ORIGINAL ARTICLE

Efficacy of a Short Multidisciplinary Falls Prevention Program for Elderly Persons With Osteoporosis and a Fall History: A Randomized Controlled Trial

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ABSTRACT. Smulders E, Weerdesteyn V, Groen BE, Duysens J, Eijsbouts A, Laan R, van Lankveld W. Efficacy of a short multidisciplinary falls prevention program for elderly persons with osteoporosis and a fall history: a randomized controlled trial. Arch Phys Med Rehabil 2010;91:1705-11.

Objective: To evaluate the efficacy of the Nijmegen Falls Prevention Program (NFPP) for persons with osteoporosis and a fall history in a randomized controlled trial. Persons with osteoporosis are at risk for fall-related fractures because of decreased bone strength. A decrease in the number of falls therefore is expected to be particularly beneficial for these persons.

Design: Randomized controlled trial.

Setting: Hospital.

Participants: Persons with osteoporosis and a fall history (N=96; mean ± SD age, 71.0±4.7y; 90 women).

Intervention: After baseline assessment, participants were randomly assigned to the exercise (n=50; participated in the NFPP for persons with osteoporosis [5.5wk]) or control group (n=46; usual care).

Main Outcome Measures: Primary outcome measure was fall rate, measured by using monthly fall calendars for 1 year. Secondary outcomes were balance confidence (Activity-specific Balance Confidence Scale), quality of life (QOL; Quality of Life Questionnaire of the European Foundation for Osteoporosis), and activity level (LASA Physical Activity Questionnaire, pedometer), assessed posttreatment subsequent to the program and after 1 year of follow-up.

Results: The fall rate in the exercise group was 39% lower than for the control group (.72 vs 1.18 falls/person-year; risk ratio, .61; 95% confidence interval, .40–.94). Balance confidence in the exercise group increased by 13.9% (P=.001). No group differences were observed in QOL and activity levels.

Conclusion: The NFPP for persons with osteoporosis was effective in decreasing the number of falls and improving balance confidence. Therefore, it is a valuable new tool to improve mobility and independence of persons with osteoporosis.

Key Words: Accidental falls; Osteoporosis; Prevention; Randomized controlled trial; Rehabilitation.

FALL-RELATED FRACTURES are a major health problem. One in 3 persons 65 years and older falls at least once a year[1-3] and approximately 5% of these falls result in fractures.[4] Persons with osteoporosis are particularly at risk for fall-related fractures because of their decreased bone strength. These fractures increase morbidity and mortality[5] and have psychosocial consequences, such as fear of falling[6] and loss of independence.[7]

Until now, treatment of osteoporosis, in an attempt to prevent fractures, mainly focused on pharmaceutical interventions. Because falls are the leading cause of fractures, falls prevention programs for persons with osteoporosis also are expected to be beneficial.[8] A recent review concluded that exercise training focusing on muscle strength, balance, and weight-bearing would be most helpful in decreasing the risk for falls and fractures in persons with low BMD.[9] Only a few studies could be identified that directly investigated the efficacy of falls prevention programs in this population.[10-12] These studies found improved balance, mobility, and fall risk scores and decreased fall rates during the intervention. However, these interventions had long durations (25wk–30mo), and none of these studies measured the efficacy of the program on fall rates assessed prospectively after the intervention had ended. There-

List of Abbreviations

ABC	Activity-specific Balance Confidence
ANOVA	analysis of variance
BMD	bone mineral density
CI	confidence interval
DXA	dual-energy x-ray absorptiometry
IRR	incidence rate ratio
LAPAQ	LASA Physical Activity Questionnaire
M1	baseline
M2	postintervention
M3	1-year follow-up
NFPP	Nijmegen Falls Prevention Program
QOL	quality of life
QUALEFFO-41	Quality of Life Questionnaire of the European Foundation for Osteoporosis

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fore, there was a need for a study investigating the effects of a short-term falls prevention program for persons with osteoporosis during a follow-up period after the intervention by means of prospective monitoring of falls.

In the general elderly population, several exercise programs have been effective in preventing falls and fall-related injuries.[13-16] Multicomponent exercise interventions targeting various aspects of mobility are most effective in decreasing fall rates.[14] One example of such a multicomponent program is the NFPP, which consists of an obstacle course, walking exercises, and training in fall techniques. The program has only 10 sessions (5wk) and resulted in a 46% decrease in fall rates.[17] This program is unique because it not only focuses on falls prevention, but participants also learn fall techniques based on martial arts to fall as safely as possible to decrease injuries. For safety reasons, persons with osteoporosis were excluded from this program.

The aim of the present study was to determine whether a short falls prevention program for persons with osteoporosis is effective in decreasing the number of falls in a randomized controlled design. For this purpose, the NFPP was adjusted to meet the specific demands and constraints of persons with osteoporosis.[18] The primary outcome measure in this study was fall rate, prospectively registered in the year after the intervention. Secondary outcomes included balance confidence, activity level, QOL, and BMD at the hips and lower back.

