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ORIGINAL ARTICLE

Effects of Exercise Programs on Falls and Mobility in Frail and Pre-Frail Older Adults: A Multicenter Randomized Controlled Trial

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ABSTRACT. Faber MJ, Bosscher RJ, Chin A Paw MJ, van Wieringen PC. Effects of exercise programs on falls and mobility in frail and pre-frail older adults: a multicenter randomized controlled trial. *Arch Phys Med Rehabil* 2006;87:885-96.

Objectives: To determine the effects of moderate intensity group-exercise programs on falls, functional performance, and disability in older adults; and to investigate the influence of frailty on these effects.

Design: A 20-week, multicenter randomized controlled trial, with 52-week follow-up.

Setting: Fifteen homes for the elderly.

Participants: Two hundred seventy-eight men and women (mean age \pm standard deviation, 85 \pm 6y).

Interventions: Two exercise programs were randomly distributed across 15 homes. The first program, *functional walking* (FW), consisted of exercises related to daily mobility activities. In the second program, *in balance* (IB), exercises were inspired by the principles of Tai Chi. Within each home participants were randomly assigned to an intervention or a control group. Participants in the control groups were asked not to change their usual pattern of activities. The intervention groups followed a 20-week exercise program with 1 meeting a week during the first 4 weeks and 2 meetings a week during the remaining weeks.

Main Outcome Measures: Falls, Performance Oriented Mobility Assessment (POMA), physical performance score, and the Groningen Activity Restriction Scale (GARS) (measuring self-reported disability).

Results: Fall incidence rate was higher in the FW group (3.3 falls/y) compared with the IB (2.4 falls/y) and control (2.5 falls/y) groups, but this difference was not statistically significant. The risk of becoming a faller in the exercise groups increased significantly in the subgroup of participants who were classified as being frail (hazard ratio [HR]=2.95; 95% confidence interval [CI], 1.64–5.32). For participants who were classified as being pre-frail, the risk of becoming a faller decreased; this effect became significant after 11 weeks of training (HR=.39; 95% CI, .18–.88). Participants in both exercise groups showed a small, but significant improvement in their POMA and physical performance scores. In the FW group, this held true for the GARS score as well. Post hoc

analyses revealed that only the pre-frail participants improved their POMA and physical performance scores.

Conclusions: Fall-preventive moderate intensity group-exercise programs have positive effects on falling and physical performance in pre-frail, but not in frail elderly.

Key Words: Accident prevention; Accidental falls; Exercise therapy; Frail elderly; Randomized controlled trials; Rehabilitation.

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FRILITY IS COMMONLY USED in the context of elderly facing functional disabilities, but the term is not a synonym for disability.^{1,2} Whereas disability indicates loss of function, frailty is related to instability and risk of loss of function.³ Bortz defined frailty as “a body-wide set of linked deteriorations including, but not confined to, musculoskeletal, cardiovascular, metabolic, and immunologic systems.”^{4(pM283)} The consequences of these deteriorations may vary, and therefore frailty can be subdivided into various types, including medical, functional, mental, and physical frailty.⁵

Numerous markers have been proposed for physical frailty, usually including measures for mobility and disability.⁶⁻¹⁰ The phenotype concept introduced by Fried et al¹⁰ is operationalized by 5 indicators: unintentional weight loss, weakness, exhaustion, slowness, and low physical activity. Each indicator is measured by accepted instruments and cutoff points have been established.¹⁰⁻¹² Frailty is considered to be present if at least 3 indicators are positive and a pre-frailty status is defined with 1 or 2 positive indicators. This classification system has been shown to be predictive for falls, worsening mobility, worsening activity of daily living (ADL), disability, hospitalization, and death.^{10,11}

Exercise interventions may be effective in preventing, delaying, or reversing the frailty process.¹³ It has therefore been argued that more intervention studies in frail populations are needed.¹³ In general, the trainability of older adults is evident. In a recent systematic review on the effects of progressive strength training, it was concluded that training results in improved muscular strength. This generalizes to improved physical functioning in terms of improved balance and walking speed, but not to improved physical disability.¹⁴ A systematic review on the effects of more general physical exercise programs in institutionalized elderly indicated a strong positive effect on muscle strength and mobility. Evidence regarding effects of exercise on gait, disability, balance and endurance is, however, inconclusive.¹⁵ Besides demonstrated effects on physical performance, there is also evidence regarding beneficial exercise effects on sleep and overall well-being.¹⁶ Finally, physical exercise is also effective in reducing falls for many individuals with physical risk factors for falls (eg, impaired strength, balance, functional ability), although the positive effects are less conclusive in frail elderly.^{17,18}

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There are more indications that the degree of frailty plays a role in the effectiveness of exercise programs that aim at fall prevention. For example, an intense Tai Chi training in elderly "transitioning to frailty," as defined on the basis of the attributes described by Speechley and Tinetti,⁶ was not effective in reducing fall risk, whereas a less intense Tai Chi training in robust older adults resulted in a fall reduction of 47.5%.^{19,20} Differential training effects have also been reported on factors related to physical frailty. Gill et al²¹ reported a significant beneficial effect in preventing functional decline by a home-based exercise program in the group with moderate frailty, but no effect among those with severe frailty. By contrast, Chandler et al²² found that better training effects occurred in the more frail participants. This study reported that the impact of exercise-induced strength gain on chair rise performance was confined to the more impaired (ie, more frail) participants. The interpretation of these seemingly conflicting results is problematic, because they are based on different frailty indicators.

The objective of the present study was to investigate the effects of 2 exercise-based fall-preventive intervention programs on falls, physical function and disability in an elderly population. No stringent exclusion criteria were used to enable generalizability of the results.¹³ The potential role of frailty on the intervention effect was further investigated in secondary analyses.

METHODS

Design

The study was carried out in 15 long-term care centers in Amsterdam, the Netherlands, and its vicinity. In these centers, people live in self-care and in nursing care residences. In self-care residences, people live independently but have access to on-site nursing care, dining, and recreational facilities. In nursing care residences, people live less independently, with care up to full nursing care. We designed the study as a multicenter, randomized, single-blind, controlled trial, with 2 levels of block-wise randomization. The participating homes were randomly assigned to 1 of the 2 exercise intervention programs, using sealed envelopes. Participants in each of the homes were then randomly distributed across an intervention and a control group, using computer-generated random numbers. The maximum size of the exercise group in each home was set at 12, with the provision that the control group should contain at least 5 participants. The outcome of the randomization was notified to the participants in a letter after baseline assessment. The medical ethics committee of the VU University Medical Center in Amsterdam approved the study protocol. The CONSORT statement²³ was used as a guideline in reporting this study.

