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# Effects of exercise and nutrition on postural balance and risk of falling in elderly people with decreased bone mineral density: randomized controlled trial pilot study

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**Objective**: To compare the effect of calcium/vitamin D supplements with a combination of calcium/vitamin D supplements and exercise/protein on risk of falling and postural balance.
**Design**: Randomized clinical trial.
**Setting**: University hospital physiotherapy department.
**Subjects**: Twenty-four independently living elderly females aged 65 years and older with osteopenia or osteoporosis and mean total hip *T*-score (SD) of −1.8 (0.8).
**Interventions**: A three-month programme consisting of exercise/protein including training of muscular strength, co-ordination, balance and endurance. Calcium/vitamin D was supplemented in all participants for a 12-month period.
**Outcome measures**: Assessment took place prior to and following the months 3, 6, 9 and at the end of the study; primary dependent variables assessed were risk of falling (Berg Balance Test) and postural balance (forceplate). Secondary measures included body composition, strength, activity level, number of falls, bone mineral content, biochemical indices, nutritional status and general health.
**Results**: Significant reductions of risk of falling (repeated measures ANOVA $F=8.90$, $P=0.008$), an increase in muscular strength (ANOVA $F=3.0$, $P=0.03$), and an increase in activity level (ANOVA $F=3.38$, $P=0.02$) were found in the experimental group as compared to the control group. Further on, there was 89% reduction of falls reported in the experimental group (experimental pre/post 8/1 falls; control group pre/post 5/6 falls).
**Conclusion**: This study provides support for our intervention programme aimed at reducing the risk of falling in elderly participants diagnosed with osteopenia or osteoporosis. The data obtained from the pilot study allow the calculation of the actual sample size needed for a larger randomized trial.

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## Introduction

Osteoporosis is a major health problem, characterized by a significant morbidity, mortality and a high economic burden.[1] Hip fractures are a frequent consequence of osteoporosis and the costs of these fractures form a relevant part of the total expenses of osteoporosis. Furthermore, hip fractures lead to reduced functional independence in the elderly.[2] In the year 2000, osteoporotic fractures accounted for $>18\,000$ hospital admissions in Switzerland; subsequently resulting in an average hospital stay of 16 days at a cost of 234 million euros.[3]

There are various factors that increase the risk of a hip fracture, an increased risk of falling[4] and osteoporosis.[5] A strong predictor of increased risk of falling in the elderly is the loss of (automatic) balance control.[6] Indeed, most elderly experience at least some decline in sensorimotor control with advanced age,[7,8] leading to problems in balance and gait.

A Cochrane Database Systematic Review showed that to reduce the risk of falling in elderly, a home-based muscle-strengthening programme, combined with balance retraining can be applied.[9] When starting an exercise programme it is necessary to take into account that the most of the elderly tend to be of low energy consumption. Hence they may be at risk for low protein intake, and thus protein status, if they are active.[10] It is important for this reason to add protein supplementation when beginning resistance strength training with the elderly.[11,12]

The promotion of exercise training in the elderly has a number of other implications. Older populations have reduced flexibility when adapting their motor control to sudden altered changes in the environment.[13] For example, a dual-task test consisting of walking on flippers (normally used for swimming) while simultaneously solving a mental calculation task resulted in significant gait impairment in the elderly, whereas young adults were minimally hindered by this combined cognitive motor task.[14] Furthermore, sensory information processing is compromised by age, so that the performance of postural tasks becomes increasingly difficult for the elderly.[15] Elderly people are much more affected by a discrepancy between visual and proprioceptive information than young adults.[16]

It also seems possible that vitamin D has an effect on the risk of falling and the risk of fracturing. First, chronic low calcium intake and vitamin D deficits are important co-factors leading to secondary hyperparathyroidism and increased bone reabsorption, which are problems associated with an increased incidence of osteoporosis and fractures in elderly people.[17] Second, it has been argued that a vitamin D supplement has an influence on falls. A three-month application of calcium/vitamin D reduced the number of falls per person by 49% compared with supplementation with calcium alone.[18] It is unclear, however, whether this is a causal relationship or not.

Thus we considered it important to test an exercise programme within an elderly population with decreased bone mineral density. The purpose of this pilot study was, therefore, to investigate the feasibility of a three-month exercise programme on fall-related outcomes, in the context of vitamin D supplementation. The authors are not aware of any previous study that has investigated such an intervention.

The study hypothesis was that exercise with proteins complemented with calcium/vitamin D supplementation has a larger effect on fall-related outcomes than a calcium/vitamin D only supplementation in elderly with decreased bone mineral density.

## Methods

### Study design

This randomized controlled prospective trial with two treatment arms was performed at the Center for Osteoporosis of the Department of Rheumatology in close co-operation with the Institute of Physical Medicine of the University Hospital Zurich.

