 n = 179	*P*-value
Age, mean ± standard deviation	82.2 ± 7.5	83.9 ± 5.8	.013
Female, %	66	78	.015
History of falls (past 6 months), %	34	46	.018
Function			
MMSE (score 0–30), median (IQR*)	24 (21–26)	13 (7–16)	<.001
Barthel activities of daily living index (score 0–20), median (IQR*)	17 (13–18)	11 (6–15)	<.001
Screened as high risk of falls, %	36	64	<.001
Independent walking, with or without aids, %	77	60	<.001
Physical restraint, belt, %	1	6	.016
Clinical characteristics, %†			
Vision impaired‡	17	35	<.001
Diagnosed dementia	18	57	<.001
Depression	30	30	.911
Delirium episodes (during the past month)	19	37	<.001
Heart disease	61	48	.013
Previous stroke/transient ischemic attack	31	30	.838
Urinary incontinence	18	45	<.001
Fractures (previous year)	12	11	.790
Prescribed drugs, (%)			
Diuretics	56	46	.053
Benzodiazepines	32	29	.503
Antidepressants	27	37	.032
Neuroleptics	23	34	.025
No. of drugs, median (IQR*)	6 (4–9)	6 (4–8)	.058

* Interquartile range (IQR) is range between first and third quartiles.
† Clinical characteristics were not determined for one to eight residents.
‡ Vision was not assessable in 17 residents in the subgroup with Mini-Mental State Examination (MMSE) <19 because of cognitive impairment.

of whether an injury was sustained. Thus, all falls were included in the study, including falls resulting 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.

All fall-related injuries were registered according to the classification system of the Abbreviated Injury Scale.[24] Classifications were "minor" for injuries limited to superficial wounds and bruises, "moderate" for intermediate-level injuries such as vertebral and wrist fractures, and

Table 2. Baseline Characteristics of the 378 Residents by Level of Cognition and by Study Group

Characteristics	MMSE ⩾19			MMSE <19		
	Intervention (n = 114)	Control (n = 85)	*P*-value	Intervention (n = 72)	Control (n = 107)	*P*-value
Age, mean ± standard deviation	81.3 ± 7.4	83.4 ± 7.4	.053	84.4 ± 5.2	83.6 ± 6.2	.354
Female, %	68	64	.470	74	80	.287
History of falls during the past 6 months, %	40	27	.068	45	47	.828
Function						
Mini-Mental State Examination (score 0–30), median (IQR*)	23 (21–26.25)	24 (21–26)	.243	12.5 (6.25–16)	13 (7–16)	.562
Barthel activities of daily living index (score 0–20), median (IQR*)	17 (15–18)	16 (12.5–18)	.076	11 (6–15.75)	12 (6–15)	.831
Screened as high risk of falls, %	39	32	.320	58	59	.942
Physical restraint, belt, %	1	1	1.000	0	9	.006
Clinical characteristics, %†						
Delirium episodes (during the past month)	20	15	.424	49	28	.005
Fractures (during the previous year)	17	6	.020	11	11	.965

* Interquartile range (IQR) is range between first and third quartiles.
† Clinical characteristics were not determined for one to eight residents.

"serious" for major fractures such as hip fractures and other femoral fractures.

Baseline Assessment

Each resident's physician completed a questionnaire regarding clinical characteristics, and a registered nurse reported delirium episodes. A record was also kept of the drugs prescribed to the residents.

Study physiotherapists interviewed and assessed all residents. Hearing was rated as impaired if normal speech could not be heard from a distance of 1 meter or a hearing aid was used. 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 using the MMSE.[25] The MMSE was chosen because it is widely used, easy to apply, and has been found satisfactory regarding construct validity and test-retest reliability.[26,27] Previous studies have suggested various cutoff points for MMSE.[26,27] The median score of this sample, 19 points, was chosen as the cutoff to divide the sample of residents into one group with higher and one with lower levels of cognition. Residents with an MMSE score of 19 or higher were defined as nonimpaired or mildly cognitively impaired (higher MMSE group), and residents with an MMSE less than 19 as moderately or severely impaired (lower MMSE group). This grouping was not intended to diagnose dementia or other disorders.

The study physiotherapists interviewed practical nurses or nurses' aides about falls during the last 6 months, the use at baseline of physical restraints, and ADLs according to the Barthel ADL index.[28,29]

All residents were screened for risk of falling and were judged to have a higher risk of falling if either of two means was positive. First, the Mobility Interaction Fall Chart,[30] a flow chart that includes "stops walking when talking," measuring a person's ability to simultaneously talk with another person and walk;[31] the "DiffTUG," which measures the ability to walk and carry a glass of water simultaneously;[32] a test of vision; and a rating of concentration were used. Second, the physiotherapist rated the fall risk globally (as low or high), with particular focus on risk-taking behavior that was considered to jeopardize balance.

