

Effects of a fall prevention program including exercise on mobility and falls in frail older people living in residential care facilities

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ABSTRACT. ***Background and aims:*** *Impaired mobility is one of the strongest predictors for falls in older people. We hypothesized that exercise as part of a fall prevention program would have positive effects, both short- and long-term, on gait, balance and strength in older people at high risk of falling and with varying levels of cognition, residing in residential care facilities. A secondary hypothesis was that these effects would be associated with a reduced risk of falling.* ***Methods:*** *187 out of all residents living in 9 facilities, ≥65 years of age were at high risk of falling. The facilities were cluster-randomized to fall intervention or usual care. The intervention program comprised: education, environment, individually designed exercise, drug review, post-fall assessments, aids, and hip protectors. Data were adjusted for baseline performance and clustering.* ***Results:*** *At 11 weeks, positive intervention effects were found on independent ambulation (FAC, p=0.026), maximum gait speed (p=0.002), and step height (≥10 cm, p<0.001), but not significantly on the Berg Balance Scale. At 9 months (long-term outcome), 3 intervention and 15 control residents had lost the ability to walk (p=0.001). Independent ambulation and maximum gait speed were maintained in the intervention group but deteriorated in the control group (p=0.001). Residents with both higher and lower cognition benefited in most outcome measures. No association was found between improved mobility and reduced risk of falling.* ***Conclusions:*** *Exercise, as part of a fall prevention program, appears to preserve the ability to walk, maintain gait speed, ambulate independently, and improve step height. Benefits were found in residents with both lower and higher cognitive impairment, but were not found to be associated with a reduced risk of falling.*
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INTRODUCTION

Impaired mobility is one of the strongest predictors for falls in older people (1). Cognitive decline in combination with impaired mobility in older people constitutes a particularly high risk for sustaining falls and hip fractures and threatens independence and quality of life (2-4). The implementation of a fall prevention program that targets mobility in older people with dementia is crucial, especially in those living in nursing homes and residential care facilities (5).

The benefits of physical activity for the promotion of health and physical function in older people in general are currently widely accepted (6, 7). Trials over the last few decades, directed to frail older people, have shown that high age is no hindrance to improving balance, strength and independent transfer through the performance of tailored exercise programs (8, 9). In addition, recent findings suggest that frail older people who suffer from cognitive impairment but are nevertheless able to follow simple instructions, also experience positive effects from exercise (10-12). No major adverse effects have been reported. However, knowledge about the benefit of exercise in residents with severe cognitive impairment is still limited (10-12). In addition, the long-term effects of exercise are not apparent (13) and also need to be evaluated in order to clarify the benefit over time.

In the community, several randomized exercise interventions have proved successful in reducing falls in older people (14-16). In contrast, in residential care and nursing homes, fall intervention programs including exercise have lacked beneficial effects on falls (14, 17). Sample size (17), type and intensity (18) of the exercise program may have influenced the results. We have shown earlier that a multi-factorial fall prevention program, including physical exercise of moderate to high intensity, is successful in reducing falls and femoral fractures (19), but on-

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ly in those residents with higher cognitive function (20). However, it has been shown that reductions in physical risk factors do not always correspond to reduction of falls, and *vice versa* (21, 22).

The primary hypothesis in this study was that exercise as part of a fall prevention program has positive short and long-term effects on gait, balance and strength in older people living in residential care facilities, at high risk of falling and with varying levels of cognition. The secondary hypothesis was that these effects are associated with a reduced risk of falling.

METHODS

Study design

Methods used in this study are described in detail elsewhere (19). Briefly, study participants were older people living in nine residential care facilities located in Umeå, a city in northern Sweden. The facilities were distributed into two groups, A and B, based on the age and number of residents, and 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. Also, to keep the groups distinct from one another, the physicians, registered nurses, physical therapists, and occupational therapists who were responsible for working with the residents in group A were not supposed to work with those in group B.

After baseline assessment of all residents, groups A and B were randomly assigned by lots (sealed envelopes) to an intervention or a control group (Fig. 1). All residents in the study received written and oral information. The residents or the relatives and guardians of residents with severe cognitive dysfunction gave their informed oral consent. The Ethics Committee of the Medical Faculty of Umeå University approved the study (§3/98).

Settings and participants

In Sweden, older people living in residential care facilities are disabled by cognitive or physical impairment. The proportion of elderly aged 80 years or older living in residential care facilities in the city of Umeå is 20.8% (Official statistics, 2002). In this study, some residents lived in private apartments and others had a private room but shared dining and living rooms. In all facilities, residents had 24-hour access to assistance with the activities of daily living, household issues and medical care.