Random assignment to the intervention or control group was performed on completion of baseline assessment with a stratified randomization procedure (Figure 1). Stratification is useful in small trials in which it can avert imbalances on prognostic factors.[19] To achieve an optimal balance, two important predictive factors: (1) risk of falling (Berg Balance Test) and (2) bone mineral density level, were selected. Sealed envelopes with random numbers were used to ensure that both groups were allocated in a balanced way; this was undertaken by a co-worker independent of the study.

The intervention group entered a three-month exercise programme that included the training of muscular strength, co-ordination, balance, and endurance and that was accompanied with nutritional (protein) supplementation. These participants additionally received calcium/vitamin D supplementation.[20] The

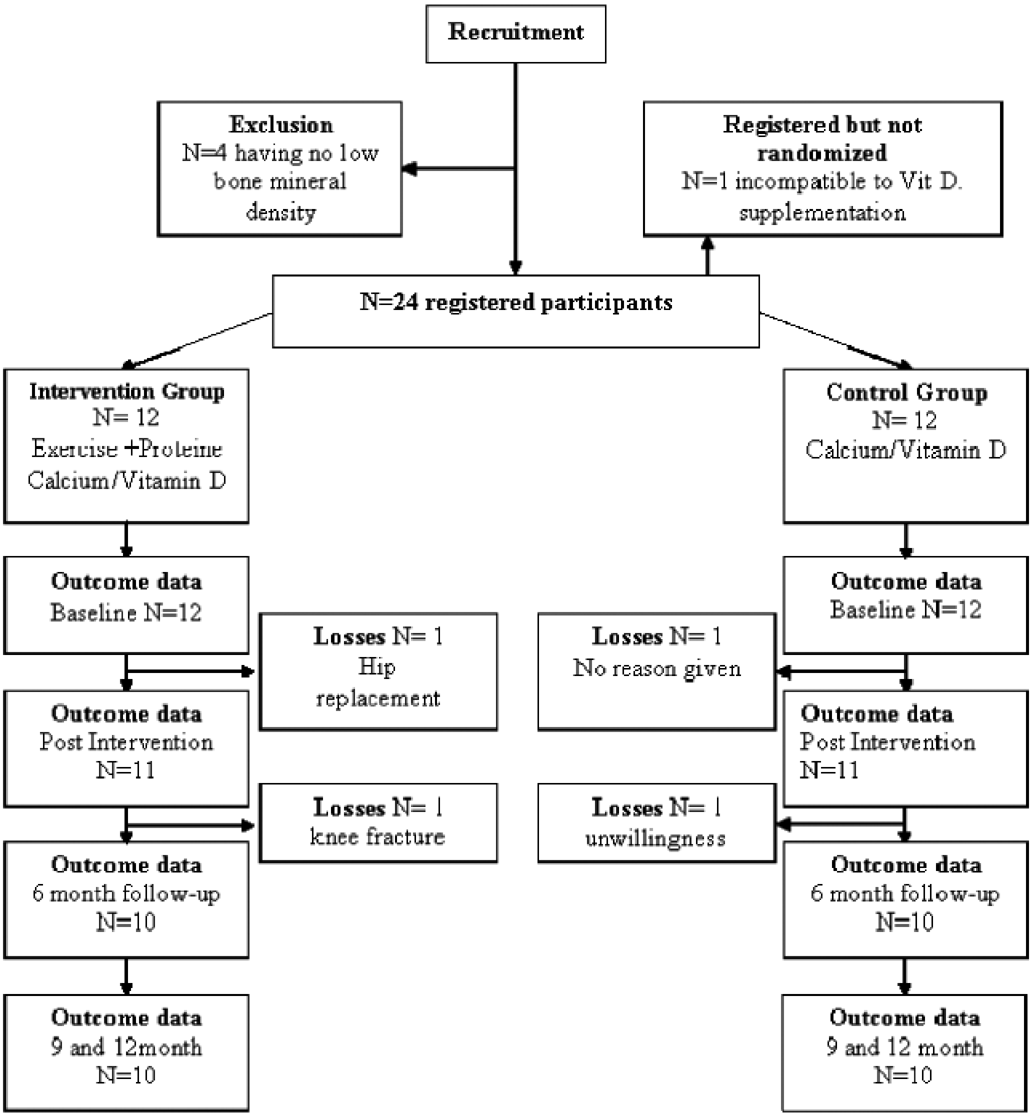


**Figure 1** Flow diagram for the study.

control group received calcium/vitamin D supplementation only. The study lasted for a period of 12 months. Follow-up measurements took place at 3, 6, 9 and 12 months following baseline.

## Participants

A total of 24 individuals were initially recruited (all female). All were living independently and travelled on their own to participate in the exercise programme. Before entering the study, the participants gave written informed consent after a physical examination by a physician to check whether they fit the set criteria for inclusion. The study was approved by the local ethics committee. The characteristics of these participants are presented in Table 1.