Study Sample

We recruited the long-term care centers between March and July 2002. Three additional centers were included in August and September 2003 to increase the sample size. In each center, we began recruitment of the participants by inviting all residents for a meeting where details about the project were given. Written information about the study was provided and residents could sign up for participation within a week after the meeting. Persons were only excluded from participation if (1) they were unable to walk 6m independently (the use of a walking aid was allowed), as this prevented participation in the exercise programs, or if (2) their cognition, as judged by the nursing staff, was so impaired that they would not be able to process the

information provided during the testing and exercising.¹³ In addition, the general practitioner of each participant judged whether there was a medical contraindication for participation. This recruitment strategy provided a group of participants with varying degrees of frailty. After agreement with the study protocol, all participants signed a written informed consent.

In 15 centers, we recruited and randomized 278 participants. The average cluster size was 18.5, ranging from 12 to 24 participants. Immediately after randomization, 40 (14.4%) participants dropped out and were excluded from all analyses. These participants were equally distributed across the intervention and control group (χ^2 test=1.096, $P=.378$). Compared with the participants who entered the study, the elderly who stopped immediately after randomization were older, more cognitively impaired, reported dizziness more often, used a walking aid less often, had a lower level of physical activity, and had a lower level of physical performance. The percentage of participants classified as frail (see Data Collection section for details) was comparable in both groups: 60.0% of the withdrawers and 48.9% of the nonwithdrawers were classified as frail (χ^2 test=1.492, $P=.277$).

In addition to the 40 participants who withdrew immediately, we excluded another 6 participants from the analyses of the fall data because no reliable fall data were available, whereas another 30 participants were excluded from the analyses of the physical function and disability data because they were unable to participate in the postintervention assessment. Reasons for missing the postintervention assessment were dropout ($n=24$) and serious illness at the time of postintervention assessment ($n=6$). Dropout occurred because the subjects either perceived their health status to be too poor ($n=10$), lost interest in the study ($n=4$), suffered from a fracture ($n=1$), were hospitalized for more than 2 weeks ($n=5$), or died ($n=4$). Seventeen (11.6% of the group that entered the study) dropouts belonged to the intervention groups and 7 (7.6%) to the control group. In summary, data of 208 subjects were entered into the analyses of the intervention effects on physical performance and disability and data of 232 subjects into the analyses of the intervention effects on falls. The participant flow is shown in figure 1.

Data Collection

Assessments. At baseline, before randomization, individual assessments were made by 2 research physical therapists who were not involved in other aspects of the study. The assessment consisted of questionnaires and performance tests, collecting information about demographic variables (age, sex), body mass index (BMI), lifestyle variables (alcohol consumption, physical activity level), physical status (mobility, physical performance, self-reported disability, walking aid use), health status (general health perception, medication, dizziness, visual impairment, Medical Outcomes Study 36-Item Short-Form Health Survey [SF-36] physical functioning and vitality subscales²⁴), and cognitive status. All postintervention assessments were completed within 10 days of the intervention period.

Background measures. BMI was calculated as body weight (in kilograms) divided by height (in meters) squared. Alcoholic beverage consumption was categorized as none, 1 to 7 drinks a week, and more than 7 drinks a week. Medication use was determined by asking about prescribed and over-the-counter medication that was used on a daily basis. This variable was subsequently dichotomized as 0 to 3 and 4 or more different medications per day. Additional aspects of health status were the presence of self-reported dizziness (yes, no) and self-reported visual impairment despite correction (yes, no). General health perception was measured with the question: "In

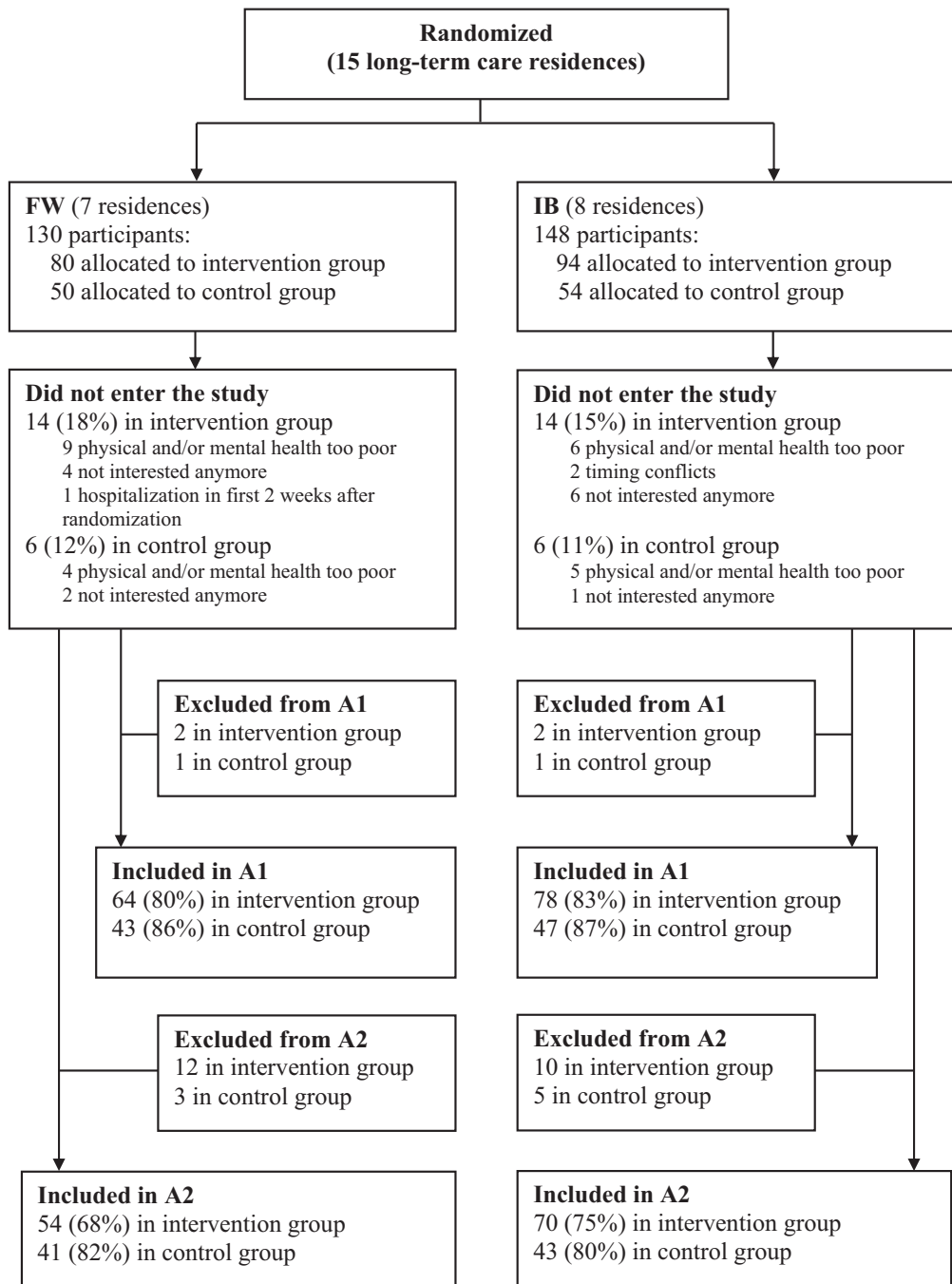


Fig 1. Flowchart of the participants who were entered in the analyses of the fall data (A1) and the analyses of physical functioning and disability measures (A2).

general, would you say your health is: excellent, very good, good, fair, or poor?" Cognitive status was assessed using the Mini-Mental State Examination (MMSE).²⁵ The physical functioning and vitality subscales of the SF-36 were scored.²⁴ The physical functioning subscale consists of 10 functional items. It measures to what extent health status has limited the ability to carry out the items in the previous 4 weeks. The vitality subscale consists of 4 questions referring to the previous 4 weeks, covering feelings of being worn-out, tired, and energetic.

