

# Effects of a Targeted Multimodal Exercise Program Incorporating High-Speed Power Training on Falls and Fracture Risk Factors in Older Adults: A Community-Based Randomized Controlled Trial

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## ABSTRACT

Multimodal exercise programs incorporating traditional progressive resistance training (PRT), weight-bearing impact training and/or balance training are recommended to reduce risk factors for falls and fracture. However, muscle power, or the ability to produce force rapidly, has emerged as a more crucial variable to functional decline than muscle strength or mass. The aim of this 12-month community-based randomized controlled trial, termed *Osteo-cise: Strong Bones for Life*, was to evaluate the effectiveness and feasibility of a multimodal exercise program incorporating high-velocity (HV)-PRT, combined with an osteoporosis education and behavioral change program, on bone mineral density (BMD), body composition, muscle strength and functional muscle performance in older adults. Falls incidence was evaluated as a secondary outcome. A total of 162 older adults (mean  $\pm$  SD;  $67 \pm 6$  years) with risk factors for falls and/or low BMD were randomized to the *Osteo-cise* program ( $n = 81$ ) or a control group ( $n = 81$ ). Exercise consisted of fitness center-based HV-PRT, weight-bearing impact and challenging balance/mobility activities performed three times weekly. After 12 months, the *Osteo-cise* program led to modest but significant net gains in femoral neck and lumbar spine BMD (1.0% to 1.1%,  $p < 0.05$ ), muscle strength (10% to 13%,  $p < 0.05$ ), functional muscle power (Timed Stair Climb, 5%,  $p < 0.05$ ) and dynamic balance (Four Square Step Test 6%,  $p < 0.01$ ; Sit-to-Stand, 16%,  $p < 0.001$ ) relative to controls. There was no effect on total body lean mass or mobility (timed-up-and-go), and no difference in falls rate (incidence rate ratio [IRR], 1.22; 95% confidence interval [CI], 0.72–2.04). In conclusion, this study demonstrates that the *Osteo-cise: Strong Bones for Life* community-based, multimodal exercise program represents an effective approach to improve multiple musculoskeletal and functional performance measures in older adults with risk factors for falls and/or low BMD. Although this did not translate into a reduction in the rate of falls, further large-scale trials are needed to evaluate the efficacy of this multimodal approach on reducing falls and fracture. © 2014 American Society for Bone and Mineral Research.

**KEY WORDS:** EXERCISE; BONE MINERAL DENSITY; HIGH VELOCITY POWER TRAINING; RANDOMIZED CONTROLLED TRIAL; OLDER ADULTS

## Introduction

Exercise is widely recommended as an effective strategy to reduce the risk of osteoporosis and fractures through its beneficial effects on bone and muscle health and fall-related risk factors. However, not all modes of exercise are equally effective for improving the various measures of musculoskeletal health and function. A number of randomized controlled trials (RCTs) and meta-analyses have shown that progressive and targeted exercise programs incorporating a combination of moderate to high-intensity weight-bearing activities and slow speed progressive resistance training (PRT) can maintain or improve hip and/or spine areal BMD (aBMD) and increase muscle mass,

strength and/or size in both postmenopausal women and older men.<sup>(1–4)</sup> However, there are mixed findings with regard to the effects of traditional slow speed PRT on measures of balance, gait, mobility, and postural sway, all of which are important for prevention of falls.<sup>(5,6)</sup> A recent meta-analysis of RCTs examining the effects of different modes of exercise on falls risk in older adults reported that high-challenge balance training was most effective for reducing falls.<sup>(7)</sup> Programs that included regular walking tended to attenuate these beneficial effects, whereas PRT alone did not prevent falls. This may be attributed in part to the fact that most PRT programs encourage slow velocity contractions (2-second to 4-second concentric [lifting] phase) at a moderate to high percentage of maximal force. However, many

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daily tasks related to mobility and daily perturbations require rapid and explosive coordinated contractions and not maximal muscle force production. Therefore, programs that focus on improving the ability to produce force rapidly—also referred to as muscle power—are likely to be more effective for enhancing muscle function and movement speed, and thereby reducing falls risk.

The clinical importance of optimizing muscle power has been highlighted in studies which have reported that deficits in muscle power are stronger predictors of disability and falls than muscle strength.<sup>(8,9)</sup> One form of training that can enhance muscle power is high-velocity (HV)-PRT, or power training, which is characterized by rapid concentric (lifting or pushing) movements followed by a slower eccentric (lowering) phase. Several recent reviews and meta-analyses of the few short-term RCTs available have demonstrated that HV-PRT is safe and feasible for older adults and more effective for improving functional outcomes (eg, chair rising time and walking speed) than traditional PRT.<sup>(10,11)</sup> Given the rapid and explosive nature of the muscle contractions associated with HV-PRT, this mode of training might also be expected to provide an effective osteogenic stimulus to enhance BMD. Therefore, the aim of this study was to evaluate the effectiveness and feasibility of a community-based, multimodal exercise program incorporating HV-PRT with additional weight-bearing and challenging balance and mobility activities for improving bone health, muscle mass and strength, and functional performance in older adults. A secondary aim of this study was to evaluate the effects of the intervention on falls incidence.

## Materials and Methods

### Study design

This study was a 12-month community-based, multifaceted RCT in which participants ( $n = 162$ ) were allocated into one of two groups: (1) the *Osteo-cise: Strong Bones for Life* multimodal exercise, osteoporosis education/awareness and behavioral change program ( $n = 81$ ) or (2) a standard care self-management control group ( $n = 81$ ). All participants were provided with and advised to take one vitamin D supplement (Blackmores, Sydney, Australia, Vitamin D<sub>3</sub>, 1000 IU/d cholecalciferol) and two calcium supplements (Blackmores Total Calcium, 350 mg of elemental calcium as calcium phosphate; 700 mg total) each day throughout the study.