Inclusion criteria were osteopenia or osteoporosis diagnosed with dual energy X-ray absorptiometry

**Table 1** Baseline characteristics of participants

| | All | Intervention group | Control group |
|---|---|---|---|
| Age | 71.2 (6.8) | 71.8 (5.4) | 70.7 (8.1) |
| Height (cm) | 160 (8.1) | 154 (6.8) | 164 (6.5) |
| Weight (kg) | 59 (9.2) | 57 (9.7) | 60 (8.9) |
| Body mass index | 23.3 (3.0) | 23.9 (3.0) | 22.6 (3.0) |
| Mean total hip *T*-score | −1.8 (0.8) | −1.9 (0.5) | −1.8 (1.0) |
| Mean lumbar spine *T*-score | −2.6 (1.2) | −2.6 (1.0) | −2.7 (1.5) |
| Falls 3 months before baseline | 13 | 8 | 5 |
| Fractures | 17 | 10 | 7 |

Values are mean (SD).

(DEXA) (Table 1), according to WHO criteria,[21] with or without prevalent fractures. Exclusion criteria: patients with any severe peripheral or central neurological disease known to influence gait, balance or muscle strength. Also patients with medical contraindications for exercise (e.g. major cardiovascular problems or postural hypotension) were excluded.

## Calcium/vitamin D supplementation

Both control and intervention group received a mineral supplementation according to physician's assessment at baseline, to correct any possible vitamin D and calcium deficiency. The supplementation of the participants was, according to baseline assessment, 1–2 tablets/day for 12 months (Calcimagon D3; 500 mg Ca, 400 IU vitamin D). The calcium supplementation was 500–1000 mg per day, whereas the vitamin D supplementation was 400–800 IU of cholecalciferol a day.[22] A three-month supply was given at each assessment.

## Exercise and protein intervention

The participants in the intervention group participated in a 12-week training programme aimed at an improvement of balance abilities and a reduction of the risk of falling. The initial two weeks were used to tailor the programme to the individual capacities of the participants. There were three sessions per week of 70 minutes each. Two sessions consisted of progressive resistance training, and individual exercises that focused on the improvement of co-ordination, balance and endurance.[17] One session consisted of a group exercise focused on balance exercises and games. A more detailed description of the exercise protocol and an exercise timetable is presented in Appendix 1.

To prevent undesirable training-induced losses in the lean tissue mass of our elderly osteoporotic sample we gave our study subjects additional protein supplements.[11] The intervention group was supplied with Resource Protein Drink (Novartis, Basel, Switzerland), a nutritional supplement enriched with proteins, albumin and amino acids for 3 months on a daily basis [11]. The daily dose per patient was 20 g (18.2 g protein, 0.2 g fat, 250 kcal).[23] Each participant received a seven-day supply ration once weekly. The participants were asked to consume their protein rations at 10 am to minimize the effect on food intake.[11] The control group received no protein supplementation.

The participants of the intervention group were encouraged to continue the exercise programme after the initial three months. The control group received a leaflet about home exercises but did not attend the in-house training programme.

## Primary outcome measures

Primary outcomes were risk of falling and postural balance. Risk of falling was assessed by means of the Berg Balance Test. The Berg Balance Test consists of 14 functional subtests with a maximal 4 points (normal performance) and a minimal 0 points (no performance possible) per subtest. A total of 0 points represents a severely impaired balance whereas 56 points does represent an excellent balance.[24] The Berg Balance Test has a high inter-rater reliability (intraclass correlation coefficient (ICC) = 0.98) and a high intra-rater reliability (ICC = 0.99)[24] and is highly specific in identifying elderly people who are prone to falling (cut-off score = 45).[25]

Postural balance was measured with the AccuSway PLUS system (Advanced Mechanical Technology Inc., Watertown, MA, USA). This system provides centre of pressure coordinates, which allows postural sway and the maximum displacement from the centroid in *x*-axis (medial–lateral, ML) and *y*-axis (anterior–posterior, AP) to be measured.

The balance platform was covered with a non-slip plastic cover. The participant took a comfortable double-leg stance without shoes on the balance plate and the outlines of both feet were marked on the plastic cover with a permanent marker. The purpose of the plastic cover for each individual was to obtain the identical position of the feet across the repeated measurements. During the actual measurement, the patient was instructed to assume a normal barefooted, comfortable standing position, with arms at the side in a neutral position and to stand still for 10 seconds. This was repeated four times with a break of 20 seconds between each measurement.[26] The average of the four measurements was taken and recorded as the result of one trial. After a 2-minute break, the procedure was repeated with eyes closed.

### Secondary outcomes

Whole body composition (WBC), as well as segmental body fat mass and lean mass, were measured upon entry and after 12 months by DEXA on a Hologic QDR 4500 scanner (Hologic Corporation Inc., Waltham, MA, USA).

