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Original Study

The Effects of Exercise on Falls in Older People With Dementia Living in Nursing Homes: A Randomized Controlled Trial

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A B S T R A C T

Objectives: To investigate exercise effects on falls in people with dementia living in nursing homes, and whether effects were dependent on sex, dementia type, or improvement in balance. A further aim was to describe the occurrence of fall-related injuries.
Design: A cluster-randomized controlled trial.
Setting and Participants: The Umeå Dementia and Exercise study was set in 16 nursing homes in Umeå, Sweden and included 141 women and 45 men, a mean age of 85 years, and with a mean Mini-Mental State Examination score of 15.
Intervention: Participants were randomized to the high-intensity functional exercise program or a seated attention control activity; each conducted 2-3 times per week for 4 months.
Measures: Falls and fall-related injuries were followed for 12 months (after intervention completion) by blinded review of medical records. Injuries were classified according to severity.
Results: During follow-up, 118 (67%) of the participants fell 473 times in total. At the interim 6-month follow-up, the incidence rate was 2.7 and 2.8 falls per person-year in exercise and control group, respectively, and at 12-month follow-up 3.0 and 3.2 falls per person-year, respectively. Negative binomial regression analyses indicated no difference in fall rate between groups at 6 or 12 months (incidence rate ratio 0.9, 95% confidence interval (CI) 0.5–1.7, $P = .838$ and incidence rate ratio 0.9, 95% CI 0.5–1.6, $P = .782$, respectively). No differences in exercise effects were found according to sex, dementia type, or improvement in balance. Participants in the exercise group were less likely to sustain moderate/serious fall-related injuries at 12-month follow-up (odds ratio 0.31, 95% CI 0.10–0.94, $P = .039$).
Conclusions/Implications: In older people with dementia living in nursing homes, a high-intensity functional exercise program alone did not prevent falls when compared with an attention control group. In high-risk populations, in which multimorbidity and polypharmacy are common, a multifactorial fall-prevention approach may be required. Encouraging effects on fall-related injuries were observed, which merits future investigations.
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Littbrand developed and has received royalties on the weighted belt used in the exercise program.

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Older people with dementia have a higher risk of falls and fall-related injuries compared with older people in general.[1–3] The increased risk can be attributed to symptoms such as cognitive and physical impairment.[1,3,4] Furthermore, people with non-Alzheimer's types of dementia (non- Alzheimer's disease), for example, Lewy body dementia and vascular dementia, seem to have a higher fall risk compared with Alzheimer's disease.[1,5] Consequences of falls (eg, hip fractures) can have a detrimental influence on functional ability and survival in older persons,[6] let alone persons with dementia, who, following a hip fracture, appear to have even worse prognosis than those without dementia.[2,7,8] The number of older people with dementia is projected to increase in the near future, and falls and fall-related injuries not only contribute to the burden of illness, but will also challenge public health resources worldwide.

In community-dwelling older populations, there is evidence that physical exercise, as a single intervention, can prevent falls.[9,10] Exercise programs involving a high challenge to balance and performed at least 3 times a week seem to have the greatest fall preventative effect.[10] Also, in older people with cognitive impairment, promising evidence of the effect of exercise on falls prevention is emerging.[10,11] However, studies in people with dementia are comparatively few, and most are set in the community.[12–14] In nursing homes, where a large proportion of the residents have dementia, there is limited evidence of beneficial effects of exercise.[10,15] Furthermore, improved ability to ambulate independently may pose a higher risk of falls and fall-related injuries through an increased exposure to high-risk situations.[15–17]

Beneficial effects on balance of a high-intensity functional exercise program in people with dementia living in nursing homes have been found previously. The program appeared to particularly benefit participants with non-Alzheimer's disease compared with people with Alzheimer's disease,[18] while no effects were observed on cognition.[19] In addition, in older people with and without dementia living in nursing homes, exercise programs have been shown to prevent falls when balance was improved.[20] The aim of this study was, therefore, to investigate the effects of a high-intensity functional exercise program on fall rate in people with dementia living in nursing homes, and if effects were associated with sex, dementia type, or improvement in balance. A further aim was to describe the occurrence of fall-related injuries.

Methods

This study was part of the Umeå Dementia and Exercise Study (UMDEX), a cluster-randomized controlled trial, set in 16 nursing homes in Umeå, Sweden.[18,19,21] The study protocol (ISRCTN31767087) is published on the ISRCTN registry.

Participants

The UMDEX study included nursing home residents who had a Mini-Mental State Examination (MMSE) score of at least 10,[22] a dementia diagnosis,[23] were aged 65 years or over, dependent on assistance in at least 1 personal activities of daily living (ADL) according to the Katz Index,[24] had the ability to stand up from a chair with armrests with assistance from no more than 1 person, physician's approval, and ability to hear and understand spoken Swedish sufficiently to participate in assessments. All participants gave informed oral consent, which was also confirmed by their next of kin. In the 864 nursing home residents screened in total, age (P = .189) and MMSE score (P = .713) did not differ between participants included and those who declined participation (n = 55; Figure 1). A larger proportion of men than women declined participation (34% vs 18%; P = .008).