At baseline, all residents in the nine facilities who were 65 years of age or older (n=402) were screened for the risk of falling. The number screened as being at 'high risk' was 187, the median age was 84 years (range 65 to 98 years) and most residents were female (75%). Few residents could walk outdoors without a walking aid (10%) or could shower without assistance (10%); a few

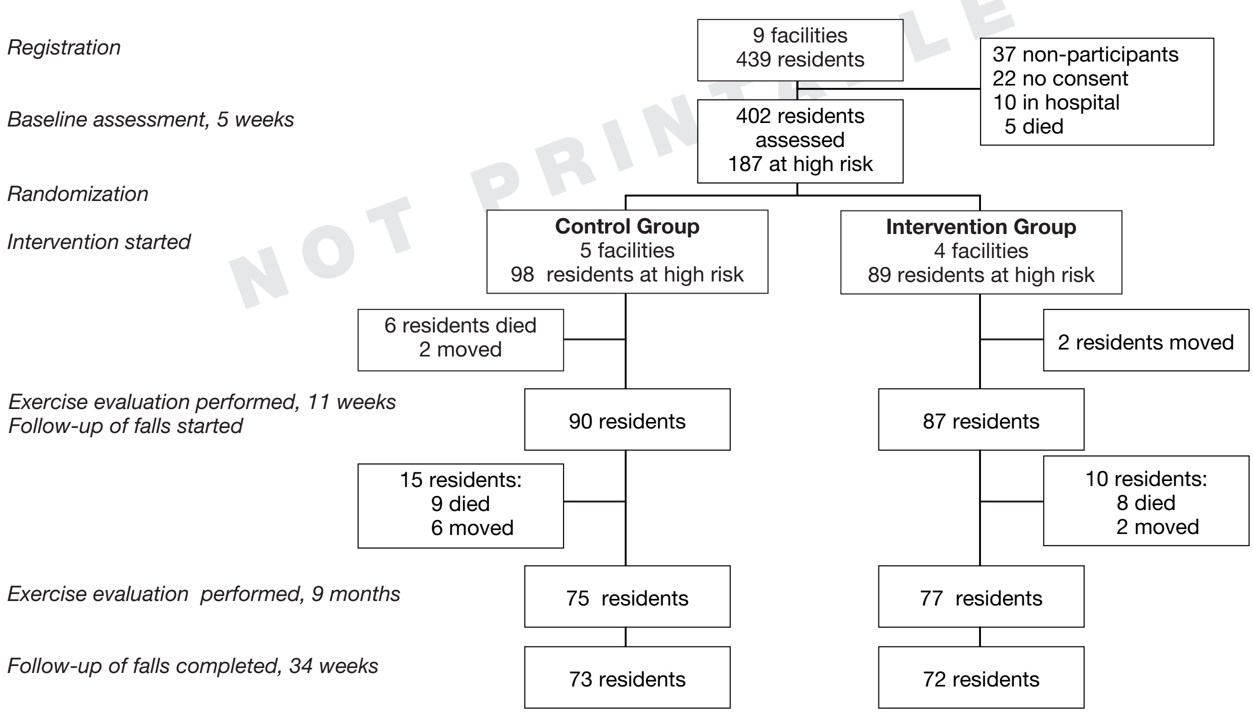

Figure 1 - *Study design.*

Table 1 - *Baseline characteristics of 187 residents screened as being at high risk of falling.*

Characteristics	**Intervention group N=89**	**Control group N=98**	***p*-value***
Age, years, Md (IQR)†	84 (81-88)	84 (80-87)	0.87
Female sex, n (%)	66 (74)	74 (76)	0.83
History of falls (last six months), n (%)	58 (65)	51 (52)	0.08
Function†			
MMSE score (0-30), Md (IQR)†‡	19 (12-22)	15 (12-20)	0.08
Barthel Index score (0-20), Md (IQR)†	14 (10-17)	13 (9-16)	0.19
Timed Up&Go, sec, Md (IQR)†‡	25.8 (17.2-40.1)	31.4 (20.0-47.1)	0.25
Independent walking, with or without aids, n (%)	62 (70)	63 (64)	0.44
Clinical characteristics, n (%)§			
Vision impaired§	33 (36)	30 (32)	0.43
Hearing impaired	32 (36)	29 (30)	0.35
Dementia	39 (44)	37 (38)	0.43
Depression	37 (42)	32 (33)	0.23
Delirium episodes (past month)	40 (45)	28 (29)	0.02
Heart disease	59 (66)	49 (50)	0.03
Previous stroke/transient ischemic attack	33 (37)	43 (44)	0.32
Psychosis	13 (15)	5 (5)	0.03
Urinary incontinence	31 (35)	29 (30)	0.69
Prescribed drugs, n (%)			
Diuretics	50 (56)	46 (47)	0.21
Benzodiazepines	21 (24)	26 (27)	0.64
Antidepressants	31 (35)	36 (37)	0.79
Neuroleptics	22 (25)	33 (34)	0.18
No. of drugs, Md (IQR)†	6 (5-9)	6 (4-8)	0.12

