The Erlangen Fitness Osteoporosis Prevention Study: A Controlled Exercise Trial in Early Postmenopausal Women With Low Bone Density—First-Year Results

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Objective: To investigate the effect of a 2-year vigorous, combined high-impact, strength, and endurance training program on bone mineral density (BMD) determined by dual-energy x-ray absorptiometry (DXA), quantitative computed tomography (QCT), and ultrasound in early postmenopausal women with osteopenia.

Design: Nonrandomized controlled trial, reporting 1-year data.

Setting: Community.

Participants: Early postmenopausal (1–8y postmenopausal) osteopenic women (DXA T score at lumbar spine or total hip between −1 and −2.5 standard deviations). The exercise group (n=59; mean age, 55.1±3.4y) and control group (n=41; mean age, 55.9±3.1y) were recruited from community registers.

Intervention: Fourteen months of exercise training, with 2 joint sessions and 2 additional home training sessions. Exercise and control groups were supplemented individually with calcium and cholecalciferol up to 1500mg of calcium and 500IU of vitamin D per day.

Main Outcome Measures: BMD at the lumbar spine and total hip measured by DXA, isometric maximum strength, and maximal oxygen consumption ($\dot{V}O_2$max) during a stepwise running test to exhaustion.

Results: Bone density increased significantly at the lumbar spine for the exercise group (1.3%, $P<.001$) and decreased in the control group (−1.2%, $P<.01$). Differences at the total hip (−0.3%, not significant vs −0.8%, $P<.05$) and the femoral neck (−0.8%, $P<.05$ vs −1.8%, $P<.001$) were nonsignificant. Changes in isometric maximum strength were significant for each region (grip strength, trunk flexors and extensors, hip flexors, leg adductors and abductors, arm flexors and extensors) in the exercise group (11%–39%) compared with nonrelevant changes (−1.1% to 3.9%) in the control group. Between-group differences were significant ($P<.01$–$.001$) for all strength parameters. $\dot{V}O_2$max increased significantly by 11% ($P<.001$) in the exercise group but decreased in the control group by 4% ($P<.05$) while showing significant between-group differences.

Conclusion: High-intensity exercise training can have a positive influence on bone density in early postmenopausal osteopenic women.

Key Words: Bone density; Exercise; Osteoporosis, postmenopause; Physical endurance; Rehabilitation; Women.

RECENT META-ANALYSES[1-5] of exercise studies have confirmed that physical exercise has a positive effect on bone mass and density. However, there was a substantial degree of heterogeneity with respect to the kind, duration, and intensity of exercise, subjects' ages, participating subjects' athletic condition, and medications that could potentially affect bone metabolism, such as hormone replacement therapy (HRT) or calcium and vitamin D supplements. Also, sample sizes were typically about 50 subjects only, and the study period rarely exceeded 12 months. Most often, the exercise impact on bone mineral density (BMD) was analyzed at the lumbar spine and the femoral neck with dual-energy x-ray absorptiometry (DXA); measurements at the radius and, less frequently, of the total body and other sites have also been used. Measurements of volumetric BMD with quantitative computed tomography (QCT) or peripheral QCT, which in principle also permit a determination of bone geometry such as cross-sectional moments of inertia, have been rarely reported.

Although it is difficult to summarize in a consistent pattern all of the different facets of the exercise studies published to date, a few general strategies on how to optimize osteogenic exercise effects have emerged: (1) a strong relationship between exercise intensity and osteogenic stimulation is observed[6-10]; (2) exercise effects are predominantly site specific and not systemic[1,3,11]; (3) exercises with unusual strain distributions, such as aerobics or games, have a higher osteogenic stimulus than more constrained exercises such as walking or running[12-14]; (4) programs that combine ground and joint reaction forces are superior to programs that apply only a single type of force[7,15-17]; (5) physical activity or exercise seems to be more effective in the developing skeletal structure than in the elderly population[14,18-24]; and (6) exercise effects on bone density seem to be different in pre- and postmenopausal women.[19,22]

Debate persists over whether the endocrine system or the mechanical stimulus is primarily responsible for bone modeling and remodeling. According to the feedback system called the mechanostat, modeling and remodeling processes are reg-

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Table 1: Exercise Program During the First 7 Months

Month 1	2	3	4	5	6	7
Endurance:						
Increased running time up to 15min			Running, 10min; aerobics, low-impact 5min, high-impact 5min; HR after 3min 70%–85% HRmax			
				Various forms of rope skipping, 3–5 times, 15–20 reps.; multidirectional jumps, 4 sets with 15 reps		
Strength:						
Session 1: 13 exercises, 2 sets, 20 reps (2-1-2s), 90-s rest; load increase 5% if >22 reps. After an initial 1-RM test, the load for 20 reps was fixed at 50% 1-RM.			Session 1: 13 exercises, 2 sets, 15 reps (2-1-2s) at 60% 1-RM, 90-s rest; load increase 5% if >17 reps		Session 1: 13 exercises, 2 sets, 12 reps (2-1-2s) at 65% 1-RM, 90-s rest; load increase 5% if >14 reps	
Session 2: 12–15 exercises, 2–4 sets with 6–10s of max intensity, 30-s rest; 3–4 elastic belt exercises, 2 sets, 20 reps			Session 2: more intense or longer isometric and elastic belt exercise		Session 2: more intense or longer isometric and elastic belt exercise; preparation for dumbbell/weighted vest training (chest press, rowing, squats/deadlift)	
Stretching (performed during rest periods of jumping and strength exercises)						
Standardized stretching program, 8–10 exercises, 1–2 sets, duration 30s						
Home training:						
		10 isometric exercises, 2–3 sets, max intensity			Rope skipping, 3 sets of different jumps, 20 reps; variation of isometric and elastic belt exercises, same modus	
		Elastic belt training, 2–3 sets, 20 reps				

Abbreviations: HR, heart rate; HRmax, maximum heart rate; 1-RM, 1 maximum repetition; reps, repetitions.

ulated by the forces acting on the bone, with the endocrine system having a tuning function only.[25-28] In this model, estrogen lowers the set point for mechanical adaptation, which means that bone formation starts at lower strains than with estrogen deficit. During early menopause, typically neither daily activity level nor external forces acting on bone drop suddenly. Thus, the increased bone loss in women during this period should be attributed to higher set points caused by the change in the hormonal system.