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

Intervention Program (11 Weeks)

The intervention program comprised strategies that targeted both general and resident-specific risk factors for falling. The residents screened as being at higher risk (n = 86) and those who experienced a fall (n = 19) during the 11-week intervention period were included in the resident-specific interventions. The intervention sample thus comprised 55 residents with an MMSE score of 19 or higher and 50 residents with an MMSE score less than 19 (Table 3). The strategies were based on the risk factors of each individual resident and were designed to be meaningful to the residents without compromising mobility. The intervention program has been described in detail elsewhere.[22]

Staff Education

All staff were invited to a 4-hour educational session; more than half attended. The sessions, led by a physician and a physiotherapist, covered risk factors for falls and intervention measures.

Environmental Modification

Environmental hazards in common areas were reduced, for example, by rearranging furniture or other objects that posed a risk for falling.

Staff and physiotherapists also made adjustments in the residents' accommodations. Adjustments included removal of loose carpets; repair of doorsteps; provision of grip bars, new beds, and firm mattresses; furniture changes; and improved lighting.

Table 3. Proportion of Residents Who Received Resident-Specific Interventions Classified As High Risk (N = 89) and Who Fell During the Intervention Period (n = 19)

Intervention	MMSE ≥19 (n = 55) %	MMSE <19 (n = 50) %	*P*-value
Adjustments in private accommodations,	35	22	.155
Exercise			
Offered to residents	82	68	.100
Performed two to three times/week	67	42	.009
Supply and repair of aids	25	30	.603
Change in medication because of			
Drug side-effects	15	22	.322
Disease increasing the risk for falls	27	18	.258
Hip protectors			
Offered to residents	47	40	.453
Used by residents	29	34	.588
Guidance to staff	76	92	.036
Postfall problem-solving conferences	51	58	.466

MMSE = Mini-Mental State Examination.

Exercise

Resident-specific training to improve physical function targeted strength, balance gait, and safe transfer. Strength and balance exercises emphasized moderate- to high-intensity training that progressively challenged the resident's capacity. The individual program was adjusted to the specific impairments and disabilities of the resident. The exercise sessions lasted from less than 1 hour to more than 3 hours per week, depending on the specific needs and motivation of the resident.

Supply and Repair of Aids

The most frequent measures concerned aids related to mobility (walkers, wheelchairs, belts for assisted walking, and fitted footwear).

Change in Medication

Medication was adjusted for specific residents because suspected side effects were believed to increase the risk of falling (e.g., benzodiazepines, antidepressants, neuroleptics, eye-drops prescribed for glaucoma, diuretics, and dopamine). In addition, pharmacological treatment was initiated or adjusted when medical conditions were believed to pose a particular fall risk (e.g., anemia, heart disease, infection, pain, and depression).

Hip Protectors

Hip protectors were offered free of charge to residents who were thought particularly likely to suffer a hip fracture. Criteria for being offered hip protectors were known or suspected osteoporosis, impaired balance, risk-taking behavior, low body mass index, a previous fracture, and poor response to the fall prevention measures.

Postfall Problem-Solving Conferences

The registered nurse followed up on falls on the same day, and the physiotherapist followed up within 3 days. At "postfall problem-solving conferences," a team comprising a physician, nurse, physiotherapist, and sometimes other staff members met weekly and discussed fall reports (143 reports in 11 weeks). The team determined the most plausible explanation for the fall of each resident. Physical restraints were not suggested for any resident who fell. Moreover, staff and study researchers held ongoing discussions about safety issues pertaining to fall-prone residents.

Usual Care

The residents assigned to the control groups received usual care. No hip protectors were provided. The only change in routine was that all reports of falls were collected weekly during the intervention and follow-up periods (11 plus 34 weeks).

Outcome and Follow-Up of Falls

The primary outcomes were the number of residents sustaining a fall, the number of falls, and time to occurrence of the first fall. The 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 postfall problem-solving conferences in the intervention groups. Nurses' aides and licensed practical nurses registered each fall they 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 the same day as the fall.

To further improve the reporting of falls, the residents' regular charts were reviewed at the end of the study. Staff were required to report falls on these charts. Of the 597 falls recorded on the regular charts, 31 (6%) had not been registered on the structured report of falls (2% in the intervention and 9% in the control group). These falls were also included in the overall analyses.