### Participants

Men and women aged 60 years and over living independently in the community in the Western suburbs and surrounding regions of Melbourne, Australia, were recruited for this study. Full details of the recruitment and screening process have previously been reported.<sup>(12)</sup> Briefly, participants were initially excluded (via the telephone) if they were aged <60 years, had a body mass index (BMI) >40 kg/m<sup>2</sup>, had a history of osteoporosis or a recent (past 6 months) low-trauma fracture, had participated in resistance training or a structured weight-bearing exercise program more than once a week in the past 3 months, were current smokers, had any medical condition or used medication known to influence bone metabolism or fracture risk, had initiated calcium or vitamin D supplementation in the preceding 6 months, were expecting to travel for more than 6 weeks throughout the intervention, and, for women, were currently using or in the previous 6 months had used hormone

replacement therapy (>0.625 mg/d Premarin or equivalent estrogen).

A total of 696 participants were pre-screened, from which 249 were invited to have an aBMD scan, measured using a Hologic Discovery W dual-energy X-ray absorptiometry (DXA) machine with the APEX Software v3.2 (Hologic, Bedford, MA, USA), and a falls risk assessment. Participants with a total hip, femoral neck or lumbar spine T-score between -1.0 and <-2.5 standard deviations (SD), or classified as at increased risk for falls or fracture based on a questionnaire adapted from Sanders and colleagues,<sup>(13)</sup> were included in the study ( $n = 162$ ). Participants were randomized to one of the two groups, stratified by sex, by an independent staff member not involved in the study using a computer generated random numbers table (Microsoft Excel; Microsoft, Redmond, WA, USA). All eligible participants were required to obtain approval from their local physician to clear them of any contraindicated medical conditions to exercise based on American College of Sports Medicine (ACSM) guidelines.<sup>(14)</sup> Reasons for exclusion are shown in Fig. 1. The study was approved by the Melbourne Health Human Research Ethics Committee and written consent was obtained from all participants. The study was registered with the Australian New Zealand Clinical Trials Registry (Reference ACTRN12609000100291 "Osteo-cise: Strong Bones for Life. An Inclusive Evidence-based Multi-component Exercise, Falls Prevention and Osteoporosis Education Program"; <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=83442>).

### Intervention

As reported,<sup>(12)</sup> *Osteo-cise: Strong Bones for Life* was a community-based multifaceted program that comprised four key components: (1) *Osteo-cise*: a multimodal targeted osteoporosis and falls prevention exercise program; (2) *Osteo-Adopt*: behavioral change strategies designed to encourage adoption and maintenance of lifelong exercise participation; (3) *Osteo-Ed*: a series of community-based osteoporosis education/awareness seminars aimed at improving participants' knowledge and understanding of osteoporosis risk factors, exercise, and nutrition so that they could actively take charge of their bone health; and (4) *Osteo-Instruct*: a "train-the-trainers" workshop designed to instruct the exercise trainers implementing the program on the aims and structure of the program and to update them on the latest osteoporosis prevention and management strategies. Detailed information on each of these components has been previously reported,<sup>(12)</sup> but a brief overview of the exercise program is provided in the following paragraph.

The *Osteo-cise* exercise program was conducted at seven local health and fitness centers and implemented by exercise trainers who had successfully completed the *Osteo-Instruct* training course. Training comprised of HV-PRT combined with diverse-loading, moderate-impact, weight-bearing exercises (60 to 180 impacts per session) and high-challenge balance/functional exercises performed 3 days per week for 12 months. HV-PRT is characterized by rapid concentric (lifting phase) movements in order to maximize both movement speed and muscle force. Specific details about the types of exercises and training progressions have been previously reported.<sup>(12)</sup> Briefly, the 12-month program was periodized and divided into an initial 4-week "adoption phase" followed by four distinct 12-week phases that were designed to be progressively more challenging.<sup>(12)</sup> A combination of pin-loaded machine weights, pulleys