Our hypothesis in this study was that a regular program of high-impact and high-intensity exercise can compensate for, or at least decrease, the bone loss in early postmenopausal women. We report the design and baseline characteristics of the Erlangen Fitness Osteoporosis Prevention Study (EFOPS), along with the data from the first 14 months of the study.

METHODS

The EFOPS is a 3-year controlled exercise trial in early postmenopausal women; it was approved by the ethics committee of the University of Erlangen, the Bundesamt für Strahlenschutz, and the Bayerisches Landesamt für Arbeitsschutz. All study participants gave written, informed consent.

Participants

A total of 137 early postmenopausal women (1–8y postmenopause) with osteopenia (DXA T score between −1 and −2.5) at the lumbar spine or the total proximal femur were recruited from population registers. Exclusion criteria were intake of medications affecting bone metabolism within the last 5 years, with the exception of calcium and vitamin D; known osteoporotic fractures (spinal radiographs were not taken); acute vertebral disk problems; inflammatory diseases; history of cardiovascular diseases; load less than 75W on cycle ergometry; and athletic activity in the last 2 decades before the study.

Recruitment strategies were based on local population registers and advertisements in local newspapers. A total of 7500 women aged 48 to 60 years were contacted by mail, of whom 1100 responded and were then contacted by telephone. A total of 606 subjects were excluded, mainly because they took medications (most often HRT, bisphosphonates, glucocorticoids) that affect bone metabolism (n=453) or because they did not meet the time frame of 1 to 8 years after menopause (n=138). Menopause was defined as self-reported lack of a menstrual cycle for more than a year. A total of 494 subjects were screened by DXA, and 225 women did not meet the inclusion criterion of osteopenia. Another 12 were excluded because of cardiovascular problems; 137 of the 257 women remaining agreed to participate in the trial—86 in the exercise groups and 51 in the control group.

Control group participants continued their normal lifestyle, which may have included habitual sports activities. The exercise group underwent the special training described below. Both groups were given calcium and vitamin D supplements, according to an individual nutritional analysis, also described below.

Exercise Regimen

All participants in the exercise group followed the same program detailed in tables 1 and 2. The general design was as follows.

The exercise program consisted of 2 weekly joint training sessions (60–70min) in groups of approximately 15 participants and of 2 additional individual home training sessions (25min). The joint training sessions were divided into 4 sequences: endurance, jumping (beginning 5mo after the study began), strength training, and stretching. The intensity of the strength training was controlled and adjusted with 1 maximum repetition (1-RM) tests every 12 to 14 weeks. The first of these tests was completed after 6 weeks of training. During the first 7 months of the study, the intensity of the training was increased slowly to minimize injury risks and to allow the participants to adjust gradually to the various sequences (table 1). After 7 months, a training scheme particularly affecting the strength sequence was introduced (table 2). Intervals of 12

Table 2: Exercise Program During the Second 7 Months

Month 8	9	10	11	12	13	14
Endurance						
Running 10min, increased ground reaction forces in aerobic sequence						
Jumping						
Multidirectional jumps, 4 sets with 15 reps; rope skipping dropped						
Strength			"Regeneration period"			
Session 1: nonlinear periodized training, 9 exercises, 2–4 sets, 10 and 3 reps (2-1-2s) at 70% and 90% 1-RM, 120-s rest			Session 1: 13 exercises, 2 sets, 20 reps (2-1-2s), 90-s rest	Session 1: linear periodized training, 9 exercises, 2–4 sets, 10 and 3 reps (2-1-2s) at 70% and 90% 1-RM, 120-s rest		
Session 2: dumbbell/weighted vests replaced elastic belt training, 2–4 sets, 10 and 3 reps (2-1-2s) at 70% and 90% 1-RM, 120-s rest			Session 2: elastic belt replaced dumbbell/weighted vests training	Session 2: dumbbell/weighted vests replaced elastic belt training 2–4 sets, 10 and 3 reps (2-1-2s) at 70% and 90% 1-RM, 120-s rest		
Stretching (in rest periods of jumping and strength exercises)						
Standardized stretching program 8–10 exercises, 1–2 sets, duration 30s						
Home training						
Variation of isometric and elastic belt exercise and rope skipping			Variation of isometric and elastic belt exercise and rope skipping			Continued

NOTE. The 11th month was spread for better readability.

weeks of high-intensity strength training were interspersed with 4 to 6 weeks of lower (regenerational) intensity.

The strength training was subdivided into 2 parts. In 1 of the 2 weekly joint sessions, the strength sequence was performed on machines[a] designed for multijoint exercises. The dynamic exercises used were horizontal leg press, leg curls, bench press, rowing, leg adduction and abduction, abdominal flexion, back extension, latissimus dorsi pull, hyperextension, leg extension, shoulder raises, and hip flexion. Movements were performed in a 2-second (concentric), 1-second (static), 2-second (eccentric) mode.