Sample and Randomization

Sample size (n = 186) for the UMDEX study was calculated based on the main outcome, the Barthel ADL Index.[18] In addition, a power simulation was undertaken using data on participants with dementia from a previous trial investigating exercise effects on falls,[20] which assumed a dispersion parameter of 2.0, a control group fall rate of 5.0 falls/person-year, and a 30% difference in fall rate between groups. A sample size of 135 participants was required to have a 80% chance of detecting such reduction in fall rate significant at the 5% level.

Participants were randomized after completion of enrolment process and baseline assessment to ensure concealed allocation. Clusters (n = 36) of 3 to 8 participants each (who lived in the same wing, unit, or floor) were formed to reduce contamination. The randomization was stratified in all nursing homes except one that had only a single cluster; the object being to have participants in both exercise and attention control groups living in each nursing home, which reduces the risk of site-specific factors influencing the outcome.

Two researchers not involved in the study performed randomization by drawing lots using sealed opaque envelopes. The Regional Ethics Review Board in Umeå approved the study (2011-205-31M).

Intervention

Physiotherapists (PT) led the exercise activities, and occupational therapists (OT) or an OT assistant led the attention control activity. Following exercise recommendations for general older populations, the intervention consisted of 5 sessions per fortnight for the duration of 4 months (40 sessions in total), with each session lasting approximately 45 minutes. Whenever possible, supervised individual sessions were offered when participants were unable to attend a group session. No activities were provided after the 4-month intervention. Participation in activities other than those provided by the study was not restricted at any time.

The exercise intervention was based on the high-intensity functional exercise program (HIFE), which includes a model for exercise selection and a definition of exercise intensity (available online at https://www.hifeprogram.se/en).[18,25,26] In brief, the HIFE comprises 39 functional exercises for improved lower limb strength, balance, and mobility to be performed with high intensity and in weight-bearing positions similar to daily activities. High-intensity in strength exercise is defined as 8–12 repetition maximum and in balance exercise when postural stability is fully challenged.[25,26] Exercises were tailored based on participants' functional deficits. Participants were supervised individually to promote the highest possible exercise intensity, and adapted accordingly through progressive adjustment of load and base of support, while also taking into account participants' symptoms and changes in health and functional status. For safety, participants wore belts with handles so that PTs could provide support if needed when postural stability was fully challenged, thereby preventing falls. Unnecessary support was avoided.

The attention control group participated in structured activities that were developed by the OTs/OT assistant that led the activities. The activities were structured around topics believed to be interesting for older people, including local wild life, seasons, and holidays. While seated in a group, participants conversed, sang, listened to music or readings, and/or looked at pictures and objects.

At the end of each session, leaders completed a structured protocol for each participant pertaining to adverse events, and in the exercise group, intensity achieved in muscle strength and balance exercises, which was estimated separately as high, moderate, or low according to the predefined scale.[25] All adverse events recorded during exercise sessions were minor or temporary.[27] In the exercise group, participants performed strength exercises with moderate intensity (40%) and at high intensity (49%) of attended sessions, and balance exercises