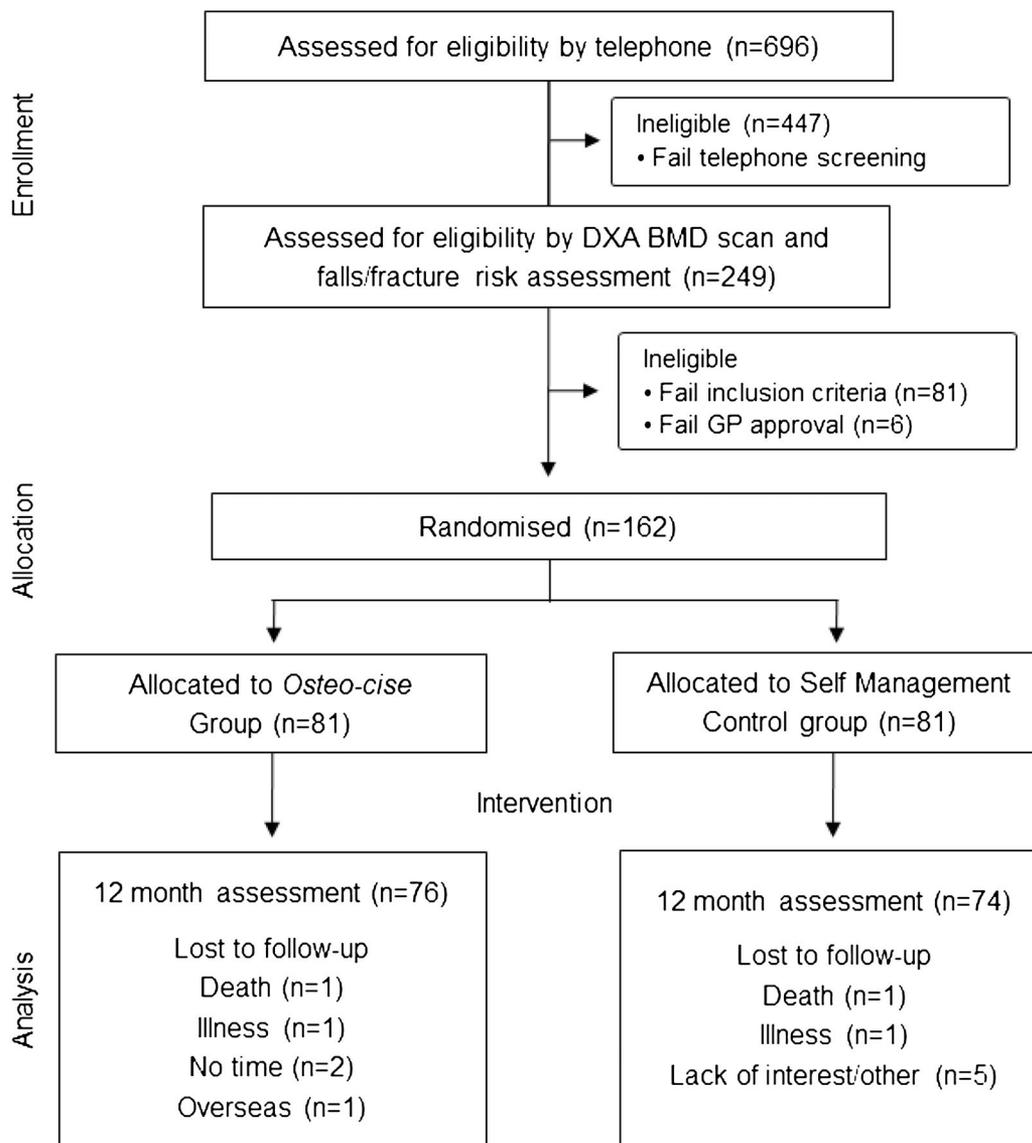


Fig. 1. Study design and flow of participants.

and free weights were used with trainers advised to choose from a battery of exercises that specifically target the muscles attached to or near the hip and spine. Training intensity was monitored using the modified Borg (1 to 10) Rating of Perceived Exertion (RPE) scale. During the “adoption phase” participants completed two sets of 12 to 15 repetitions at 40% to 60% of one-repetition maximum (1-RM) (RPE 3 to 4) with 1 to 2 minutes rest between sets. Thereafter, participants commenced HV-PRT for the lower extremity exercises and completed two sets of 8 to 12 repetitions of each exercise at an intensity of 5 to 8 on the RPE scale, which represents “hard to very hard” exertion.

Weight-bearing impact exercises were selected by exercise trainers from a battery of exercises that were found to be safe and effective for improving femoral neck and lumbar spine BMD in middle-aged and elderly men.<sup>(1,2)</sup> Exercises were divided into three categories: stationary movements (eg, stomping, mini tuck

jumps); forward/backward movements (eg, box step-ups, backward and forward pogo jumps); and lateral/multidirectional movements (eg, side-to-side shuffle, lateral box jumps). Three sets of 10 to 20 repetitions for two to three weight-bearing exercises were included in each training session. Training intensity was progressively increased by increasing the height of jumps and/or by adding additional weight (eg, dumbbells), increasing the rate of impact loading or introducing multidirectional movement patterns (eg, diagonal loads) to alter the load distribution. High-challenge balance and functional exercises were categorized into three types: (1) fit ball exercises (eg, fit ball sitting with heel lifts); (2) standing balance exercises (eg, single-leg standing); and (3) dynamic functional exercises (eg, heel-toe walking). Two challenging balance exercises were performed in each session with each exercise maintained for up to 30 seconds or performed for a given number of repetitions, and participants (in consultation with their trainer) were instructed to progress an

exercise to the next level of difficulty once it was no longer challenging.

### Self-management control group

The self-management control group was requested to continue their usual care and were provided with general consumer information about osteoporosis, available from Osteoporosis Australia ([www.osteoporosis.org.au](http://www.osteoporosis.org.au)), to enable them to actively take charge of their own musculoskeletal health.

### Measurements

#### *Anthropometry, physical activity, dietary status, and medical history*

Height to the nearest 0.1 cm and body weight to the nearest 0.1 kg were measured using standard procedures. Daily dietary energy (kJ), calcium (mg), fat (g), protein (g) and carbohydrate (g) intake were estimated from a 24-hour food diary, used to record the total type and amount of food and beverage consumed. The food diary was checked for completeness by the research staff and all dietary information was entered and analyzed using Australia-specific dietary analysis software (Foodworks; Xyris Software, Highgate Hill, Australia). The Community Healthy Activities Model Program for Seniors (CHAMPS) physical activity questionnaire was used to assess current participation in weight-bearing and total leisure time physical activity (hours per week).<sup>(15)</sup> Information on medical, medication use, menstrual, smoking and falls history as well as alcohol intake were determined by questionnaire as reported.<sup>(12)</sup>

#### *BMD and body composition*

Lumbar spine (L<sub>2</sub>–L<sub>4</sub>) and proximal femur aBMD (g/cm<sup>2</sup>), total body lean mass (kg) and fat mass (kg) were assessed using DXA (Hologic Discovery W, APEX Software v3.2, Hologic Inc., 1986–2010). All follow-up scans were analyzed using the “comparison” feature of the Hologic APEX program. The short-term coefficient of variance (CV) for the BMD and body composition measures in our laboratory ranged from 0.8% to 1.5% and 0.6% to 1.2%, respectively.