Muscle strength of quadriceps femoris was measured with a MicroFet device (Force Evaluating and Testing, Hoggan Health Industries Inc. West Draper, UT, USA) in a standardized sitting position with the knee in 30° flexion.[27,28] A hand-held dynamometer was placed distally at 80% of the tibia length. A measurement protocol was used to counterbalance any order (or learning) effects. The test–retest reliability for the protocol used has been reported at ICC 0.94.[29]

The patient physical activity level was determined with the self-administered Freiburger Questionnaire of Physical Activity. This questionnaire covers occupational, household and leisure activities during a one-week period and takes 5–15 minutes to complete. Reliability has been reported between 0.55 and 0.97 ($P < 0.001$), whereas validity of the total activity was $r = 0.42$, $P < 0.01$.[30]

The general health of the participants was determined through the Short Form-36 questionnaire (SF-36), which shows validity when used by elderly patients.[31]

Falls in our study were defined as 'unintentionally coming to rest on the ground, floor, or other lower level'.[32] Neither 'coming to rest against furniture, a wall or other structure', nor 'high-trauma falls (e.g, falling from a ladder) and falling as a consequence of sustaining a violent blow' were included as falls in this study. Falls were assessed by interview at each assessment.

Bone mineral content (BMC) was measured upon entry and after 12 months at both antero-posterior projection of the lumbar spine (L2–L4) and the non-dominant hip (total hip) using DEXA. The pre-post test measures were performed by the same technician. All results were expressed in grams.

Biochemical markers were measured upon entry and after 12 months. These markers reflect bone metabolism and could provide evidence that the intervention induced the hypothesized biological changes. Bone metabolism was assessed in each patient, measured in morning serum and morning urine after fasting.

Assessments took place at the start of the programme and at 3, 6, 9 and 12-month follow-ups.

Adherence to the exercise programme was assessed, using the individual progressive loading scheme of the patient, which was monitored following each training session. The assessors were blinded for all measurements, except for the Berg Balance Test.

### Statistical analysis

The comparability of both groups on prognostic and outcome variables at baseline was analysed with two-sample *t*-tests. The normality of the distribution was checked with the Kolmogorov–Smirnov one-sample test. Data on postural balance and risk of falling were analysed using ANOVA (repeated measures) to look for significant interaction (group × time) effects ($\alpha = 0.05$). The reliability coefficient of the measurement is determined by calculating an ICC.[33] The secondary outcome variables were analysed similarly. The percentage of change of fallers was used to compare the two groups.

Missing measurements were filled in with the series mean of the patient's other four measurement results. The exercise compliance was defined as the number of exercise sessions reported divided by the number of maximum exercise sessions possible. Data were entered, stored and analysed using the Statistical Package for Social Sciences (SPSS, version 11.5).

## Results

Twenty patients completed the study. One participant stopped because of hip replacement surgery and one participant due to knee fracture. Two participants left the study due to unwillingness to participate or without giving a specific reason. Figure 1 shows the patient flow diagram.

**Table 2** Results from each measure at each time point in the two groups ($n = 10$ for each group)

| | Baseline | | | 3 months | | 6 months | | 9 months | | 12 months | | ANOVA | | ICC |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | IG | CG | *P* | IG | CG | IG | CG | IG | CG | IG | CG | *F* | *P* | |
| **Berg Balance Test score** | | | | | | | | | | | | | | |
| Mean (SD) | 51.7 (4.3)* | 53.2 (2.4) | 0.3 | 55.3 (1.5) | 52.9 (2.2) | 55.5 (0.8) | 52.7 (2.2) | 55.3 (1.1)* | 52.7 (2.8) | 55.6 (0.7) | 51.9 (4.5) | 8.90* | 0.008* | 0.90* |
| Range | 43/56 | 49/56 | | 52/56 | 49/56 | 54/56 | 49/56 | 53/56 | 47/56 | 53/56 | 41/56 | | | |
| **Anterior–posterior (cm)** | | | | | | | | | | | | | | |
| Mean (SD) | 0.60 (0.19) | 0.67 (0.16) | 0.4 | 0.62 (0.21) | 0.71 (0.11) | 0.54 (0.18) | 0.73 (0.27) | 0.58 (0.23) | 0.68 (0.20) | 0.52 (0.15) | 0.65 (0.18) | 1.32* | 0.27* | 0.92* |
| Range | 0.28/0.85 | 0.40/0.88 | | 0.25/0.83 | 0.79/0.86 | 0.28/0.93 | 0.37/1.20 | 0.33/1.10 | 0.47/0.98 | 0.30/0.78 | 0.39/0.87 | | | |
| **Medial–lateral (cm)** | | | | | | | | | | | | | | |
| Mean (SD) | 0.38 (0.16) | 0.47 (0.18) | 0.2 | 0.42 (0.20) | 0.49 (0.20) | 0.47 (0.23) | 0.56 (0.17) | 0.45 (0.21) | 0.53 (0.18) | 0.39 (0.17) | 0.47 (0.16) | 0.10* | 0.75* | 0.95* |
| Range | 0.20/0.65 | 0.26/0.89 | | 0.22/0.79 | 0.24/0.84 | 0.20/1.00 | 0.32/0.78 | 0.26/1.00 | 0.31/0.80 | 0.23/0.72 | 0.29/0.80 | | | |
| **Activity (FAS) (kcal/week)** | | | | | | | | | | | | | | |
| Mean (SD) | 1557 (647) | 2018 (1036) | 0.3 | 2586 (995) | 2098 (1343) | 2494 (1376) | 2400 (1360) | 1914 (845) | 2334 (1265) | 1821 (661) | 2200 (1057) | 3.38* | 0.02* | NA* |
| Range | 699/2269 | 744/3526 | | 1287/4506 | 583/4576 | 826/4855 | 469/4200 | 512/2849 | 718/3992 | 738/2866 | 580/3711 | | | |
| **Strength (N)** | | | | | | | | | | | | | | |
| Mean (SD) | 117 (46) | 141 (56) | 0.3 | 136 (44) | 132 (40) | 137 41) | 129 (43) | 125 (44) | 161 (75) | 144 (60) | 150 (58) | 3.0* | 0.03* | 0.94* |
| Range | 63/209 | 54/258 | | 64/215 | 61/204 | 80/209 | 49/207 | 58/187 | 51/310 | 68/257 | 39/259 | | | |

