

Randomized placebo-controlled trial of brisk walking in the prevention of postmenopausal osteoporosis

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Abstract

Objective: to evaluate the effects of brisk walking on bone mineral density in women who had suffered an upper limb fracture.

Design: randomized placebo-controlled trial. Assessments of bone mineral density were made before and at 1 and 2 years after intervention. Standardized and validated measures of physical capacity, self-rated health status and falls were used.

Setting: district general hospital outpatient department.

Subjects: 165 women drawn from local accident and emergency departments with a history of fracture of an upper limb in the previous 2 years. Women were randomly allocated to intervention (self-paced brisk walking) or placebo (upper limb exercises) groups.

Intervention: both groups were seen at 3-monthly intervals to assess progress, measure physical capacity and maintain enthusiasm. The brisk-walking group were instructed to progressively increase the amount and speed of walking in a manner that suited them. The upper limb exercise placebo group were asked to carry out a series of exercises designed to improve flexibility and fine hand movements, appropriate for a past history of upper limb fracture.

Results: drop-outs from both intervention and placebo groups were substantial (41%), although there were no significant differences in bone mineral density, physical capacity or health status between drop-outs and participants. At 2 years, among those completing the trial, bone mineral density at the femoral neck had fallen in the placebo group to a greater extent than in the brisk-walking group [mean net difference between intervention and placebo groups 0.019 g/cm^2 , 95% confidence interval (CI) -0.0026 to $+0.041 \text{ g/cm}^2$, $P = 0.056$]. Lumbar spine bone mineral density had increased to a similar extent ($+0.017 \text{ g/cm}^2$) in both groups. The cumulative risk of falls was higher in the brisk-walking group (excess risk of 15 per 100 person-years, 95% CI 1.4-29 per 100 person-years, $P < 0.05$). There were no significant differences in clinical or spinal x-ray fracture risk or self-rated health status between intervention and placebo groups.

Conclusion: the promotion of exercise through brisk-walking advice given by nursing staff may have a small, but clinically important, impact on bone mineral density but is associated with an increased risk of falls. Self-paced brisk walking is difficult to evaluate in randomized controlled trials because of drop-outs, placebo group exercise, limited compliance and lack of standardization of the duration and intensity of walking. Further work is needed to evaluate the best means of safely achieving increased activity levels in different groups, such as older women and those at high risk of fractures.

Keywords: bone mineral density, elderly people, osteoporosis, physical activity, randomized controlled trial

Introduction

The strength of a bone is related to its mineral content, the alignment of collagen fibres, the type of bone and overall bone shape. There is a strong relationship between bone mineral density, trabecular architecture and strength, but whether a bone will break following a particular load also depends on the angle of the force and the rate of loading [1, 2]. Osteoporosis results in the loss of bone strength which, in combination with an increased tendency to fall, accounts for the rise in hip fracture incidence with age. The dramatic increase in hip fracture over the last 30 years [3] cannot be fully explained by an ageing population and may be associated with an increasingly sedentary lifestyle [4], which is supported by the relationship between physical fitness and femoral neck bone mineral density [5] and physical activity and fracture of the hip [6, 7].

Hormone replacement therapy is an effective treatment for the prevention of postmenopausal osteoporosis. However, less than 10% of British women are currently being offered treatment [8] and the long-term impact of treating all postmenopausal women for decades is unknown, although it is likely to be low because of continued low coverage, limited long-term adherence to treatment and side effects. Physical exercise is being promoted as an alternative preventive approach as it is thought to increase femoral neck strength [9], improve lower limb muscle strength [10] and reduce rates of decline in bone mineral density [11].

Most osteoporotic fractures, with the exception of those of the spine, occur as the result of falls. The annual prevalence of falls in women ranges from 20% at age 65 to 84% at age 85 [12] and over this same age range the risk of hip fracture increases from 2 per 1000 per year to around 30 per 1000 per year [13]. Falls are associated with immobility, ill health, use of prescribed medication, muscle weakness, poor balance and impaired vision and hearing [14-18]. Although attempts to identify risk factors for fracture among fallers have not been successful [19], it is likely that muscle strength and customary physical activity are important determinants of both falls and hip fracture [6, 7, 20-22].