#### *Muscle strength, functional muscle power, and performance*

Maximum muscle strength of the lower limbs (bilateral leg press) and back (seated row) was assessed using three-repetition maximum (3-RM) testing. Functional stair climbing muscle power (Watts, W) was assessed by the Timed Stair Climb Test, whereby participants were instructed to climb a flight of stairs (10 steps, 14-cm rise/step) as quickly as possible without the use of handrails or any other aid. Functional muscle performance was assessed using the following battery of validated tests: the 30 Second Sit-to-Stand, Four Square Step Test, and the Timed Up and Go Test with a secondary cognitive task (counting backward from 100 by 3). Details on all of the above tests have been reported.<sup>(12)</sup>

#### *Compliance, falls, and adverse events*

Compliance with the *Osteo-cise* exercise program was determined using the exercise cards completed by participants and checked regularly by the trainers. Compliance with the calcium and vitamin D supplements was calculated from a tablet count when remaining bottles were returned at each testing appointment. Although this study was not powered to detect a

significant difference in falls outcomes, participants were instructed to document any falls (or fractures) sustained on a monthly “falls calendar,” which was returned to investigators at the end of each month via postage-paid envelopes. A fall was defined as “unintentionally coming to the ground or some lower level, other than as a consequence of a sudden onset of paralysis, epileptic seizure, or overwhelming external force.”<sup>(16)</sup> Participants were asked to report any adverse events/injuries sustained during the program at each testing session and exercise trainers were also asked to document any adverse events in a dedicated *Osteo-cise* folder. For this study, an injury was defined as a musculoskeletal complaint or pain requiring the participant to seek treatment such as icing, medication or review by a health professional, or to withdraw from or modify their exercise program.

### Statistical analysis

Sample-size calculations were based on the expected mean difference between the groups for the change in the primary outcome measures of femoral neck BMD and functional muscle power based on previous exercise trials.<sup>(2,17)</sup> We estimated that to have 90% power of detecting a 1.8% difference in femoral neck BMD (assuming an SD of 3.5) at the two-tailed test with an alpha level of 0.05, we would require 60 participants in each group. For functional muscle power, we estimated that 24 participants per group would provide 90% power to detect a 15% net difference for the change relative to baseline (two-tailed, alpha level of 0.05), assuming a SD of 15%. Therefore, with an anticipated 20% dropout rate, a minimum of 72 participants per group (144 in total) was required. All statistical analyses were conducted using Stata statistical software (version 11.0; Stata Corp, College Station, TX, USA). All data were analyzed on an intention-to-treat basis; ie, data from all participants were included in the analyses regardless of compliance. Participants who discontinued exercise and other dropouts were measured at follow-up if they agreed to return for testing. No data was imputed for the few participants with missing data. Baseline characteristics between the groups were compared using independent *t* tests for continuous variables and chi-squared tests for categorical variables. Pooled time-series regression analysis for longitudinal data was used to test for time effects and group-by-time interactions, adjusting for sex. Between-group differences were calculated by subtracting the within-group changes from baseline in each group. Within-group changes were presented as either absolute changes or percentage changes from baseline. The incidence rate ratio for the number of falls in each group was analyzed using negative binomial regression, which allows for overdispersion. Log-binomial regression models were also used to compare the relative risks of the number of participants with one or more falls and multiple falls in each group. The Cox hazard-regression model was used to analyze the difference in time to first fall between groups after adjusting for age sex and history of falls. All data are presented as means ± SD or 95% CI unless stated, and the significance level was *p* < 0.05.

## Results

### Baseline characteristics, study attrition, and adherence

There were no differences between groups for any of the baseline characteristics (Tables 1, 2). Twelve participants (*Osteo-cise*, *n* = 5; control, *n* = 7) withdrew from the study over

12 months leaving 150 participants (93%) for the final analysis. The reasons for withdrawal are outlined in Figure 1. Mean  $\pm$  SD compliance to the exercise program was 59%  $\pm$  32% (median 74%), which was equivalent to approximately two sessions per week. Overall 23.5% of the participants attended on average less than one session per week, 21.0% attended between 1.0 and 1.9 sessions and 55.5% attended 2 to 3 sessions per week. The mean compliance with the calcium and vitamin D supplements was similar in each group (calcium: *Osteo-cise*, 89.2%; controls, 89.9%; vitamin D: *Osteo-cise*, 93.2%; controls, 93.5%). Attendance at the three *Osteo-Ed* sessions by the *Osteo-cise* participants was 82% for the first session titled "Osteoporosis: what are the risk factors?," 63% for the session titled "Exercise for optimal bone and muscle health," and 65% for the third session, "Nutrition for healthy bones."

### Adverse events

Over 12 months there were 40 musculoskeletal complaints or injuries reported by 34 of the 81 *Osteo-cise* participants (63% in the first 6 months). The body sites of these complaints were the knee ( $n = 15$ ), shoulder ( $n = 9$ ), hip ( $n = 7$ ), ankle/foot ( $n = 3$ ), back/neck ( $n = 3$ ) and elbow/wrist ( $n = 3$ ). Twenty-one (53%) of the complaints were pre-existing injuries aggravated by participation in the program and 27 (67%) required some form of treatment (icing, medication, health professional review). Six participants withdrew from the training as a result of their injury. For the remaining 28 participants who reported an injury, the trainers were able to modify the exercises to allow them to continue to participate in the program.