Frailty indicators. The 5 frailty indicators were adapted from the ones described by Fried et al¹⁰:

Unintentional weight loss. Weight loss could not be calculated as body weight was only assessed at baseline. As an alternative, BMI of less than 18.5kg/m² was used as the criterion for this indicator.¹²

Weakness. Instead of operationalizing weakness by means of grip strength, the SF-36 physical functioning score with a cutoff score of 75 points was used.¹¹

Exhaustion. Exhaustion was deemed present when the SF-36 vitality scale score was less than 55 points.¹¹

Slowness. Slowness was assessed by means of walking speed using sex- and height-corrected cutoff scores.¹⁰

Low physical activity. Physical activity was assessed with the Longitudinal Aging Study Amsterdam Physical Activity Questionnaire,²⁶ inquiring about walking, cycling, up to 2 different sport-like activities, and household activities in the previous 2 weeks. If an activity had been performed in the previous 2 weeks, the amount of time spent on this activity and the frequency in the previous 2 weeks was obtained by subsequent questions. Mean physical activity, expressed in minutes a day, was used as a frailty indicator; a score smaller than 65 minutes a day implies that the indicator is present.²⁷

A summarizing score was calculated by summing the 5 indicators with each indicator contributing 1 point if present. Subsequently, frailty was defined as a clinical syndrome based on the presence of 3 or more indicators. When 1 or 2 indicators were present the subject was defined to be pre-frail and those with no indicator present were classified to be nonfrail.¹⁰

Outcome measures. Falls constituted the primary outcome measure, because fall prevention was the first goal of the exercise programs. Factors related to physical frailty, in terms of mobility and performance-based measures of physical function, and self-reported disability were the secondary outcome measures.

Falls. A fall was defined as an event that resulted in a person coming to rest unintentionally on the ground or other lower level.²⁸ Near-falls were not included. Falls were registered from the beginning of the intervention for a maximum period of 52 weeks or until study dropout. Falls were registered by means of a fall calendar, on which each participant marked daily whether he/she had or had not fallen. Each month the calendars were collected and sent to the study center. In addition, institutional fall registration systems that are routinely filled out by the nursing staff were checked for missed fall incidents. The fall data were expressed in terms of the number of fallers, fall incidence rates, and time to first fall. Fall incidence rates, indicating the number of falls per year, were calculated as the number of falls recorded divided by the number of follow-up weeks, multiplied by 52.

Mobility. We used the 28-point version of the Performance Oriented Mobility Assessment (POMA) as a measure for mobility.²⁹ In this test, 8 dynamic balance tasks and 9 characteristics of the walking pattern are scored on 2- or 3-point scales. The balance tasks are sitting balance, rising from a chair and sitting down again, standing balance (eyes open, eyes closed), and turning balance. Walking characteristics are gait initiation, step length, height, step length symmetry and continuity, path direction, and trunk sway. The POMA was originally designed as a measure for mobility and fall risk in elderly populations.²⁹ Interrater reliability and test-retest reliability for the POMA score were calculated for a subgroup of 30 participants of the study sample and expressed in terms of the Spearman rank correlation (ρ). Interrater reliability was estimated as ρ equal to .91 from 2 independent raters who scored the POMA simultaneously. The test-retest reliability was assessed in the same group of participants and the same 2 raters scored the POMA on 2 successive days. The ρ between the 2 POMA scores for both raters were .86 and .82, respectively. High correlations between the balance subscale and the Berg Balance Scale (Pearson $r=.91$)³⁰ and between the POMA gait subscale and physical performance test scores ($r=.78$)³¹ have been reported, which supports the concurrent validity of the subscales. The POMA scores have been used to predict falls.^{32,33} In nursing home residents, the POMA proved to be sensitive to mobility improvement.³⁴

Performance-based physical function. To assess physical function, scores on 4 standardized physical performance tests were combined, namely:

Walking speed test.³⁵ Walking speed was defined as the time needed to walk 6m as fast as possible. It was measured with a stopwatch and converted to milliseconds. The use of a walking aid was allowed, but similar circumstances in this respect were maintained in the pre- and postintervention assessment.

Timed chair stands test.³⁶ For this test, the time needed to stand up and sit down 5 consecutive times as fast as possible was recorded. An armless chair was used, and the arms of the subject were folded across the chest.

Timed Get Up & Go test.³⁷ This test was scored as the time needed to stand up from a standard armchair, walk 3m, turn, walk back 3m and sit down again at the fastest speed. The use of a walking aid was allowed during this test and if needed, hands could be used during stand-up, but similar circumstances in this respect were maintained in the pre- and postintervention assessment.

FICSIT-4 balance test.³⁶ This test included 4 foot positions: (1) parallel with both feet placed as close together as possible, (2) semi-tandem with the heel of 1 foot placed to the side of the first toe of the other foot, (3) tandem with 1 foot placed behind the other on a straight line, and (4) standing on 1 leg. For each position a maximum time of 10 seconds was taken. If a score was less than 3 seconds, no further attempts were made in subsequent positions. A summary score for the 4 positions was computed as proposed by Rossiter-Fornoff et al.³⁶

For all 4 mobility tests, the best score out of 2 attempts was taken for further analyses and the mobility test scores were summarized as proposed by Guralnik et al.³⁸ For each individual test, 1 to 4 points were given corresponding to the quartiles of the study sample distribution. If a subject was not able to perform the test, 0 points were given. The points were summed to a summary physical performance score, ranging from 0 (unable to perform any of the tests, severely impaired mobility level) to 16 points (performance in the best quartile for each test, high mobility level).

Disability. We assessed self-rated functional disability in ADLs and instrumental ADLs using the Groningen Activity Restriction Scale (GARS).³⁹ A strong association between the GARS and the SF-20 subscale for physical functioning has been reported ($r=-.72$),⁴⁰ supporting concurrent validity.

