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Cochrane Review on exercise for preventing and treating osteoporosis in postmenopausal women

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Osteoporosis is a pathological condition characterized by the increased risk of fractures related to the reduction of bone density.[1] It has been better defined as a pathological condition characterized by low bone density, alterations of the microarchitecture which lead to an increase in bone fragility and therefore an increased risk of fractures.[2] The most common manifestations of osteoporosis are fractures of the femur, vertebrae and wrist.

According to the World Health Organisation's definition of osteoporosis, about 30% of the women in the postmenopausal period have osteoporosis.[3, 4]

The excess mortality associated with fractures of the femur is estimated at about 20%, and the cumulative risk of fractures for a woman in her 50s can reach 60%.[5, 6]

The value of exercise as a means of preventing the loss of bone mass has become less and less controversial. In the past 20 years numerous publications have, with varying strength, documented its usefulness. It is however necessary to define: what type of exercise is really effective, which programme, for how long, and in which manner it should be implemented.

Cochrane's revision

The aim of the revision was to determine the effectiveness of exercise on bone mass expressed in BMD in women during postmenopause. The hypothesis tested was: exercise slows down bone loss in women during menopause.

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Methods

All controlled randomised studies on exercise in healthy postmenopausal women were considered. The method of randomisation had to be well defined, and studies which involved assignation, for example, according to an open list, in alteration, or based on the date of birth or number of the hospital were excluded.[7] There were no restrictions of language.

The research was carried out on EMBASE and MEDLINE between 1st January 1966 and December 2003, using the following keywords: "Osteoporosis", "Exercise", "Bone mineral density", "Postmenopausal", and "Fractures". Being aware that electronic research carried out on MEDLINE was not sensitive enough to identify all the relevant randomised studies [8] the work was completed using the bibliography found in articles and on Current Contents.

The quality of the studies was evaluated giving an opinion on the following levels: the bias, the method of randomisation used, the blindness, the withdrawals and the dropouts.

TABLE I.—*Included studies in systematic revision.*

Study ID	Methods	Participants	Interventions	Outcomes	Notes
Bravo 1996	RCT Duration: 1 year experimental design: parallel group Blinding: assessor, single data analysis, efficacy	142 postmenopausal (>12 months) women from Canada between the ages of 50 and 70, with low bone mass	Exercise group: 1 hour long exercise classes, 3/week per 12 months. 1. warms up 2. 25 min of rapid walking: 15 min of stepping down and up or aerobic dancing, each had to progressively reach 60-70% of her heart rate reserve 3. localized exercise: 10-15 min of exercise in sitting, standing, prone position, involving the muscles of upper limbs, abdominal and the back 4. cool down period with relaxation movements stretching balancing and coordination exercises Control group: to continue their daily routing activities PLUS education	BMD spine, BMD femur	Quality score: 2 Randomization: 2 Blinding: 0 Withdrawals and drop-outs: 0
Chow 1987	RCT Experimental design: parallel group Data analysis: efficacy	58 women from Canada	Control: continue daily routine activities, any regular fitness exercises aerobic: 3/week, 5-10 min of stretching and calistenic warm up, exercise of aerobic activities (walking, jogging, dance) Aerobic and strength: 3/week, 10-15 min session of low intensity strength training (isometric and isotonic contractions of limbs and truck muscles) 10 repetitions for each muscle group	Calcium Bone Index	Quality score: 3 Randomization: 2 Blinding: 0 Withdrawals and drop-outs: 1
Ebrahim 1997	RCT Duration: 2 years	165 women who had sustained an upper arm fracture in the past 2 years	Self-paced brisk walking or upper limb exercises		Quality Score: 2 Randomization: 1 Blinding: 0 Withdrawals and drop-outs: 1
Grove 1992	RCT Duration: 1 year Experimental design: parallel group Blinding: open	15 postmenopausal women	Control, non exercising low impact exercise high impact exercise	BMD Lumbar spine	Quality Score: 2 Randomization: 1 Blinding: 0 Withdrawals and drop-outs: 1
Hatori 1993	RCT Duration: 7 months experimental design: parallel group Data analysis: efficacy	33 postmenopausal women from Japan, age 46-67 years 21 exercise program and 12 controls	Control: no exercise Moderate intensity: 90% of the heart rate High intensity: 110% of the heart rate Exercises: 3/week during 7 months Stretching of the legs, torso and arms, followed by 30 min of walking on flat grass-covered ground	% change in BMD Lumbar spine (DEXA)	Quality Score: 1 Randomization: 1 Blinding: 0 Withdrawals and drop-outs: 0