Randomized controlled trials are the most appropriate means of examining the effects of interventions. We therefore set up a trial to examine the following questions: does brisk walking increase the bone mineral density of the femoral neck, reduce the number falls experienced or reduce the rate of spinal fractures?

Methods

Subjects

The study was confined to postmenopausal women who had sustained an upper arm fracture in the past 2

years. These women were chosen on the grounds that they are easy to identify, are at increased risk of further osteoporotic fracture [23] and are liable to be well motivated for preventive treatment. Addresses of suitable subjects were obtained consecutively from the registers of the accident and emergency department and orthopaedic fracture clinic of two East London hospitals. Each woman was sent a letter explaining the purpose of the study and inviting her to make an appointment to attend for an initial assessment. Women who declined this invitation were not contacted again; up to three mailings were sent to women who did not reply. Women were recruited in sufficient numbers to achieve a 90% power of being able to detect a 0.05 g/cm^2 (which increased to a 0.07 g/cm^2 with allowance for drop-outs) difference in bone mineral density between placebo and intervention groups at the 5% level of significance. Subjects gave written informed consent to all procedures and ethical committee approval was obtained for the study.

Women were randomly assigned using a series of prepared envelopes containing a computer-generated allocation to either a brisk-walking intervention or exercises for the upper limb. Women were included whatever their level of baseline activity. Women on treatment for osteoporosis with bisphosphonates, with an expected survival of less than 1 year, with cognitive impairment or too frail to withstand the brisk-walking intervention or travel for measurements were excluded from the study.

Measurements

All subjects had an initial assessment comprising a questionnaire and examination conducted by a research nurse. This provided data on general health and physical activity using previously validated questionnaires—the Nottingham Health Profile [24] and the London Health and Fitness Questionnaire [25]. The Nottingham Health Profile gives a self-rated indication of health status by assessing the extent of problems: scores range from 0 (no problems) to 100 (maximum problems) on each of six dimensions. In addition height, weight, age at menarche and menopause, smoking and alcohol consumption, use of hormone replacement therapy and other medication and falls experienced were recorded. Physiological measures of leg extension power were made for each leg using a rig designed for the purpose of measuring the explosive power in Watts, as the best of five attempts [26]. Grip strength was measured in each hand using an isokinetic handgrip dynamometer [27], as the best of three attempts. Stamina was assessed using a step test in which subjects stepped up and down using an 8-inch-high box with surrounding rails. The test was conducted in 3 min stages starting at roughly half the subject's estimated normal pace [28]. All these

measurements were repeated at each 3-monthly follow-up visit.

Bone mineral density was measured by an independent nurse researcher (K.E.) unaware of the women's trial status, using a dual energy x-ray absorptiometry scanner (Lunar DPX). Vertebral fractures were assessed using the ratio of anterior to posterior vertebral height as identified from lateral spinal x-rays [29]. We used a 25% difference between vertical heights measured using a steel ruler as the criterion for definition of a fracture and counted only one fracture per vertebra and results were presented as the mean number of vertebrae with one or more fractures. X-rays were all conducted using a single machine and a standardized procedure. The kV used for each subject was recorded to enable comparable films to be taken at each time point. Measurement of bone mineral density and spinal vertebral fractures were made at baseline and 1 and 2 years. Films were read by a single observer (P.W.T.) blinded to the identity of the subjects.

Brisk-walking group

Subjects were supervised by a research nurse who gave advice about general health and a balanced diet and encouraged them to gradually work up to walking for 40 min three times a week. 'Brisk' was defined as walking at a pace that was faster than usual walking for the subject but not so fast as to be uncomfortable or to cause shortness of breath. They were seen every 3 months to discuss any problems, reinforce the intervention and allow physiological measurements to be taken. Monthly telephone calls were made to check compliance and to monitor the occurrence of falls.

Placebo group

Subjects randomized to the placebo group were seen by the same nurse-interviewer and given advice about general health, a balanced diet and simple exercises for the upper limb to improve function following the fracture. They were also seen at 3-monthly intervals and monitored in a similar manner to the brisk-walking group. The subjects were told that their health and fitness was under investigation and that the specific aim was to improve their wrist and upper arm function after the fracture.