Interventions

We investigated 2 exercise programs, both derived from programs with evidence for effectiveness in preventing falls. Key components in both programs were balance and functional strength, because these are the most prominent domains that should be addressed in elderly facing functional limitations.⁴¹ Furthermore, it was taken into consideration that group-based training is recommended for elderly persons to increase motivation for participation. The exercises were tailored to the functional needs of the participants, maintaining a moderate intensity that focuses on long-term sustainability and enjoyment.⁴²

The first program, referred to as *functional walking* (FW), was derived from the tailored exercise program developed by Robertson et al⁴³ in New Zealand. FW consisted of 10 exercises forming the core program, which focus on balance, mobility, and transfer training. Each exercise was described in 3 or 4 variations to provide various levels of complexity, thus creating the possibility for individual tailoring. The exercises consisted of standing up from a chair, reaching and stepping forward and sideward, heel and toe stands, walking and turning, stepping on and over an obstacle, staircase walking, tandem foot standing, and single-limb standing (see appendix 1

for a description of the exercises). Emphasis was put on a correct and safe performance rather than on speed and maximum performance.

The second program, referred to as *in balance* (IB), was derived from principles of Tai Chi. Various trials in older populations have demonstrated positive effects of Tai Chi on balance, strength, falling, fear of falling, and general health perception.⁴⁴ However, in a population with limited mobility, Tai Chi forms per se are less suitable because of their challenging nature for balance and coordination. Therefore, specific adjustments were made. The IB program included the 7 therapeutic elements of Tai Chi that have been identified as most beneficial for elderly persons.⁴⁵ In the beginning of the program, attention was paid to somatosensory feedback signals coming from ankle and hip motions that can be used as input for balance control. Combined with exercises increasing ankle range of motion, proprioception and sensation can be improved,⁴⁶ and co-contractions that are often present to compensate for diminished sensory input may be removed.⁴⁷ Later in the program, Tai Chi forms were introduced with the emphasis on slow and continuous motions, trunk rotation, and weight shifting (see appendix 2 for a description of the exercises). Again, the exercises were tailored to the individual abilities of the participants, in that participants were allowed to perform some exercises in a sitting instead of standing position because of fatigue or poor balance control.

It should be clear from the above that the descriptions of the exercises in appendixes 1 and 2 refer to "ideal" programs. Given the heterogeneity of the group of participants individual modifications were inevitable, as will always be the case when working with groups of elderly in clinical practice. Complete standardization of the exercises across all participants in each program is simply impossible, and when attempted, would certainly be counterproductive.

The frequency and duration of the sessions were the same for both programs. Each program started with 1 session per week for 4 weeks, followed by twice-weekly sessions for 16 weeks. Each session lasted 90 minutes, including a 30-minute social component of sitting together with a drink, intended to maintain and increase motivation.^{16,42} The first 4 sessions were meant to familiarize the group with the aim of the program and with the exercises.

All groups had their own instructor and an assistant. The instructors, who were experienced in providing exercise activities for elderly persons, and their assistants were trained in carrying out the program in a 1-day training course. A member of the research group visited each exercise group seven times during the intervention period to achieve that the exercise protocol was carried out correctly.

To check if the control group had not increased its physical activity level as a result of "contamination" by the experimental groups, we required all participants to report their amount of physical activity at the postintervention assessment in the same way as at the preintervention assessment. In all groups there appeared to be a reduction of about 5 minutes a day, and no significant differences between the groups were observed in this regard.

Statistical Analysis

Baseline characteristics of the participants and baseline values of the outcome measures are reported as means with standard deviations (SDs) for continuous variables and numbers with percentages for categorical data.

The calculation of required sample size was based on the assumption that the exercise intervention would reduce the percentage of fallers by 50% (from 50% to 25% fallers), during

a follow-up period of 52 weeks.^{20,43} With a power of 80%, α set at 5%, and a dropout rate of 20%, 66 participants should be included in each intervention group and in the control group, corresponding to a total of 198 participants. As in Wolf et al,⁴⁸ we assumed a negligible effect for randomization by center.

The intervention effect was determined from the number of fallers, analyzed by the time to first fall data using Kaplan-Meier survival curves and Cox proportional hazard regression analyses. For each participant the time to first fall, the date of study dropout, or the end of the study was recorded, whichever came first. The log-rank test was used to test the association between group assignment and falling. The time to first fall was analyzed by means of Cox proportional hazard regression analyses. First, univariate models were used to estimate the unadjusted intervention effects, expressed in terms of a hazard ratio (HR) with the 95% confidence interval (CI). Cox regression analysis assumes proportionality of the HRs during the follow-up period, which was checked by adding an interaction term between group and time. The cutoff value for time was chosen by visual inspection of the Kaplan-Meier curves. Statistical analyses of mobility, physical performance, and disability data were performed using multilevel linear regression models. In the regression analyses, potential confounders were added one by one to the univariate models and were only included in the final model if they changed the intervention effect by at least 10%. Variables that were considered to be potential confounders are frailty, age, sex, MMSE, alcohol consumption, medication, use of a walking aid, dizziness, visual impairment, functional performance (POMA, physical performance score), and disability (GARS). In addition, it was investigated whether FW and IB had different intervention effects. If there was no evidence for such a difference at a 10% significance level, the intervention groups were combined to increase statistical power.

In post hoc analyses, the dichotomized frailty variable (ie, frail, pre-frail) was added to the regression model to evaluate whether frailty was an effect modifier for the intervention effect. Effect modification was determined by adding the frailty by group product term to the regression model. Separate subgroup analyses were performed only when the product term was statistically significant at a 10% level.

All statistical tests were 2-tailed and a critical P value of .05 was set, unless stated otherwise. All analyses were conducted on an intention-to-treat basis, so that all participants completing a postintervention assessment were included. Statistical analyses were performed using SPSS^a for Windows and MLWin.^b

RESULTS

Participants

The mean age of the participants who entered the trial was 84.9 years (range, 63–98y); 188 (79.0%) were women. On average 64 minutes a day were spent on habitual physical activity, mainly in the form of light household work that accounted for 47 minutes of activity per day. The number of persons active in some form of sports-like activity was 150 (63.3%) and on average this accounted for 13 minutes of physical activity per day. Examples of frequently reported activities were walking, gymnastics, and biking on a home trainer. These activities were typically performed at a low-intensity level. A large proportion of the sample exhibited mobility impairment as 175 (73.5%) persons used a walking aid indoors. Based on the frailty index, 51.1% ($n=120$) were classified as pre-frail and 48.9% ($n=115$) as frail. From the 120 pre-frail participants, 15 had a frailty sum score of 0. The latter group would therefore have been classified as nonfrail by Fried et al.¹⁰ Additional scores on demo-

