Full Title: Effects of a one year randomised controlled trial of resistance training on lower limb bone and muscle structure and function in older men.

Running Title: Exercise intervention to prevent bone loss in men.

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CONFLICT OF INTEREST

No authors have a conflict of interest.

A one year RCT of resistance training compared with a control group was undertaken in 143 men aged 55 to 80 yrs. Although hip bone mineral density, lean body mass and function increased in both groups, lean body mass and function but not bone density increased more in the resistance group.

ABSTRACT

INTRODUCTION: Previous studies have demonstrated a positive effect of resistance training on bone mineral density (BMD) in postmenopausal women but the effect in men is unclear. The aim was to examine the effect of a one-year resistance-training program on bone and lean body mass in 143 men aged 55-80 years, randomized to either resistance training or active control.

METHODS: Resistance exercises were selected to provide loading at the hips. Measurements were taken at 0, 6 and 12 months for BMD (whole body, hip and spine), lean body mass, strength and functional fitness.

RESULTS: The intervention showed a significant increase in total hip BMD for both groups at 12 months (active control 1014 to 1050 mg/cm^2; resistance 1045 to 1054 mg/cm^2, $p<0.05$) with no increased effect of resistance training compared to active control. However compared to the active control group the resistance group increased their lean body mass (active control 0.1±2.1%; resistance 1.5±2.7%, $p<0.05$), fitness (active control 4.6±11.1%; resistance 13.0±13.4%, $p<0.05$), and lower limb muscle strength (active control 14.3±16.8%; resistance 39.4±30.87%, $p<0.05$).

CONCLUSIONS: In contrast to previous findings in older women, in older men a resistance training program does not increase hip bone mass more than walking 30 minutes three times a week.

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KEYWORDS: resistance training, bone density, randomized, strength, exercise.

INTRODUCTION

The principles of the effects of increases in strain magnitude have been developed in animal studies. These mechanical loading studies in animals have shown that bone is primarily sensitive to short periods of loading, high peak strain magnitudes, rapid changes of strain, unusual strain distributions, variation in the way strain is distributed across a section of the bone and rapid desensitization to an effect (1-8). Thus the results of animal studies suggest that greater strain magnitudes and unusual strain distributions provide the most effective stimulus for bone formation (9-11). Translating this to the human model suggests that exercise which varies the skeletal loads should have a positive effect on skeletal structure.

Intervention studies of weight-bearing exercise in pre- and postmenopausal women have demonstrated a positive effect on bone mass (12-14). However, more favourable effects on the skeleton have been found with resistance training in both pre-menopausal (12, 13, 15) and postmenopausal women (16-18). In particular, RCTs of progressive resistance training but not walking have been shown to increase bone mass in postmenopausal women (14, 16-19).

Neives et al. conducted a study in younger men which found that differences in bone mass and geometry confer greater skeletal integrity in males, which may contribute to lower incidence of stress and osteoporotic fractures in males (20). It is not clear what level of physical activity is sufficient to maintain bone mass in older men because few randomized controlled exercise intervention studies have been undertaken in older men. To test this hypothesis properly, the effect of a resistance training intervention compared to an active control group was undertaken. The effects on muscle were also studied to act as a positive control.