The strength sequence of the second joint session consisted of an isometric exercise regimen. During the first 7 months, participants performed 12 to 15 different isometric exercises at different angles within the range of motion (table 1). All major muscles groups, including muscles around the elbows, shoulder, trunk, hip, and knee joints, were trained by using defined movements. In addition, 3 to 4 different exercises for the upper trunk were performed with elastic belts. The intensity was increased subjectively by shortening the belt.

After 7 months, dumbbell and weighted vests replaced the elastic belts (table 2). Wide-grip bench press, 1-arm dumbbell rowing, and squats with weighted vests and beverage boxes were performed. Movements were performed in a 2-second (concentric), 1-second (static), 2-second (eccentric) mode. After a 4-week phase to become accustomed to the proper lifting technique, the subjects' strength was determined by a 10-repetition maximum test. The intensity and its variation, as well as the number of sets and repetitions during the dumbbell and weighted-vest session, were comparable to our high-intensity regimen with the resistance machines.

The training during the second year of the study was similar to the training in the second 7 months. Attendance was assessed every 12 weeks with subject-specific training logs and attendance lists kept by the trainers.

Measurements

The various measurements and the associated timing according to the EFOPS protocol are summarized in table 3.

Anthropometric data. We measured height, weight, and body composition by using the impedance[b] and 11-point caliper techniques.[c]

Bone densitometry. Bone densitometry was measured by DXA (QDR 4500A[d]) at the lumbar spine (L1-4), the proximal femur, and the forearm by using standard protocols described in the manufacturer's user's manual. In addition, QCT was performed at the lumbar spine (L1-3) by using the standard Osteo protocol[29] on a Somatom Plus 4.[e] Ultrasound measurements were taken at the calcaneus by using a gel-based system (Sahara[d]).

Table 3: Timing of EFOPS Measurements

Variable	Screening	Baseline	Follow-Up 1	Follow-Up 2
Time to study start	−3.5mo	−2mo	14mo	26mo
Anthropometric data		X	X	X
DXA: PA L1-3 and femur	X		X	X
DXA forearm	X			X
QCT L1–3		X		X
Ultrasound calcaneus		X	X	X
Sport-specific tests		X	X	X
Questionnaire		X	X	X
Nutritional analysis		X	X	X
Blood/urine samples		X		X

Abbreviation: PA, posteroanterior.

Sport-specific tests. Maximum strength of the trunk extensors and flexors, the hip flexors, the leg adductors and abductors, and the arm flexors and extensors was determined in the isometric mode by using a Schnell-Trainer dynamometer and a Schnell M-3 isometric tester.[f] We followed the testing protocol of Tusker,[30] which is recommended for research. After receiving detailed oral instructions, subjects performed 2 initial tries of low intensity. Then, without further warm-up, they made 2 maximum efforts, each lasting 5 seconds, with a 40-second rest period between efforts. The higher value of the 2 maximum efforts was used for data analysis. Subjects were not particularly motivated for the test, neither at baseline nor at the follow-up measurements at 12 and 24 months, and results were not immediately provided to them. Strength data were recorded as force times lever arm (in newton meters). For each measurement, the length and axis of the lever arm and the seat position of the participant were recorded to ensure optimum repeatability at the follow-up tests. Reproducibility of the isometric strength tests was assessed by measuring 25 subjects twice. The coefficient of variation (CV) was better than 5% for all tests.

To assess maximum isometric strength of the trunk flexors and extensors, the subjects were positioned on the dynamometer seat in the upright position and were supported by thigh and hip straps. The participants had to press forward (trunk flexion) or backward (trunk extension) against the fixed lever arm, touching the upper chest (flexion) or the acromial site (extension). Hip flexors were assessed in the prone position with the hip fixed by straps. The lever arm axis was positioned at 60° at the trochanteric site. Each subject had to press with her right knee against the lever arm, thereby flexing the hip.

Maximum isometric strength of the right leg adduction and abduction was measured with subjects lying in the lateral position with the hip fixed. The lever arm angle was adjusted 15° upward, the axis was aligned with the axis of the hip joint, and the end of the lever arm was positioned at the ankle. The subjects had to press upward against the fixed resistance for leg abduction and press downward for leg adduction. Arm flexors and extensors were again measured with subjects sitting upright with the hip and shoulders fixed. A fixed base supported the upper arms. The axis of the lever arm was aligned along the elbow axis. The angle of the elbow joint was adjusted at 90°, with no flexion or extension at the wrist. Grip strength of the dominant hand was measured with a Jamar dynamometer[g] in accordance with the procedure suggested by Mathiowetz et al.[31] However, our subjects were standing during the test. Dominance was assessed through interviews with the subjects.

Endurance was assessed by using a stepwise treadmill test up to a voluntary maximum. We used the standardized procedure developed by Platen,[32] with the difference being that we used a treadmill instead of a cycle ergometer. Subjects who could not achieve a minimum heart rate of 155 beats/min were excluded from the analysis. After starting with 6km/h (0° slope), speed was increased in steps of 1km/h every 3 minutes. Maximal oxygen consumption ($\dot{V}O_2max$), maximal carbon dioxide consumption, and expired ventilation were determined breath by breath with a Zan 600 open spirometric system.[h]

Questionnaire. A detailed questionnaire completed by the participants in both the exercise and control groups combined several parts: part 1 contained questions about their quality of life (QOL) and the frequency and grade of their pain at various skeletal sites according to Fahrenberg et al.[33] Part 2 asked about historical and immediate prestudy exercise levels, as well as normal daily load levels from work, household, and gardening activities. Part 3 assessed common osteoporotic risk factors. The questionnaires used at 12 and 24 months additionally concentrated on changes during the respective study periods with regard to QOL, pain, and additional sporting activities outside the EFOPS training program.