Follow-up

Subjects were followed up every 3 months and had full assessments at 1 and 2 years. Brisk-walking and placebo follow-ups were conducted at different times. Subjects were offered a free taxi to and from the clinic. Telephone contact was also maintained each month to discuss any problems with the exercise programmes. Drop-outs from the study were telephoned several times and attempts were made to persuade them to continue with the study.

All analyses were carried out using Statistical Package for the Social Sciences. The main outcomes compared were bone mineral density (for which differences from baseline levels were compared for the two groups), fall frequency and fracture rates at 1 and 2 years among those women completing the trial.

Results

In all, 508 women who had sustained an upper arm fracture were contacted. We received replies from 246 women (48%), of whom 173 (34%) accepted the invitation to attend. We finally randomized 165 (33%) women as eight women refused to take part in the study after the initial assessments. A large number of women [68 (41%)] dropped-out of the study, all but four in the first year. Drop-outs were evenly distributed between the placebo and brisk-walking groups. Reasons for dropping-out were unwillingness to continue (40), illness (10), death (two), exercise-related trauma (one) and other unspecified difficulties (15). In all, 49 women in the brisk-walking group and 48 women in the placebo group completed the trial and a further three women in the brisk-walking group and two women in the placebo group stayed in the trial for a year. All the women who remained in the intervention arm of the trial reported carrying out regular brisk walking for at least 40 min three times a week.

The women randomized to brisk walking were slightly younger than the women in the placebo group but were very similar in terms of health status, Nottingham Health Profile scores, smoking, use of diuretics and exercise behaviour. Of the four women on hormone replacement treatment, two were assigned to brisk walking and two to placebo. The women who dropped-out during the study tended to be less physically fit, as shown by their significantly higher resting heart rates (see Tables 1 and 2).

Changes in bone mineral density, x-ray findings, physical capacity (baseline values subtracted from 1 and 2 year values) and falls are shown in Tables 3 and 4. Both brisk-walking and placebo groups showed small increases in lumbar spine bone mineral density. Femoral neck bone mineral density tended to decline in both groups and was greater in the placebo group. The net changes (intervention group changes minus placebo group changes) in femoral neck bone mineral density showed a trend in favour of the brisk-walking group at 2 years: 0.019 g/cm^2 , 95% confidence interval (CI) -0.0026 to $+0.041 \text{ g/cm}^2$, $F = 3.76$ $P = 0.056$ (by ANOVA with adjustment for baseline bone mineral density and age covariates). This mean net change in femoral bone mineral density at 2 years represents a net 2% (95% CI -0.3 to $+5\%$) advantage on baseline levels among those women in the brisk-walking group.

The spinal fractures observed on x-rays expressed in terms of the group mean total number of wedge and

Table 1. Comparisons between brisk-walking and placebo exercise groups, contrasting those who dropped-out with those who completed the study

	Brisk-walking group		Placebo exercise group	
	Completed study (n = 49)	Dropped-out (n = 32)	Completed study (n = 48)	Dropped-out (n = 36)
Age, years (SD)				
On starting study	66.4 (7.8)	67.3 (8.5)	68.1 (7.8)	70.5 (11.0)
At menopause	48.7 (5.5)	48.1 (10.4)	48.1 (6.1)	48.1 (11.1)
Health status, number (%)				
Goes out daily	43 (88)	28 (88)	43 (90)	29 (81)
In good health	25 (51)	14 (44)	29 (60)	20 (56)
Never smoked	22 (45)	9 (28)	23 (48)	10 (28)
On diuretics	8 (16)	4 (12)	11 (23)	5 (14)
Nottingham Health Profile, mean (SD)				
Energy	16 (31)	16 (26)	20 (31)	16 (27)
Pain	15 (23)	16 (24)	24 (30)	14 (23)
Emotion	9 (13)	14 (14)	16 (20)	16 (22)
Sleep	22 (30)	17 (22)	16 (20)	30 (32)
Isolation	6 (12)	15 (20)	14 (22)	10 (20)
Mobility	17 (19)	17 (17)	20 (22)	18 (16)
Exercise status, number (%)				
Very fit	8 (16)	7 (22)	14 (29)	7 (19)
Walked 20-30 min in past week	20 (41)	18 (56)	19 (40)	13 (36)
Attends exercise class	10 (20)	6 (19)	6 (12)	3 (8)

biconcave fractures (i.e. a value of 0.20 means that the 49 women in the brisk-walking group experienced 10 x-ray-determined fractures over the time period) tended to increase over the 2 years of follow-up but no consistent or statistically significant differences emerged between the groups.