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Study ID	Methods	Participants	Interventions	Outcomes	Notes
Kerr 1996	RCT Experimental design: parallel group Blinding: open Data analysis: efficacy	56 women from Australia, ages 4-70, between 1-15 postmenopausal	Group 1: endurance group: 3 sets of maximal load lifted 20 times for each exercise (low load and high repetition). Started with 20% rm (max lift) leg and 10% RM arm. Each session they were encouraged to attempt an additional repetition. When they were able to complete 3 sets of 25 repetitions they attempted the next weight increment. Group 2: strength group: 3 sets of maximal load lifted 8 times for each exercise (high load and low repetiton). Started with 40% RM (max lift) arm and 60% RM leg. Exercises: 3/week. Upper limb: biceps curl, wrist curl, reverse wrist curl, triceps extension with pulley, forearm pronation and supination. Lower limb: leg press, hip abduction/adduction, hip flexion/extension, hamstring curl. Control: control lateral limb	Femur BMD neck, forearm ultradisk, radium mid radius 1/3	Quality score: 3 Randomization: 2 Blinding: 0 Withdrawals and drop-outs: 0
Lau 1992	RCT Duration: 10 months Experimental design: parallel group Data analysis: efficacy	50 women from China (Hong Kong), hostel for elderly, aged 62-92	Calcium supplementation of 800mg Load-bearing exercise four times a week plus a daily placebo tablet Calcium supplementation daily and load bearing exercise 4 times a week Placebo tablet	% change in BMD, Adverse Effects	Quality score: 3 Randomization: 2 Blinding: 0 Withdrawals and drop-outs: 1
Lord 1996	RCT Duration: 1 year Experimental design: parallel group Blinding: open data analysis: efficacy	179 women from Australia, aged 60-85 years	Control group: no organized activity Exercise group: 12 months trial (1 hour exercise classes twice weekly for 4 10-12 week sessions). Exercise: 5 warm up period: 35 min conditioning period (aerobic exercise, activities for balance, hand-eye and foot-eye coordination and stretching exercises); stretching period 15 min; relaxation 15 minutes	BMD, Lumbar spine, femoral neck, trochanter	Quality score: 2 Randomization: 1 Blinding: 0 Withdrawals and drop-outs: 1
Martin 1993	RCT Duration: 12 months Experimental design: parallel group Blinding: open	76 women from Florida, outpatients	Controls: calcium and vit D, no exercise 45 min of exercise Exercise: 3 times a week, 1 year, start and end with 3-5 min of warm up to 60% of max heart rate. Then treadmill to 7% grade (inclination) and to 70% max heart rate in the first 2-4 weeks, and after to 85% (gradually)	BMD lumbar spine, proximal forearm, distal forearm, body mass	Quality score: 2 Randomization: 1 Blinding: 0 Withdrawals and drop-outs: 1
Mayoux-Benhamou 1997	RCT Duration: 1 year Experimental design: parallel group Blinding: open	51 women from France, aged 55-61, outpatient clinic	Active: IA active during 3 y; IB in the 1st yr control and in 2nd and 3rd active Control: IIB in the 1st yr active, in the 2nd and 3rd y control, IIA controls during the 3 y of follow-up Exercise: 60 daily flexions of each hip, in 2 or 3 sessions, sitting with a sand bag weighing 5 kg on the knee	TBMD lumbar spine	Quality score: 2 Randomization: 1 Blinding: 0 Withdrawals and drop-outs: 1