Nutritional analysis. The individual dietary intake was assessed by a 5-day protocol completed by each participant after each was given careful instructions. Their complete food intake was noted. For precise weighing of the consumed food, participants were given identical digital household scales. The analysis of the protocols was performed in collaboration with the University of Bayreuth, by using Prodi-4,5/03 Expert software.[i] This program extracts a total of 1500 different basic nutritional ingredients.

The ingredients are first calculated separately for each food intake and then averaged over the 5-day assessment period. Because some subjectivity remains when the participants' protocols are entered into the program, particularly in cases where the program does not offer the exact food consumed, the interoperator reproducibility of our method was tested. Fifteen protocols were analyzed separately by 2 research assistants. The CVs for energy, fat, carbohydrate, protein, calcium, phosphorous, and vitamin D intake were less than 5%.

Based on the calcium and vitamin D results from the analysis, participants received supplemental calcium and vitamin D to ensure a total daily intake of 1500mg of calcium and 500IU of vitamin D.

Blood and urine samples. Blood samples were drawn from an antecubital vein in the morning after an overnight fast. Different portions of the serum from the samples were frozen at −30°C and −70°C after being centrifuged at 3000rpm for 20 minutes. Urine was collected during the 24-hour period before the blood sampling. The urine samples were pipetted in 10-mL portions and kept frozen at −30°C and −70°C for later analysis.

Statistical Analysis

Unless otherwise stated, all measured values are reported as means and standard deviations (SDs). The Kolgomorov-Smirnov test was used to check for normal distribution. For normally distributed variables, differences within and between groups were assessed with paired and unpaired *t* tests; otherwise, the Wilcoxon or Whitney-Mann *U* tests were used. All tests were 2 tailed; a 5% probability level was considered significant. We used SPSS, version 10.08,[j] for statistical analysis.

RESULTS

Baseline Characteristics

Table 4 gives a comparison of the most important anthropometric and nutritional data, as well as osteoporotic risk factors at baseline, for both the exercise and control groups. Except for slight nonsignificant differences in energy, calcium, and phosphorous intake (higher in the exercise group), the 2 groups were perfectly matched.

Compliance and Dropout Rates

Seventy-three women in the exercise group and 43 women in the control group completed the first 14 months of the study; 21 dropped out. This dropout rate corresponds to an overall dropout rate of 15% in both groups. Of the 21 subjects, 9 quit because of occupational changes, they moved away, their working hours changed, or their workload became incompatible with the training schedule. Five subjects stopped training because of unrelated serious diseases (eg, tumor, asthma). One sustained a hairline fracture of the os pubis in a fall during the

Table 4: Baseline Data of Exercise and Control Groups

Variable	Exercise Group (n=86)	Control Group (n=51)	Difference
Age (y)	55.1±3.3	55.8±3.1	NS
Height (cm)	163.8±6.8	162.4±6.6	NS
Weight (kg)	67.6±9.6	67.0±13.6	NS
BMI (kg/m^2)	25.2±3.3	25.4±4.4	NS
Total body fat (%)	36.0±5.0	35.0±7.2	NS
Age at menarche (y)	13.4±1.4	13.3±1.6	NS
Age at menopause (y)	50.5±3.3	50.4±3.1	NS
Irregular menstrual cycle for >1y during lifetime (%/group)	16%	18%	NS
No. of pregnancies	2.0±1.1	1.9±1.3	NS
Physical activity*	4.1±1.3	4.0±1.2	NS
Energy intake at baseline (kJ/d)†	7731±1366	7577±2143	NS
Protein intake at baseline (g/d)	68.5±15.8	68.8±17.6	NS
Calcium intake at baseline (mg/d)	1055±379	989±290	NS
Phosphorus intake at baseline (mg/d)	1299±368	1175±338	NS
Vitamin D intake at baseline (μg/d)	5.1±4.1	5.5±5.3	NS
Osteoporosis of parents or siblings (%/group)	16%	14%	NS
Use of oral contraceptives during lifetime (%/group)	70%	73%	NS
Use of corticosteroids (>5mg/d) or thyroxin (≥75mg/d) for >6mo during lifetime (%/group)	11%	12%	NS
Coffee intake at baseline (mL/d)	766±345	815±365	NS
Smoker at baseline (%/group)	9%	10%	NS
DXA PA L1-4 (g/cm^2)	.874±.094	.869±.090	NS
DXA total hip (g/cm^2)	.857±.081	.841±.070	NS
DXA ultradistal radius (g/cm^2)	.421±.052	.408±.050	NS
CT trabecular L1-3 (g/cm^3)‡	94.0±19.9	95.9±17.8	NS
CT cortical L1-3 (g/cm^3)‡	251.7±404	257.5±40.0	NS

NOTE. Values are mean ± SD or percentage.
Abbreviation: NS, not significant.
* Based on a scale from 1 (very low) to 7 (very high), according to a subjective assessment of professional, household, and recreational activities.
† n=50 for the control group; n=85 for the exercise group for all nutritional intake parameters.
‡ n=48 for the control group; n=80 for the exercise group.

aerobic training. Another 4 (exercise group, n=2; control group, n=2) listed study-related reasons for quitting, and 2 women dropped out for unknown reasons. An additional 16 participants were excluded from the 14 months' analysis for the following reasons: medication or diseases affecting bone metabolism (exercise group, n=3; control group, n=1); significant changes of physical activity outside the EFOPS program (control group, n=1); and insufficient training frequency, defined as participating in fewer than 2 of the 4 weekly training sessions averaged over the 14-month period (joint group and home sessions were equally weighted; exercise group, n=11).