MATERIALS AND METHODS

Subject recruitment

A flow diagram of the recruitment process is shown in Figure 1. Males aged 55 to 80 years were recruited by letters sent to individuals randomly selected from the Western Australian voting register which requires compulsory registration for all adults. Volunteers were screened using a health survey administered during a telephone interview. The inclusion criteria required subjects to be able to commit to three 1 hr exercise sessions per week, be physically capable of undertaking an exercise program and not already exercising at a moderate intensity more than 2 hr/week. "Brisk walking" was the criterion used to define moderate intensity exercise ("that which made you huff and puff"). Participants were excluded if they participated in this level of exercise more than twice a week. Participants were adjudged physically capable of undertaking an exercise program on completion of the PAR-Q questionnaire plus the ACSM's Guidelines for Exercise Testing and Prescription (21). Exclusion criteria included performance of resistance training in the previous 5 years, receiving medications or having medical conditions known to affect bone density, having cardiovascular, physical or orthopedic disabilities that would place the subject at risk or limit their ability to perform exercise, having a BMI > 30, taking calcium supplements (> 500mg/day) or smoking. Eligible subjects attended an information seminar at which an informed consent document, approved by the Curtin University of Technology Human Ethics Committee, was signed. Prior to randomization 13 men withdrew due to a requirement for a stress ECG, or because they could no longer commit the time. A further three men whose bone mineral density (BMD) <-2.5 T score were excluded.

Study design and interventions

Assignment of subjects was by block randomization to reduce the imbalance in numbers assigned to 2 groups: resistance exercise or active control group. Using a computer-generated randomization program with a block size of 8, every 8 subjects were allocated four to resistance exercise and four to the active control group at random. Outcome measure data was collected at baseline, 6 and 12 months.

The resistance training group attended three 1-hour supervised exercise sessions per week for 1 year at the rehabilitation gymnasium, in the School of Sport Science, Exercise and Health at The University of Western Australia where they were supervised by qualified exercise physiologists. The program followed the American College of Sports Medicine's Guidelines for Resistance Training in the Elderly (22) in which a high intensity progressive resistance exercise program of 3 sets of 8 repetition maximum (RM) for each resistance exercise was undertaken.

Subjects completed a warm up and aerobic component consisting of riding a stationary bicycle or walking for 10 minutes followed by stretching. This was followed by 45 minutes of resistance weight training exercises. In the first 8 weeks participants completed each of the exercises with three sets of 15 repetitions using minimal resistance to allow for adaptation of connective tissue and to teach correct exercise techniques. From 8 weeks onwards they progressed to three sets of each exercise with eight repetitions maximum (3 x 8RM), this is the maximum amount of weight which can be lifted eight times in each set. Once subjects were able to continue beyond eight and achieve 10 repetitions in the third set, the weight was increased and this process repeated for the remainder of the study. Attendance, compliance and weight lifted were recorded using exercise records.

The exercises were selected based on our previous research (16, 17) and designed in particular to load the hip. The exercises were hip flexion, hip extension, hip abduction, hip adduction calf raise and tricep pushdown undertaken on purpose built isotonic machines consisting of a weight stack, cable and cam to allow for changes in resistance through a range of motion. In addition wrist curl, reverse wrist curl, bicep curl, forearm pronation/supination were undertaken using free weights.

The active control group was invited to attend a seminar where they were provided with advice for a walking program, according to public health recommendations, and stretching. They were advised to undertake an unsupervised 30 minute walk three times per week but no additional exercise for the duration of the study. This was based on the recommendations of the National Physical Activity and Health Guidelines for Adults in existence at the time of study (23). The control group were advised to walk because we felt it was unethical to advise people to remain inactive for the duration of the study, given the body of evidence to support increased exercise in older adults (21). Through regular monthly contact with control subjects, we did ensure that they did not exceed the exercise limits required for them to remain in this group. Two control group subjects were identified as too active and included in the Intention to Treat Analysis.