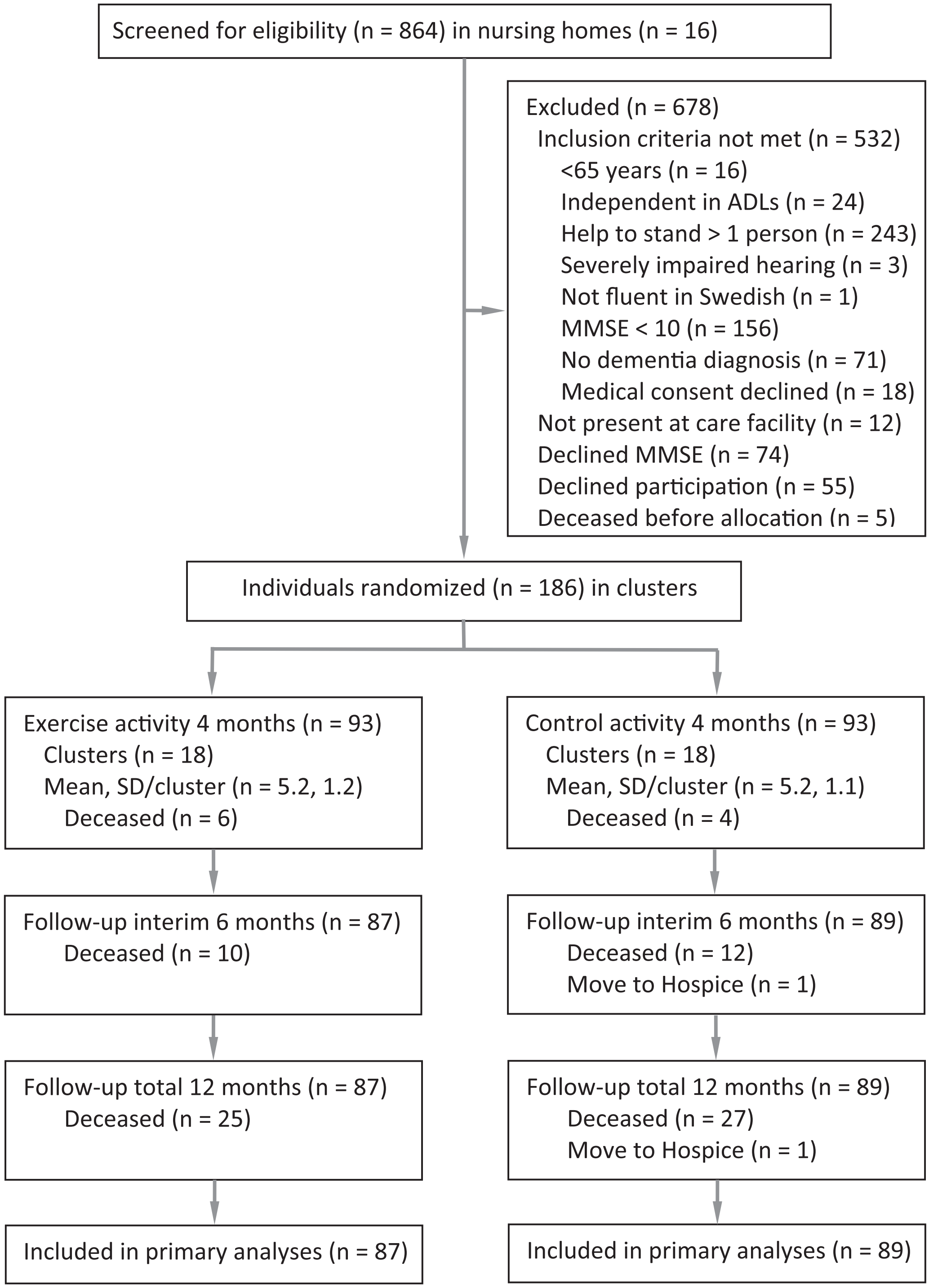

Fig. 1. Flow of participants throughout the study.

with moderate intensity (26%) and high intensity (68%) of attended sessions.[27]

Outcome Measures

Data on falls during the 4-month intervention and the 12-month follow-up period (a total of 16 months) were collected by review of fall incident reports in electronic medical records at nursing homes. Nursing homes are required to routinely report time and place, as well as consequences of falls. In addition, medical records at nursing homes and the regional county council health care provider were reviewed for references to falls during intervention and follow-up period. All reviewers were blinded to group allocation, and the study hypothesis was not disclosed to participants, relatives, or staff. The primary, preplanned outcome measure was fall rate at 6- and 12-month follow-up, measured from the end of the intervention period when conceivably exercise effects on muscle strength, balance, and mobility were at optimum levels. In addition, fall rate during intervention was analyzed for safety purposes. A fall was defined as an event in which the participant unintentionally came to rest on the floor or on the ground, regardless of whether or not an injury was sustained or what caused the fall. This definition is similar to one used in a previous study set in nursing homes,[20] and includes falls resulting from, for instance, acute disease or an epileptic seizure. In community-dwelling populations, the recommended definition of falls also includes falls coming to rest on a "lower level,"[28] for example, the uncontrolled sitting down from loss of balance during rising from a chair. This part was omitted because it would likely not be reported as a fall in our population.

Descriptive Assessments

Trained research staff (PTs and physicians), blinded to activity allocation, performed all measurements. Dependence in ADLs was measured using Barthel ADL Index (0–20).[29] Gait speed was measured over 4.0 m.[30] Global cognition was measured using the MMSE (0–30)[22,31] and the Verbal fluency test was used to measure executive function.[32] Nutritional status was assessed using the Mini-Nutritional Assessment (0–30).[33] Vision was considered impaired when unable to read a word printed in 5-mm capital letters, with or without glasses, at normal reading distance. Hearing was considered impaired when unable to hear a conversation held at usual speaking voice from a distance of 1 m, with or without hearing aids. Self-reported health was evaluated using the first question from the Short-Form-36 Health Survey.[34] Nurses performed blood tests, which were analyzed by standardized methods at the (the University Hospital of Umeå). Behavioral and psychological symptoms in dementia were measured using the Neuropsychiatric Inventory (0–144).[35] Symptoms of depression were assessed using the 15-item Geriatric Depression Scale (0–15).[36] Electronic records of past medical history, which included brain imaging in most cases, current pharmaceutical treatment, and assessment results, were used to record dementia type, depressive disorders, and delirium diagnoses. A specialist in geriatric medicine reviewed and confirmed these diagnoses according to DSM-IV-TR criteria.[23] Balance was measured using the Berg Balance Scale (BBS, 0–56)[37] at baseline, and on intervention completion. Data on fall-related injuries was collected in conjunction with falls over 16 months in total. All injuries related to falls were classified according to maximum severity using the abbreviated injury scale[38]: injuries limited to superficial wounds and bruises as minor; intermediate-level injuries, such as head injuries, vertebral, wrist or ankle fractures as moderate; and major fractures, such as hip fractures and other femoral fractures as serious.