Seven women had poor training attendance because health problems such as influenza or non–training-induced injuries interrupted their training for 4 to 8 weeks. Overall, the 14-month analysis was based on data from 59 women in the exercise group and from 41 women in the control group. In this cohort, average attendance was 75% (85% in the joint sessions, 64% in the home sessions). When comparing the exercise or control groups at baseline (n=86, n=51) with the corresponding group in the analysis (n=59, n=41), we did not find significant differences for any of the variables listed in table 4.

Fourteen-Month Results

Changes in the anthropometric data and in the dietary intake were nonsignificant after the first 14 months, with 1 exception. We analyzed intragroup changes in the 2 groups, as well as changes in the pooled population. All were nonsignificant. The differences between the 2 groups also remained insignificant after 1 year. The exception was dietary vitamin D intake, which remained unchanged in the exercise group but decreased in the control group by 18.8%. Including our vitamin D supplementation, total daily vitamin D intake in the control group averaged 13.5μg, and in the exercise group it was 14.1μg (not significant [NS]).

Changes in bone density are summarized in table 5. BMD in the lumbar spine significantly increased by 1.3% ($P<.001$) in the exercise group and decreased by 1.2% ($P<.01$) in the control group. There was a significant difference between the 2 groups in percentage changes. In the total hip, BMD was stable in the exercise group and slightly decreased in the control group by 0.8% ($P<.05$). However, the difference in the percentage of changes between groups was not significant. This was also true for the femoral neck, where BMD significantly decreased in both groups.

A more specific investigation of bone loss and/or gain is presented in the histograms in figures 1 through 4. In the spine, 44 (75%) subjects in the training group had increased BMD, while 15 had decreases. The percentage decrease in BMD of 12 (20%) subjects in the training group was higher than the average percentage decrease in the control group. In the training group, BMD increased in 26 (44%) subjects at the total hip and increased in 24 (41%) women at the femoral neck. We found a higher bone loss in 41% of the exercising women at the total hip and in 36% at the femoral neck when compared with the average decreases in the control group.

Table 5: Bone Density Changes of Spine and Hip After 14 Months

Variable	Exercise Group (n=59)	Control Group (n=41)	Difference
DXA PA L1-4 (g/cm^2)			
Baseline	.877±.096	.875±.091	NS
14-mo follow-up	.888±.102	.864±.091	NS
Change (%)	1.3±2.7‡	−1.2±2.5†	‡
	(95% CI, 0.6–2.0)	(95% CI, −2.0 to −0.5)	
DXA total hip (g/cm^2)			
Baseline	.857±.083	.847±.066	NS
14-mo follow-up	.855±.081	.840±.069	NS
Change (%)	−0.3±2.0	−0.8±2.4*	NS
	(95% CI, −0.8 to 0.2)	(95% CI, −1.5 to −0.1)	
DXA femoral neck (g/cm^2)			
Baseline	.724±.070	.720±.067	NS
14-mo follow-up	.719±.075	.707±.066	NS
Change (%)	−0.8±2.9*	−1.8±3.1‡	NS
	(95% CI, −1.5 to −0.1)	(95% CI, −2.8 to −0.9)	

NOTE. Values are mean ± SD or 95% CI. The last column indicates the level of significance of the differences between the exercise and control groups for the given visit and measured site. The rows labeled Change show the difference from baseline to follow-up visits in percentages relative to the baseline visit.
Abbreviation: CI, confidence interval.
* $P<.05$.
† $P<.01$.
‡ $P<.001$.

Changes in isometric strength measures are shown in table 6. In the exercise group, isometric strength of all muscle groups showed significant increases of 11% to 32%. In the control group, changes remained nonsignificant, with the exception of the arm flexors, where a 3.9% increase was measured. The difference in percentage changes between the 2 groups was also significant for all parameters measured. Finally, $\dot{V}O_2$max changes are shown in table 7. Subjects with a heart rate less than 150 beats/min were excluded from the analysis because of their presumably weak compliance (exercise group, n=3; control group, n=2). Again, the exercise group (11%, $P<.001$) benefited from the training, but not the control group (−3.6%, $P<.05$).

DISCUSSION

Several exercise studies have examined the effects of different training regimens in various body regions in men and women.[1-5] Often, age, as well as prestudy bone mineral status, varied considerably within the groups investigated in a particular study. Thus, it remains difficult to differentiate exercise effects in specific age groups. In women, typically only a coarse differentiation between pre- and postmenopausal age

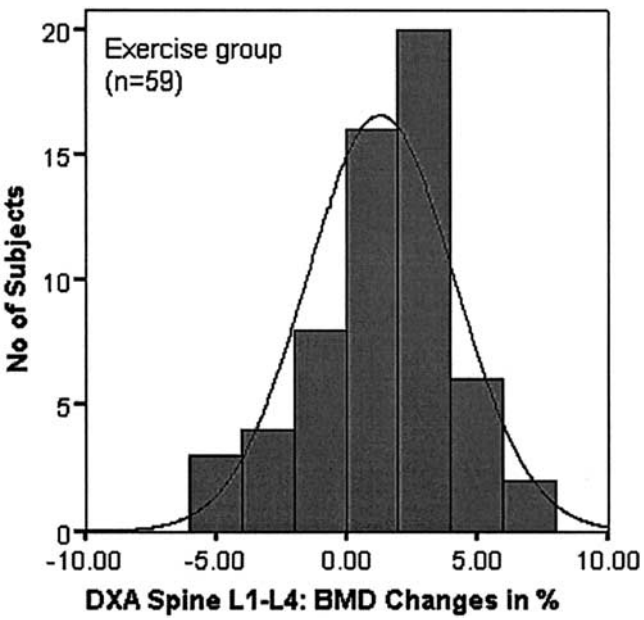

Fig 1. BMD changes at the lumbar spine in the exercise group.

