



EFFECT OF A BALANCE-TRAINING PROGRAMME ON POSTURAL BALANCE, AEROBIC CAPACITY AND FREQUENCY OF FALLS IN WOMEN WITH OSTEOPOROSIS: A RANDOMIZED CONTROLLED TRIAL

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Objective: To investigate the effect of a 12-month complex balance-training programme on static and dynamic postural balance, aerobic capacity and frequency of falls in women with established osteoporosis.

Design: Randomized controlled trial in which the intervention group was assigned a 12-month exercise programme (3 times a week for 30 min) and the control group had no intervention.

Subjects: A total of 100 osteoporotic women with at least one previous fracture.

Methods: Performance-based Timed Up and Go (TUG), Berg Balance Scale (BBS) and stabilometric platform tests were used to evaluate balance. Aerobic capacity was measured by bicycle ergometry.

Frequency of falls was assessed using a falls diary.

Results: After 1 year, there was a statistically significant difference between the improvement achieved in the intervention and control groups on the performance-based TUG, BBS and stabilometric platform tests ($p < 0.05$). Mean metabolic equivalent (MET) value decreased in the intervention group, from 4.91 to 3.82 (a significant difference from the change achieved in the control group; $p = 0.05$). Relative risk of falls was 0.534 at 1 year ($p = 0.17$).

Conclusion: The 12-month balance-training programme significantly improved postural balance and increased aerobic capacity in women with established osteoporosis.

Key words: osteoporosis; accidental falls; balance; exercise programme.

Accepted Apr 4, 2018; Epub ahead of print May 16, 2018

J Rehabil Med 2018; 50: 542–547

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Most anti-osteoporotic medications introduced in the last 2 decades aim primarily to improve bone mineral density. Some of these medications reduce the risk of fracture as well as increasing bone mineral density, but falls, often, still result in osteoporotic fracture, despite optimized therapy and increased mineral density. Furthermore, falls are responsible for 90% of the increase in hip fractures, worldwide (1). One-third of the worldwide population over 65 years is reported to fall at least once a year, 10–15% of these

MAIN MESSAGE

Loss of balance and falling are serious risk factors for patients with osteoporosis. Falls often result in fractures that require medical attention and may even be fatal. In addition to pharmacological therapy, there is clinical evidence to support the importance of exercise to prevent falls and improve balance. The effect of a 1-year complex balance-training programme, combining exercises to improve postural balance with aerobic elements, was studied in female patients with established osteoporosis. The women in the exercise group improved their postural control and balance, increased their aerobic capacity, and had fewer falls than those who did not undertake the exercise programme.

falls result in fractures, and nearly 60% of those who have experienced a fall in the previous year fall again (2). Gillespie and colleagues (3) find that although 1 in 5 falls may require medical attention, fewer than 1 in 10 results in a fracture. As for hip fractures, the mortality rate in the year following the fracture is over 20% worldwide, which is in line with that of thyroid or breast cancer. Loss of function and autonomy among survivors of hip fracture is a further concern, as well as the 24-h care that may be required (4). Approximately 200 million people are affected by osteoporosis and 8.9 million fractures occur every year worldwide (5). Therefore, both primary and secondary fracture prevention are essential, including the prevention of falling, which is a major risk factor.

The effectiveness of exercising, alongside pharmacological therapy, has been studied by Howe et al. (6) in preventing bone loss and fractures in postmenopausal women. Further large-scale studies have investigated the effect of training programmes on balance in older people (3, 7), and have shown that loss of balance ability through weakened postural control is one of the greatest risk factors for falls in patients with established osteoporosis¹ (7). Ordu Gokkaya et al. (8) found significantly impaired pulmonary function, aerobic capacity and serious deconditioning in severely osteoporotic patients. A decrease in physical activity levels

¹ 'Established' osteoporosis is the WHO definition of osteoporosis when the patient has already had one or more fragility fractures.

and aerobic capacity can result in changes in balance, increased susceptibility to falls, and impairment in functional capacity in older age (9–11). Therefore, in addition to strengthening postural control and balance, improving aerobic endurance has a key role to play in reducing the risk of falls among patients with established osteoporosis.

The aim of this study was to determine whether a 12-month complex exercise programme, combining postural balance-improving exercises with aerobic elements, can significantly improve postural control, increase aerobic capacity and reduce the frequency of falls among women with established osteoporosis compared with those who do not undertake such a programme.