Table 1: Background Characteristics of the Study Sample

Variable	FW (n=66)	IB (n=80)	Control (n=92)
Age (y)	85.4±5.9	84.4±6.4	84.9±5.9
Sex (% women)	53 (80.3)	61 (76.3)	74 (80.4)
BMI (kg/m ²)	27.4±5.1	29.0±5.4	27.4±4.9
MMSE (range, 0–30)	25.0±4.1	25.0±4.0	25.1±3.7
Living situation (% living alone)	58 (87.9)	67 (83.8)	83 (90.2)
Education level (% only primary school)	27 (40.9)	31 (38.8)	41 (45.1)
Alcohol consumption			
None	31 (54.4)	39 (54.9)	45 (55.6)
1–7 glasses weekly	10 (17.5)	17 (23.9)	17 (21.0)
>7 glasses weekly	16 (28.1)	15 (21.1)	19 (23.5)
Medication	5.3±2.8	4.9±3.0	5.1±3.1
No. ≥4 per day (% yes)	44 (73.3)	47 (63.5)	57 (63.3)
Incontinence (% yes)	14 (25.0)	27 (36.5)	27 (30.3)
History of stroke (% yes)	15 (27.3)	18 (24.7)	17 (19.3)
Self-reported dizziness (% often)	10 (15.2)	9 (11.4)	11 (12.0)
Self-reported visual impairment (% yes)	17 (25.8)	17 (21.3)	19 (20.7)
Pain (% severe)	11 (16.7)	14 (17.5)	14 (15.4)
General health perception			
Poor	1 (1.5)	2 (2.5)	0 (0.0)
Fair	24 (36.4)	25 (31.3)	35 (38.0)
Good	28 (42.4)	35 (43.8)	39 (42.4)
Very good	9 (13.6)	13 (16.3)	13 (14.1)
Excellent	4 (6.1)	5 (6.3)	5 (5.4)
Use of a walking aid			
% yes, indoors	51 (77.3)	61 (76.3)	63 (68.5)
% yes, outdoors	61 (92.4)	68 (85.0)	79 (85.9)
Physical activity (min/d)	64±52	59±50	67±46
SF-36			
Physical functioning (range, 0–100)	45.6±23.7	36.8±25.1	44.2±27.8
Vitality (range, 0–100)	55.3±21.8	53.2±19.5	54.6±20.5

NOTE. Values are n (%) or mean ± SD.

graphic and clinical characteristics for each group of participants are presented in tables 1 and 2. No significant differences between the 3 groups with regard to these characteristics were found.

Preintervention scores ± SD for the secondary outcome measures are presented in table 3. The average POMA score was 19.7±5.1. None of the participants scored 0 points on the physical performance score, whereas 14 (6.7%) scored the maximum of 16 points. Twenty-two (10.6%) participants scored less than 4 points on the physical performance scale,

indicating that they were not able to perform at least 1 of the 4 functional performance tests. The average GARS score was 41.8±13.1. The IB group was slightly more functionally limited and disabled compared with the FW group and control group, with lower scores on the POMA and physical performance score and higher scores on the GARS. However, these differences did not reach statistical significance.

Compliance

On average, 32 (range, 25–36) intervention sessions were completed, of the 36 initially scheduled. The actual number of sessions varied between the homes due to organizational reasons. The median relative compliance was 88% (25th–75th percentile, 74%–94%) for FW and 84% (65%–92%) for IB.

Exercise Effects on Falls

Forty (62.5%) participants in the FW group and 45 (57.7%) in the IB group suffered from at least 1 fall compared with 48 (53.3%) in the control group (χ^2 test=1.291, $P=.524$) (table 4). One hundred ninety-two (82.8%) participants had the maximum follow-up time of 52 weeks and 18 (8%) had a follow-up less than 20 weeks. Fall incidence rates were highest in the FW group, with 3.3±5.6, 2.3±4.6, and 2.5±4.6 falls per year in the FW, IB, and control groups, respectively. However, there was no statistically significant difference (1-way analysis of variance [ANOVA], $P=.278$). When the maximum number of falls per participant was set to 4, fall incidence rates in the intervention groups were 1.9±2.2 and 2.0±3.6 for FW and IB,

Table 2: Frequency of Positive Scores on the 5 Frailty Indicators and the Classification of the Frailty Phenotype for the Study Sample in Both Exercise Groups and in the Control Group

Variable	FW (n=66)	IB (n=80)	Control (n=92)
Frailty indicator			
Low BMI (% yes)	0 (0.0)	0 (0.0)	1 (1.1)
Exhaustion (% yes)	34 (52.3)	39 (48.8)	40 (44.4)
Physical inactivity (% yes)	42 (62.6)	41 (63.8)	48 (52.7)
Slow walking speed (% yes)	29 (44.6)	35 (43.8)	39 (43.3)
Weakness (% yes)	57 (86.4)	72 (90.0)	75 (83.3)
Frailty phenotype			
Not frail	4 (6.2)	4 (5.0)	7 (7.8)
Pre-frail	25 (38.5)	33 (41.3)	47 (52.2)
Frail	36 (55.4)	43 (53.8)	36 (40.0)

NOTE. Values are n (%).

Table 3: Results for the POMA, Physical Performance Scale (PPS), and GARS: The Confounder-Adjusted Effects of the Interventions, Calculated in Multilevel Linear Regression Models, per Intervention Relative to the Control Group and Adjusted for Baseline Values

Group	POMA (range, 0–28)	PPS (range, 0–16)	GARS (range, 18–98)
FW (n=54)			
Pre	20.2±4.5	9.4±4.2	40.6±13.4
Post	22.1±4.9	9.8±4.5	40.0±12.9
IB (n=70)			
Pre	19.2±4.9	8.2±3.8	44.3±12.0
Post	21.2±5.0	8.3±4.1	44.1±12.2
EX (n=124)			
Pre	19.7±4.7	8.7±4.0	42.7±12.7
Post	21.6±4.9	9.0±4.3	42.3±12.6
Control (n=84)			
Pre	19.8±5.6	8.7±4.6	40.3±13.7
Post	20.3±5.8	8.7±4.7	41.4±14.8
Intervention effects			
EX vs control: FW vs control	1.2 (0.3 to 2.1)*	0.4 (–0.1 to 0.9)	–2.3 (–4.4 to –0.1)*
IB vs control	1.4 (0.5 to 2.2)†	0.1 (–0.4 to 0.5)	–1.2 (–3.0 to 0.5)
EX vs control	1.3 (0.6 to 2.0)†	0.2 (–0.2 to 0.6)	–1.0 (–2.4 to 0.5)
FW vs IB (<i>P</i> value)	.984	.478	.629
Frailty EM (<i>P</i> value)	.073	<.001	.604
Intervention effects			
EX vs control: Frail subgroup	0.5 (–0.6 to 1.7)	–0.7 (–1.3 to –0.0)*	NS
EX vs control: Pre-frail subgroup	1.1 (0.4 to 1.8)†	0.7 (0.3 to 1.2)†	NS

NOTE. Values are pre- and postintervention group mean ± SD and effects (95% CI). For POMA and PPS, higher scores indicate a better performance; for GARS, lower scores indicate a better performance. Abbreviations: EM, effect modification; EX, exercise; NS, not significant. **P*<.05. †*P*<.01.

respectively, compared with 1.6±2.2 for the control group (1-way ANOVA, *P*=.850).