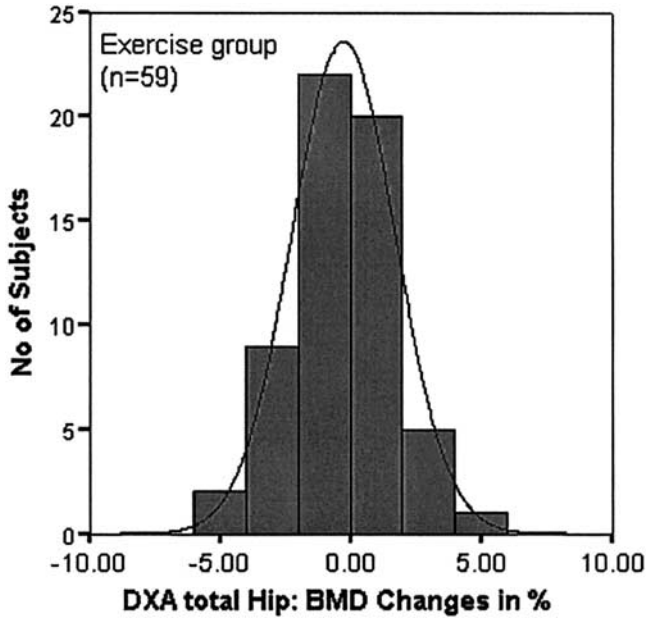

Fig 2. BMD changes at the total hip in the exercise group.

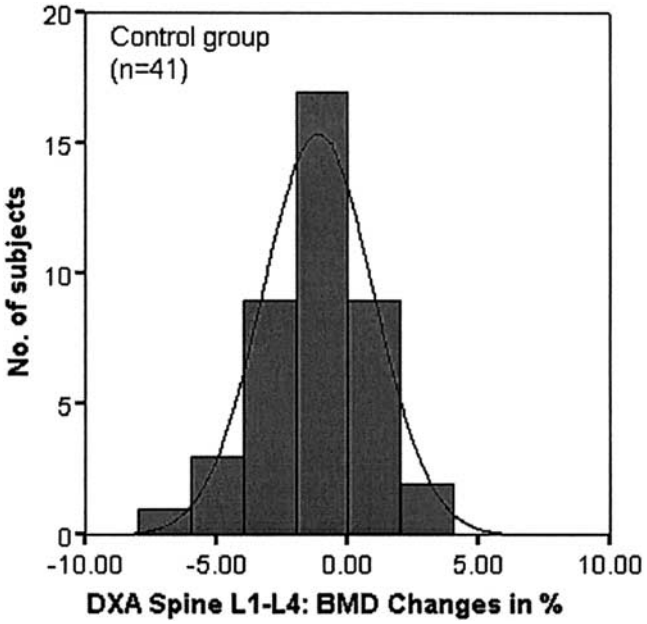

Fig 3. BMD changes at the lumbar spine in the control group.

groups is performed, without focusing on the special situation of the critical early postmenopausal years. Also, in many publications, the training program consists of a limited variety of exercises (eg, jumps, weight training, aerobics), or the training is optimized toward a dedicated body region.

In our study, we investigated the effects of a training program with reasonable intensity and frequency in an early postmenopausal cohort with reduced bone density. Because of the hormonal change, the bone loss is accelerated, and it is questionable whether exercise results observed in younger or older women are transferable to this life cycle. Obviously, it is important to at least reduce bone loss in these women for several years. Our participants were osteopenic, according to the World Health Organization,[34] but they did not want to take long-term preventive drug treatment (eg, estrogens, bisphosphonates).

Based on the results of a previous study,[35] we excluded from data analysis subjects who attended fewer than 2 exercise sessions a week. That study showed that a low training frequency of fewer than 2 sessions a week, even if combined with a high training intensity, was not effective. This is indirectly confirmed by insignificant BMD increases (or decreases) in exercises studies with low to moderate training frequencies.[36-38] We concede that the threshold of 2 sessions/week is somewhat arbitrary, but a detailed analysis of the dependence of training frequency and intensity on BMD and other outcome variables is beyond the scope of this article.

Besides BMD, we measured several other parameters (tables 4, 6, 7). As can be seen in those tables, the exercise and control groups were perfectly matched at baseline. Because of dropouts in the first 14 months, subject cohorts included in the 14-month analysis differed from those at baseline (reported in table 4). However, reanalysis of the subjects remaining after 14 months showed no relevant differences between the 2 groups at baseline.

We did not conduct a randomized study, which is the design of choice in double-blind, placebo-controlled pharmaceutical studies. Obviously, randomization is much more difficult in exercise studies because many participants may refuse to be randomized to the study arm they do not prefer. In particular, it may be difficult to persuade subjects who want to exercise not to do so for another 2 or 3 years. Conversely, the increased motivation may result in exaggerated exercise effects that cannot be realized in general. There are conflicting data on this issue. Wolff et al[5] concluded in their meta-analysis that nonrandomized, controlled studies showed an exercise effect twice as high as that in randomized studies, while the meta-analysis by Kelley et al[3] showed the opposite effect (effect size: .44 for exercise vs 1.08 for control).