METHODS

Participants

Women who underwent osteodensitometry in the Osteoporosis Centre of the National Institute of Rheumatology and Physiotherapy, Budapest, Hungary, in the year prior to the study were selected to be enrolled in the trial according to the following criteria.

Inclusion criteria. Age over 65 years; community-dwelling (living on their own, with or without a partner); established postmenopausal osteoporosis based on the World Health Organization (WHO) criteria (T-score below –2.5 standard deviations (SD) in lumbar spine, femur neck or total femur region) (12); and at least 1 osteoporotic fracture in their personal medical history.

Exclusion criteria. Significant degenerative spine disorders; congenital or acquired deformity of the spine, thorax or feet; traumatic fracture; severe visual or auditory impairment; neuromuscular diseases; organic psychosyndromes; advanced cardio-respiratory or cerebrovascular diseases; predisposition to orthostasis or hypoglycaemia; use of assistive walking devices; inability to walk 10 m independently; participation in clinician-guided exercise programme (as osteoporotic therapy) in the previous 6 months.

Ethics approval was obtained from the Semmelweis University Regional and Institutional Committee of Science and Research Ethics (trial registration number 152/2010). All participants were informed about the study, had the opportunity to ask questions, and provided written consent prior to the study.

The study was performed between 1 January 2011 and 31 March 2012 at the Osteoporosis Centre of the National Institute of Rheumatology and Physiotherapy.

Study design and outcomes

A total of 100 participants were randomly assigned to the intervention or control groups; randomization was performed

based on the assigned number in the patient diary (using a numbered series of pre-filled envelopes specifying the group). Individuals in both groups continued to receive their standard anti-osteoporotic medication (e.g. calcium and vitamin D). The intervention group ($n=50$) attended a complex balance-training programme, while the control group ($n=50$) did not undertake any clinician-guided physical exercise programme (Fig. 1). A physiotherapist blinded to the study groups assessed participants' balance in static and dynamic positions and a blinded intern assessed the aerobic capacity in both groups at the start and end of the study. Patients kept a falls diary, in which they recorded the number of times they fell every month and posted it back to the blinded physiotherapist.

The static and dynamic postural balance of all participants were measured at the start and end of the trial with a computer-controlled device, the Bretz stabilometer (13); furthermore, performance-based Timed Up and Go (TUG) and Berg Balance Scale (BBS) tests were used according to their respective protocols (14, 15).

The Bretz stabilometer, a device similar to other new balance assessment tools (16, 17), has proven to be a reliable device for the quantitative assessment of changes in postural sway necessary to regain balance. This enables both static and dynamic posturometric examination to be performed.

Bretz stabilometer measurements

Balance in the static posture was assessed with the Romberg test, carried out in 2 positions. Movement of the patient's centre of pressure (CP) was analysed with the patient standing straight, with eyes open ("Romberg" 1 position) and eyes closed ("Romberg" 2 position) for 20 s. A practice measurement was conducted in all participants. The motion of the patient's CP was visualized on a monitor during the assessment and was subsequently stored on a personal computer for further evaluation. During the test, participants were asked to minimize

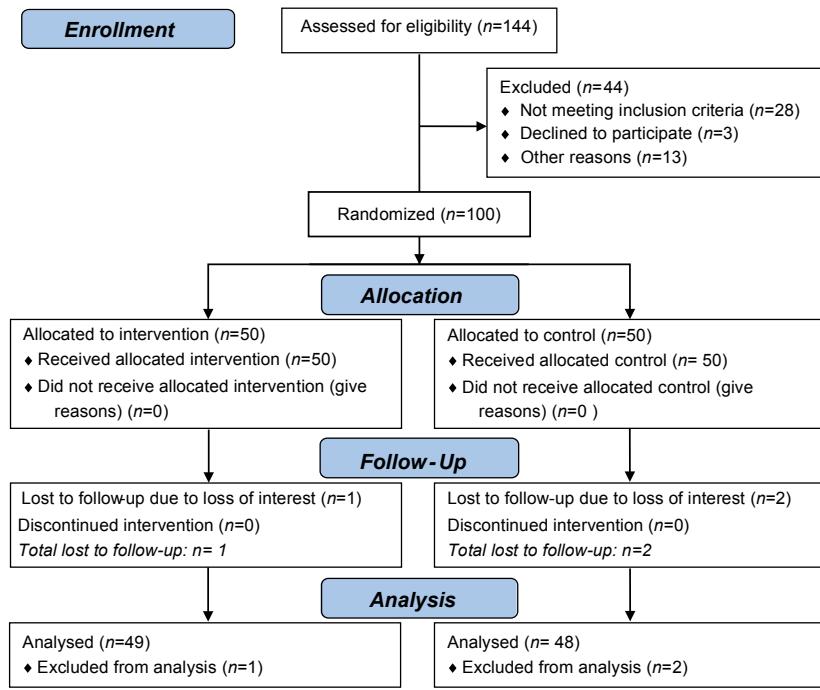


Fig. 1. CONSORT 2010 Flow Diagram.