Figure 2 shows the Kaplan-Meier curves for time to first fall during the follow-up period of 52 weeks by group. No significant group differences were found (log rank test, *P*=.489). However, the patterns of both intervention groups exhibit a change around week 11. This suggests a time dependency, which will be analyzed later.

The unadjusted HRs and 95% CIs for the time to first fall for the FW and IB groups relative to the control group were 1.31 (95% CI, 0.86–1.99) and 1.18 (95% CI, 0.78–1.77), respectively. Only the dichotomized physical performance score (0–8 points vs 9–16 points) had a significant confounding effect, resulting in adjusted HRs of 1.59 (95% CI, 1.04–2.44)

and 1.09 (95% CI, 0.72–1.64) for the FW and IB groups, respectively. In these confounder-adjusted models the intervention effects of FW and IB were comparable (*P*=.096). Therefore the groups were combined, forming a single exercise group for further analyses. The adjusted HR for the exercise group compared with the control group was 1.36 (95% CI, 0.94–1.96), indicating the absence of a significant difference between the exercise group and the control group with regard to time to first fall (table 5).

Frailty appeared to be a strong effect modifier in the post hoc analyses (*P*=.002). The intervention had opposite effects in the frail and pre-frail subgroups with a nonsignificant fall risk-

Table 4: Descriptive Fall Data by Group

Outcome	FW (n=64)	IB (n=78)	Control (n=90)
No. of falls			
0	24 (37.5)	33 (42.3)	42 (46.7)
1	9 (14.1)	20 (25.6)	18 (20.0)
2	10 (15.6)	8 (10.3)	10 (11.1)
3	5 (7.8)	8 (10.3)	3 (3.3)
≥4	16 (25.0)	9 (11.5)	17 (18.9)
No. of fallers	40 (62.5)	45 (57.7)	48 (53.3)
No. of follow-up weeks	49±9	45±14	48±11
Fall incidence rate*	3.3±5.6	2.4±4.6	2.5±4.6
Recorded†	1.9±2.2	2.0±3.6	1.6±2.2

NOTE. Values are n (%) or mean ± SD. *Fall incidence rate is the number of falls per person-year. †Recorded number of falls is the number of falls per participant when the maximal number is set at 4 to avoid overweighting by subjects who fell more than 4 times.

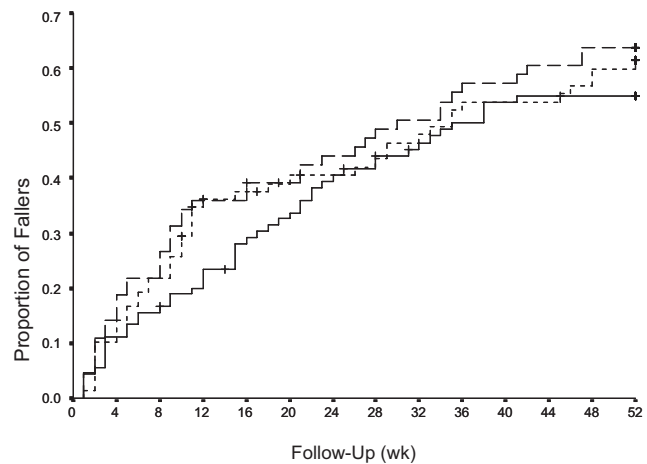


Fig 2. The proportion of fallers versus weeks of follow-up. Legend: FW, ---; IB,; control, —.

Table 5: Effects of the Interventions on Time to First Fall, After Correction for Confounders

Group	Intervention Effect
FW	1.59 (1.04–2.44)*
IB	1.09 (0.72–1.64)
Exercise [†]	1.36 (0.94–1.96)
Frail subgroup	
Total period [‡]	2.95 (1.64–5.32) [§]
Pre-frail subgroup	
Total period (wk) [‡]	0.62 (0.29–1.33)
<12	1.18 (0.55–2.54)
≥12	0.39 (0.18–0.88)*

NOTE. Values are HR (95% CI).

* $P < .05$.

[†]FW versus IB ($P = .096$); frailty effect modification ($P = .002$).

[‡]Time-dependent covariate: frail subgroup ($P = .350$), pre-frail subgroup ($P = .052$).

[§] $P < .001$.

reducing effect in the pre-frail subgroup (HR=0.62; 95% CI, 0.29–1.33) and a significant fall risk-increasing effect in the frail subgroup (HR=2.95; 95% CI, 1.64–5.32) (see table 5).

To test the proportionality assumption, an interaction term group (treatment vs control) by period (≤ 11 wk vs > 11 wk) was added to the Cox regression model. The 11-week cutoff point was derived from figure 2. This analysis showed that there was a significant time by group interaction in the pre-frail subgroup ($P = .052$), but not in the frail subgroup ($P = .350$). Separate HRs were therefore calculated for the first 11 weeks and the remaining 41 weeks for the pre-frail subgroup (see table 5). For the participants that were classified as pre-frail, there was no intervention effect in the first 11 weeks (HR=1.18; 95% CI, 0.55–2.54), but thereafter the participants in the exercise group were less likely to become a faller (HR=.39; 95% CI, .18–.88). For this group the intervention reduced the risk to become a faller by 61%.

Exercise Effects on Physical Performance and Disability

FW and IB had a comparable intervention effect on the POMA, physical performance score, and GARS outcome measures; therefore the groups were combined into a single exercise group. In the main analyses, a small, but significant, positive intervention effect was seen in the POMA only (see table 3). The POMA score increased by 1.3 (95% CI, 0.6–2.0) in the exercise group compared with the control group. In the subsequent post hoc analyses, frailty appeared to be a highly significant effect modifier for the physical performance score ($P < .001$) and to a lesser extent for the POMA ($P = .073$). In the frail subgroup the physical performance score was lower after the intervention (difference, -0.7 ; 95% CI, -1.3 to 0.0 ; $P = .039$). By contrast, there was strong evidence for a positive intervention effect on the physical performance score in the pre-frail subgroup of 0.7 (95% CI, 0.3–1.2; $P < .001$) points. Also for the POMA, a significant improvement in the pre-frail subgroup (difference, 1.2; 95% CI, 0.5–1.8; $P = .001$) was found and no effect in the frail subgroup (difference, 0.5; 95% CI, -0.6 to 1.7 ; $P = .369$). No significant intervention effects were found for the GARS (difference, -1.0 ; 95% CI, -2.4 to 0.5 ; $P = .181$).