Our training regimen was designed to meet the following objectives: it should focus on the most common fracture sites—hip and spine—with less emphasis on the forearm; it should be possible to easily transfer the program to sports or athletic clubs, fitness studios, or public health organizations; it should minimize the risk of traumatic fractures, stress injuries, and arthritic complications; and it should optimize compliance. Compared with other exercise studies with similar cohorts,[1,4] our dropout rate of 15% was low, and the attendance at training sessions, in particular, the joint training sessions, was high.

The training intensity was progressively increased during the first 7 months (tables 1, 2) so that the participants could slowly adapt to the exercises. Other than 1 hairline fracture after a fall during the aerobic session, no musculoskeletal complications occurred. While this concept minimizes the risk of injuries and should increase compliance, effects on bone were expected to be smaller compared with study designs that increase intensity more rapidly. In keeping with these expectations, after 14 months we observed a significant increase of BMD at the lumbar spine of 1.3% in the exercise group and a significant decrease of 1.2% in the control group. In the total hip BMD, we observed no change in the exercise group and a small but significant decrease of 0.8% in the control group. When analyzing the neck specifically, BMD decreased by 0.8% in the exercise group and by 1.8% in the control group.

Several other exercise studies with women 1 to 10 years postmenopause failed to show significant effects on BMD. In 2

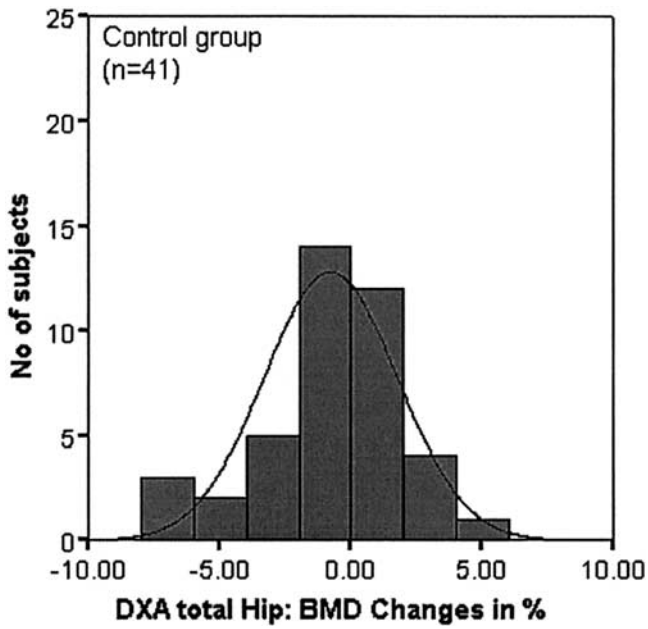

Fig 4. BMD changes at the total hip in the control group.

Table 6: Changes of Isometric Strength Measures After 14 Months

Variable	Exercise Group (n=59)	Control Group (n=41)	Difference
Grip strength (kg) baseline	27.0±6.5	22.1±7.5	*
Grip strength (kg) follow-up	30.0±4.8	22.2±6.4	‡
Change (%)	11.1±12.1‡	0.5±16.8	†
	(95% CI, 8.0–14.2)	(95% CI, −4.6 to 5.6)	
Trunk extensors (Nm) baseline	97.4±29.2	107.3±38	NS
Trunk extensors (Nm) follow-up	129.1±31.2	107.4±39	‡
Change (%)	32.4±29.1‡	0±21.2	‡
	(95% CI, 25.0–39.8)	(95% CI, −6.5 to 6.5)	
Trunk flexors (Nm) baseline	57.1±17.2	53.2±16.1	NS
Trunk flexors (Nm) follow-up	69.3±19.3	53.2±13.3	‡
Change (%)	21.4±24.3‡	0±17.7	‡
	(95% CI, 15.2–27.6)	(95% CI, −5.4 to 5.4)	
Hip flexors (Nm) baseline	36.2±9.9	37.4±12.7	NS
Hip flexors (Nm) follow-up	41.3±9.7	37.0±9.3	*
Change (%)	14.1±17.8‡	1.1±14.8	‡
	(95% CI, 9.6–18.7)	(95% CI, −5.6 to 3.4)	
Leg adductors (Nm) baseline	97.7±21.5	104.0±22.7	NS
Leg adductors (Nm) follow-up	112.9±23.1	104.6±22.0	NS
Change (%)	15.6±18.8‡	0.6±13.9	‡
	(95% CI, 10.8–20.4)	(95% CI, −3.7 to 4.8)	
Leg abductors (Nm) baseline	75.7±8.5	78.8±22.1	NS
Leg abductors (Nm) follow-up	85.6±20.0	80.2±22.3	NS
Change (%)	13.1±15.9‡	1.7±12.4	†
	(95% CI, 9.1–17.2)	(95% CI, −2.1 to 5.5)	
Arm flexors (Nm) baseline	63.8±12.5	61.6±14.3	NS
Arm flexors (Nm) follow-up	74.6±9.2	64.0±16.31	‡
Change (%)	16.9±17.7‡	3.9±9.6*	‡
	(95% CI, 12.4–21.4)	(95% CI, 1.0–6.8)	

NOTE. Values are mean ± SD or 95% CI. The last column shows significance levels of differences between the exercise and control groups for the given visit and parameter. The rows labeled Change show the difference from baseline to follow-up visits in percentages relative to the baseline visit. Changes between baseline and follow-up were not significant.
* $P<.05$.
† $P<.01$.
‡ $P<.001$.

articles, Bassey[19,39] found either negative or no changes after 12 months of heel-drops and high-impact aerobics (DXA lateral spine: −2.5% in exercise group, −1% in control group; DXA femoral neck: 0.1% in exercise group, −0.8% in control group) and after a special jumping training (DXA spine: −0.2% in exercise group, −0.1% in control group; DXA femoral neck: −1.7% in exercise group [$P<.05$], −0.5% in control group). However, the latter program increased BMD at the lumbar spine and the femoral neck in premenopausal women,[19] indicating differential effects in women at different ages and menopausal status. However, in the study by Kemmler and Riedel,[40] comparable BMD increases of 1.8% to 2.5% (all $P<.05$) among pre-, early post-, and late postmenopausal women who exercised for 10 months were observed.