movement of the CP without looking at the screen, to measure postural sway. Stabilometer software was used to evaluate the movement of the CP, enabling determination of its lateral movement, movement backwards and forwards, the total length of its movement (all in mm), and the radius of the circle that covered 95% of the motion path.

To evaluate dynamic postural balance, participants had to complete 3 tasks (coordination tests 1, 2 and 3), in which they had to move their CP individually according to the specific task. The monitor was placed in front of the participants at a distance of 1.5 m, 1.1 m above the floor, and different figures were displayed to them that formed the basis of the exercise. All participants could practice the exercise once before measurements were taken. The programme evaluated the results automatically and data were stored on computer for further analysis.

Coordination test 1. A triangle ("idealized pine tree") was displayed on the monitor, with the corners and midpoints of the sides marked as the target points ("candy form"). Participants had to move their CP so as to reach these target points as quickly as possible. When their CP covered all the target points, the figure disappeared from the screen, noting successful completion of the task. Participants had 20 s to accomplish this task. Performance on the test was based on the percentage of points removed from the monitor display within 20 s. If all points were reached, the time taken to perform the task was recorded.

Coordination test 2. Participants had to direct the cursor signalling the position of the CP into an asymmetrically located point on the monitor. The programme calculated the performance time (in s).

Coordination test 3. A 2×2 cm square was displayed in the middle of the screen. Participants had to move their CP so that it coloured as much of the square's territory as possible in 20 s, while minimizing the time spent outside the box. They could see the motion of the CP and the coloured area on the monitor. Dynamic posture balance was assessed and described by the size of the area the participant managed to colour within the time limit by moving the CP (as a % of the total area). In addition, the time the CP remained within the square was measured and recorded (as a % of the total time).

Performance-based balance tests

The TUG is a simple test to evaluate a patient's mobility. It assesses the time individuals need to rise from a chair, walk 3 m, turn, walk back to the chair and sit down. Patients are asked to walk at a speed that feels safe for them to complete the task. Less than 10 s is considered normal mobility, and 10–20 s is acceptable in the older population or those with movement disability (14).

The BBS was used for a computerized performance-based assessment of balance. It takes 15–20 min to complete. The patient is required to accomplish 14 simple balance-related tasks; for example, standing up from a sitting position. The tasks are scored from 0 to 4, 0 indicating that the patient is unable to perform the task, 4 points are given when the patient completes the task completely and independently. The final score on the BBS is the sum of the points received for each task. In this study we used a score between 41 and 56 points to indicate that a patient could walk independently (15).

Bicycle ergometry measurement of aerobic capacity

Bicycle ergometry measurements were made following the Bruce protocol (18). After a 1-min warm-up at 10 watts (W), the exercise started from 0 W, with an increment of 25W/3 min. Speed and resistance were increased periodically and

repeatedly (cardiac work and oxygen demand increase in parallel with physical workload); at the end of the test there was a 5-min cool-down at 10 W. Maximum heart rate was calculated by subtracting the patient's age from 220. Ergometry measurements took approximately 30 min. The test finished when participants reached the target heart rate, experienced angina during the exercise, had a significant blood pressure elevation, or any abnormal electrocardiogram (ECG) patterns appeared.

Since, due to fatigue, some of the participants in the older age group could not reach the target heart rate, maximum rate of oxygen consumption (VO_2) could not be calculated in all cases. Metabolic equivalent (MET) was therefore used to characterize their aerobic capacity (1 MET = 3.5 ml/min/kg at rest). The intensity of the workload is thus expressed by a number that shows the extent to which the exercise completed by the patient increased VO_2 . The fitter the patient, the lower the value of MET, i.e. the lower oxygen consumption is when completing a given task.

Frequency of falls

Falls are defined as an unexpected loss of balance resulting in coming to rest on the floor, ground, or an object below knee level (19). Participants were provided with a falls diary consisting of monthly fall sheets, on which they could record whether they had fallen (with a cross) or not fallen (with a tick) each day. Participants were asked to record the fall as soon as it happened or at the end of the day and return the fall sheets in pre-addressed envelopes every month. Fall sheets were collated by the blinded physiotherapist leading the assessments, who also followed up monthly with the patients regarding any missing fall diaries.