Data Analysis

Baseline characteristics were summarized as means (standard deviation) or frequencies (percentages). An a priori strategy for the selection of adjusting variables was adhered to. Comparisons between exercise and attention control groups were conducted for all variables in Table 1 (preselected as possible confounders) using Student *t*-test or Pearson χ^2 test, in addition to associations ($r \geq 0.3$) with fall rate at 6 and 12 months using Pearson correlation coefficient. No variables differed significantly between groups at baseline bar antidepressant use ($P = .04$), which was adjusted for in analyses. No variable was found to associate with change in outcome measures above predefined levels.

In an intention-to-treat approach, all available data for participants were analyzed according to original allocation and regardless of level of attendance. Incidence rates (IRs) for falls were calculated in relation to person-year using number of observation days, deducting 9107 (16%) days absent in cases of relocation or death. Negative binomial regression was used to analyze the IR ratio (IRR) of falls between exercise and attention control groups for the different time periods, with observation days as exposure term and adjusted for age, sex, antidepressants, and cluster. Negative binomial regression analysis is recommended when fitting models for count data that has a Poisson distribution and are also over-dispersed (the variance exceeds the mean).[39]

Subgroup comparisons according to type of dementia, longitudinal change in balance, and sex were conducted. Differences in effects on fall rate in subgroups were analyzed by adding an interaction term to adjusted models. Dementia type was dichotomized into Alzheimer's disease vs all other (non-Alzheimer's disease) types of dementias[18]; in part to aid comparison of results with studies that include participants with Alzheimer's disease only, and also because previous studies indicate that relevant differences between these 2 dementia subgroups may exist.[5,18] Change in functional balance was based on the median difference in the BBS (post- minus preintervention) in the total sample, and defined as a BBS score of ≥ 2.[20]

In additional analyses, logistic regression was used to compare fall-related risk of moderate/serious vs no/minor injuries, adjusted for age, sex, and antidepressants, between exercise and control groups.

All analyses were performed using IBM SPSS statistics for Macintosh v 23.0 (IBM Corp. Armonk, NY.) and StataCorp. 2013. Stata Statistical Software for Macintosh: Release 13.1. (StataCorp LP, College Station, TX). All statistical tests were 2 tailed and a *P* value of $< .05$ was considered to be statistically significant.

Results

In total, 141 women and 45 men, with mean ± standard deviation (SD) age of 85.1 ± 7.1 years and a MMSE score of 14.9 ± 3.5 were included (Table 1). Sixty-seven (36.0%) participants had Alzheimer's disease and 119 (64%) had non-Alzheimer's disease; of which 77 participants had vascular dementia, 15 mixed Alzheimer's disease and vascular dementia, and 27 had other types of dementia. Over the 4-month intervention period, adherence in the exercise group was 73% and in the attention control group, 70%.

Data on falls during follow-up is summarized in Table 2. In total during the 12-month follow-up, 34 (19%) of the participants fell once and 84 (48%) fell at least twice. The number of falls per person ranged from 0 to 28. There was no difference in fall rate (IRR) between exercise and control group at either 6- or 12-month follow-up [IRR 0.9, 95% confidence interval (CI) 0.5–1.7, $P = .838$ and IRR 0.9, 95% CI 0.5–1.6, $P = .782$, respectively; Table 2, Figure 2]. No differences in exercise effects on falls were found according to sex, dementia type, or change in balance (Table 3). Of 473 falls, 271 (57%) resulted in no injury (128 and 143 in exercise and control group, respectively) and 173 (37%) in minor injury (92 and 81 in exercise and control group, respectively). In 10 (2%) of the falls (7 and 3 in exercise and control group, respectively), a differentiation between no or mild injury could not be determined because of insufficient documentation. Eleven (2%) of the falls resulted in moderate injury; 1 injury in the exercise group (patella fracture) vs 10 injuries in the control group (3 pelvic fractures, 1 patella fracture, 2 ribcage fractures, 1 elbow fracture, 1 vertebral compression fracture, and 2 humerus fractures). Eight (2%) of the falls resulted in serious injury (4 hip fractures in exercise and control groups each). Of the 19 participants with moderate to serious injurious falls, 18 required a visit or admission to a hospital (5 in the exercise group and 13 in the control group).