Physical stamina showed a significant improvement in the brisk-walking group when improvements, deteriorations and no change in step-test performance were compared over 2 years (35 and 20% improved in brisk-walking and placebo groups respectively, χ^2 trend = 4.2, $P = 0.04$). Grip strength and leg extension

Table 2. Comparisons of baseline levels of outcome measures between brisk-walking and placebo exercise groups, contrasting those who dropped-out with those who completed the study

	Brisk-walking group		Placebo exercise group	
	Completed study (n = 49)	Dropped-out (n = 32)	Completed study (n = 48)	Dropped-out (n = 36)
Bone mineral density, g/cm ² (SD)				
Lumbar spine	0.997 (0.194)	0.941 (0.171)	0.938 (0.168)	1.071 (0.228)
Femoral neck	0.806 (0.122)	0.786 (0.105)	0.765 (0.145)	0.840 (0.178)
Physical capacity, mean (SD)				
Body mass index	26.6 (4.3)	25.4 (3.9)	26.3 (4.8)	26.4 (5.6)
Right grip (kg)	18.0 (6.5)	16.1 (6.5)	16.5 (6.4)	13.9 (6.4)
Right leg extension (W)	81.7 (30.4)	79.2 (34.4)	76.6 (25.5)	68.3 (27.5)
Resting heart rate	73.2 (11.8)	75.1 (9.5)	77.3 (11.2)	78.4 (10.8)*
No. of falls in past year (% of group falling)				
None	20 (41)	15 (47)	26 (54)	20 (56)
1	19 (39)	8 (25)	14 (29)	9 (25)
2+	10 (20)	9 (28)	8 (17)	7 (19)

* $P < 0.05$.

Brisk walking and postmenopausal osteoporosis

Table 3. Changes in bone mineral density, physical capacity and radiograph findings between baseline, 1 and 2 years: changes are baseline values subtracted from year 1 and year 2 values

	Group		<i>t</i> value, <i>P</i>
	Brisk-walking (<i>n</i> = 49)	Placebo exercise (<i>n</i> = 48)	
Bone mineral density, g/cm² (SD)			
Lumbar spine			
Year 1	0.005 (0.043)	0.017 (0.041)	-1.50, 0.14
Year 2	0.017 (0.051)	0.017 (0.054)	-0.04, 0.97
Femoral neck			
Year 1	0.001 (0.047)	-0.007 (0.045)	0.92, 0.36
Year 2	-0.002 (0.042)	-0.021 (0.065)	1.63, 0.11
Physical capacity			
Right grip (kg)			
Year 1	0.55 (4.2)	-0.26 (3.9)	1.00, 0.32
Year 2	0.66 (3.6)	-0.19 (4.0)	1.10, 0.28
Right leg (W)			
Year 1	15.8 (24.8)	7.4 (27.2)	1.62, 0.11
Year 2	16.9 (26.9)	14.3 (25.8)	0.48, 0.63
Resting heart rate			
Year 1	0.4 (7.9)	-2.1 (10.8)	1.33, 0.19
Year 2	1.2 (11.7)	-4.0 (11.5)	2.21, 0.03
Step test stage completed			
Year 1	0.10 (1.04)	0.10 (1.2)	-0.02, 0.99
Year 2	0.21 (0.98)	-0.28 (1.3)	1.85, 0.07
Radiographs: vertebral fractures			
Year 1	0.50 (1.50)	-0.21 (2.28)	-1.67, 0.10
Year 2	0.25 (1.60)	0.29 (2.00)	0.09, 0.93

power did not show any differences between the groups or over the course of the 2 years.