Interventions

The complex balance-training programme compiled by our physiotherapists combined postural balance-improving exercises and aerobic elements that were completed in the outpatient setting as well as at home. Patients attended the programme 3 times a week for a 30-min physiotherapist-guided sessions, and received printed materials regarding exercises they could practice at home on days they did not attend an exercise session at the hospital. The exercises patients completed at home were less complex postural control exercises and included elements from the Otago exercise programme, a controlled fall prevention programme designed to improve muscle strength and balance, which has been shown to reduce the number of falls by approximately 30% (20).

Our balance-training programme is a combination of functional stabilization training and exercises focusing on improving balance, and it therefore includes conventional back, torso and lower extremity muscle strengthening exercises as well as proprioceptive dynamic posture training (21). This training follows a learning principle with a focus on strengthening the transversus abdominis and multifidus muscles, thus enhancing stability through improving the function of the deep postural muscles. The training programme was adapted for older participants who have an elevated risk of falls by combining elements from the Otago programme with exercises that aim to strengthen the torso and improve balance.

There are 3 levels of progressivity in our exercise programme, which are performed in a step-wise manner (one phase needs to be completed to allow progression to the next level). The first, static phase, focuses on stabilization. Participants practice maintaining static posture, first in a sitting position then progressively moving onto standing on both feet, leading to unilateral support of standing on one foot. The exercises were made progressively more difficult by changing the size or quality of the supporting

surface (e.g. using unstable surfaces, such as a stability trainer or Dynair cushion, thereby making the body's centre of gravity position more difficult to maintain). In the second, dynamic phase, additional arm and leg exercises are performed once the exercises in the static phase can be performed confidently. The therapeutic effect is increased by varying the speed of the movement and by adding elastic resistance using elastic straps. In the final, functional phase, the goal is to achieve automatic stabilization of the torso when performing different exercises and activities of daily living. The functional phase also assists participants in developing stabilization skills when changing position and posture during sports and work activities.

Participants in the intervention group were also asked to complement their exercise programme with regular walking, for which they received a structured schedule compiled by the physiotherapists. The walking programme consisted of 25–35 min walks that included 2–3-min fast-paced intervals. The walks got progressively more difficult by including more frequent fast-paced intervals. The aim of the walking programme was to complement the balance-training programme with aerobic elements and thus to increase participants' aerobic capacity. Participants discussed the progress of the walking programme with the physiotherapists at their regular exercise appointments.

Statistical methods

Sample size justification was not performed at the beginning of the study because all eligible patients in our database had been considered for inclusion in the study. Statistical analysis was carried out using SPSS version 19.0 for Windows software. The baseline characteristics of the participants were analysed using descriptive statistics. Independent-sample *t*-tests and Mann–Whitney *U* tests for continuous data and χ^2 test for categorical data were used to compare baseline values of the intervention and control groups and to determine whether there was a statistically significant difference between the outcomes of the intervention and control groups after the intervention, i.e. between-group difference in change scores (statistically significant difference was considered at $p < 0.05$).

RESULTS

Anamnestic and demographic (baseline) data were collected before randomization, using a questionnaire. The results are summarized in Table I. Participants' mean age was 69.33 and 69.10 years in the intervention and control groups, respectively ($SD = 4.56$ years in the intervention and 5.30 years in the control group). Of the total number of 144 osteoporotic women screened,

Table I. Baseline characteristics of participants ($n = 100$)

Group	Intervention group ($n = 50$)	Control group ($n = 50$)
Age, years, mean (SD)	69.33 (4.56)	69.10 (5.30)
Body mass index, mean	24.17	24.38
Medical history, n (%)		
Hip osteoarthritis	1 (2)	0 (0)
Knee osteoarthritis	2 (4)	3 (6)
Diabetes mellitus	6 (12)	4 (8)
Hypertension	29 (58)	31 (62)
Pulmonary disease	2 (4)	1 (2)

SD: standard deviation.

100 met the inclusion criteria and were eligible to enrol in the trial. Subjects who were excluded following screening either did not meet the inclusion criteria (most often because they had not had an osteoporotic fracture in the past) or were excluded due to the exclusion criteria (see "Other exclusions"; Fig. 1).