METHODS

Participants and Study Design

Persons older than 65 years with osteoporosis (by means of DXA; T score ≤ -2.5 at the femoral neck or lower back) and a fall history (at least 1 fall in the previous year) were eligible for the study. A fall history is the most important predictor for future falls.[19,20] Because of the nature of the intervention, participants had to be able to walk at least 15 minutes without a walking device. Exclusion criteria were severe cardiac, pulmonary, or musculoskeletal disorders or pathologic states associated with a higher fall risk (eg, neurologic disorders).

Participants were recruited in 3 ways. First, DXA measurements performed at the outpatient clinics of the Rheumatology Departments of the Sint Maartenskliniek and the Radboud University Nijmegen Medical Centre in the previous year were screened for eligible patients (T score ≤ -2.5). Second, a direct mailing was sent to members of the Dutch Osteoporosis Patient Council. Third, advertisements were placed in local newspapers. When persons responded to these advertisements, it first was verified whether osteoporosis had been diagnosed in the past. If not, DXA was performed.

After a baseline assessment M1, the researcher performed block randomization using non–see-through envelopes. The probability of allocation to the exercise group was independent of recruitment method. Subsequently, the exercise group participated in the NFPP for persons with osteoporosis, whereas the control group received no intervention, but maintained usual care (eg, medication, regular physical therapy). After the program had ended, the second assessment took place at M2, followed by an assessment after 1-year follow-up at M3.

This study was conducted in agreement with the Declaration of Helsinki and was approved by the Medical Ethics Committee for the region Arnhem-Nijmegen. All participants gave written informed consent before participation.

Program

The NFPP for persons with osteoporosis was composed during 6 consensus meetings by a multidisciplinary team of physical therapists, occupational therapists, researchers, and rheumatologists. Fall techniques of the original NFPP were evaluated for the peak impact forces involved, on the basis of which the set of exercises was adjusted to ensure their safety for persons with osteoporosis.[21] The NFPP for persons with osteoporosis had the 6 elements of education, an obstacle course, walking exercises, weight-bearing exercises, correction of gait abnormalities, and training in fall techniques.[18] The program consisted of 11 sessions during 5.5 weeks and is described in more detail in Appendix 1. The program was provided by experienced physical and occupational therapists trained in the background, methods, and techniques of the program.

Measurements

Falls were registered prospectively during a 1-year follow-up period. Balance confidence, activity level, and QOL were assessed at M1 and posttreatment (M2, M3). DXA of the hips and lower back was performed at M1 and M3.

Fall rate. The primary outcome measure of this study was fall rate (average number of falls per person a year). After the intervention had ended, participants registered their falls for 1 year on fall calendars that had to be returned every month. On this calendar, participants wrote down whether fall(s) had occurred in the past month. If so, they indicated when it occurred, gave a short description of the fall(s), and reported injuries. That information was used to determine whether the reported fall met the common definition of a fall, which is an unexpected event in which the participant comes to rest on the ground, floor, or lower level. This method to monitor falls is recommended by the Prevention of Falls Network Europe.[22] Fall calendars were scored by an independent researcher who was blinded to group allocation. When no fall calendar was received within 2 weeks after the start of the month, the participant was reminded by telephone.

Balance confidence. The short version of the Dutch translation of the ABC Scale was completed at home by participants to determine balance confidence.[23-26] The short-ABC has proved to be a valid and reliable measure that assesses balance confidence rated for 6 activities of daily living with a minimum score of 0% (no confidence) and a maximum score of 100%.[25] Mean score over the items per person was used in statistical analysis.

Activity level. Activity level was measured in 2 ways. First, participants' activities were assessed in a structured interview by using the LAPAQ.[27] Participants were asked how much time they had spent in the previous 2 weeks walking outside, bicycling, gardening, light household activities, heavy household activities, and sports. Each item was scored in terms of frequency and duration. Total score for the LAPAQ (range, 0–420; higher scores reflect higher activity levels) was used for analysis.

Furthermore, activity level was assessed using a pedometer (Yamax Digi walker, SW 650)[a] to measure the number of steps a day for 7 subsequent days. Participants were instructed to wear the pedometer during all waking hours. When the number of steps on 1 day was less than 20% or more than 180% of the mean value for that specific person, this day was considered not representative and excluded from further analysis. Mean number of steps a day was used in statistical analysis.

Quality of life. Participants completed the QUALEFFO-41 at home to assess QOL.[28,29] The 41 questions of the QUALEFFO-41 cover the 5 domains of pain, physical function, leisure and social function, general health perception, and mental function. A score of 0% (high QOL) to 100% (low QOL) could be determined by using a standardized calculation