*$p<0.05$ indicating statistical significance.
†Md= median, IQR= inter quartile range.
‡MMSE was not assessable in 3 residents in intervention group and 8 residents in control group, because of aphasia or other medical reasons. TUG could not be assessed in 20 residents in intervention group and 31 residents in control group.
§Clinical characteristics were missing for 0-2 residents. Vision was not assessable in 7 residents because of cognitive impairment.

were non-ambulatory (11%) or entirely dependent when eating (4%). Eleven residents had a Mini-Mental State Examination score (MMSE) of zero and 2 residents scored 30. Additional baseline characteristics are presented by intervention and control group in Table 1.

Baseline assessments

Study physiotherapists used two means to screen for risk of falling. First, residents were classified as being at higher risk of falling according to the Mobility Interaction Fall Chart (23) if they stopped walking when talking to an accompanying person, walked more slowly when carrying a glass of water, or had impaired vision or difficulty in concentrating. Second, the physiotherapist globally rated the fall risk as higher if residents exhibited risk-taking behavior considered to jeopardize balance. If residents were not classified to be at higher risk of falling by either of these two measures, they were considered to be at lower risk of falling.

Each resident's physician completed a questionnaire concerning clinical characteristics and drugs prescribed. The study physiotherapists rated hearing as impaired if the resident could not hear normal speech from a distance of 1 metre 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. Licensed practical nurses or nurses' aides were interviewed to determine whether previous falls had occurred during the 6 months preceding the study, and whether physical restraints were used. Activities of daily living were rated according to the Barthel index (24).

Global cognitive function was screened using the Mini-Mental State Examination (MMSE). The MMSE includes orientation, registration, attention and calculation, recall, language and copying, and the maximum score is 30 (25). Previous studies have suggested various cut-off points for the MMSE (26). We used the median, 19, as the cut-off, and defined residents with an MMSE cognitive level of ≥19 as being non-impaired or mildly cognitively impaired ('higher MMSE group'), and those with an MMSE cognitive level of <19 as being either moderately or severely impaired ('lower MMSE group'). This grouping was not intended to diagnose dementia or other disorders.

The Functional Ambulation Categories (FAC) scale was used to estimate independent transfer (27). The FAC (score 0-5) details the amount and type of human support needed. Need for support from more than one person scores 0, and ambulating independently on uneven ground, stairs and slopes scores 5.

Gait was measured by timed self-paced gait speed ("walk at your own comfortable speed") and after a short rest followed by timed maximum gait speed ("walk as fast as you can safely walk") over a 10-metre course outlined by tape markings on the floor. Residents were instructed to start from standing in a corridor or other open area and to pass the marked end of the course without changing the speed of their gait. There were no carpets on the floor, and residents used their ordinary walking aids. The assessor walked beside residents if needed for safety reasons.

The Berg Balance Scale was used to rate balance (28). It examines balance in terms of 14 items testing the ability to maintain a position (sitting or standing). Ratings consider safety, time and distance (0-4 scores per item, maximum sum of scores, 56) in tasks of various levels of difficulty, ranging, for example, from 'sitting or rising from a chair' to 'tandem standing'. The scale has been validated in a home for the elderly and in acute stroke patients and has shown satisfactory test-retest reliability.

'Step height' provided an estimation of balance and lower extremity muscle strength in combination by measuring residents' capacity to step up to one or more wooden boxes (minimum height 5 cm, piled at 5 cm intervals to a maximum of 50 cm) and step down in a forward direction with no use of support or handrail (29). The boxes were placed half a metre from the wall to provide security and the assessor was standing beside them when residents stepped up, and in front when they stepped down.

Intervention

The 11-week intervention program comprised strategies that targeted both general and resident-specific risk factors for falling. The general strategies were educating staff in fall prevention and modifying the environment. Resident-specific strategies comprised: implementing exercise programs, supplying and repairing aids, reviewing drug regimens, having post-fall problem-solving conferences, and providing free hip protectors (SAFEHIP®, Sahvatex A/S, Ikast, Denmark). All strategies were designed to be meaningful to residents without compromising mobility.