During the intervention, no difference in fall rate between exercise and control group was observed (IRR 1.2, 95% CI 0.8–2.0, $P = .398$; Supplemental Table 1, Figure 2). No falls occurred during activity sessions. Interaction analyses indicated a difference in falls according to dementia type during the intervention (IRR 2.6, 95% CI 1.0–6.7, $P = .048$), where participants with Alzheimer's disease in the exercise group fell more than the control group (Supplemental Table 1). No difference in exercise effects on falls according to sex was found (Supplemental Table 1). Of the 190 falls that occurred in the exercise and control group, 87 (46%) resulted in no injury (52 and 35 in the respective groups) and 92 (48%) in minor injury (50 and 42 in respective groups). In 2 (1%) of the falls (1 in exercise and control groups each), a differentiation between no or mild injury could not be

Table 1
Characteristics and Baseline Measures

Characteristics	Total (n = 186)	Exercise (n = 93)	Control (n = 93)
Age, mean (SD)	85.1 (7.1)	84.4 (6.2)	85.9 (7.8)
Female	141 (75.8)	70 (75.3)	71 (76.3)
Dementia type:			
Alzheimer's disease	67 (36.0)	34 (36.6)	33 (35.5)
Vascular dementia	77 (41.4)	36 (38.7)	41 (44.1)
Mixed Alzheimer's/vascular dementia	15 (8.1)	8 (8.6)	7 (7.5)
Other type of dementia	27 (14.5)	15 (16.1)	12 (12.9)
History of ≥1 fall previous year, *n* = 173*	94 (50.5)	49 (57.6)	45 (51.1)
History of ≥1 fall previous wk*	13 (7.0)	7 (7.5)	6 (6.5)
Diagnoses and medical conditions:			
Depressive disorders	107 (57.5)	53 (57.0)	54 (58.1)
Delirium previous wk	102 (54.8)	48 (51.6)	54 (58.1)
Previous stroke	57 (30.6)	33 (35.5)	24 (25.8)
Heart failure	56 (30.1)	24 (25.8)	32 (34.4)
Myocardial infarction	37 (19.9)	19 (20.4)	18 (19.4)
Previous hip fracture	53 (28.5)	28 (30.1)	25 (26.9)
Angina pectoris	49 (26.3)	21 (22.6)	28 (30.1)
Diabetes mellitus	29 (15.6)	18 (19.4)	11 (11.8)
Prescription medication:			
Analgesics	112 (60.2)	55 (59.1)	57 (61.3)
Antidepressants	102 (54.8)	58 (62.4)	44 (47.3)
Diuretics	88 (47.3)	41 (44.1)	47 (50.5)
Vitamin D-calcium supplement	60 (32.3)	32 (34.4)	28 (30.1)
Cholinesterase inhibitors	40 (21.5)	25 (26.9)	15 (16.1)
Memantine	12 (6.5)	7 (7.5)	5 (5.4)
Benzodiazepines	40 (21.5)	19 (20.4)	21 (22.6)
Neuroleptics	31 (16.7)	11 (11.8)	20 (21.5)
Number of drugs, mean (SD)	8.3 (3.8)	8.4 (4.0)	8.2 (3.7)
Blood samples:			
Vitamin D ≤ 50 nmol/L, *n = 161*	83 (51.6)	37 (50.0)	46 (52.9)
Parathyroid hormone > 6.9 pmol/L, *n = 161*	42 (26.1)	16 (21.9)	26 (29.5)
Creatinine clearance ≤30, *n = 152*	17 (11.2)	5 (7.2)	12 (14.5)
Assessments:			
Gait speed 4 m, m/s, mean (SD), *n* = 185†	0.45 (0.2)	0.45 (0.2)	0.45 (0.2)
Pain when walking, *n = 185*	35 (18.9)	15 (16.3)	20 (21.5)
MMSE (0–30), mean (SD)	14.9 (3.5)	15.4 (3.4)	14.4 (3.5)
Verbal fluency	6.4 (3.8)	6.8 (4.1)	6.0 (3.5)
Geriatric Depression Scale-15, (0–15) mean (SD), *n* = 183‡	3.8 (3.2)	4.0 (3.4)	3.6 (2.9)
Neuropsychiatric Inventory (0–144), mean (SD)	14.8 (14.2)	15.2 (15.8)	14.4 (12.6)
Mini-Nutritional Assessment (0–30), mean (SD), *n = 185*	21.1 (2.7)	21.3 (2.8)	20.9 (2.6)
Vision impairment	26 (14.0)	10 (10.8)	16 (17.2)
Hearing impairment	32 (17.2)	12 (12.9)	20 (21.5)
Self-reported health; good, very good, or excellent	119 (64.0)	60 (64.5)	59 (63.4)
Barthel ADL Index (0–20), mean (SD)	10.9 (4.4)	10.7 (4.5)	11.0 (4.4)
Mobility (on level surfaces)§			
Immobile	17 (9.1)	11 (11.8)	6 (6.5)
Wheelchair independent, including corners	14 (7.5)	6 (6.5)	8 (8.6)
Walks with help of one person (verbal or physical)	44 (23.7)	27 (29.0)	17 (18.3)
Independent (but may use any aid; for example, stick)	111 (59.7)	49 (52.7)	62 (66.7)
BBS (0–56), mean (SD)	28.9 (14.5)	28.6 (14.3)	29.3 (14.7)
Sitting to standing¶			
Stands without using hands and stabilize independently	67 (36.0)	37 (39.8)	30 (32.3)
Stands independently using hands	69 (37.1)	30 (32.3)	39 (41.9)
Stands using hands after several tries	13 (7.0)	6 (6.5)	7 (7.5)
Needs minimal aid to stand or stabilize	14 (7.5)	8 (8.6)	6 (6.5)
Needs moderate or maximal assist to stand	23 (12.4)	12 (12.9)	11 (11.8)