BMD and anthropometric measurements

BMD was measured at the hip, lumbar spine (L1-L4) and total body at baseline, 6 months and 12 months using a Lunar Prodigy DPX-L dual-energy X-ray (DXA) machine (Lunar Corp., Madison, WI, USA) with Encore 2004 analysis software version 8.50. Subjects were scanned in a standard cotton gown. Positioning of patients for each scan was made according to standard procedures, and all follow-up scans were analyzed using the manufacturer’s scan comparison mode. Daily calibration checks were conducted throughout the study using the spine phantom provided by the manufacturer. Immediately prior to completion of baseline testing, the cathode ray tube of the DXA machine required replacement. A cross-calibration study was performed before and after replacement of the cathode ray tube to control for comparison between measurements for the remainder of the study. Corrections to BMD were not required between measurements. The left hip was scanned in all subjects except where the subject had a hip replacement, in which case the right hip was scanned ($n=3$). Total body BMD and body composition including lean body mass, fat mass and percentage body fat were measured whilst the patient was lying supine on the table with their arms by the side and knees and ankles held together by straps. The long term co-efficient of variation (CV) of the spine phantom over four years was 0.36%. In our laboratory, the short term CV for repeated measurements of lumbar spine and total hip were 0.9 % and 0.2 % respectively. The CVs for total body BMD, lean mass and fat mass were 0.3 %, 0.5 % and 0.9 % respectively.

Anthropometric measurements were taken at baseline, 6 months and 12 months according to international standards for anthropometric assessment (24). Body weight was recorded in day clothes on a digital scale to the nearest 0.01 kg. Height was measured using a stadiometer with the stature stretch method to the nearest 0.1 cm.

Diet, Strength and Functional Fitness Measurement

The dietary intake was assessed at baseline by a 3-day food record (two weekdays and one weekend day). The amount of food and drink consumed was recorded using either food scales or household measures. The records were analysed by trained nutritionists using Foodworks 2007 nutrient analysis software (Xyris Software, Brisbane, Queensland Australia). Strength testing was conducted at baseline, 6 and 12 months for hip adductor strength and leg press using a 3-RM test which measured the maximum load that a subject can lift three times. The same machines (Pulse Star manufactured by Pulse Fitness PLC, Congleton, UK) were used for testing and training. In addition to the standard 5 kg stacked, pin-loaded plates, smaller load increments of 1 kg could be achieved with the addition of supplementary weights to the stack. Functional fitness was assessed at baseline, 6 months and 12 months by a 6-minute walk test which measures the maximum distance that can be covered by an individual within 6 minutes. The test requires the subject to walk continuously between two markers situated 25 m apart at as fast a pace as possible, subjects were permitted to slow or stop and rest if necessary (25). Both groups also completed a physical activity questionnaire at baseline, 6 and 12 months during the bone density appointment. The questionnaire, the International Physical Activity Questionnaire (IPAQ) short form, (www.ipaq.ki.se), quantified the physical activities carried out by the subjects in terms of energy expenditure and classify them into low, moderate or high physical activity level.

Statistical methods

The mean BMD for males greater than 60 is 0.99 g/cm^2 (26). A sample size calculation was undertaken before the study commenced in which it was hypothesized that the one-year progressive resistance exercise would prevent bone loss in men. The rate of bone loss in men was considered to be between 0.2 to 0.8% per year at the neck of femur and total femur site respectively (26-28). Assuming a conservative rate of bone loss of 0.65% per year and using a standard deviation of 0.014 g/cm^2 for the difference in BMD between successive femur measurement sites scans, it was calculated that in order to detect a significant difference between groups, 62 subjects were required in each group at a power of 80% and a 5% level of significance. Based on previous intervention studies a 10% drop-out rate was expected therefore the aim was to recruit 68 participants per group.

We performed a 2-factor repeated measures ANOVA on the IPAQ data (main effects = Group (2 levels) and Time (3 levels)). The effects of the exercise regimes were compared using a mixed-model repeated measures analysis of variance in which the baseline value was a covariate and the intervention time interaction as the principle outcome. Data were analyzed using both per protocol (completed the program and achieved > 70% attendance) and intention to treat data. Because there was no significant difference between the analyses, results presented are for the intention to treat data. Data are reported as the mean and SD two tailed testing was used in each analysis.