The brisk-walking group experienced far more falls than the placebo group over the first year of the trial,

Table 4. The occurrence of falls and fractures among brisk-walking and placebo groups at 1 and 2 years

	<i>n</i> (rate per 100 person-years)	
	Brisk walking	Placebo
Falls		
Year 1		
Total falls	42 (80.1)	26 (52.0)**
Percent falling	42%	36%
Year 2		
Total falls	29 (59.2)	28 (58.3)
Percent falling	35%	38%
Cumulative falls risk	71 (70.3)	54 (55.1)*
Fractures		
Year 1	2 (3.8)	3 (6.0)
Year 2	4 (8.2)	1 (2.1)
Cumulative risk	6 (5.9)	4 (4.1)

Differences between brisk-walking and placebo groups: ***P* < 0.01, **P* < 0.05.

with 42 falls (80 per 100 person-years) experienced by 52 women and 26 falls (52 per 100 person-years) by 50 women in the intervention and placebo groups respectively (difference 28 per 100 person-years, 95% CIs of difference 16-40 per 100 person-years). At 2 years, both the numbers of falls experienced and the proportions of women experiencing one or more falls were similar in both groups. The cumulative falls risk over the 2 years of the trial was significantly worse among women in the brisk-walking group who experienced an excess of 15.2 falls per 100 person-years (95% CIs 1.4-29 falls per 100 person-years). Clinical fractures rates were similar in the two groups. Of the 10 women suffering a fracture, two women in each group suffered fractures outdoors which were attributed to tripping on uneven paving stones.

Use of hormone replacement therapy, diuretics, disodium etidronate, vitamin and calcium supplements at 2 years did not show any differences between intervention and control groups, and prescribing levels were low.

Nottingham Health Profile scores showed only small changes over the 2 years of the study, ranging from -6.5 to +8.1 for the sleep dimension which showed the largest changes. There were no significant

differences between the brisk-walking and placebo groups.

Discussion

Among those who remained in the trial, we have demonstrated that a simple regimen of self-paced brisk walking may reduce loss of bone mineral density at the femoral neck and is associated with a mean 2% net difference (95% CI -0.3 to +5%) in bone mineral density at this site over 2 years. At the lumbar spine no difference between the brisk-walking and placebo groups was observed, although neither group experienced a fall in bone mineral density at this site. The occurrence of falls was high in the brisk-walking group during the first year, and by the end of the trial the brisk-walking group had sustained a significant excess of falls. However, the clinical fracture rates were similar in the two groups and there were no significant differences in the numbers of spinal fractures found on x-ray examination. The brisk-walking group had greater improvements in stamina, as indicated by the step-test findings at 2 years. It might be anticipated that the brisk-walking group would have experienced improvements in leg extension power and the wrist exercise group would have shown increases in grip strength but neither of these outcomes showed any significant changes.

The rate of loss of bone mineral density among postmenopausal women who have already sustained an upper limb fracture is likely to range between 1 and 2.5% per year [30]. The women in our placebo group experienced a 2.8% fall in femoral bone mineral density compared with a fall of 0.25% among the brisk-walking group over 2 years. This suggests that the placebo group participants were comparable with other published series and that brisk walking may not increase bone mineral density but does reduce the rate at which age-related declines occur.

Exercise programmes have been shown to increase bone mineral density at the wrist [31] and spine [32], but there are few data concerning the long-term effects of exercise on either bone mineral density or trabecular structure at the femoral neck. A recently published randomized controlled trial comparing high-intensity strength training in 20 intervention and 19 control women demonstrated net increases in bone mineral density over 1 year of 0.027 g/cm² and 0.028 g/cm² at the femoral neck and lumbar spine respectively and also reported improvements in muscle strength and balance [33].

Observational studies have been more widely used than randomized controlled trials to assess the effects of exercise, but such studies are subject to selection bias and confounding. Exercise is reported to reduce risk of fracture [34] and improve joint flexibility [35], co-ordination and balance [36, 37]. It may also reduce

falling [38]. However, exercise is not without its disadvantages. Vigorous programmes are associated with low compliance and a high incidence of injuries [39], while exercise of low intensity and low frequency is likely to have only limited effects [40].