**Table 1.** Characteristics of the Participants at Baseline by Group

Characteristic	<i>Osteo-cise</i>	Control
<i>n</i>	81	81
Women, <i>n</i> (%)	60 (74)	59 (73)
Age (years)	67.7 $\pm$ 6.5	67.2 $\pm$ 5.5
Height (cm)	164.0 $\pm$ 8.0	164.9 $\pm$ 8.9
Weight (kg)	73.3 $\pm$ 11.5	75.1 $\pm$ 14.9
BMI (kg/m <sup>2</sup> )	27.2 $\pm$ 3.8	27.6 $\pm$ 4.8
Current HRT use (%)	6.8	5.1
Previous HRT use (%)	52.5	37.3
Ex-smokers (%)	31.3	29.6
Areal BMD (g/cm <sup>2</sup> )		
Lumbar spine	0.971 $\pm$ 0.135	0.968 $\pm$ 0.146
Femoral neck	0.730 $\pm$ 0.081	0.713 $\pm$ 0.082
Total hip	0.889 $\pm$ 0.102	0.880 $\pm$ 0.105
Muscle strength and power		
Leg muscle strength (kg)	58.0 $\pm$ 17.3	58.2 $\pm$ 18.1
Back muscle strength (kg)	36.8 $\pm$ 13.8	41.0 $\pm$ 18.3
Functional muscle power (W)	236 $\pm$ 52	242 $\pm$ 60
Muscle function		
30 Second Sit-to-Stand (number of stands)	14.5 $\pm$ 3.5	14.9 $\pm$ 3.0
Four Square Step Test (seconds)	8.1 $\pm$ 1.4	8.0 $\pm$ 1.2
Dual-task Timed Up and Go (seconds)	10.2 $\pm$ 4.2	9.8 $\pm$ 3.2

Values are mean  $\pm$  SD or as indicated.

HRT = hormone replacement therapy; BMD = bone mineral density.

### Changes in physical activity and diet

As shown in Table 2, there were no significant within-group changes or between-group differences for the changes in total leisure time physical activity, participation in weight-bearing exercise (outside of the intervention) or diet throughout the intervention, with the exception that daily carbohydrate intake decreased in the *Osteo-cise* group.

### Changes in BMD

After 12 months, the *Osteo-cise* group experienced a significant 1.1% (95% CI, 0.3% to 2.0%) greater increase in lumbar spine aBMD compared with controls (Table 3). This was due to a significant 1.5% (95% CI, 0.8% to 2.1%) increase in aBMD in the *Osteo-cise* group but no marked change in the controls (0.3%; 95% CI, -0.3% to 1.0%). At the femoral neck, there was a significant 1.0% (95% CI, 0.2% to 1.9%) greater increase in aBMD in the *Osteo-cise* group compared with controls, which was due to a non-significant 0.6% (95% CI, 0.0% to 1.2%;  $p = 0.06$ ) increase in the *Osteo-cise* group and a 0.4% (95% CI, -1.0% to 0.2%;  $p = 0.21$ ) non-significant loss in the controls. There were no significant between-group differences for the change in total hip aBMD.

### Changes in body composition, muscle strength, and functional performance

There were no significant changes in weight, total body lean mass or fat mass after 12 months in either group (Table 3). For leg and back muscle strength, the *Osteo-cise* group experienced a greater gain relative to controls after 6 months (net difference: bilateral leg extension: 9.5%, 95% CI, 3.7% to 15.2%; seated row: 13.3%, 95% CI, 6.3% to 20.3%; both  $p < 0.001$ ), which were maintained after 12 months (Fig. 2). The *Osteo-cise* group also experienced a 4.5% (95% CI, 0.6% to 8.3%;  $p < 0.05$ ) greater gain in functional muscle power compared with controls after 6 months, which persisted after 12 months (4.8%; 95% CI, 0.9% to 8.6%;  $p < 0.05$ ) (Fig. 3). Similar significant exercise-induced net gains were observed after 6 months for the 30 Second Sit-to-Stand (11.4%, 95% CI, 5.5% to 17.3%;  $p < 0.001$ ) and the Four Square Step Test (5.6%; 95% CI, 0.9% to 10.3%;  $p < 0.05$ ) (Fig. 3). Although these between-group differences remained significant after 12 months, the *Osteo-cise* group experienced a further 7% improvement in the 30 Second Sit-to-Stand test during the final 6 months. There were no between-group differences for the Timed Up and Go Test after 6 or 12 months.

### Falls and fractures

Over 12 months, the *Osteo-cise* group experienced 46 falls (in 29 participants) whereas the control group reported 34 falls (in 25 participants). Only one fracture (wrist fracture) was recorded throughout the 12 months, which occurred in a participant in the *Osteo-cise* group as a result of an accident during training. As indicated in Table 4, there were no significant differences in falls incidence between the groups or the number of participants sustaining one or more falls or multiple falls. Cox proportional hazards model analysis also revealed that there was no between-group differences in the time to first fall (hazard ratio [HR], 1.31; 95% CI, 0.76-2.27;  $p = 0.33$ ).

### Discussion

The main finding from this 12-month community-based RCT was that the multifaceted *Osteo-cise: Strong Bones for Life* osteoporosis prevention program, incorporating a combination

**Table 2.** Baseline and 12-Month Habitual Physical Activity and Dietary Intakes for the *Osteo-cise* and Control Groups

Variable	<i>Osteo-cise</i>		Control	
	Baseline (n = 81)	12 months (n = 76)	Baseline (n = 81)	12 months (n = 74)
<b>Physical activity</b>				
Total leisure time (hours/week)	13.4 ± 7.5	14.6 ± 8.3	15.0 ± 7.1	14.4 ± 7.1
Weight-bearing exercise (hours/week)	2.5 ± 3.3	3.0 ± 3.5	2.7 ± 3.5	2.6 ± 2.7
<b>Diet</b>				
Energy intake (kJ/d)	7700 ± 2078	7488 ± 2980	7778 ± 2324	7457 ± 2319
Carbohydrate (g/d)	214.1 ± 105	192.6 ± 87.4 <sup>b</sup>	207.5 ± 78	192.0 ± 70.2
% Energy from carbohydrates	43.6 ± 8.2	41.8 ± 8.8	44.4 ± 10.1	43.0 ± 10.3
Fat (g/d)	66.0 ± 30.1	65.7 ± 36.5	65.1 ± 27.2	65.2 ± 30.3
% Energy from fat	31.1 ± 9.2	32.1 ± 8.8	30.1 ± 8.3	31.4 ± 9.8
Protein (g/d)	91.7 ± 37.5	90.7 ± 35.4	90.0 ± 33.4	91.5 ± 36.7
% Energy from protein	20.2 ± 5.4	21.2 ± 5.3	20.3 ± 6.3	20.9 ± 5.4
Calcium (mg/d) <sup>a</sup>	771 ± 300	807 ± 393	846 ± 387	855 ± 394

Values are mean ± SD.