BBT, Berg Balance Test; IG, intervention group; CG, control group; ICC, intraclass correlation coefficient; NA, not applicable.
Values are given as mean (SD) or range = min/max.
*Significant $P < 0.05$.

Due to administrative reasons, two measurements from the intervention group, one at six months and one at 12 months, were missing and two measurements at nine months were missing from the control group. The exercise compliance of the intervention group was 93%. A change in home exercise by the control group was monitored with the Freiburger Questionnaire of Physical Activity. All data for both groups appeared to be normally distributed. There were no statistical differences for the prognostic variables at baseline (Table 2).

## Primary outcome measures

*Risk of falling*

The intervention group showed a significant decrease in the Berg Balance Test (ANOVA $F = 8.90$, $P = 0.008$, with a lower bound adjustment) (Table 2). The reliability (ICC) of this measurement in our study was 0.90. The change is expressed in Figure 2a. Two individuals of the intervention group scored under 45 points (43 points and 44 points) at baseline. At the end of the study they scored 50 and 56 points respectively. These two participants suffered a total of five falls before the start of the study. At the end of the study only one of these individuals suffered a fall during the 12-month study period. The change of scores between baseline and the follow-ups are shown in Table 3.

*Postural balance*

Maximal sway in AP and ML showed no interaction effect between the groups (Table 2). The ICC of this measurement was 0.92 for AP and 0.95 for ML direction. The results are expressed in Figure 2b,c. The change of scores between baseline and the follow-ups are shown in Table 3.

## Secondary outcomes

The Freiburg Questionnaire of Physical Activity ($F = 3.38$, $P = 0.02$) and the quadriceps muscle strength ($F = 3.0$, $P = 0.03$) showed a significant interaction effect between the groups, ANOVA with sphericity assumed (Table 2). There was no significant difference between the groups at month 9 ($F = 0.76$, $P = 0.40$) and 12 ($F = 1.18$, $P = 0.29$) as determined with one-way ANOVA.

The ICC of the quadriceps muscle strength measurement in our study was 0.94 (Table 2) and the change of scores are shown in Table 3.

There was no change of lean and fat mass (WBC) in both groups. No change in bone mineral content and important bone markers in both groups were found. Only the total hip bone mineral content showed a significant increase for the control group (Table 4).

The reported falls were reduced within the intervention group by 100% and within the control group by 80% after the first three months. After six months the decrease was 100% for the intervention group and 40% control group; at months 9 and 12 reduction was 75% for the intervention group, but an increase of 20% in falls was seen in the control group. The reported falls over the 12-month period are shown in Figure 3. One participant in the intervention group sustained a knee fracture after a fall during a holiday at month 9 from baseline. No other fractures occurred during the study

