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**EFFECT OF A COMPLEX EXERCISE PROGRAMME ON
POSTURAL BALANCE, ENDURANCE AND FALLS IN WOMEN
WITH ESTABLISHED OSTEOPOROSIS**

Summary Ph.D. Thesis

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INTRODUCTION

Osteoporosis is the most common cause of fragility fractures because of reduced density and quality of bone. The lifetime risk of osteoporotic fracture from age 60 in men has been estimated to be between 10-25%, in women 40-48 % depending on the population studied. In older populations of osteoporosis, additional significant risk factors for the age are impaired sight and hearing, muscle strength and proprioception.

Falls are responsible for 90% of the increase in hip fractures, which are the most serious osteoporotic fractures. One third of the worldwide population over 65 years is reported to fall at least once a year, 10-15% of these falls result in fractures, and nearly 60% of those who have experienced a fall in the previous year fall again. As for hip fractures, the mortality rate in the year following the fracture is over 20%, which is in line with that of thyroid or breast cancer. Loss of function and autonomy among the survivors is a further concern as well as the continuous 24-hour care required in several cases.

Taking all these into account, the most important goal of osteoporosis therapy is the prevention of fragility fracture and thus the improvement of patients' mobility, quality of life and the preservation of their self-sufficiency. The currently available therapies in 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 antiosteoporotic medication. Therefore it would be necessary to use an exercise programme which has been shown to improve patient balance, as a key to preventing falls, in this population to optimize treatment.

The effectiveness of exercising, alongside pharmacological therapy, has been studied 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 and have shown that loss of balance ability through weakened postural control is of the greatest risk factors for falls in patients with established osteoporosis. Another studies pointed out significantly impaired pulmonary function, aerobic capacity and a serious deconditioning in severely osteoporotic patients. A decrease in physical activity levels and in aerobic capacity can result in changes in balance, increased susceptibility to falls, and impairment in the functional capacity in older age. Based on these evidences the successful decrease of the risk of fragility fractures in advanced osteoporosis can be accomplished if the antiosteoporotic

medication has been combined with complex exercise programme, which improves the patients' balance control and furthermore the aerobic endurance.

Aim of our study was to investigate the efficacy of a complex exercise programme, including traditional physical exercise's elements, sensomotor and aerobic training with different progressivity levels. In terms of postural balance assessments, both performance-based and quantitative static and dynamic postural balance tests assessed by stabilometer were used. Regarding the assessment of aerobic capacity, which is one of the most important indicators of aerobic endurance, bicycle ergometric, and spirometric examinations were carried out. Our work can be an additional possibility in the treatment of advanced osteoporotic women.

AIMS OF THE THESIS

I. The aim of our study was to investigate the effectiveness of a 12-month sensomotor balance training programme combined with aerobic elements. As a primary endpoint, we aimed to monitor changes in postural control in women with established osteoporosis using both performance tests and a computerised stabilometer. The secondary endpoint was to record the frequency of falling.

II. In our study we sought to find an answer to the question as to whether in response to a 12-month sensomotor balance training programme combined with aerobic elements any meaningful change occurs in the aerobic endurance of women with advanced and established osteoporosis as indicated by ergometric and spirometric results.

ETHICAL ASPECTS

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

STUDY METHODS

Individuals who underwent osteodensitometry in the Osteoporosis Centre of the National Institute of Rheumatology and Physiotherapy in the year prior to the study were selected to be enrolled in the trial according to the following criteria. Inclusion criteria: aged over 65 years, community-dwelling (living on their own, with or without a partner), established postmenopausal osteoporosis based on the WHO criteria (T-score \leq -2.5 SD in lumbar spine, femur neck or total femur region) and at least one 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 metres independently, participation in clinician-guided exercise programme (as osteoporotic therapy) in the previous six months. 100 participants were randomly assigned to the intervention or the control group;

randomization was performed based on the assigned number in the patient diary. Individuals in both groups continued to receive their standard antiosteoporotic medication, the intervention group (n=50) attended a complex balance exercise programme, while the control group (n=50) did not do any clinician-guided physical exercise programme.

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

To characterize patient endurance, aerobic capacity was measured by a bicycle ergometer expressed in metabolic unit (MET) at the beginning and end of the test. To further evaluate patient stamina, the spirometer was used, where one of the most important parameters, the vital capacity was measured in litres under standardized conditions at the beginning and end of the programme.

To measure frequency of falls participants were provided with a falls diary consisting of monthly fall sheets, in which they could record whether they have fallen (with a cross) or not each day (with a tick).