The exercise program was designed individually according to the findings at baseline assessment and comprised balance and ambulation, strength and endurance, flexibility, and safe movement behavior. The resident-specific program lasted 11 weeks, to achieve positive effects of intensive strength exercise. The main goal was progressively to challenge the capacity of each resident (8). The exercise regimen was supervised by the study physiotherapists and performed individually in the apartments or in small groups (5-8 residents) in face-to-face training within the facility. The study physiotherapists kept exercise records and completed an exercise questionnaire for each resident.

Balance exercises were performed during standing and walking activities, inside and outside the facility, and when sitting. Capacity of residents was challenged, for example, by an obstacle course or an unstable base of support, turning and sitting down, or by throwing/catching a ball. Ambulation exercises focused on safe, skilled transfer (e.g., alterations in speed, carrying an object, walking without regular aids, talking while walking, walking transfer in and out of the elevator) and were practised in varying surroundings.

Resistance training exercises focused on the lower extremities. Intensity was set intentionally high, matched to each resident by estimation of the ability to accomplish 8-10 repetitions (80% of 'One-Repetition-Maximum') (30). Free weights, elastic bands, and body weight provided resistance. Exercises such as chair stand exercises and stair or box climbing were performed both with and without free weights.

Physical activation in terms of gait training and other exercises was carried out when the physiotherapists estimated that exercises at a challenging level were not possible. In these cases, the purpose was to enhance the joy of movements or to encourage exercise when a high level of intensity could not be achieved for some reason.

Safe movement behavior focused on training tasks that posed a high risk of falling, for example, learning strategies that would allow independent visits to the toilet.

Eight physiotherapists were employed part-time (a total of 200 hours/week) until the end of the intervention period, and three were employed part-time (a total of 10 hours/week) during a follow-up period. All members of the permanent staff, regardless of profession, participated in the prevention of falls (e.g., guidance, activation and supervision, or environmental adjustment).

Usual care

The residents assigned to the control group received the usual care. The consultative tasks of the regular physiotherapist were not changed. The only change in routine was that all fall reports were collected weekly during the intervention and follow-up period.

Outcomes

The evaluation of performance outcomes was planned to be carried out 11 weeks (short-term evaluation) and 9 months following randomization (long-term). The follow-up for falls lasted 34 weeks after the end of the intervention period. In total, the study, including assessments, lasted for a year.

The primary outcome comprised the short and long-term changes in FAC (ambulation), self-paced and maximum gait speed, as well as short-term changes in the Berg Balance Scale (balance) and step height. These outcomes were also compared by subgroups of residents with higher and lower levels of cognition, MMSE ≥19 and MMSE <19, respectively.

The secondary outcome was the relation of improved mobility to the risk of falling. A fall was defined as an event in which the resident unintentionally came to rest on the ground or floor, regardless of whether or not 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.

In order to further optimise the reporting of falls, the regular charts for each resident were reviewed at the end of the study. Staff were required to report falls on these charts. Of the 401 falls recorded in the regular charts, 1 fall in the intervention and 16 falls in the control group had not been registered on the structured fall report. These falls were also included in the analysis.

During the intervention period, 8 residents in the control group and 2 in the intervention group moved or died, leaving 90 residents in the control group (C) and 87 in the intervention group (I) at the 11-week performance reassessment (Fig. 1). At the 9-month reassessment, 75 (C) and 77 residents (I) respectively remained in the study. Before the end of the follow-up for falls, two (C) and five more residents (I) had died or moved. Participation in the exercise intervention did not appear to cause drop-outs.

The baseline characteristics (performance outcomes, demographics, history of falls, function, diseases, specific medications, number of medications) of the residents who remained in the study at 9 months did not differ significantly between intervention and control groups.

Some residents who remained in the study did not participate in reassessment. The reasons why the baseline assessments of maximum gait (the performance with most drop-outs) was not repeated at 11 weeks, in order of frequency, were: `did not want to/did not understand the instructions´ (12 and 8% in intervention and control groups, respectively), `lost the ability to walk´ (0 and 5%), and `other reasons´ (2 and 3%); and at 9 months: `lost ability to walk´ (4 and 19%), `did not want to/did not understand the instructions´ (7 and 8%), and `other reasons´ (5 and 0%). Comparing the baseline performance of gait, balance and baseline characteristics by intervention and control group, both in the subgroup of residents who were reassessed (11 weeks and 9 months) and in those who dropped out, the only difference was a higher prevalence of heart disease in the intervention residents who were reassessed, and of `previous falls´ in those who dropped out (only self-paced gait).

The residents who participated in the reassessments of gait speed compared with those who dropped out, in general showed more positive baseline performance outcomes. Baseline ADL and MMSE scores were also higher, and previous falls and heart disease less prevalent in those who participated than in those who dropped out, at both 11 weeks and 9 months.