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Study ID	Methods	Participants	Interventions	Outcomes	Notes
Nelson 1994	RCT Duration: 1 year Experimental design: parallel group Blinding: open	40 postmenopausal (5 years) Caucasian women from USA, aged 50 to 70	Exercise group (n=21) 52 weeks (2 weeks off for vacation), 2 times week, 45 min sessions, 3 sets of 8 repetition: high intensity strength training (concentric and eccentric contractions: hip extension, knee extension, lateral pull down, back extension, abdominal flexion using pneumatic resistance machine). Control group (n=19): they were asked to maintain their current level of physical activity during the year	BMD lumbar spine, femoral neck, TB (BMC)	Quality score: 2 Randomization: 1 Blinding: 0 Withdrawals and drop-outs: 1
Presinger 1995	RCT Duration: 5 years Experimental design: parallel group Blinding: open data analysis: efficacy	146 women from Austria, outpatient clinic aged 45-75 postmenopausal for at least 1 year	Exercise group: warm ups, stretching exercises and resisted and complex exercises each performed for at least 20 min. Regular exercise: at least 3 times a week for 20 min or longer stopped exercise treatment, performed it regularly or less than 1 h per week Control group: without therapy	BMD, SPA, radium proximal	Quality score: 1 Randomization: 1 Blinding: 0 Withdrawals and drop-outs: 0
Prince 1991		122 women from Australia	Control Exercise alone: 1 weekly exercise class (low impact aerobic exercise for 1 hour, 30% of the time devoted to arm exercises) supervised by a trained physiotherapist and 2 brisk 30 min walks per week Exercise plus calcium Exercise plus hormone therapy	% change from baseline, forearm BMD, vertebral BMD	Quality score: 4 Randomization: 2 Blinding: 2 Withdrawals and drop-outs: 0
Prince 1995	RCT Experimental design: parallel group Blinding: double, patient, pnvestigator Data analysis: efficacy	168 women from Australia	Placebo tablets Tablets containing 1g calcium lactate-gluconate Exercise group took calcium and were asked to exercise for 4 h/week. Two hours in supervised exercise classes (weight bearing) and 2 hours of walking at a rate that would increase heart rate to 60% of the peak heart rate of their age Milk powder containing 1 g calcium	Femoral neck, ultraradius, BMD spine, BMD hip	quality score: 4 Randomizatio n: 2 Blinding: 2 Withdrawals and drop-outs: 0
Pruitt 1996	RCT Duration: 1 year Experimental design: parallel group Blinding: open Data analysis: efficacy	40 Caucasian women, aged 65-79	Control group: continue their customary activities High intensity resistance training (HI): they performed 1 set of 14 repetitions at 40% 1 repetition max (IRM) as a warm up, followed by 2 sets of 7 repetitions at 80% IRM Low intensity training (LI) they performed 3 sets of 14 repetitions at 40% IRM Exercises: both group performed 10 exercises for 1 hour (with Nautilus and Universal gym equivalent), 3 days/week under supervision for 1 year	Lumbar, total hip, femoral neck, drop-outs, Ward's triangle	Quality score: 2 Randomization: 1 Blinding: 0 Withdrawals and drop-outs: 1

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Study ID	Methods	Participants	Interventions	Outcomes	Notes
Revel 1993	RCT Duration: 1 year Experimental design: parallel group	78 women from France	Psoas group: strengthening exercise for both Psoas muscles: 60 flex with 5 kg on the knees, 2-3/day for 1 year Deltoid group: strengthening exercise for both deltoid muscles: 60 adb with 1 kg in each hand, 2-3/day for 1 year Subgroup "assiduously" psoas: women who performed the exercises assiduously Subgroup "assiduously" deltoid: women who performed the exercise assiduously	TBMD	Quality score: 2 Randomization: 1 Blinding: 0 Withdrawals and drop-outs: 1
Sinaki 1989	RCT Duration: 2 years Experimental Design: Parallel Group Blinding: Data Analysis: Intention-to-treat	65 healthy Caucasian women from USA	Exercise group: back extensions in prone position with a back pack that contains weights equivalent to 30% of the max isometric back muscle strength in pound, 10 times, once a day, 5 days a week Control: nothing	BMD lumbar spine	Quality score: 2 Randomization: 1 Blinding: 0 Withdrawals and drop-outs: 1
Smidt 1992	RCT Duration: 1 year Experimental design: parallel group Blinding: single, assessor Data analysis: Intention-to-treat	49 Caucasian postmenopausal women from Iowa, USA	Exercise group: 3 sets of 10 repetitions for each of 3 exercises: sit up, double leg raise, prone trunk extension (90 repetitions); 3-4 times/week over a period of 12 months. Each month 2-5% increase in exercise resistance. Target exercise intensity level was 70% of the maximal strength test measures. Control: to maintain the current lifestyle		Quality score: 2 Randomization: 1 Blinding: 0 Withdrawals and drop-outs: 1

As stated in the objectives of the revision, the effect of exercise on bone was valued with the variation of bone density measured with single-photon (SPA), dual-photon absorptiometry (DPA), dual X-ray absorptiometry (DXA) at the beginning of the study and at yearly intervals.