Studies that emphasized resistance training showed heterogeneous results. After 6 months of dynamic resistance training by 2 exercise groups, Bemben et al[41] found neither significant changes at the lumbar spine or proximal femur (DXA) nor differences when compared with a control group. Similarly, Maddalozzo and Snow[42] showed no relevant changes after 6 months of high-intensity resistance training (70%–90% 1-RM). More positive effects were found by Pruitt et al[43] in a group of subjects after 9 months of dynamic resistance training (≈70% 1-RM), who showed a significant increase of 1.6% in spinal BMD (dual photon absorptiometry) compared with a 3.6% decrease in their control group. Surprisingly, the decrease at the neck was higher in the exercise group than in the control group (−2.7% vs −0.8%). After 12 months of low-intensity, high-

Table 7: Changes in $\dot{V}O_2$max After 14 Months

Variable	Exercise Group (n=55)	Control Group (n=37)	Difference
$\dot{V}O_2$max (L/min) baseline	1.74±.41	1.69±.37	NS
$\dot{V}O_2$max (L/min) follow-up	1.93±.33	1.62±.29	†
Change (%)	10.9±17.8†	3.6±10.9*	†
	(95% CI, 6.2–15.6)	(95% CI, −7.1 to −0.1)	

NOTE. Values are mean ± SD or 95% CI.
* $P<.05$.
† $P<.001$.

repetitive psoas training, Revel et al[44] reported a significant between-group difference for trabecular BMD by using QCT (0% vs −8.9%).

Overall, our current study showed higher BMD increases at the lumbar spine and comparable or higher BMD results at the hip. A drawback of the studies cited above is their limited duration (<12mo) and small sample sizes; thus, they might not have had enough power to show small changes. Only 2 studies[19,40] included more than 50 subjects. Calcium was supplemented in only 3 studies,[19,39,41] and vitamin D in none.

Recently published values[45-47] of annual bone density loss in healthy early postmenopausal women followed longitudinally are around 1.5% at the lumbar spine and between 1.1% and 1.4% at the femoral neck. These rates decelerate 4 to 5 years after menopause. In our control group, which spanned the entire period of 1 to 8 years after menopause, the bone loss rates of 1.2% at the spine and 0.8% at the hip were slightly lower than the values cited above, particularly if we consider that our measurement interval was longer than 12 months. Part of the difference can be attributed to our calcium and vitamin D supplementation.

When we analyzed bone loss more specifically at the spine, we found that, in 80% of the exercising subjects, the percentage BMD change was higher than the average change in the control group. Corresponding numbers are 59% for the total hip and 64% for the femoral neck. If we define nonresponding as negative or no change of BMD after intervention, 25% (spine), 56% (total hip), and 59% (neck) of the exercising women were nonresponders. For the spine, these numbers are slightly higher compared with the nonresponder rates reported in pharmaceutical studies with alendronate (15% nonresponders) or HRT (20%).[48]

We did not detect any significant training effects on BMD at the proximal femur. We attribute this to the short duration of high-intensity training, which did not start before month 7. It is known from pharmaceutical trials that the femur is more inert to interventions compared with the spine, where the ratio of trabecular versus cortical bone is higher. Thus, we expect significant results at the proximal femur in year 2 or 3 of our ongoing trial.

Besides bone density, strength and endurance are important variables influencing general health, falls, independence, and QOL. $\dot{V}O_2$max as a central parameter of the efficiency of the cardiovascular system increased in the exercise group and decreased in the control group, which is comparable to other osteoporosis exercise studies that focused on endurance.[16,49-51] Isometric strength results in general are difficult to compare because test protocols vary. Exercise studies measuring trunk extensors and flexors in the isometric modus, using a test protocol comparable to ours,[35,38,52,53] showed somewhat lower increases for trunk extensors (20%–29%) and comparable results for trunk flexors (26%–30%).

Our training program is easily adaptable by other organizations. It conforms with German rehabilitation recommendations in the field of osteoporosis that favor 2 joint sessions per week. In our program, 1 session was carried out on standard machines available in any fitness study, and we used only a few other readily available devices, such as elastic belts and dumbbells. The trainers, typically physical education students from our university, completed some dedicated seminars on osteoporosis, which, for example, in Germany are routinely offered by local and regional sports organizations. This means the experience necessary to supervise training can be gained easily and cost effectively.

CONCLUSION

We showed that a controlled multifactorial exercise training program combining running, aerobics, rope skipping, jumps, and isometric and dynamic strength training can be successfully integrated into the life of early postmenopausal women. Contrary to many other studies that showed either negative effects or no effects on density, we observed a significant BMD increase at the spine after 14 months. However, no significant effect was found for BMD at the hip. Endurance and strength increased at rates comparable to those reported in exercise studies that focused especially on these parameters. Our dropout rate was low, compliance was reasonable, and indications of adverse side effects, such as osteoarthritis, were not observed.

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