**Table 3** Change scores between baseline and follow up 3, 6, 9 and 12 months

| | Δ 0/3 months | | Δ 0/6 months | | Δ 0/9 months | | Δ 0/12 months | |
|---|---|---|---|---|---|---|---|---|
| | IG | CG | IG | CG | IG | CG | IG | CG |
| Berg Balance Test (SD) | +3.6 (3.2) | −0.3 (1.2) | +3.8 (3.6) | −0.5 (1.1) | +3.6 (3.5) | −0.5 (1.4) | +3.9 (4.0) | −1.3 (2.7) |
| AP (SD) | +0.02 (0.13) | +0.04 (0.12) | −0.06 (0.11) | +0.06 (0.21) | −0.03 (0.16) | +0.01 (0.14) | −0.08 (0.08) | −0.02 (0.13) |
| ML (SD) | +0.05 (0.12) | +0.02 (0.13) | +0.08 (0.15) | +0.06 (0.21) | +0.08 (0.12) | +0.06 (0.10) | +0.02 (0.07) | −0.01 (0.09) |
| Activity (SD) | +1029 (675) | +80 (720) | +938 (973) | +382 (746) | +358 (767) | +317 (601) | +265 (338) | +182 (553) |
| Strength (SD) | +18.9 (15.0) | −10.2 (21.6) | +20.2 (13.6) | −13.2 (19.2) | +8.6 (25.2) | +19.4 (70.3) | +27.5 (28.0) | +8.7 (24.9) |

Δ, change from baseline; SD, standard deviation; BBT, Berg Balance Test; IG, intervention group; CG, control group; AP, anterior–posterior; ML, medial–lateral.
Values are given as mean, (+) increase and (−) a decrease.

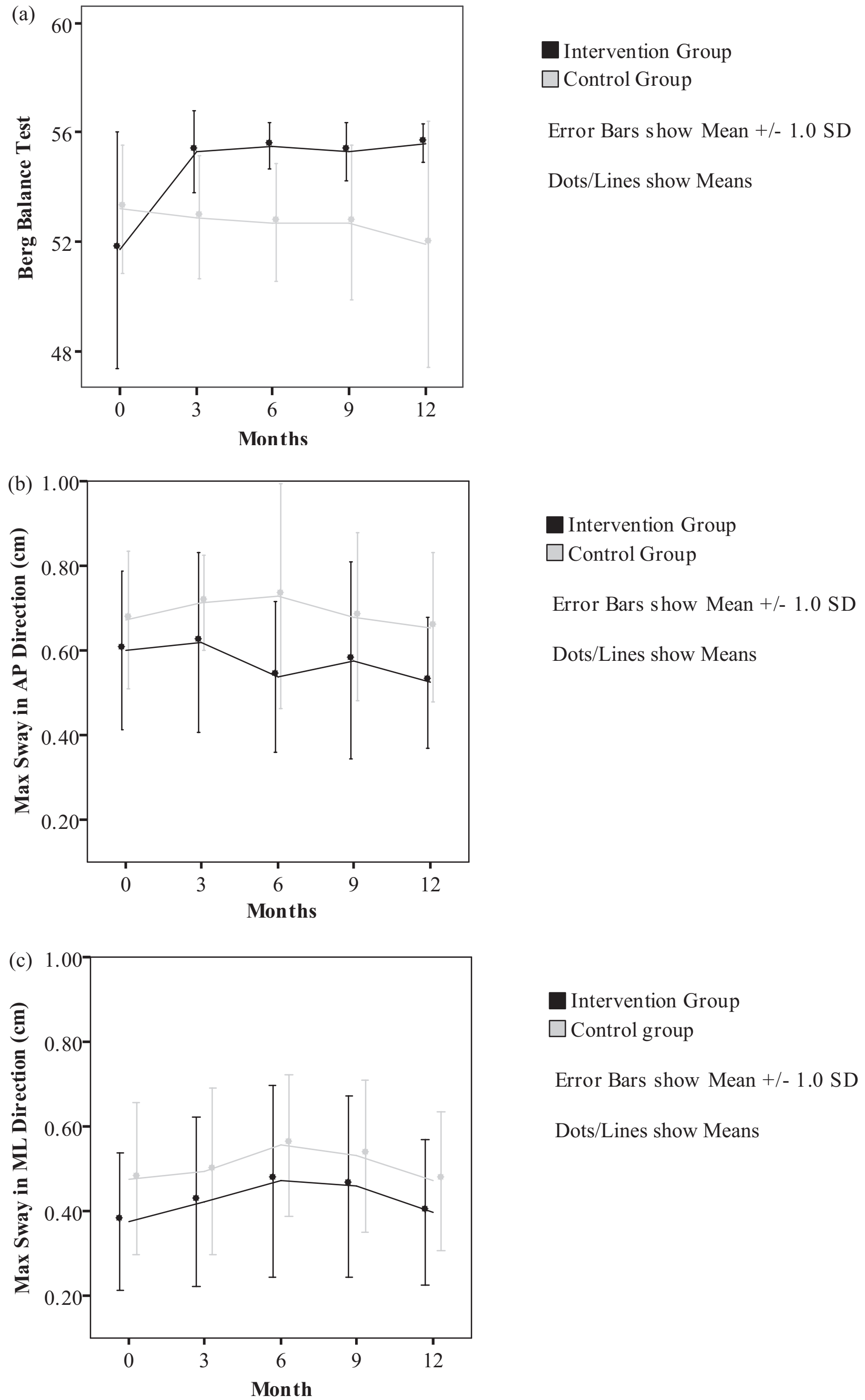


**Figure 2** (a) Outcome of the risk of falling (Berg Balance Test) and the postural balance in anterior–posterior (AP) and medial–lateral (ML) directions. (b) Outcome of the postural balance in AP direction. (c) Outcome of the postural balance in ML direction.