RESULTS

The recruitment and disposition of study subjects is shown in Figure 1. There were no significant differences between the resistance training and active control groups for any of the baseline characteristics (Table 1). Of the 143 men recruited to the study 21 withdrew (16 resistance group; 5 active control group) yielding an overall study retention rate of 85.3%, with no significant difference between the two groups. Six of these subjects agreed to undergo follow up measurements and were included in the intention to treat analysis, 15 were lost to follow up (11 resistance training; 4 active control). Reasons for withdrawal from the resistance training group were bypass surgery *n=1*; fracture of T12 *n=1*; hip replacement *n=1*; depression *n=1*; hip problems *n=1*; undiagnosed chronic illness *n=1*; moved *n=3*; and personal reasons *n=7*. Reasons for withdrawal from the active control group were depression *n=1*; moved *n= 3* and personal reasons *n = 1*.

The progressive resistance exercise group achieved, on average, 71% compliance with the exercise program, based on attendance at three exercise sessions per week over the 12 month study period; 32% of the group achieved at least 80% compliance. Exercise compliance for the active control group was not monitored.

The effects of exercise interventions on bone mineral density

The changes in BMD with respect to baseline are reported in Table 2. Both groups had a significant increase in total hip and trochanter BMD at 12 months but not the whole body or spine. However the resistance exercise intervention had no additional benefit over the active control group.

Effects of exercise interventions on strength and functional fitness

The effect of the exercise interventions on muscle strength and fitness is shown in Table 3. Both the resistance and active control groups showed a significant increase in leg press strength and in hip adductor strength. There was a significant improvement in leg press strength and hip adductor strength at six and 12 months for the resistance training group compared to the active control group.

Self-reported physical activity scores (IPAQ) showed an increase in the scores over the 12 months. There was a significant main effect for Time ($F=14.18$; $p<0.0001$), with significant improvements in both groups from baseline (resistance 2016 ± 2198; control 1772 ± 1952 MET-minutes/week) to 6 months (resistance 2874 ± 2450; control 2567 ± 2700 MET-minutes/week), and again from 6 to 12 months (resistance 3655 ± 3360; control 3293 ± 4073 MET-minutes/week). No Group main effect ($p=0.44$), nor interaction ($p=0.98$) was observed. The results indicate both groups improved their habitual activity over time and many moved from "Moderate" activity at baseline (> 600 to < 3000) MET-minutes/week) to "High" activity classifications by 12 months (>3000 MET-minutes/week).

A significant effect on improved functional fitness was identified in both groups over the 12 months period and again there was a significant fitness improvement in the resistance group compared to the active control group.

Effects on body composition

The percentage changes in body composition relative to baseline are reported in Table 3. There was a significant increase in lean mass for the resistance group at 6 and 12 months compared to the active control group in which there was no change from baseline. There was also a significant decrease in percent body fat in the resistance group at 6 and 12 months compared to the active control group but no significant difference in weight or fat mass. Waist girth and BMI did not change (data not shown).

DISCUSSION

In this 1-year randomized controlled trial of 143 men a supervised resistance exercise program which increased leg strength, functional fitness and lean body mass had no additional benefit over unsupervised walking in the active control group on hip BMD. In both groups there was a small but significant increase in hip BMD, the area specifically targeted in the exercise regimens. This was comparable to that obtained by resistance exercise but not walking or endurance exercise in women (14-17, 19, 29). Thus, the threshold strain magnitude for osteogenesis in men may be higher than that for postmenopausal women, in that in older men a resistance exercise program had no additional benefit on bone over those who were advised to walk for 30 minutes three times a week.