Statistical Analysis

The baseline characteristics of residents were compared using the chi-square test and Fisher exact test for nominal data, Student t test for continuous data, and the Mann-Whitney U test for ordinal or skewed data. To calculate the incidence rates, observation days were counted from the start to the end of the follow-up or until the resident moved or died. For the analysis of hazard rates, observation days were counted to the day when the first fall occurred. Days spent outside the facility, if more than 3, were subtracted.

All residents were included in the analyses regardless of adherence to the intervention program and regardless of hospitalization or death during the follow-up period.

In all the statistical analyses using logistic analysis, Cox regression, and Poisson regression analysis, standard errors were adjusted for clustering (Stata software package, version 7.0, Stata Corp., College Station, TX) because the residents lived in nine different facilities and might not have been individually independent.[33]

To look for difference in intervention effect between subgroups of cognition, an interaction analysis was performed in the logistic regression, Cox regression, and Poisson regression analyses.[34] The main explanatory variable, "study group" (intervention/control), was categorized with regard to higher or lower level of MMSE to calculate the intervention effect. For this purpose, a variable of four categories was formed: higher MMSE—intervention (reference), higher MMSE—control, lower MMSE—intervention, and lower MMSE—control. The following baseline factors were adjusted for and entered into the models: Barthel index (ordinal data, 0–20), physical restraints, delirium, sex, history of falls (binary data), and age (continuous data).

The number of residents sustaining at least one fall was presented by study group, and logistic regression analysis was used to determine the odds ratio (OR) of being a faller (having fallen at least once = 1, having not fallen = 0) by means of Stata software, command "logistic."

Time to first fall was analyzed using Cox regression methods[35] using Stata software, command "Cox," and the effect of treatment was expressed as a hazard ratio (HR).

The crude number of falls per observation day was calculated. In addition, the incidence rate ratio (IRR) was calculated in a Poisson regression analysis, "negative binomial regression." This method takes into account "overdispersion" of falling—the possibility of multiple events per resident.[34]

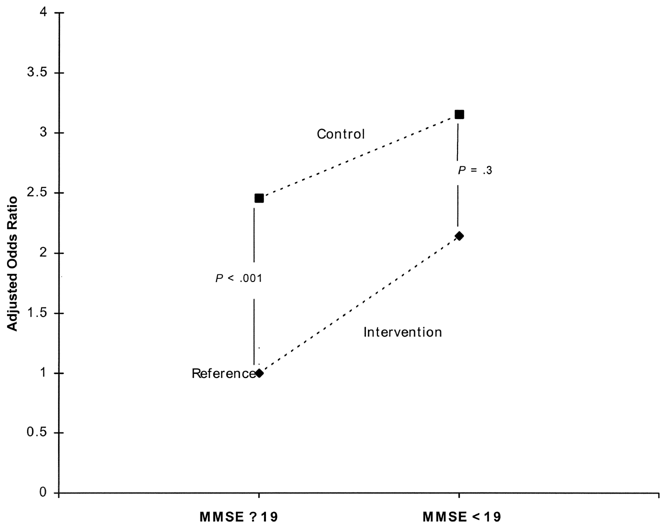

Figure 2. Interaction analysis by study group comparing the odds ratio of being a faller of residents with Mini-Mental State Examination (MMSE) scores of 19 or greater and less than 19. The MMSE ≥19—intervention group is the reference group. Adjusted odds ratios were as follows: MMSE ≥19—control group = 2.5 (95% confidence interval (CI) = 1.7 – 3.6), MMSE <19—intervention group = 2.1 (95% CI = 0.9 – 4.8), and MMSE <19—control group = 3.2 (95% CI = 2.2 – 4.5).