**Table 4** Biology and densitometry

| | Intervention group ($n = 10$) | | Control group ($n = 10$) | | ANOVA | |
|---|---|---|---|---|---|---|
| | T0 | T12 | T0 | T12 | *F* | *P* |
| WBC lean mass (g) (SD) | 31606 (4189) | 31209 (4201) | 35451 (4052) | 35269 (3850) | 0.05 | 0.83 |
| WBC fat mass (g) (SD) | 20654 (6381) | 20643 (6208) | 19879 (5780) | 20159 (5880) | 0.39 | 0.54 |
| WBC BMC (g) (SD) | 1662 (246) | 1659 (235) | 1940 (307) | 1959 (306) | 1.65 | 0.22 |
| Total hip BMC (g) (SD) | 25.7 (5.3) | 25.8 (5.1) | 27.3 (4.4) | 28.2 (4.4) | 7.52 | 0.01* |
| Total spine BMC (g) (SD) | 32.0 (5.7) | 32.7 (5.7) | 32.5 (8.4) | 34.0 (7.7) | 1.36 | 0.26 |
| Body mass index (SD) | 23.9 (3.0) | 23.8 (3.0) | 22.6 (3.0) | 22.5 (2.9) | 2.23 | 0.15 |
| D-Pyr/creat. (SD) reference value 3.0–9.5 (nmol/mmol) | 7.0 (1.6) | 7.1 (1.9) | 6.1 (2.0) | 6.7 (2.6) | 0.19 | 0.70 |
| 25-OH Vit. D (SD) reference value 10–42 (µg/L) | 31.10 (9.5) | 30.05 (6.9) | 31.80 (7.7) | 38.38 (10.8) | 4.00 | 0.06 |
| Total alkaline phosphatase (SD) reference value 3.4–19.8 (U/L) | 11.7 (4.7) | 9.3 (3.4) | 11.5 (3.0) | 11.1 (4.5) | 0.08 | 0.80 |

WBC, whole body composition; BMC, bone mineral content; D-Pyr/creat., deoxypyridinium/creatinine; 25-OH Vit. D, 25-OH vitamin D; SD, standard deviation; T0, baseline; T12, follow-up at 12 months.
*$P < 0.05$.

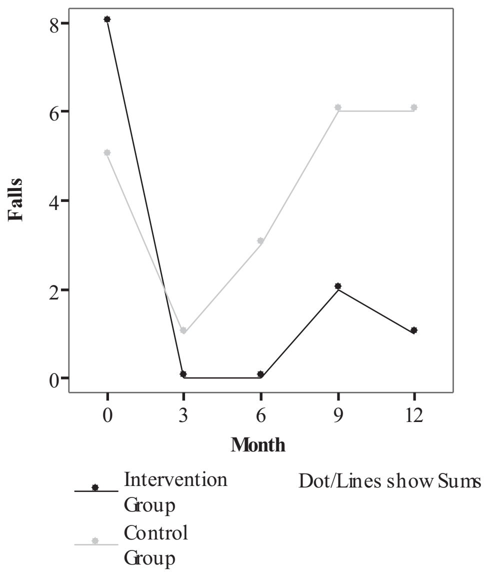


**Figure 3** Reported falls.

period in either group. Both groups had no change in the SF-36 questionnaire during the entire study.

## Discussion

We investigated whether the calcium/vitamin D supplementation intervention programme *plus* exercise/protein would have a larger effect on fall-related outcomes than a calcium/vitamin D supplementation only in elderly with low bone mineral density.

Our results showed a significant decrease in the risk of falling as a consequence of the three-month intervention programme. These changes were not observed in the control group.

However the Berg Balance Test showed a ceiling effect in the intervention group after the three-month intervention.[34] This indicates that the test chosen was too easy for most of the participants. Interesting are the two individuals with a score of less than 45 points at baseline. Subjects scoring under 45 points have a higher risk of falling.[35] These two participants showed a large improvement on the Berg Balance Test score after the intervention (from 43 to 50 and 44 to 56). They had had five falls before the study, which represented more than half of the total falls of the intervention group. However, these two individuals improved so much that only one suffered a single fall event within the 12-month follow-up period. No similar individual improvements were seen in the control group (Table 2).