SD, standard deviation.
Values are frequencies (percent, %) unless stated otherwise. Cursive number after covariate indicates available measurements when values were missing.
*Reported retrospectively by care personnel.
†Missing data was imputed to 0.01 m/s when unable to complete the gait speed test because of physical impairment.
‡When at least 10 questions were answered in the GDS-15, missing data was imputed using the mean of questions answered.
§According to Barthel ADL Index item 7.
¶According to Berg Balance Scale item 1.

determined because of insufficient documentation. Six (3%) of the falls resulted in moderate injury (3 each in exercise and control groups). Three (2%) of the falls resulted in serious injury (1 hip fracture in the exercise and 2 in the control group).

Participants in the exercise group were less likely to sustain moderate or serious injuries as a result of falls during the 12-month follow-up [odds ratio (OR) 0.31, 95%CI 0.10–0.94, P = .039; Supplemental Table 2]. No differences between groups were observed at the 6-month follow-up (OR 0.98, 95% CI 0.19–5.18, P = .980) or during the intervention (OR 0.23, 95% CI 0.23–4.02, P = .946).

Discussion

This study of people with dementia living in nursing homes observed no exercise effects on fall rate compared with a control activity, independent of sex or change in balance. However, during

Table 2
IRs and IRR of Falls per Person-Year During Follow-Up in Exercise and Control Group

Group	Follow-Up 6 Mo					Follow-Up 12 Mo				
	≥1 Fall n (%)*	Total Falls (Obs d)	IR	IRR (95% CI)†	*P*	≥1 Fall n (%)	Total Falls (Obs d)	IR	IRR (95% CI)†	*P*
Exercise, n = 87	45 (52)	111 (14 967)	2.7	0.9 (0.5, 1.7)	.838	57 (66)	232 (27 830)	3.0	0.9 (0.5, 1.6)	.782
Control, n = 89	42 (47)	113 (14 746)	2.8	1 (reference)		61 (69)	241 (27 479)	3.2	1 (reference)	

Obs d, observation days.
*Number of participants (proportion) who fell at least once.
†From negative binomial regression analyses with observation days as exposure term and adjusted for age, sex, antidepressants and cluster.

the intervention, exercise effects on falls differed according to dementia type, with a higher fall rate in people with Alzheimer's disease, which diminished as follow-up proceeded. Although the risk of sustaining moderate to severe fall-related injuries did not differ between groups at the interim follow-up, it was lower in the exercise group at the end.

The lack of a fall preventative exercise effect complies with the result of a study investigating the effects of exercise as a single intervention in people with dementia living in nursing homes.[40] Furthermore, the result are in line with 3 previous studies in people with dementia living in the community.[12–14] The studies observed positive effects on physical function, such as muscle strength, balance, mobility, or fitness, but not falls prevention. That physical exercise alone has limited impact on falls in this population is further substantiated by results from our study, which observed no exercise effects on falls, neither in the whole group nor amongst participants who improved their balance.

The risk of falls was high in this study, and likely influenced by the selection of people with dementia who were relatively ambulant from a high-risk setting such as nursing homes. In this population where multimorbidity and polypharmacy is common, additional modifiable risk factors, for example, related to acute medical conditions or drug side effects may need to be targeted alongside exercise.[4,41] Contrary to single interventions as the one investigated in our study, multifactorial interventions show possible, albeit inconsistent effects in nursing homes.[15] A falls preventative effect of a multifactorial intervention has also been suggested in a study of people with dementia following hip fracture.[42,43] Furthermore, falls prevention has been shown when cognitive training was incorporated alongside exercise in people with dementia.[44]

Although the exercise program did not prevent falls, it may have had some effect on preventing injuries, including fractures, related to the fall. Because not all falls result in fractures, the characteristic of the fall, for example, location of impact and protective responses may be important determinants of related injuries.[45,46] Improved ability to extend a leg or arm, take a step, or grab onto an object could potentially alter the direction or break the momentum of the fall, thus, influencing the location or energy of impact, and ultimately effecting the severity of the injury.[45] However, previous systematic reviews in older people have observed diverse results on fracture prevention from exercise.[47,48]

Beside the positive effects of exercise, it has been suggested that ability to ambulate and be physically active may increase the risk of falls and fall-related injuries, through an increased exposure to high-risk situations.[16,49] In our study, activity level was not adjusted for in analyses, which could explain the lack of effects on fall rate during the follow-up, as well as during the intervention. It is also noteworthy that, during the intervention, exercise effects differed according to dementia type. Amongst participants with Alzheimer's disease, the exercise group had a higher rate of falls compared with the control group. Inferences regarding differences in exercise effects during the intervention are restricted because falls could have occurred before reaching optimum exercise effects on physical function, or be a result of subgroup imbalances, where participants with Alzheimer's disease had better balance and mobility but worse cognitive function at the start of the intervention.[18] Nevertheless, the result could indicate that additional caution is required during exercise interventions in people with Alzheimer's disease.