In terms of postural balance assessments, performance-based TUG and BBS test scores showed a statistically significant difference between the intervention and control groups after 1 year ($p < 0.005$; Table II).

Both static postural balance tests assessed by stabilometer showed significant improvement at the end of the trial, including the "Romberg 1" and "Romberg 2" positions ($p \leq 0.001$; Table II).

During Coordination test 1, to evaluate dynamic postural balance, the mean time needed to fulfil the task was calculated. Coordination test 2 also measures the mean performance time. There was a statistically significant improvement in the intervention group after 1 year on both tests ($p < 0.003$; Table II). Coordination test 3 determines the period of time the CP is located within the designated area (as a % of the total area). There was a significant improvement in this measure as well in the intervention group ($p = 0.01$; Table II).

Regarding assessment of aerobic capacity by bicycle ergometry, during the 1-year programme the registered initial MET values of the intervention group were bet-

Table II. Results of static and dynamic postural tests at baseline and 1-year assessment

Tests	Intervention group, $n = 49$ (95% CI)	Control group, $n = 48$ (95% CI)	<i>p</i> -value
TUG (mean time, s)			
Baseline	8.89 (6.77, 11.01)	9.95 (6.46, 13.44)	
1 year	6.74 (5.84, 7.64)	10.64 (6.62, 14.66)	
Absolute change	-2.15 (-2.56, -1.72)	0.69 (-0.23, 1.62)	0.005*
BBS (mean time, s)			
Baseline	49.23 (46.63, 51.83)	48.52 (38.72, 58.32)	
1 year	42.27 (40.47, 44.07)	50.15 (44.95, 55.35)	
Absolute change	-6.96 (-7.47, -6.44)	1.63 (-0.27, 3.54)	0.001*
Romberg 1 (open eye; mean radius, mm)			
Baseline	14.25 (11.65, 16.85)	13.73 (10.49, 16.97)	
1 year	10.47 (8.77, 12.17)	14.50 (12.12, 16.88)	
Absolute change	-3.78 (-4.24, -3.31)	0.77 (0.11, 1.42)	0.001*
Romberg 2 (closed eye; mean radius, mm)			
Baseline	20.87 (18.17, 23.57)	19.76 (16.16, 23.36)	
1 year	16.07 (13.87, 18.27)	19.75 (17.15, 22.35)	
Absolute change	-4.80 (-5.48, -4.11)	-0.01 (-0.82, 0.79)	0.001*
Dynamic 1 (mean time, s)			
Baseline	13.15 (8.62, 17.68)	13.25 (7.75, 18.75)	
1 year	11.05 (6.94, 16.06)	14.00 (9.06, 18.94)	
Absolute change	-2.10 (-3.38, -0.83)	0.75 (-0.65, 2.15)	0.001*
Dynamic 2 (mean time, s)			
Baseline	5.74 (0.44, 10.77)	5.80 (1.20, 10.40)	
1 year	4.22 (0.42, 8.02)	5.57 (0.87, 10.27)	
Absolute change	-1.52 (-2.72, -0.31)	-0.23 (-1.70, 1.25)	0.003*
Dynamic 3 (% of assigned time spent within boundaries)			
Baseline	88.07 (79.20, 97.57)	88.87 (80.13, 97.61)	
1 year	93.72 (87.12, 100.32)	88.76 (80.86, 96.66)	
Absolute change	5.65 (3.74, 7.53)	-0.11 (-2.04, 1.82)	0.001*

95% CI: 95% confidence interval; TUG: Timed Up and Go test; BBS: Berg Balance Scale; *Significant result.

ween 2.40 and 7.80, with a mean of 4.91 (SD 1.33). In the control group, the initial mean MET value was 4.83 (SD 1.26). The difference between the 2 initial mean values was not significant. One year later the mean value in the intervention group had decreased to 3.82 (SD 1.25) in the intervention and to 4.95 (SD 1.36) in the control group, with a significant difference between the groups in terms of the change scores ($p=0.05$).

As for the frequency of falls, 6 patients in the intervention group fell, and 11 patients in the control group fell. There were a total of 7 and 16 falls in the intervention and control groups, respectively. Therefore, the experimental event rate for the number of patients who fell was 0.122 and the control event rate was 0.229, thus the relative risk of falls is 0.534 ($p=0.17$).

There were no reported adverse events due to the exercise programme, and those participants who completed the programme had high adherence (over 80%). Participants who were lost to the study were not included in the analysis because they were lost at the beginning of the study (mainly due to loss of interest).