<sup>a</sup>Calcium intake does not include supplemental calcium.

<sup>b</sup>*p* < 0.05 within-group change from baseline.

of HV-PRT with a diverse range of weight-bearing impact and challenging balance activities, led to modest but significant improvements in both lumbar spine and femoral neck aBMD as well as muscle strength, lower limb functional muscle power and dynamic balance in older adults with risk factors for falls and/or low BMD. These improvements did not translate into a reduction in incidence of falls, however, the sample size in this study was insufficient to draw definitive conclusions about the efficacy of this program on preventing falls. Although further large-scale, long-term trials are needed to evaluate whether this multimodal program can reduce falls within community-dwelling older adults, the findings from this study support previous intervention trials, systematic reviews, and meta-analyses<sup>(1,4,18–22)</sup> suggesting that multimodal exercise programs are likely to be most effective for improving a number of musculoskeletal and functional outcomes in older adults.

To our knowledge, this is the first RCT to demonstrate that a multimodal exercise program incorporating HV-PRT was effective for increasing femoral neck and lumbar spine aBMD in older adults. In a previous 12-month RCT in 53 postmenopausal osteopenic women, von Stengel and colleagues<sup>(23)</sup> reported that HV-PRT was more effective than slow-speed PRT for maintaining total hip and lumbar spine aBMD. Both groups in this study were also prescribed multidirectional jumping and a gymnastics session to improve fall-related abilities plus a weekly home-based session, but muscle function was not assessed. The authors suggested that the beneficial skeletal effect of the HV-PRT program was most likely due to the high strain rate associated with the rapid concentric muscle contractions. Indeed, when they quantified the loading characteristics associated with the leg-press exercise they found that HV-PRT

**Table 3.** Mean Body Weight, Total Body Lean Mass, Fat Mass, and Lumbar Spine and Proximal Femur BMD for the *Osteo-Cise* and Control Groups at Baseline and the Percentage Within-Group Changes and Net Differences for the Change Relative to Baseline Between the Groups

Variable	<i>Osteo-cise</i>		Control		Net difference (95% CI)
	Baseline (n = 81)	% Change (n = 76)	Baseline (n = 81)	% Change (n = 74)	
<b>Body composition (kg)</b>					
Weight	73.3 ± 11.5	−0.2 (−1.0 to 0.6)	75.1 ± 14.9	−0.2 (−1.2 to 0.8)	0.0 (−1.3 to 1.2)
Lean mass	42.7 ± 7.9	0.8 (−0.3 to 1.9)	43.6 ± 9.8	0.4 (−0.6 to 1.5)	0.4 (−1.1 to 1.9)
Fat mass	27.3 ± 8.0	−0.8 (−2.6 to 1.1)	28.3 ± 9.1	−1.0 (−3.3 to 1.3)	0.2 (−2.7 to 3.2)
<b>BMD (g/cm<sup>2</sup>)</b>					
Lumbar spine	0.971 ± 0.135	1.5 (0.8 to 2.0) <sup>c</sup>	0.968 ± 0.146	0.3 (−0.3 to 1.0)	1.1 (0.3 to 2.0)*
Femoral neck	0.730 ± 0.081	0.6 (0.0 to 1.2) <sup>a</sup>	0.713 ± 0.082	−0.4 (−1.0 to 0.2)	1.0 (0.2 to 1.9)*
Total hip	0.889 ± 0.102	0.9 (0.4 to 1.4) <sup>c</sup>	0.880 ± 0.105	0.5 (0.1 to 1.0) <sup>b</sup>	0.4 (−0.3 to 1.0)

All data represent means ± SD or means with 95% CI. All statistical analyses were adjusted for sex. Net difference represents the net unadjusted difference for the percentage changes from baseline between groups.

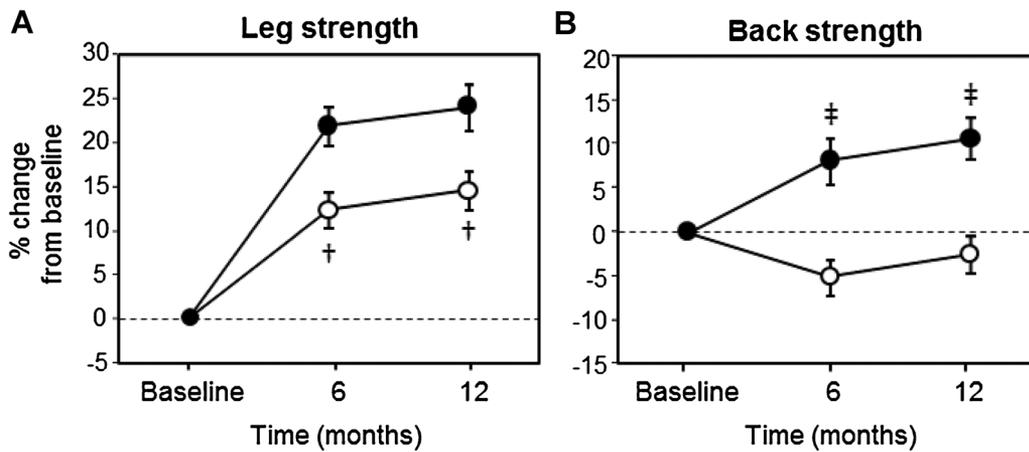
BMD = bone mineral density; CI = confidence interval.

\**p* < 0.05 difference between groups.