This study had many strengths but also some limitations. It targeted a high-risk population underrepresented in fall preventative

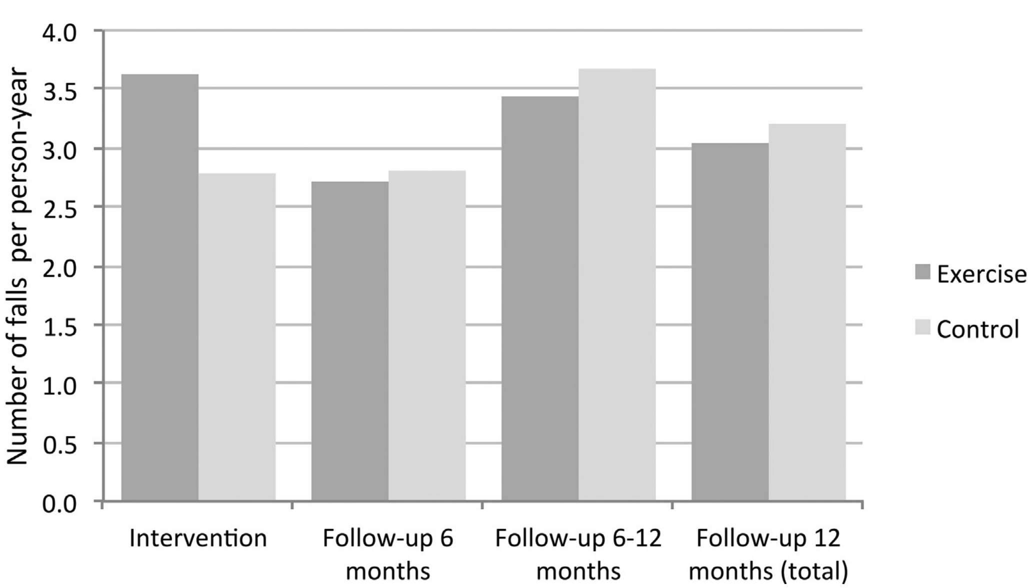

Fig. 2. Fall rate per person-year throughout intervention and follow-up according to activity group.

Table 3
IRs and IRRs of Falls per Person-Year During Follow-Up in Exercise and Control Group According to Subgroups

Subgroup	Follow-Up 6 Mo						Follow-Up 12 Mo					
	≥1 Fall n (%)*	Total Falls (Obs d)	IR	IRR (95% CI)†	Interaction (95% CI)†	*P*	≥1 fall n (%)	Total Falls (Obs d)	IR	IRR (95% CI)†	Interaction (95% CI)†	*P*
Sex												
Exercise women, n = 64	34 (53)	94 (11132)	3.1	1.1 (0.7, 1.8)	2.2 (0.7, 7.3)	.181	41 (64)	170 (20933)	3.0	0.9 (0.5, 1.5)	0.7 (0.2, 2.2)	.563
Control women, n = 70	33 (47)	82 (11591)	2.6	1 (reference)			47 (67)	188 (21452)	3.2	1 (reference)		
Exercise men, n = 23	11 (48)	17 (3835)	1.6	0.6 (0.3, 1.3)			16 (70)	62 (6 897)	3.3	1.1 (0.6, 2.26)		
Control men, n = 19	9 (47)	31 (3155)	3.6	1.3 (0.5, 3.2)			14 (74)	53 (6 027)	3.2	1.0 (0.4, 2.1)		
Dementia type												
Exercise Alzheimer's disease, n = 32	15 (47)	49 (5631)	3.2	1.5 (0.6, 3.8)	2.0 (0.6, 6.6)	.239	19 (59)	98 (10536)	3.4	1.1 (0.5, 2.5)	1.3 (0.5, 3.5)	.634
Control Alzheimer's disease, n = 33	13 (39)	28 (5493)	1.9	1 (reference)			26 (79)	79 (10286)	2.8	1 (reference)		
Exercise non-Alzheimer's disease, n = 55	30 (55)	62 (9336)	2.4	1.3 (0.6, 2.6)			38 (69)	134 (17294)	2.8	1.0 (0.5, 1.8)		
Control non-Alzheimer's disease, n = 56	29 (52)	85 (9253)	3.4	1.7 (0.7, 4.3)			35 (63)	162 (17193)	3.4	1.2 (0.7, 2.0)		
Change in balance												
Exercise BBS ≥2, n = 50	28 (56)	67 (8623)	2.8	1.3 (0.8, 2.2)	1.7 (0.6, 4.9)	.303	34 (68)	145 (16393)	3.2	1.3 (0.7, 2.4)	1.7 (0.7, 4.2)	.286
Control BBS ≥2, n = 26	17 (65)	28 (4543)	2.3	1 (reference)			20 (77)	63 (8401)	2.7	1 (reference)		
Exercise BBS ≤1, n = 31	13 (42)	38 (5572)	2.5	1.1 (0.6, 2.3)			19 (61)	80 (10080)	2.9	1.1 (0.6, 2.2)		
Control BBS ≤1, n = 60	24 (40)	81 (9810)	3.0	1.5 (0.7, 3.2)			40 (67)	173 (18387)	3.4	1.4 (0.7, 2.8)		