DISCUSSION

The FW and IB exercise programs were effective in reducing fall risk and improving the scores on the POMA and the physical performance score in the subgroup of pre-frail elderly.

In this subgroup small, but significant, beneficial effects were found for the physical performance measures, whereas the effect on fall risk reduction was more pronounced. Fall risk was not reduced immediately after the start of the intervention, but positive effects became apparent after 11 weeks of exercise. In the frail subgroup, however, the risk to become a faller was significantly increased by the intervention, without any significant changes in physical performance measures.

These findings may have important implications for the development of fall-preventive exercise programs. It should, however, be borne in mind that physical activity prescription must ensure that interventions are challenging, yet safe, which seems to be more difficult for more frail groups.¹⁸ An increased fall risk for frail elderly induced by exercise interventions, which was found in our frail subgroup, has been reported by several researchers.^{49–51} On the other hand, the reduction of fall rate by 61%, as established in our pre-frail subgroup, is highly promising when compared with the effects of other effective exercise interventions.^{19,52–56} Furthermore, based on our results, exercise programs should last at least 3 months before a beneficial effect on falling can be expected. This compares favorably with the studies of Becker et al,⁵⁷ who found that intervention effect on falling became apparent only after 6 months of training, and of Wolf et al,¹⁹ who reported effects after 4 months of training. It is observed that in these studies conclusions on time dependency were based on visual inspection and/or multiple comparisons, instead of demonstrating the time dependency by group by period interaction analyses.

Previous reports of differential intervention effects were based on age or physical function. Robertson et al⁴³ based the distinction on age; their individual exercise program in community-dwelling elderly was most effective in the participants aged over 80 years. Morgan et al⁵¹ based the distinction on physical function; they found that their low-intensity group exercise intervention in community-dwelling elderly at risk for falling was beneficial in preventing falls in participants with lower levels of physical function (SF-36 physical function subscale score < 55 points), whereas participants with higher levels of physical function (SF-36 physical function subscale score ≥ 55 points) exhibited an increased risk for falling. Unlike our findings, these results imply that exercise interventions are more successful in the more frail elderly. This contradiction cannot be readily explained. It is conjectured that our study sample was more frail on average than the samples in the studies by Robertson⁴³ and Morgan,⁵¹ who provided no information about the frailty classification.

A number of methodologic points about our study are worth noticing. The first is that we did not perform stratified randomization, although frailty was a good discriminator for the differential intervention effects. This should, however, not have affected our main conclusions, because the frail and pre-frail subgroups were distributed evenly across the intervention groups. The second is that we opted for broad, rather than stringent, inclusion criteria for the recruitment of participants. This was done to enable generalization of the conclusions to our entire institutionalized population. The use of broad inclusion criteria obviously resulted in a relatively heterogeneous study sample with a wide range of medical conditions and functional limitations. While this might explain the lack of significant overall intervention effects and wide confidence intervals, the introduction of potential confounding variables, other than frailty, did not affect our conclusions. Finally, despite finding highly significant results, the study might be underpowered. Our initial power analysis assumed a negligible effect for randomization by center, but, in fact, the percentage of fallers in the control groups ranged from 0% to 83% between the centers.

This level of intercluster variability results in a design effect of 4.4, thus increasing the desired group size to 290 participants in each group.⁵⁸ Based on this design effect, the power of our study would decrease to 55%. However, it should be noted that the intercluster variability could not be estimated with high precision, owing to the small number of control participants.

The absence of significant positive training effects might also be attributed to inadequacy of training intensity, frequency, duration, and/or specificity of the exercise mode.⁵⁹ We used exercises that did not reach maximum intensity with twice-weekly sessions during a 20-week period, as we wanted to create a situation that could be incorporated into daily life. The programs followed exercise guidelines for the elderly, such as supervised training conditions, tailored balance and strength exercises, and progressive exercise protocols.^{42,60} Nevertheless, our group-based programs did not induce changes in physical performance measures in the frail part of the study sample. This finding suggests that this group needs an individual and more vigorous training approach than the presently evaluated one. However, a high-intensity individual training would make the program unsuitable for long-term incorporation into daily life. Another reason for preferring moderate intensity programs is that a key element in sustaining exercise participation of older people is the opportunity to socialize. The latter condition requires group training.⁴² Moreover, it is far from certain that more intense exercises would have been possible for the frail participants in our study, given that, for example, some of them did not always succeed in performing the exercises in the intended standing position and had to resort to a sitting position because of fatigue. Finally, the main goal of the currently investigated exercise programs is to reduce fall risk, rather than to improve physical performance. Various exercise programs have shown considerable fall risk reduction without major changes in physical performance.^{20,52,54}

CONCLUSIONS

Elderly people can reduce their risk of falling by participating in moderate intensity group-exercise programs. However, this beneficial effect is limited to those who are not yet frail. For frail elderly, the currently evaluated exercise programs may even increase the risk of falling. We therefore recommend including group-exercise programs as part of a fall-preventive intervention for nonfrail and pre-frail elderly only. For frail elderly, safety-enhancing interventions such as the use of hip protectors and environmental modifications might be preferable.⁶¹

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APPENDIX 1: FUNCTIONAL WALKING

Standing up from a chair

1. With the use of arms for push-off and seat height adjusted to 120% of the lower-limb length (defined as the vertical distance between the lateral knee joint line and the floor, measured with the lower limb at a right angle to the floor).
2. Without the use of arms for push-off and with seat height adjusted to 120%.
3. Without the use of arms for push-off and with seat height adjusted to 100%.
4. Without the use of arms for push-off and with seat height adjusted to 80%.

For all variations: 2 series of 5 repetitions.

Standing with the feet parallel shoulder width apart

1. Clapping hands ahead and behind the body, with minimum support for balance corrections (2 series of 5 repetitions).
2. Turning head and trunk to both sides as far as possible without support (2 series of 5 turns to each side).
3. Lifting the limbs alternating outwards without support (2 series of 5 lifts of both legs).
4. Throwing balls with a partner 1–2m apart, while counting the number of throws and without support (2 series of 20 throws).

Moving objects (smaller and larger ones of different weight) between 2 tables

1. Sitting in a chair with the tables placed arm-distance away (4 series).
2. Sitting in a chair with the tables placed 15–20cm further away compared with 1 (4 series).
3. Standing upright and stepping forward, sideward (left and right), and backward, without bringing the trunk above the stepping limb (3 series to all sides with both legs).
4. Standing upright and stepping forward, sideward (left and right) and backward, bringing the trunk above the stepping limb (3 series to all sides with both legs).

Heel stands and walk

1. Standing on heels with support (10 seconds, 2 series).
2. Standing on heels without support (10 seconds, 2 series).
3. Walking along a straight line on heels with support (10 steps, 2 series).
4. Walking along a straight line on heels without support (10 steps, 2 series).