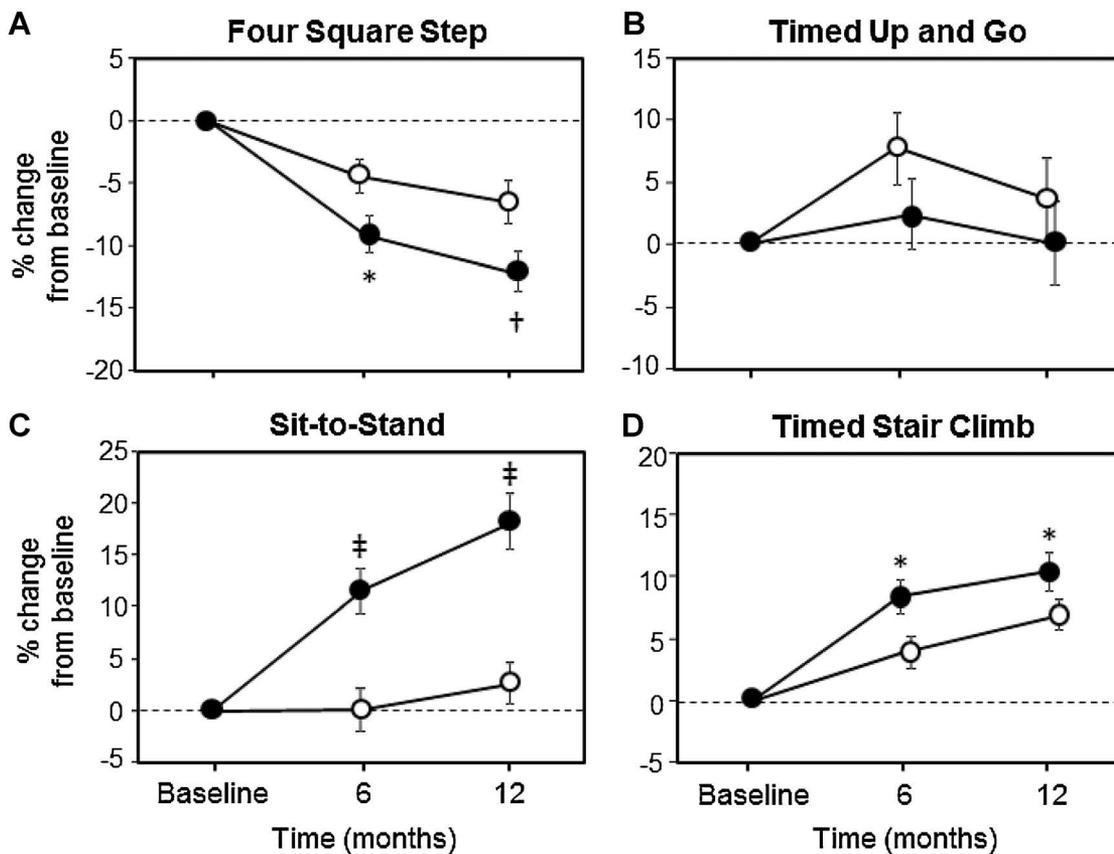
<sup>a</sup>*p* = 0.06.

<sup>b</sup>*p* < 0.05.

<sup>c</sup>*p* < 0.001 within-group change from baseline.



**Fig. 2.** Mean percentage changes ( $\pm$  SE) from baseline for leg (A) and back (B) muscle strength in the *Osteo-cise* (black circles) and control group (open circles).  $\dagger p < 0.01$ ,  $\ddagger p < 0.001$  between-group difference for the change from baseline.



**Fig. 3.** Mean percentage changes ( $\pm$  SE) from baseline for (A) dynamic balance (Four Square Step Test), (C) 30-Second Sit-to-Stand, (B) mobility (Timed Up and Go), and (D) functional muscle power (Timed Stair Climb) in the *Osteo-cise* (black circles) and control group (open circles). \* $p < 0.05$ ,  $\dagger p < 0.01$ ,  $\ddagger p < 0.001$  between-group difference for the change from baseline.

**Table 4.** Falls and Fractures in the *Osteo-cise* and Control Groups During the 12-Month Intervention

Outcomes	<i>Osteo-cise</i>	Control	IRR/RR (95% CI)	<i>p</i>
<i>n</i>	81	81		
Fracture, <i>n</i> (%)	1 (1.2)	0 (0)	–	–
Previous falls, <i>n</i> (%)	11 (13.6)	10 (12.4)	–	–
Falls, <i>n</i> (rate)	46 (0.57)	34 (0.42)	1.22 (0.72–2.04) <sup>a</sup>	0.46
≥1 Fall, <i>n</i> (%)	29 (35.8)	25 (30.9)	1.15 (0.66–1.99) <sup>b</sup>	0.62
≥2 Falls, <i>n</i> (%)	13 (16.1)	6 (7.4)	1.99 (0.74–5.36) <sup>b</sup>	0.17

Fall rate calculated as the number of falls reported over 12 months (*n*) divided by the number of participants in each group.

IRR = incidence rate ratio; RR = relative risk.

<sup>a</sup>IRR calculated for comparing the rate of falls between the groups, adjusting for age, sex and history of falls.