Statistical analysis

Baseline characteristics of the study groups were compared by Student's *t*-test for continuous data, Mann-Whitney *U*-test for ordinal and skewed data, and Chi-square and Fisher's exact test for binary data. The Chi-square test was also used to compare the proportion of residents who had lost the ability to walk by study group.

Data were analyzed on an 'intention to treat basis' including all the 187 residents who had participated in baseline assessments and reassessments, regardless of participation in the exercise program, and regardless of adherence to it (intervention group). The cognition subgroups were also compared using an 'intention to treat approach'.

Step height and FAC (ordinal data) measures were dichotomized because of skewness (0/1, <5 cm, ≥5 as well as <10, ≥10) and (0/1, < category 4, ≥4), respectively.

In analyses of 'self-paced and maximum gait speed', we took the natural logarithm as an outcome because of outliers and skewed data. Data for gait speed, missing at reassessment (11 weeks and 9 months) were transformed by imputation (missing value=0.01 metres/second), when the resident had physically declined since baseline and thus lost the ability to walk.

All regression analyses were adjusted for clustering (Stata software, version 7; Stata Corp., College Station, Texas) because the residents in the nine facilities might not be individually independent. The following factors (binary), related to frailty and fall risk, were also adjusted for and entered into the models: heart disease, episodes of delirium, and `previous falls´ (trend for significance).

We used analysis of covariance (ANCOVA) for evaluation of gait speed and balance by study group. Gait speed (metres per second) and the Berg Balance Scale (scoring 0-56) were dependent variables. The main independent variable was 'study group' (binary), and each resident's baseline performance was entered as a covariate into the model, thus allowing variation in baseline measurements to be taken into account. Analyses were tested for interaction by adding an interaction term to the model (study groups*baseline performance).

Improved step height and FAC were analyzed using logistic regression analysis with adjustment for baseline performance. Interaction ('epidemiological') was also analyzed by means of a four-category variable, combining 'study group'(0/1) and 'baseline performance (0/1)', using 'the baseline performance (0)–control group (0)' as a reference.

We also compared the effects of the two subgroups with regard to cognitive function (higher and lower). In the linear regression analyses (ANCOVA) of numerical performance outcomes, 'cognition groups' and 'study groups' formed three dummy variables with 'the lower cognition–control group' as a reference. These analyses were also tested for interaction. In the logistic regression analyses, the same variables formed a combined four–category variable. These data did not allow analysis of interaction.

An index was formed by 'step height' (binary, <5 cm, ≥5) and 'FAC' (binary, <4, ≥4) to analyze the relation of exercise to the risk of falling. Changes in performance were coded as follows: decrease in at least one of the performances and no change in the other yields 0 (lowest category), no change in either performance or decrease in one and improvement in one yields 1 (middle category), and improvement in at least one of the performances and no change in the other yields 2 (highest category). A logistic regression analysis was performed using 'falling' as dependent variable and the three-categorical index as the category variable adjusting for study group.

In the analyses, $p<0.05$ indicated statistical significance. For inferential statistical analyses, we used Stata software, version 7.0, and SPSS software, version 10 (SPSS Inc., Chicago, Illinois).

RESULTS

In the intervention group, 75 out of the 89 residents were offered exercise, and 66 started to participate in the exercises. Nine did not want to attend, 4 received other fall preventive measures, 7 were severely ill or in hospital, and 3 were not included for other reasons.

Thirty-one of the 66 residents (47%) exercised all weeks in accordance with the 11-week exercise program. The 66 residents participated for a median (IQR) of 10 weeks (8-11) out of the 11-week exercise period; 85% of them exercised 2-3 times a week, 53% had 1-3 hours' exercise per week, while 6% had more than 3 hours per week.

Participants practised balance exercises when standing (73%), walking (64%), and sitting (77%), and engaged in strengthening exercises (56%), endurance training (18%), physical activation (56%), flexibility exercises (36%) and safe movement strategies (32%). No significant adverse events were reported from the exercise sessions.

Mobility outcomes

Performance assessments at baseline, 11 weeks and 9 months are presented in Table 2. The Analyses at 11 weeks and 9 months were adjusted for baseline factors and clustering, and were analyzed for interaction.

Short-term effects (11 weeks)

Greater gains in step height were found in the intervention group than in the control group concerning the proportion of residents who were able to climb a box of at least 5 cm with no support (from 24% to 39% versus no change, $p<0.001$, respectively) as well as 10 cm or more (from 13 to 34% versus 14 to 17%, respectively, $p=0.001$).