Toe stands and walk

1. Standing on toes with support (10 seconds, 2 series).
2. Standing on toes without support (10 seconds, 2 series).
3. Walking along a straight line on toes with support (10 steps, 2 series).
4. Walking along a straight line on toes without support (10 steps, 2 series).

Walking along a straight line forward, backward, and sideward

1. Walking without support.
 2. Stepping over sticks (height, 3cm) that are lined up over a distance of 8m with a variable interstick distance that can be covered in one step without support.
 3. Walking while carrying a cup filled with water.
 4. Walking while carrying a tray so the feet cannot be seen.
- For all variations: 4 series of 10 steps.

Stepping

1. Stepping up and down a step (15–20cm), with support (2 series of 5 steps up for both legs as the leading leg).
2. Stepping onto the step with the leading leg, tipping with the nonleading leg on the step and stepping off the step without placing the nonleading leg onto the step without support (2 series of 5 steps up with both legs).
3. Stepping over the step without support (2 series of 10 steps).

Getting up and down a staircase (7–10 steps)

1. Step by step with support of the rails.
 2. Step over step with support of the rails.
 3. Step over step without support.
 4. Step over step, while holding a cup or tray.
- For all variations: 3 series.

Heel-toe standing and walking, that is, 1 foot placed directly before the other foot

1. Standing with support (3 series of 10 seconds with both feet in front).
2. Standing without support (3 series of 10 seconds with both feet in front).
3. Walking with support (3 series of 10 steps).
4. Walking without support (3 series of 10 steps).

One-leg stand

1. Standing on 1 leg with support.
2. Standing on 1 leg without support.
3. Standing with support and holding a ball, cup, or tray.
4. Standing without support while swinging the nonsupporting leg forward and backward.

For all variations: 3 series of 10 seconds for both legs.

APPENDIX 2: IN BALANCE**Relaxation exercises**

1. Swinging both arms forward and backward while standing with feet placed side-by-side and with special focus on relaxed wrists. The same with 1 foot placed ahead and the other 1 placed behind, taking care of weight transfer.
2. Standing position with the feet more than shoulder width apart. Lowering the body, swing both arms to the left and right in front of the body while the body is initiating the arm swing. Focus on weight transfer.
3. Standing with feet almost closed together, swinging 1 arm forward and the other backward simultaneously. Focus on the pelvis, which shows a horizontal swing from the left to the right, causing trunk rotation and a loose arm swing.

For all exercises: repeat as often as needed and if needed the exercises can be performed seated in an armless chair.

Stretch and relax exercises

1. Swinging slowly both arms in a forward and up direction with 1 foot placed in front and body weight moving forward and transferred to the leg in front (stretching phase). When the arms are going down, the leg placed behind is slightly bending and body weight is transferred to this hind leg (relaxing phase).
2. While standing, lift 1 arm oblique sideways and upwards, producing stretch on the same trunk side, while inhaling. Lower the arm slowly and repeat for the other side.
3. Standing with 1 foot in front of the other. Shifting the weight to the front leg, both arms are slowly spread out to the side while inhaling, causing an expanding effect on the chest. Hold this for 2 seconds and then slowly shift the weight back and lower the arms while exhaling. The rear leg is slightly bent.

For all exercises: the movements must be executed in a very slow way, causing alternately a stretching strain on the body and a relaxation. The stretch and relaxation must be felt. If possible inhale while stretching and exhale while relaxing.

Pelvis exercises

1. Forward and backward rotation of the pelvis while sitting, without leaning against the back of the chair. Focus on the activating impulse from the buttocks, more specific the tuber ischiadicum.
2. Lifting the left and right buttock alternating while sitting and pushing the buttock into the chair.
3. Making clockwise and counterclockwise circles on the ischia by pelvic rotation.
4. Walking back and forth on the buttocks while sitting on a chair by lifting the left and right buttock alternating.
5. Forward and backward rotation of the pelvis while standing with the knees slightly bended, emphasizing a relaxed execution.

For all exercises: 5 repetitions. For exercise 1–4: the impulses of the movement are generated by the tuber ischiadicum. This causes a powerful and effortless execution.

Foot and ankle exercises, sitting on a chair

1. Moving the toes, including spreading out and grasping, first for each foot separately and later with both feet simultaneously.
2. Making circles with the forefoot by ankle rotation, while keeping the heel on the floor (5 repetitions to the left and 5 to the right).
3. Pro- and supination of both feet simultaneously while sitting and standing holding a chair (5 repetitions to both sides).
4. Circling movement with the foot: touch the heel on the floor, then go further to the outside of the foot touching the floor, then the toes, lifting the heel and at the end the inside of the foot touching the floor. Repeat this circle-like movement 5 times. Do the same with the other foot, both feet simultaneously and in standing position with support of a chair.

For all exercises: movements are made slowly and as big as possible, feeling the stretch.

Leg strengthening

1. Pushing the heel firm in the ground while sitting and hold this position for 6–9 seconds, then relax (8 repetitions for both legs separately).
2. Front knee strengthening while sitting in a chair and lifting the leg straight for 8 seconds (8 repetitions).
3. Knee bending while standing with the feet shoulder width apart (8 repetitions).
4. Lowering the weight in 1 foot bending the knee and simultaneously stretching out the other leg to the front, touching the heel on the floor.
5. Standing with both feet more than shoulder-width apart and then bending the knees and lowering the trunk and coming back up (5 repetitions).

Balance exercises

1. Rubbing firmly one's legs and ankles with the hands.
2. Walking over bags filled with beans, pasta, or chestnuts, while sitting.
3. Standing with the feet shoulder width apart and trying to relax the back, supported with relaxed breathing. Lumbar back relaxation by slightly lowering the os coccygis "reaching" to the floor.
4. Standing with the feet shoulder width apart and making a slow and easy swinging movement bringing body weight alternately to the left and right limb. The movement starts with lowering the weight slightly to 1 leg

while relaxing and exhaling, then shifting the weight to the other leg and standing up. Relaxing the lumbar back.

5. Walking in slow motion, concentrating on shifting body weight, relaxation, inner feeling of safety and foot placement.

For all exercises: continue as long as needed. Exercises 1 and 2 aim at improving sensibility for fine disturbances of balance, resulting in a feeling of safeness while standing and walking in exercises 3–5.

Balance dance

The balance dance is a simplified form of Tai Chi in which all previous exercises cumulate. Body weight is shifting continuously in a slowly fluent and relaxed manner in all directions (forward, backward, upward, downward, and sideward), using arm movements and breathing rhythm to support weight shifting and relaxation.

Functional exercises

1. Stand up from a chair, emphasizing ground support.
2. Stand up from a bed.
3. Stand up from the floor, with and without support of a chair and in different ways.
4. Walking focusing on erectness and lightness of the body, positioning of the head and the use of relaxed knees in a forward motion.

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Suppliers

- a. Version 11.5; SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.
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