We did not see any significant change within the postural balance measures. There was a reduction in AP direction between three and six months. This reduction remained when compared with the baseline values (Table 3). We expected that the patients of the intervention group would stay active after the three-month intervention, so that a positive effect on balance would remain even after the intervention itself finished. This expectation seemed to be confirmed by the Freiburg Questionnaire of Physical Activity data. The questionnaire showed a considerable increase in activity for the intervention group measured three months and six months following baseline assessment. A wear-off in questionnaire-determined activity was observed at 9 and 12 months. However, this did not result in significant differences between the intervention and control groups.

No change of postural control was found in maximal displacement of ML direction. One explanation for this finding is that lateral control is accomplished by the hip abductors/adductors while the forward–backward direction is controlled by the ankle plantar and dorsiflexors.[36] In our programme the exercise was focused on the anterior/posterior direction. Therefore quadriceps training was a major exercise in our programme.

Previous recommendations have stated that it is important to add protein supplementation when starting resistance strength training with the elderly.[12] The anabolic effect of starting resistance strength training in the elderly did not seem to take place in our intervention group, possibly due to the protein supplementation during the exercise period. This result is supported by the unchanged body mass index of our participants.

The number of falls dropped dramatically in both groups within the first three months (Figure 3). One reason for the reduction of falls within the control group could be the educational lecture given at the beginning of the study. Similar short-term patient education effects have been seen in rheumatoid arthritis patients.[37] However, these effects generally vanish over time. This was also observed in the present study. Within six months, the control group returned to the number of reported falls at baseline, whereas the intervention group stayed at a lower level.

The progression of osteoporosis slowed down in all participants in both groups. The significant change in total hip bone mineral content within the control group can be explained by the small size of the group and the fact that all participants received optimal individual osteoporosis treatment. Bone metabolism results showed that all the patients were within the reference value at baseline and at the end of the programme. Bone reabsorption activity decreased, but none of the changes were significant. It is possible that the groups were too small to detect a significant change. Future research should substantiate this assumption.

A limitation of our pilot study is the small number of participants. However, the collected data allow for the calculation of the sample size needed for a larger study that has enough power.[33,34] To avoid a type I or II error in a future study we need, based on our observed values (Table 2), an estimated sample size of 116 participants in total for a two group pretest–posttest design (mean SD). This would result in 80% power at an $\alpha$-level of 0.05.

Another limitation of the present study is that it is not possible to determine whether all parts of the calcium/vitamin D *plus* exercise/protein programme were needed in order to see a change or whether one individual part of the programme could be responsible for the change. Future studies, therefore, should compare different components of the programme. Also, a more defined fall assessment (e.g. fall calendar) would reduce imprecise fall data.

Furthermore, the generalizability of our study was limited as only women who were independent in the community with relatively well-preserved balance took part. A future study should strive to include men in order to be able to assess the effects of the interventions and generalizability. This issue should be addressed in a future study.

In conclusion, this study provides support for our intervention programme aimed at reducing the risk of falling in elderly participants diagnosed with osteopenia or osteoporosis. The data obtained from the pilot study will allow the power calculation of the actual sample size needed for a larger randomized long-term controlled trial aimed at studying potential beneficial effects.

## Clinical messages

- The combination of calcium/vitamin D and exercise/protein intervention programme reduced the risk of falling.
- These effects lasted up to nine months after the end of the intervention programme.

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## Competing interests

None.

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**Contributors**

JS is the guarantor, and designed and wrote the study. ED wrote and monitored the study. MS designed. TM wrote and monitored. DU initiated the study.

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## Appendix 1 – The exercise protocol and timetable

The progressive resistance training consisted of dynamic exercises and isometric exercises with fixed weights, within a certain range of motion. Barbells and dumbbells were used for training because of the co-ordinative aspects.[A1] The individual training load was determined with eight repetitions maximum. The training sessions comprised the completion of three sets of eight repetitions, with recovery periods of 1–2 minutes between sets. A personal training log, supervised by a physical therapist, was used to ensure a progressive loading (eight repetitions maximum) and to ensure individuality and security.[A1–A3]

The aim of the co-ordination/balance training was to stimulate the sensory information system (visual, vestibular and somatosensoric) and enhance the pace and adequacy of adaptive reactions. Thus the participants were trained to react in a more suitable way in dynamic situations with and without external disturbance. Examples are exercises with slow and fast movement and/or with eyes open and closed and/or with cognitive distraction whilst performing exercise.[A4]

### Exercise timetable

| | Monday | Wednesday | Friday |
|---|---|---|---|
| 25 min | Progressive resistance Steps, squats, back-extension, leg-press | | Progressive resistance Steps, squats, back-extension, leg-press |
| 25 min | Isometric exercise Coordination/ balance Wobble board, balance board | | Isometric exercise Coordination/ balance Wobble board, balance board |
| 45 min | | Group exercise Balance, games | |
| >20 min | Endurance Exercise bike | Endurance Exercise bike | Endurance Exercise bike |

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