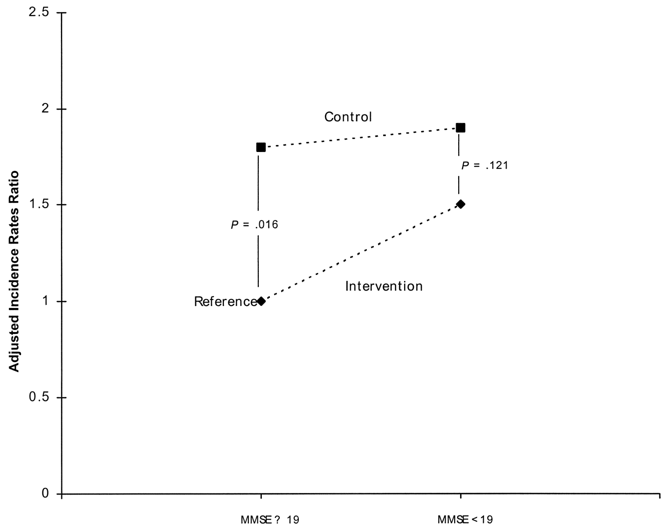

Figure 3. Interaction analysis by study group comparing the incidence rates of falls of residents with a Mini-Mental State Examination (MMSE) score of 19 or greater and less than 19. The MMSE ≥19—intervention group is the reference group. Adjusted incidence rate ratios were as follows: MMSE ≥19—control group = 1.8 (95% confidence interval (CI) = 1.1–2.9), MMSE <19—intervention group = 1.5 (95% CI = 0.9–2.7), and MMSE <19—control group = 1.9 (95% CI = 1.2–3.0).

In Figures 2 and 3, deviation from parallelism of lines indicates interaction (difference in intervention effect dependent on MMSE group) according to an epidemiological definition of interaction.[34]

The total number of injuries was compared using crude incidence rates and the proportion of femoral fractures using Fisher exact test.

In the analyses, 95% confidence intervals (CIs) were used. For the inferential statistical analyses, Stata software, version 7.0 was used.

RESULTS

Residents Falling

During the follow-up, 184 of 362 residents experienced 597 falls, 85 of 191 (45%) residents in the higher and 99 of 171 (58%) in the lower MMSE subgroup. The proportion of residents who fell, number of falls, and incidence rates of falls by MMSE and by study group are shown in Table 4.

An interaction test comparing the MMSE groups showed that the adjusted odds ratio for falling in the higher MMSE group was significantly higher in the control than in the intervention group, whereas no significant difference was found between the study groups in the lower MMSE group (Figure 2).

Time to First Fall

In the higher MMSE group, the time to first fall was significantly longer for the intervention than for the control group in a Cox regression analysis, whereas, in the lower MMSE group, no significant difference was found ($P <$ .001 and $P =$ .420, respectively). The adjusted HRs (95% CIs) were as follows: higher MMSE—intervention (reference (1.0), higher MMSE—control (1.8 (1.4–2.3), lower MMSE—intervention (1.8 (1.1–3.2), and lower MMSE—control (2.2 (1.7–2.8).

Fall Events

A significant difference in crude IRRs between the intervention and control groups was found with regard to the higher MMSE group but not the lower (Table 4). Also, when comparing the adjusted IRR of the higher and lower MMSE groups in a Poisson analysis, a significant difference was found in the higher but not in the lower MMSE group (Figure 3).

Injuries

Fifty-nine minor, moderate, or serious injuries occurred in the higher MMSE group (32 and 27 injuries in the intervention and control groups, respectively (crude IRR = 0.9; 95% CI = 0.5–1.5)) and 81 injuries in the lower MMSE group (31 and 50 injuries, respectively (crude IRR = 0.9; 95% CI = 0.5–1.3)).

The 191 residents with a higher MMSE level sustained five femoral fractures, three of which were in the intervention group. In the lower MMSE group, the 171 residents sustained 10 femoral fractures, all of which were in the control group ($P =$ .006).

DISCUSSION

This subgroup comparison of a multifactorial fall-prevention program revealed a beneficial effect regarding the number of residents falling and falls by residents with a higher level of cognition but not by those with a lower

Table 4. Residents Falling, Falls, and Crude Incidence Rate Ratios of Falls (n = 362)

	MMSE ≥19		MMSE <19	
Outcome	Intervention (n = 112)	Control (n = 79)	Intervention (n = 69)	Control (n = 102)
Residents with any fall, %	38*	54*	54†	61†
Falls, n	119	144	144	190
Falls per resident, range	0–11	0–26	0–16	0–13
Incidence rate per person year (95% CI)	1.77‡ (1.46–2.1)	2.9‡ (2.43–3.38)	3.5§ (2.93–4.07)	3.34§ (2.86–3.82)

* $P = .020$; † $P = .352$.
‡ Incidence rate ratio (95% confidence interval (CI)) = 0.61 (0.48–0.78).
§ Incidence rate ratio (95% CI) = 1.05 (.84–1.30).
MMSE = Mini-Mental State Examination.

level. However, the intervention program reduced femoral fractures in the lower cognition group.