Balance measured by the Balance Scale showed a change in the median score from 23 for residents who were assessed at baseline (or the median from 24 for those who were also assessed at 11 weeks) to 33 at 11 weeks in the intervention group and from 19 to 21 in the control group; however, this difference was not significant ($p=0.101$ before adjustment for clustering, $p=0.517$ after that).

The ability to ambulate independently according to FAC was maintained in the intervention but decreased in the control group ($p=0.026$).

Measured maximum gait speed was also unchanged in the intervention group, whereas speed was significantly reduced in the control group, indicating short-term differences between groups ($p=0.002$, Table 2).

A similar pattern was found in self-paced gait speed at 11 weeks ($p=0.038$, data not shown). By this time, 5 residents in the control group had lost the ability to walk at all. A value of 0.01 metres/second (m/s) imputed for the missing values in maximum gait speed also showed a difference, although significance was lost when adjusting for clustering (Table 2).

Long-term effects (9 months)

In the intervention group, residents slightly improved the ability to ambulate independently (FAC) at 9 months (75% as compared with 70% at baseline), while the control group lost this ability (45% as compared with 64% at baseline, $p<0.001$).

At 9 months, there were significantly more residents in the control group (n=15) than in the intervention group (n=3) who had lost the ability to walk 10 metres (Fig. 2; Chi-square=10.7, df=1, $p=0.001$).

Maximum gait speed was almost unchanged compared with baseline in the intervention group, whereas a significant reduction was seen in the control group. When a value of 0.01 m/s was imputed for those not able to walk, a decrease from 0.67 m/s to 0.65 m/s in the intervention group and from 0.62 m/s to 0.37 m/s in the control group was found, indicating a significant difference between groups ($p=0.001$). Similar findings were ap-

Table 2 - *Physical performance in 187 residents assessed at baseline, in those reassessed at end of the intervention (11 weeks) and at end of follow-up (9 months), and change in performance outcomes by study group (p-value).*

Outcomes	**(I) n* 89**	**(C) n* 98**	**Intervention group**	**Control group**	***p*-value†**
Step height, ≥5 cm, n (%)					
baseline	87	96	21 (24)	19 (20)	0.857
11w	77	85	30 (39)	17 (20)	<0.001
Step height, ≥10 cm, n (%)					
baseline	87	96	11 (13)	13 (14)	0.477
11 w	77	85	26 (34)	14 (17)	0.001
Berg Balance Scale, median (range 10th to 90th percentiles)					
baseline	82	92	23 (7-46)	19 (4-42)	0.086
11 w	71	80	33 (6-48)	21 (4-46)	0.517
Functional Ambulation Categories, ≥4, n (%)					
baseline	89	98	62 (70)	63 (64)	0.435
11 w	81	86	58 (72)	48 (56)	0.026
9 mo	71	73	53 (75)	33 (45)	<0.001‡
Fast gait speed, median m/s (range 10th to 90th percentiles)					
baseline	74	74	0.67 (0.31-1.09)	0.62 (0.31-1.08)	0.447
11 w	64	56	0.67 (0.27-1.18)	0.58 (0.24-0.95)	0.002
11 w §	64	60	0.67 (0.27-1.18)	0.56 (0.18-0.94)	0.098
9 mo	53	40	0.68 (0.31-1.04)	0.50 (0.23-1.18)	0.108
9 mo §	56	54	0.65 (0.24-1.05)	0.37 (0.01-0.98)	0.001

*'n': total baseline sample size of intervention and control groups, respectively, and number of residents who actually participated at 11 weeks and 9 months.
†*p*-values: statistical differences between study groups. At 11 weeks and 9 months, regression analyses were adjusted for baseline factors heart disease, delirium (past month) and previous falls, as well as for baseline performance and clustering.
‡Interaction ("epidemiological").
§Values missing because of 'lost ability to walk' were imputed as 0.01 m/s.

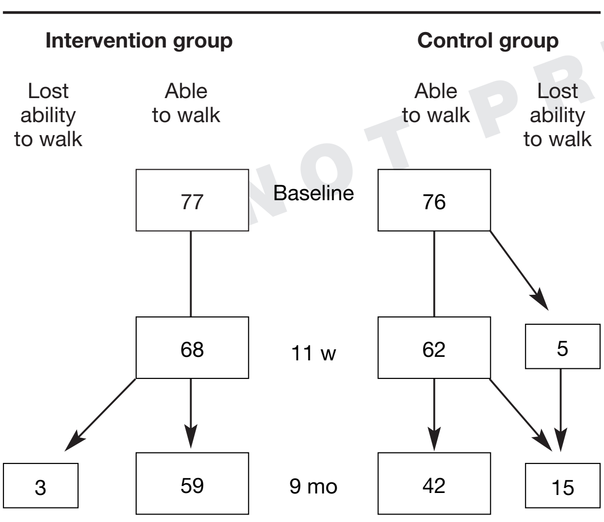

Figure 2 - *Number of residents by study group who were able to walk 10 m at baseline, 11 weeks and 9 months, and number of residents who had lost the ability to walk at reassessment. Other reasons for not participating in reassessments at 11 weeks and 9 months were death, resident moving, not being able to understand, or no consent.*

parent for self-paced gait speed (*p*=0.025, data not shown).