DISCUSSION

The most important goal of osteoporosis therapy is the prevention of fragility fractures, and thus improvement of patients' mobility, quality of life and preservation of their independence. Currently available therapies for advanced osteoporosis significantly increase bone mineral density and therefore limit the risk of fracture; however, it is also known that when osteoporotic patients fall they tend to suffer a fracture despite anti-osteoporotic medication (5). Prevention of falls in older osteoporotic patients is further complicated by a number of fall risks, such as impaired sight and hearing, muscle strength and proprioception. It is therefore necessary to use an exercise programme that is proven to reduce the frequency of falls in this population in order to optimize treatment.

A large number of studies have been conducted to investigate the effect of different exercise programmes on balance ability in osteoporotic patients (22–28). Most of them used performance-based tests, mainly TUG and BBS, to assess the efficacy of these programmes. Studies analysing movement of the centre of mass (i.e. the change in balance position) using a computer-based technique (16, 17) represent a quantitative assessment in addition to performance-based tests.

The primary significance of this study is that both performance-based and computer-based methods were used to evaluate the effect of a complex exercise programme on postural balance and staying power in women with advanced osteoporosis. This study is also novel in that traditional strengthening exercises of the back, trunk and lower extremities were combined

with elements of proprioceptive posture training (29). These exercises need to be carried out with caution in osteoporotic patients, given their high complexity and thus increased difficulty compared with conventional strengthening exercises. Participants in this study exercised with respect to anti-gravitation load, in both sitting and standing positions, which supported them in practising common everyday life situations and activities encountered in their daily lives.

Another novelty and strength of the current study is that, using bicycle ergometry, it assessed aerobic capacity as one of the most important indicators of stamina. Results of ergometry provided evidence that a balance-training programme combined with aerobic elements simultaneously influenced the muscular, respiratory and cardiovascular systems, leading to improved aerobic capacity. This resulted in a more precise performance of the exercises, reduced completion time and improved participants' mobility by the end of the programme by ameliorating the sensomotor system, rendering clinical significance for this study. The intervention group performed significantly better in keeping balance (a crucial factor in prevention of falls), which was confirmed by performance-based tests, static and dynamic posturometric tests assessed by stabilometer and a decrease in the frequency of falls (although this was not significant).

This study has some limitations. The randomization method may have introduced bias; however, this is unlikely because the assignment sheet was locked away in a secure office by the investigator from the person who generated the allocation sequence. Complete blinding was not possible, as physiotherapists leading exercise sessions were knowledgeable about the participants in the intervention group. Sample size justification was also not conducted at the beginning of the study, which might have reduced the study power and the ability to generalize based on the results; however, all potentially available patients were screened for the study. Furthermore, while participants were exercising and walking at home, they were not supervised by a physician, which could have had a negative impact on the quality of the exercises performed. During bicycle ergometry, the MET was used to measure aerobic capacity, rather than $\text{VO}_2 \text{ max}$, due to exhaustion of older participants during this assessment. Fall diaries were only checked monthly by physiotherapists, and participants may not have accurately recorded their falls as this was not supervised. The results are only able to offer generalization as far as postmenopausal, community-dwelling women with established osteoporosis are concerned.

In conclusion, regular exercise is indispensable, in addition to medical therapy, for patients with established osteoporosis. Combining elements of traditional exercises, sensomotor training and aerobic exercises

has proven effective in improving postural balance, increasing aerobic capacity and preventing falls. Therefore, this type of exercise programme, adapted to osteoporotic patients with high risk of falling, is recommended for inclusion in the physiotherapeutic protocol for this population.

- Completing a complex balance-training programme including traditional exercises, sensomotor training and aerobic exercises can improve postural balance in women with established osteoporosis.
- Completion of the combination balance-training programme can also significantly increase the aerobic capacity of patients.
- Balance improvements in osteoporotic women of older age can be measured and assessed quantitatively by stabilometric tests in addition to performance-based tests.

ACKNOWLEDGEMENTS

The success of this research was greatly contributed to through the work of Professor Károly Bretz, Klára Tóth, Csilla Éltető, Bernadette Monek, physiotherapists, Erzsébet Nátly, Mária Mátyás assistants, Ádám Mester, MD, PhD radiologist, and Dr Márton Pálinkás, MD.

Ethical approval. The trial was approved by the regional ethics committee (Semmelweis University Regional and Institutional Committee of Science and Research Ethics).

The authors have no conflicts of interest to declare.

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