In the present study, the residents with a lower level of cognition were older and more functionally impaired than those with a higher cognitive level, and a larger proportion were at greater risk of falling. Several signs of frailty, such as episodes of delirium, urinary tract infections, poor vision, and the use of neuroleptics and antidepressants, were also more prevalent in the former group. In addition, a majority of the residents in the lower cognition group was likely to suffer from impaired concentration, memory, perception, and understanding, which may have made prevention more difficult. Consequently, interventions requiring participation in physical exercises, skilled use of aids, and memorizing strategies for avoiding falls were likely to be more difficult for this group to cope with. In the present study, fewer residents in the lower MMSE group than in the higher MMSE group were found to adhere to the exercise intervention. The intensity of training in the lower-cognition group may also have been too low to be effective. To achieve positive results in balance and strength, it has previously been shown that the exercises should challenge the limits of the resident's capacity.[37] It has also been shown that physically frail nursing home residents with mild cognitive impairment benefit from exercise (e.g., through improved balance and strength),[37] whereas the effects in residents with more-severe cognitive impairment are inconclusive.[17,18,38] Hypothetically, targeted supervision of the residents' transfer and attention to changes in acute health condition, apart from exercise, may be important factors to emphasize in the anticipation and reduction of falls by residents with lower levels of cognition.

Although the MMSE subgroups differed with respect to many important fall risk factors, it should be noted that all analyses of intervention effects according to higher and lower MMSE groups were adjusted for important baseline fall risk factors (age, Barthel index, history of falls, physical restraints, delirium, and sex).

No effect was found regarding the total number of injuries in any of the MMSE groups, but minor injuries such as bruises, which were not immediately detectable, abrasions, and rib fractures may have been detected more often in the intervention group where the staff were engaged in postfall assessment, and consequently true differences between study groups may have been missed.

In contrast to the negative results in reducing the fall rate, the multifactorial prevention program appeared to have a beneficial effect on femoral fractures in the lower MMSE group. All 10 femoral fractures occurred in the control group. One explanation for these findings may be that the residents with cognitive impairment have a particularly high risk of suffering a fracture and that only the residents in the intervention group used hip protectors. Agreement to use protectors was similar in the two MMSE groups; thus, despite the limited number of residents studied, this study seems to confirm the findings of other authors that the use of hip protectors appears to reduce the risk of hip fractures.[21] To our knowledge, this is the first prevention program including hip protectors that specifically focused on older people with cognitive impairment.

Although it is assumed that, to be successful, fall-intervention programs should target known risk factors in high-risk groups of older people, the actual definition of "high risk of falling" is ambiguous. Most previous studies on fall prevention have focused on selected groups of older people, but they did not specifically target those with cognitive impairment.[36] Several studies have excluded older people who were not able to cooperate or were significantly cognitively impaired[12,13,15,17,18,20,39] or have been directed to an entire nursing home sample including a wide range of physical and cognitive impairments.[16] Consequently, the results of previous investigations may not be valid for the group of residents suffering from both physical and cognitive impairments and are at highest risk of falling,[40] which was the population targeted in this study.

This study had some limitations. Individual randomization was considered inappropriate, because the interventions focused on residents, staff, and environment in each facility and because some staff members were responsible for several facilities and consequently had to be part of the same study group. Nevertheless, the analyses adjusted for clustering of residents in the nine facilities. Another limitation is that ascertainment of falls through prospective recording by the staff does not guarantee that all falls were known and reported. Some residents, predominantly those with cognitive impairment, may have risen independently after a fall without being observed, resulting in nonreporting of the event. In addition, the intervention status of the facilities was nonblinded, which could pose a risk of reporting bias. The size of the subgroups is a further limitation. Because of lack of previous fall-prevention studies in cognitively impaired older people, the rate of falling and the planned intervention effect in the lower MMSE group was overestimated. To detect a statistically significant effect ($\alpha = 0.05$, two-tailed; the power set to 0.80) on falls in the lower cognition group (given the present sample size), the OR of falling should have been 2.9. Although it is possible that there was a small intervention effect also in the lower cognition group, detecting this effect would have required a much larger sample size.

The comparison of subgroup effects was performed using interaction analysis of the entire sample of residents to make a comparison of the point estimates (OR, HR, IRR) possible and to avoid selection bias. The MMSE was used for the global screening of cognitive function. The terms "nonimpaired or mildly impaired" and "moderately and severely impaired" were used to characterize the higher and lower cognitive levels of cognition as suggested by Forsell et al.,[41] but the etiology of the cognitive impairment was not within the scope of this study.

The problem of falls in the section of the older population with cognitive dysfunction is increasing and cannot be ignored. The high incidence of falls and injuries underlines the need for prevention.[42]

CONCLUSION

The subgroup comparison revealed a beneficial effect regarding falls in the higher cognition group. In the lower cognition group, no beneficial effect on falls was seen, but femoral fractures were reduced. What interventions need to be emphasized to reduce falls in frail older people with lower cognition and how the coping ability of the residents is to be optimized remains to be investigated.

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