Brisk walking is a moderate-intensity activity that improves stamina as measured by a step test [41]. It is socially acceptable, well tolerated in elderly people [42] and has been shown to reduce high-density lipoproteins [43] and reduce obesity [44]. Some trials have not demonstrated unequivocal effects of exercise on bone mineral density [45, 46].

Our trial has several strengths that deal with deficiencies in previous work. A randomized controlled trial design avoids the possibility of selection bias and reduces the chances of confounding inherent in any observational study design. The avoidance of volunteers as a source of participants ensured that the findings are more generalizable than those derived from potentially health-orientated volunteers. The use of a placebo form of exercise avoided the possible effects of distraction and social engagement that might influence self-perceived health status. The physical capacity measures aided the monitoring of women and were intended to enhance compliance with exercise regimens. The inclusion only of women at high risk of fracture increased the likelihood that a clinically relevant group was studied and that substantial declines in bone mineral density would occur. The intervention followed practice that might be expected in health promotion programmes and avoided the close scrutiny and supervision of exercise seen in some trials. Finally, the study was of longer duration than previous trials and thus provides a reasonable estimate of long-term effects of exercise.

Our study highlights several of the problems of carrying out randomized controlled trials of exercise in populations. These include substantial numbers dropping-out, lack of observer blindness for some outcomes, limited compliance and lack of standardization of the intervention.

It is possible that the comparability of intervention and placebo groups was reduced by selective loss of subjects who might have benefited most from brisk walking or retention of those subjects with the highest bone mineral density in the placebo group. However, the drop-outs were similar to those women remaining in the study (see Tables 1 and 2). Consequently, it seems unlikely that losses due to drop-outs have had a major effect in biasing the comparisons made.

The compliance of women with brisk walking may have been less than adequate to achieve optimal effects. The research nurse was careful to prescribe a 'tailor-made' exercise plan, taking account of the personal circumstances of each woman but with the aim of eventually building up to 40 min of brisk walking at least three times a week. We have no way

of validating the accuracy of the exercise reports made by women and it is possible that they gave unreliable information.

Evidence of the value of brisk walking has been extrapolated from theoretical evidence [47] and small short-duration trials where walking was closely supervised and monitored. In practice, it is quite possible that the advice to take up or increase brisk walking among women may have only a small effect on bone mineral density such that any benefit could easily be outweighed by risks of falling and their potentially serious psychological and physical consequences.

In a relatively poor inner-city population promotion of brisk walking was of limited interest, with only one-third of those approached agreeing to be involved and only one in five of those originally approached willing to continue with brisk walking or placebo exercise over 2 years. This experience may not be typical of other areas and may reflect the special constraints of trial methods with an increased emphasis on measurement. However, uptake and compliance with brisk walking of this order among a high-risk and therefore supposedly motivated group of women is low, and this would limit severely the potential impact of this form of exercise on the public health.

Further efforts to increase acceptability of and adherence to programmes of brisk walking and other physical activities among older women are needed [48]. Specific ideas that require evaluation include the effect of group walking programmes, use of defined walking routes, comparisons with other forms of exercise such as strength training and psychological reinforcement (e.g. rewards). Also, it is essential that these women should not be put at greater risk of falls and associated fracture as a consequence of taking part in brisk walking or other activities. More specific advice about avoidance of falls, walking carefully—particularly when footpaths are uneven—and choice of footwear may help in reducing the observed excess of falls.

While the body of scientific evidence supporting the role of exercise in achieving improvements in many aspects of health is not disputed, it does appear that more attention must be given to evaluating the best means of achieving increased levels of activity among particular groups, such as older women and those at high risk of osteoporosis and fracture.

Acknowledgements

The Wolfson Family Trust provided a grant for the conduct of this study. Linda Rowland assisted with the study. Geoffrey Pratt and Lanol de Silva assisted with obtaining x-rays. We thank Archie Young for valuable comments on the manuscript.

Key points

- Brisk walking reduces the rate of decline of femoral neck bone mineral density in postmenopausal women.
- Brisk-walking advice causes a significant increase in falls.
- Few women were interested in taking part in a trial of brisk walking.
- Evaluation is difficult because of high levels of drop-outs, compliance and standardization of brisk walking.

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S. Ebrahim et al.

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Received 4 December 1996