Reasons for the lack of additional benefit from the progressive resistance training program found in this study are not easily explained. Analysis of the self-reported physical activity data showed that many in the control group reported increasing their habitual activity by 12 months. This may have impacted on the outcome variables as both groups significantly increased their bone density at the total hip and trochanter sites. It may be that the load to the bone supplied by the resistance exercise was not greater than that supplied by habitual exercise activities. The resistance program consisted of exercises undertaken mostly with isotonic machines designed to load the hip region. Although the participants were continually encouraged to progressively increase the weight lifted it is possible that the compliance achieved and therefore bone loading from the exercises was not sufficient for osteogenesis, but was sufficient for increasing muscle strength. Alternatively, the type of exercises selected in this study may not have had any additional benefit for bone loading compared with habitual exercise. In this study we employed a similar resistance training protocol to what we have used in two studies in postmenopausal women, showing the resistance exercises were site specific and load dependent (17, 30). It is possible that in men different types of exercises may be more effective. For example, in a 1-year study of older men supplemented with calcium-vitamin D and exercise, there was a significant exercise effect at the femoral neck (31). The exercise program consisted of a progressive resistance exercise program but in addition, included high-impact jumping exercises. In our study the participants undertook a similar progressive resistance training program but did not do any jumping exercises. This variation in the exercise protocol may account for the difference in results to the current study. Interestingly, the bone loss predicted to occur in men of between 0.2 – 0.8% per year at the femoral neck on the basis of previous studies (27, 28, 32, 33) did not occur in the active control group at any site measured, suggesting that this level of physical activity was sufficient to maintain bone mass.

The study employed a high intensity, progressive resistance exercise program encompassing principles of bone overload to maximise the potential for increases in bone mass. The fact that muscle strength and functional fitness increased more in the resistance exercise program provides a positive control for exercise intensity in this group. Further more it is important to understand that it would be difficult to increase the intensity of the resistance exercise regimen because of the difficulties associated with maintaining compliance in this age group. In this study the compliance with the protocol was 71%.

Several studies have looked at the effect of resistance training on BMD in men but have not had sufficient statistical power to provide real comparison thereby providing limited understanding of the adaptation of bone to exercise in older men (34). A meta-analysis conducted by Kelley et al. (34) suggests that site specific exercise may help increase and/or maintain BMD at the femur and lumbar spine in older men. Unfortunately these intervention studies were not randomized, and in two studies, the intervention was only for 16 weeks (35, 36), It has been argued that one bone remodeling cycle takes 3-4 months to complete the sequence of bone resorption, formation and mineralization, and to achieve a new steady state bone mass that is measurable a minimum of 6-8 months is required (37). Hence the recommendation for an appropriate length of study to accommodate these factors is at least 12 months (17). The strength of this study is the large sample size, the high study retention and exercise compliance and the randomized controlled design. However, the results indicate that further research is needed in older men before we are able to provide clear exercise guidelines on the type and amount of exercise for bone health in older men.

In conclusion the resistance intervention was effective in inducing muscle strength gains but not in inducing increases in hip bone mass compared to walking alone. These results suggest that in older men, in contrast to our previous findings in women, resistance exercise does not have any additional benefit on hip bone mass over walking alone. Because the supervised resistance training exercise program was found to be more effective at improving fitness, muscle strength and lean body mass compared with advice to walk three times a week, older men should be encouraged to undertake a resistance intervention for muscle but not bone health.

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Table 1 Baseline characteristics (mean ± SD) for resistance training and active control groups