The complex balance exercise 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 three times a week for a 30-minute physiotherapist-guided session and they also received printed materials of 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. There are three levels of progressivity in our physiotherapist-guided sensomotor balance exercise programme and it is a combination of functional stabilization training and exercises focusing on improving balance. It therefore includes conventional back, torso and lower extremity muscle strengthening exercises as well as proprioceptive dynamic posture training, modified in its sensomotory elements in order to improve balance control and reduce falling in the study population. Participants in the intervention group were also asked to complement their exercise programme with regular walking, for which they received a structured schedule put together by our physiotherapists. The aim of the walking programme was to complement the balance exercise programme with aerobic elements and thus to increase participants' aerobic capacity.

A 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 $p < 0.05$). Relative risk (RR) was also calculated for falling.

RESULTS

The participants' average age was 69.33 and 69.10 years in the intervention and control group, respectively. According to the inclusion and exclusion criteria, 100 osteoporotic women out of the 144 screened could enrol in the trial.

RESULTS SUPPORTING THESIS I.

In terms of postural balance assessments, performance-based Timed Up and Go and Berg Balance Scale tests scores showed a statistically significant difference between the intervention and the control groups after one-year follow-up (TUG $p < 0.005$, BBS $p < 0.001$).

Both static postural balance tests assessed by stabilometer showed significant improvement at the end of the trial, including the 'Romberg I' and 'Romberg 2' positions (Romberg 1' $p < 0.001$, Romberg 2' $p < 0.001$).

During Coordination test 1 to evaluate dynamic postural balance we calculated the average time one needed to fulfil the task; Coordination test 2 also measures the average performance time. We found a statistically significant improvement in the intervention group after one year on both tests (Coordination 1 $p < 0.001$, Coordination 2 $p < 0.003$). Coordination test 3 determines the period of time the CP is located within the designated area (as a % of the total area). We found a significant improvement on this measure as well in the intervention group ($p < 0.001$).

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

RESULTS SUPPORTING THESIS II

Regarding the assessment of aerobic capacity by bicycle ergometry, the registered initial MET values of the intervention group and control group were similar, the difference between the two initial average values was not significant. A year later the average value in the intervention group decreased with a significant difference between the two in terms of the change scores (MET $p < 0.0017$).

During spirometry, at the beginning of the test, there was no significant difference between the vital capacity results of the intervention and control groups. In measurements taken after a year, the absolute change of the average vital capacity value in the intervention group was remarkable. The difference in absolute values between the two groups was significant (Vitalcapacity $p < 0.01$).

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

DISCUSSIONS, CONCLUSIONS AND NEW RESULTS

I. Based on our randomised, controlled study conducted among women with established osteoporosis, it appears that the intervention group which completed a sensomotoric balance training programme performed significantly better in keeping balance (a crucial factor in prevention of falls), which was confirmed by performance-based tests such as Timed Up and Go and Beg Balance Scale tests as well as by static and dynamic posturometric tests assessed using a quantitative Bretz stabilometer. There was no significant difference in the number of falls at the end of the one-year balance training programme; it is

remarkable, however, that at the end of the programme there were half as many falls among participants of the intervention group as in the control group.

II. The results of our investigation suggest that a sensomotor balance training programme combined with aerobic elements significantly improves the aerobic capacity, assessed by bicycle ergometry and spirometry, as one of the most important indicators of aerobic endurance.

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. These exercises need to be carried out with caution in osteoporotic patients, given their high complexity and thus increased difficulty compared to conventional strengthening exercises. Participants in this study exercised with respect to antigravitation load, both in sitting and in standing positions, which supported them in practising common everyday life situations and activities encountered in their daily lives.

Another novelty and strength of our study is that by means of bicycle ergometry and spirometry, we assessed aerobic capacity as one of the most important indicators of stamina. Results of ergometry and spirometry provided evidence that balance exercise programme combined with aerobic elements influenced simultaneously the muscular, respiratory and cardiovascular systems and resulted in improved aerobic endurance. 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. Our results confirm our hypothesis that exercise programmes, which aim to address reduced proprioception, to strengthen sensomotor function and aerobic capacity, in addition to strengthening muscles and endurance, are effective in reducing the number of falls owing to balance instability for established osteoporotic women.

Therefore, this type of exercise programme, adapted to osteoporotic patients with a high risk of falling, is recommended for inclusion in the physiotherapeutic protocol for this population.

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