Mobility outcomes in cognition subgroups

When comparing performance outcomes of the intervention and control groups with both higher and lower MMSE, respectively, the intervention groups showed improvement in most short- and long-term outcomes, in both MMSE groups, whereas the control groups showed reductions in most outcomes, indicating significant intervention effects, similar for both cognition groups (Table 3).

Exercise improvements and reduced falling

When a three-categorical index of improved mobility was related to the number of residents who had fallen, higher categories were not associated with a reduced risk of falling. The index comprised 3 categories, according to the change from baseline to assessments at 11 weeks in step height and FAC. The lowest category included 25 residents (8 in the intervention group), the middle category 112 residents (51 in the intervention group) and the highest category 24 residents (18 in the in-

Table 3 - *Physical performance outcomes in residents with MMSE ≥19 and <19 in intervention and control groups (n=176).*

	MMSE ≥19					MMSE <19				
Outcomes	**(I) n 44**	**(C) n 27**	**Intervention group**	**Control group**	***p*-value***	**(I) n 42**	**(C) n 63**	**Intervention group**	**Control group**	***p*-value***
Step height, ≥5 cm, n (%)										
baseline	44	27	13 (30)	7 (26)	0.742	40	62	8 (20)	12 (19)	0.934
11 w	42	24	18 (43)	7 (29)	0.104	34	56	12 (35)	10 (18)	0.023
Step height, ≥10 cm, n (%)										
baseline	44	27	7 (16)	5 (19)	0.776	40	62	4 (10)	8 (13)	0.657
11w	42	24	15 (36)	5 (21)	0.025	34	56	11 (32)	9 (16)	0.001
Functional Ambulation Categories, ≥4, n (%)										
baseline	44	27	34 (77)	19 (70)	0.516	42	63	27 (64)	40 (64)	0.810
11 w	42	24	34 (81)	17 (71)	0.034	37	57	23 (62)	28 (49)	0.155
9 mo	36	23	30 (83)	12 (52)	<0.001	34	45	23 (68)	17 (38)	<0.001
Median fast gait speed m/s (10^{th} to 90^{th} percentiles)										
baseline	39	21	0.73 (0.29-1.20)	0.82 (0.33-1.41)	0.648	34	49	0.60 (0.30-1.01)	0.56 (0.32-1.06)	0.810
11 w †	37	17	0.82 (0.29-1.25)	0.75 (0.27-1.40)	0.045	26	40	0.56 (0.26-1.05)	0.51 (0.03-0.87)	0.127
9 mo †	31	20	0.74 (0.04-1.11)	0.51 (0.01-1.26)	0.054	25	31	0.51 (0.27-0.96)	0.31 (0.01-0.78)	0.002

MMSE= Mini-Mental State Examination, not determined in 11 residents.
*p<0.05: statistical differences by study group. At 11 weeks and 9 months, regression analyses were adjusted for baseline factors heart disease, delirium and previous falls, as well as for baseline performance and clustering.
†Values were imputed as 0.01 m/s.

tervention group). In the lowest category, 17 residents had fallen (68%, reference), in the middle category, 69 residents (63%, adjusted OR 0.78; 95% CI 0.2-2.6), and in the highest category, 13 residents (54%, adjusted OR 0.65; 95% CI 0.2-1.8). Based on this index, a statistically significant difference between intervention and control groups was not found (adjusted OR 0.58; 95% CI 0.3-1.2, p=0.147).

DISCUSSION

This study showed that residents in the intervention group compared with those in the control group were more likely to maintain their ability to walk, ambulate without personal support, retain their gait speed, and increase their ability to climb a box ('step height'). Positive effects were found in most performance outcomes in residents with both higher and lower MMSE scores. The reduction in functional fall risk factors was not found to be associated with a reduced risk of falling. It must be noted that these results were found both immediately after the intervention period, as well as nine months following baseline assessments, when analyzed by 'intention to treat' analysis and adjusted for baseline performance and clustering.