<sup>b</sup>RR calculated for comparing the number of fallers in each group.

was associated with a 16% higher relative loading magnitude, an 82% higher relative loading amplitude and a 262% higher loading rate relative to slow-speed PRT.<sup>(23)</sup>

It is widely recognized that bone is a mechanosensitive tissue which alters its mass and/or structure in response to increased strain (exercise). Previous research in animals has shown that loads which are dynamic, high in magnitude, applied rapidly and are unusual in their distribution are particularly effective for producing an osteogenic response.<sup>(24–27)</sup> Thus, even though compliance with the *Osteo-cise* program was modest (mean 59%), the beneficial skeletal effects in our intervention are most likely attributed to the fact that the training program included all of the above loading characteristics, incorporated the principle of progressive overload, and specifically targeted muscles attached to or near the hip and spine. Although it is not possible to determine whether the loading associated with the HV-PRT or the weight-bearing impact exercise contributed predominantly to the adaptive skeletal responses, the estimated magnitude (approximately two to six times body weight) and dose of loading (60 to 180 impacts per session) associated with the weight-bearing component of the program were similar to that used in our previous multimodal exercise trial in older men<sup>(1,2)</sup> and other targeted impact loading intervention trials which observed similar exercise-induced skeletal gains at the proximal femur or lumbar spine in premenopausal and/or postmenopausal women.<sup>(21,28–30)</sup>

The reason for the lack of a significant net gain in total hip aBMD in our study is unclear, although a number of previous multimodal exercise interventions in older adults have also failed to observe an osteogenic effect at this site after 12 to 14 months.<sup>(1,31)</sup> Of the exercise intervention trials that have demonstrated beneficial effects on total hip aBMD in older adults, most have been conducted over a longer period (18 months to >2 years).<sup>(18,21,32)</sup> In the Erlangen Fitness Osteoporosis Prevention Study (EFOPS) incorporating a multimodal exercise intervention in postmenopausal women, total hip aBMD was maintained in the exercise relative to the control group (–0.2% versus –1.9%) after 3 years of training, but no significant effect was detected after 12 months.<sup>(31,32)</sup> This suggests that a longer duration of training (≥18 months) may be required to elicit significant exercise-induced gains in total hip aBMD in older adults.

One of the strengths of the *Osteo-cise* program was that it was also effective for improving muscle strength, functional muscle power and dynamic balance. Although the gains in muscle strength were lower than that observed in a number of previous trials using traditional PRT methods,<sup>(33–35)</sup> they were consistent

with those observed in several other studies incorporating HV-PRT.<sup>(36–41)</sup> These modest gains in strength are likely due to the focus of this mode of training on optimizing movement speed rather than peak muscle force. This may also explain why there were no significant exercise-induced increases in lean mass in our study. This indicates that most of the gains in strength were likely related to neural adaptations (eg, improved motor-unit firing rate, synchronization and levels of activation) and/or changes in fiber type distribution (eg, an increase in the size of type II fast twitch fibers).<sup>(42)</sup>

The significant exercise-induced improvements in functional muscle power and dynamic balance can likely be attributed to the principle of training specificity. That is, the *Osteo-cise* program was designed to incorporate high-challenge balance training to optimize balance and mobility, and HV-PRT with dynamic moderate-impact exercises to target muscle power and movement speed. Indeed, consistent with our findings, several previous short-term HV-PRT trials conducted over 2 to 6 months in community-dwelling older adults reported 9% to 11% exercise-induced gains in stair-climb performance,<sup>(36,38)</sup> and 13% to 17% gains in chair-rise ability relative to controls.<sup>(36–38)</sup> Recent reviews and meta-analyses have also reported that high-challenge balance training or programs incorporating two or more types of exercise which target both muscular and somatosensory balance systems were most effective for reducing the risk of falls in older adults.<sup>(6,43)</sup>

Although this study was not designed or powered to detect an effect of the *Osteo-cise* program on falls, we found that those in the *Osteo-cise* group tended to experience more falls than controls but there were no significant differences in falls rate between groups. Although these results must be interpreted with caution due to the small sample size, it has been speculated that participants undertaking exercise as part of an intervention may become more physically active outside the intervention, thereby exposing them to more “at-risk” activities for falling. However, in the current study there were no changes in total leisure time or weight-bearing physical activity in those assigned to the *Osteo-cise* program. A more likely reason for the lack of an exercise effect relates to the relatively high-functioning, ambulant population studied. Although this study was designed to recruit older adults with risk factors for falls and/or low BMD, over 90% were recruited based on having osteopenia alone. Further larger and longer-term studies are warranted to evaluate the efficacy of this program for preventing falls in older adults.

There are several aspects of the *Osteo-cise* program that will require modification before it can be considered for widespread implementation. For instance, compliance with the exercise

program was modest, averaging 59% over the 12 months, despite the use of established behavioral strategies to maximize adoption and adherence such as goal setting and identification of barriers to physical activity. Although it is reassuring that this modest level of compliance was still associated with improvements in BMD and muscle function, alternative behavioral strategies will need to be considered to optimize long-term behavioral change. In addition, over 40% of the participants in the *Osteo-cise* program reported one or more musculoskeletal complaints over the 12-month intervention. However, it is worth noting that over one-half of these were aggravations of pre-existing injuries and the majority of participants were able to continue training with modification of their exercise program. Aggravation of knee joint pain was the most common complaint, which was typically associated with the weight-bearing impact exercises. This suggests that some modification is needed with regard to the type(s) of impact exercises prescribed as well as the timing and level of progression for the various exercises included in the *Osteo-cise* program, particularly for those with pre-existing lower limb joint pain, given that most the complaints occurred within the first 6 months of the intervention.

In conclusion, we believe that the *Osteo-cise: Strong Bones for Life* community-based, multifaceted osteoporosis prevention program represents an effective approach to improve multiple musculoskeletal and functional performance measures in older adults with risk factors for falls and/or low BMD. Although further large-scale trials are needed to evaluate the efficacy of this multimodal intervention on the rate of falls, from a public health perspective we have demonstrated that this program can be successfully delivered in the community setting by local exercise trainers. Although further developments are needed to address issues related to exercise compliance and incident musculoskeletal complaints before the program is ready for more widespread implementation, we believe that this package represents a promising community-based model to improve musculoskeletal health and function in older adults with risk factors for osteoporosis, falls and fracture.

## Disclosures

All authors state that they have no conflicts of interest.

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version of manuscript: JG, CAB, PRE, CAN, KS, KH, and RMD. RMD takes responsibility for the integrity of the data analysis.

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