non-Alzheimer's disease, vascular dementia, mixed Alzheimer's disease and vascular dementia, and other types of dementia; obs d, observation days.
*Number of participants (proportion) who fell at least once.
†From negative binomial regression analyses with observation days as exposure term and adjusted for age, sex, antidepressants, and cluster.

exercise trials and had few exclusion criteria. However, generalization may be restricted to the more ambulant portion of people with dementia living in nursing homes. The incidence of falls was collected through a review of falls reports, and a review of medical records at the nursing homes and at the regional county council health care provider, all conducted by blinded reviewers. Thus, even if the number of falls were reliant on adequate reporting by nursing staff, the thorough review reduced the number of missed fall events. Though the structured exercise program is consistent with falls, preventative recommendations regarding exercise mode, intensity, and frequency, effects may not have reached sufficient levels to prevent falls. Despite the improvements in balance observed, a higher dose of exercise may be required for greater effects on falls. In addition, sample size simulation was based on a 30% reduction in fall rate compared with the control group, which was not accomplished in this study and implies limited statistical power.

Conclusions/Relevance

The findings from this study suggest that compared with an attention control activity, a high-intensity functional exercise program, as a single intervention, does not prevent falls in people with dementia living in nursing homes. The result supports previous research suggesting that in high-risk populations where, as in this study, multimorbidity and polypharmacy are common, a multifactorial fall-prevention approach may be required. Caution may be indicated in people with Alzheimer's disease when the exercise intervention is on-going. The study observed encouraging effects on fall-related injuries, which merits future investigations.

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Appendix

Supplemental Table 1
IRs and IRRs of Falls per Person-Year During Intervention in Exercise and Control Group in Total Sample and According to Subgroups

Subgroup	Intervention					
	≥1 Fall n (%)*	Total Falls (obs d)	IR	IRR (95% CI)†	Interaction (95% CI)†	*P*
Total						
Exercise, n = 93	41 (44)	107 (10787)	3.6	1.3 (0.8, 2.0)	–	.398
Control, n = 93	44 (47)	83 (10903)	2.8	1 (reference)		
Sex						
Exercise women, n = 70	30 (43)	94 (11132)	3.3	1.2 (0.7, 2.1)	0.9 (0.3-2.8)	.902
Control women, n = 71	33 (47)	82 (11591)	2.7	1 (reference)		
Exercise men, n = 23	11 (49)	17 (3835)	4.5	1.5 (0.7, 3.4)		
Control men, n = 22	11 (50)	31 (3155)	2.9	1.2 (0.6, 2.3)		
Dementia type						
Exercise Alzheimer's disease, n = 34	17 (50)	58 (3950)	5.4	2.1 (1.0, 4.3)	2.6 (1.0, 6.7)	.048
Control Alzheimer's disease, n = 33	16 (49)	25 (3927)	2.3	1 (reference)		
Exercise non- Alzheimer's disease, n = 59	24 (41)	49 (6837)	2.6	1.0 (0.6, 1.8)		
Control non- Alzheimer's disease, n = 60	28 (47)	58 (6976)	3.0	1.2 (0.6, 2.4)		

non-Alzheimer's disease, vascular dementia, mixed Alzheimer's disease and Vascular dementia, and other types of dementia; obs d, observation days.
*Number of participants (proportion) who fell at least once.
†From negative binomial regression analyses with observation days as exposure term and adjusted for age, sex, antidepressants, and cluster.

Supplemental Table 2
The Risk of Fall-Related Injuries of Moderate to Major Severity during Intervention and Follow-Up

Group	Intervention				Follow-Up 6 Mo				Follow-Up 12 Mo			
	N	Injury, n (%)	OR (95% CI)*	*P*	N	Injury, n (%)	OR (95% CI)*	*P*	N	Injury, n (%)	OR (95% CI)*	*P*
Exercise	93	4 (4)	0.95 (0.23, 4.02)	.946	87	3 (3)	0.98 (0.19, 5.18)	.980	87	5 (6)	0.31 (0.10, 0.94)	.039
Control	93	4 (4)	1 (reference)		89	3 (3)	1 (reference)		89	14 (16)	1 (reference)	

N, number of participants with complete data.
*From logistic regression analyses adjusted for age, sex, antidepressants.