Characteristic	Resistance Training Group			Active Control Group		
Number of Subjects		73			70	
Age (years)	64	±	6	64	±	6
Morphometry						
Weight (kg)	82.4	±	10.7	83.0	±	11.4
Height (cm)	176.6	±	6.8	177.5	±	7.3
BMI (units)	26.4	±	3.1	26.3	±	3.0
DXA Body Fat (kg)	22.4	±	7.0	22.0	±	7.4
Percentage Body Fat[a] (%)	26.7	±	5.9	26.0	±	6.5
DXA Lean Body Mass (kg)	56.2	±	5.6	57.0	±	6.1
Percentage Lean Body Mass[a] (%)	68.2	±	5.2	68.7	±	5.4
Bone density						
Lumbar Spine BMD (mg/cm^2)	1244	±	188	1243	±	170
Total Hip BMD (mg/cm^2)	1046	±	155	1034	±	155
Trochanter BMD (mg/cm^2)	895	±	151	890	±	144
Femoral Shaft BMD (mg/cm^2)	1216	±	203	1213	±	197
Neck of Femur BMD (mg/cm^2)	971	±	135	987	±	217
Total Body BMD (mg/cm^2)	1234	±	108	1234	±	89
Diet						
Energy (Kilojoules)	9727	±	1993	9947	±	1858
Protein (grams)	101	±	22	101	±	19
Fat (grams)	85	±	25	87	±	22
Carbohydrate (grams)	243	±	63	250	±	61
Alcohol (grams)	20	±	17	21	±	18
Calcium (mg)	1015	±	550	961	±	317
Strength						
3-RM Hip Adduction (kg)	78	±	14	78	±	15
3-RM Leg Press (kg)	100	±	19	104	±	21
Fitness						
6-Minute Walk Test (m)	627	±	70	633	±	73
IPAQ score (MET-minutes/week)^	2016	±	2198	1772	±	1952

[a] Calculated from dual-energy x-ray absorptiometry.

[^] Calculated from the International Physical Activity Questionnaire

Table 2 Changes from baseline (mean ± SD) in whole body, lumbar spine and hip BMD, comparing the Resistance Training Group (n=61) with the Active Control Group (n=66).

BMD (mg/cm^2)	Resistance Training Group			Active Control Group		
	Baseline	6 Months	12 Months	Baseline	6 Months	12 Months
Whole Body	1231 ± 110	1237 ± 113	1230 ± 108	1236 ± 87	1246 ± 92	1243 ± 90
Lumbar Spine	1236 ± 189	1236 ± 188	1235 ± 185	1245 ± 168	1252 ± 170	1246 ± 175
Femoral Neck	966 ± 142	963 ± 139	969 ± 140	972 ± 136	968 ± 132	966 ± 128
Femoral Shaft	1228 ± 194	1229 ± 188	1235 ± 190	1219 ± 174	1225 ± 167	1230 ± 166
Trochanter	896 ± 160	904 ± 152	916 ± 155*	895 ± 140	903 ± 127	915 ± 132*
Total Hip	1045 ± 161	1047 ± 156	1054 ± 157*	1041 ± 142	1045 ± 133	1050 ± 133*

* $p<0.05$ Significant within group change from baseline

Table 3 Percentage changes from baseline (mean ± SD) in strength, fitness and body composition comparing the Resistance Training Group (n=61) with the Active Control Group (n=66).

	Resistance Training Group		Active Control Group	
Variable	**6 Months**	**12 Months**	**6 Months**	**12 Months**
Strength				
Leg Press 3-RM (%)	23.8 ± 29.9*†	39.4 ± 30.8#†	10.6 ± 16.3†	14.3 ± 16.8†
Hip Adduction 3-RM (%)	20.4 ± 23.8#†	39.8 ± 25.9#†	8.5 ± 17 4†	12.7 ± 18.8†
Fitness				
6 Minute Walk Test (%)	6.7 ± 11.8†	13.0 ± 13.4#†	3.6 ± 10.1†	4.6 ± 11.1†
Body composition				
Weight (%)	-0.2 ± 2.7	0.2 ± 3.8	-0.1 ± 2.2	-0.1 ± 3.5
Lean Mass (%)	0.9 ± 2.4*	1.5 ± 2.7#	0.0 ± 2.2	-0.1 ± 2.1
Fat Mass (%)	-0.9 ± 8.9	-2.3 ± 12.1	0.6 ± 10.0	1.4 ± 15.0
Percentage Body Fat (%)	-1.9 ± 7.1*	-2.7 ± 9.2*	0.6 ± 8.9	1.2 ± 12.0

Lean Mass and Fat Mass change derived from DXA whole body scan.
* $p<0.05$ significant between group change, # $p< 0.01$ significant between group change, † $p<0.01$ significant within group change from baseline