In contrast to most other studies, this study included all residents regardless of MMSE score. Our findings correspond with those from some other nursing home studies, in which only the most cognitively impaired residents were excluded, in showing positive effects in mobility (10-12).

Promising long-term effects at 9 months were found for most performance outcomes with regard to walking (FAC, gait speed) in this study. Previous studies have shown a strong relationship between muscle strength in the lower extremities and walking speed, especially in those who have low strength values (31). Our findings support the assumption that new habits concerning activation among both residents and staff at the intervention facilities would contribute to positive long-term effects. Nevertheless, bias cannot be ruled out. The high number of residents who died, moved, or could not be reassessed at 9 months emphasizes the difficulty in performing a long-term follow-up in a frail residential sample. We found, however, that the only difference in baseline characteristics of the drop-outs, as well as the remaining residents by study groups, was a higher prevalence of heart disease in the intervention residents who were reassessed and of previous falls in the drop-outs.

The Berg Balance Scale did not show any significant effects. This is in contrast to the improvement in `step height´, in which one component is balance. Several residents may have had difficulties in understanding the instruction of the timed balance tasks and in adapting their own functional limitations to the demands. This may have resulted in anxiety or negligence, and the use of the Berg Balance Scale in this target group must be validated. Some previous exercise interventions in nursing homes have lacked positive effects regarding balance and others have had positive effects (10, 18), although the most cognitively frail residents were excluded from these studies. Additional research is needed to explain the discordant results.

We found no evidence of association between an index of change in mobility, i.e., improvements in abilities to ambulate or to climb a box independently, and the risk of falling. However, two of the index categories, the middle category with unchanged performance as well as the highest, `gained ability in at least one of the performances´, indicated non-significantly lower fall rates compared with the lowest category, `lost ability in at least one of the performances´. In the community, fall exercise intervention studies have shown positive effects on fall reduction although, to date, this has not been found in residential care facilities or nursing homes (5). In our study, exercise may have contributed to maintaining walking ability in some residents with a high risk of falling, who would otherwise have become sedentary and less likely to fall (32). Yet, improved mobility did not lead to an increased risk of falling in this frail target group, which may be considered a positive finding. As suggested by others, activity level and related factors, such as being able to perform activities more often and independently, should be taken into account when estimating intervention effects on fall rates (33).

It should be noted that, in the present study all residents at high risk assigned to both intervention and control groups were included in the analyses. As a result, one-quarter of the residents in the intervention group never started to participate in the exercises because, for example, other safety measures were given priority, or serious illness occurred. Some residents who did in fact start missed several exercise opportunities for various reasons. However, all residents assessed at baseline, at 11 weeks and 9 months, were included in the evaluations according to the 'intention-to-treat design', which supports the positive results.

In order to solve the problem of missing values regarding some residents who had lost the ability to walk, these values were transformed into a very low value for gait speed (0.01 m/s). However, this manoeuvre created a new problem, as the significant effect on maximum gait speed at 11 weeks was lost, despite the fact that the median gait speed of the control group was lowered. Cluster-adjustment analysis probably contributed to this result, as all transformed values (5 missing values) were from the same control facility.

This study has limitations. The intervention was multifactorial and evaluation of performance did not take the possible influence of other safety interventions into account (e.g., drugs, environment). Consequently, with this design it is possible that other factors may have interacted with exercise. Cluster randomization was used in this study to avoid contamination of treatment condition, but adjustments were made for clustering in all regression analyses. Another drawback is that, in contrast to the condition at baseline, reassessments were not blind. As all residents and staff in the facilities were involved in the intervention, there was a high risk that blindness would have been lost. Furthermore, the non-significant difference that was found in the risk of falling may partly be the result of the low number of residents and power of the study.

Self-induced activities of daily living might not be expected to provide enough stimuli to maintain strength and mobility in frail older people living in residential care facilities. However, older people who suffer from disuse of the musculo-skeletal system have been found to have a great potential for improvement (8, 34). The clinical implications of our results are that frail older people who have access to exercise are able to improve in strength and mobility, but the optimal exercise program for increasing safety and reducing the risk of falling remains to be investigated. Long-term effects may demand exercise opportunities, at least partly integrated into the normal routines of the facilities. Residents with severe cognitive impairment should not be excluded by routine from exercise and fall prevention studies, as they have a lot to gain from maintaining physical function and well-being.

CONCLUSIONS

This exercise program, as part of a multifactorial fall intervention study, preserved the ability of very frail older people to walk and ambulate independently and had positive effects on gait speed and step height, both when assessed immediately post-intervention and after 9 months. Benefits were found in residents with both lower and higher cognitive impairment, but were not found to be associated with a reduced risk of falling.

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