All the results were converted into the percentage of bone loss per year and the difference between the percentage lost in the group with exercises and the percentage lost in the control group in this meta-analysis was considered as the measure of effect.

Each effect of the treatment was weighed with respect to the variations: in such a procedure the greatest weight was attributed to the most reliable results, that is, to the studies with the highest number of samples.

For each study a check was carried out on — other than the BMD variation — the accuracy of the measuring system of bone density, besides the adherence, that is, the percentage of the participants who completed the programme, and the attendance, that is, the average attendance per session during the period of the study (percentage of attendance of the sessions).

The data was extracted also evaluating the allocation of the subjects, the use of blindness, the percentage of those lost during the follow-up, the type of participants and the type of intervention. The methodological quality was also evaluated on this basis and gave the measure of risk of the existence of bias in assessing the results of the effects of treatment.

Statistical analysis

We estimated that the importance of the effect of treatment highlighted with a given number of participants should have been able to define the level of sig-

TABLE II.—*Accuracy in BMD measure in included studies.*

Bravo	DEXA	Not available
Chow	Non riportato	—
Ebrahim	DPX	Not available
Grove	DPA	3%
Hatori	DEXA	0.4%
Lau	DX-ray densitometry	Not available
Lord	DEXA	0.8 spine, 1.8 neck of thigh bone, 1.6% trochanter
Martin	Single photon	2%
Nelson	DPX	Spine 1.0%, neck of thigh bone 2.1%, total body 0.6%
Preisinger	Single photon	2%
Price 1991	Forearm densitometer	1.3-1.5%
Prince 1995	DEXA	1%
Pruitt	DXA	1.5%
Revel	TC	2-5%
Sinaki	DPA	1.7%
Smidt	DPA	0.9%

nificance with α=0.05 and with 80% of strength (β=0.2).

Description of the results

Ninety trials were considered and examined by 2 revisers (BS, DB), who, in an independent way, selected the studies to be included in the meta-analysis and evaluated the methodological quality. In this manner 17 studies which met the criteria for inclusion were included.[9-25]

There was 100% agreement between the revisers on the choices of studies to be included.

For all of the studies the methodological quality was evaluated on the basis of the description of the modality of randomisation, of the drop out and of blinding (Table I).

The accuracy of the measuring system of bone density used varied from between 0.4% to 3% (Table II), the attendance (the average attendance per session during the period of training) from 56% to 100%, and the adherence (the percentage of the participants who completed the study) from 65% to 82% (Table III).

The accuracy of the measuring systems is obviously of fundamental importance like bias in the evaluation of the δ in the samples and in the controls. In the same manner, the registered compliance, if <70%, notably reduces the value of the results obtained in the studies.

The extreme lack of homogeneity in the physical exercise programmes which the women underwent was dealt with by subdividing the types of training into 3 big categories: those which represented mainly aerobic exercises (calistenics, fitness and muscular strengthening, exercises with elastics or with weights, and a little walking), muscular strengthening with machines, and walking at different speeds. The checks were always represented by the absence of the same exercise.

TABLE III.—*"Attendance" and "adherence" in included studies.*

	Length	No. of patients	Attendance	Adherence
Bravo	12 mo	52	73%	—
Chow	2 y	16	83%	70%
Grove	12 mo	5	Low impact 80% SD 6.6 High impact 82.6% SD 4.1	—
Ebrahim	2 y	49	—	—
Hatori	7 mo	12	—	—
Kerr	12 mo	25	87% (75% sessions)	82%
Lau	10 mo	11	—	—
Lord	12 mo	58	72.9%	79.4% (>50 sessions)
Martin	12 mo	16	85.2% SD 12.7, (1-6 mo) 82.4% SD 15.8, (6-12 mo)	55 out of 76
Nelson	12 mo	20	100% (twice a week for 50 weeks)	
Preisinger	3 y SD 1.3	39	48%	—
Prince a 1991	2 y	41	56% (at least 10 sessions out of 12 weeks)	
Prince b 1995	2 y	42	39%	
Pruitt	12 mo	8	78.6%	65%
Revel	12 mo	23	55% (at least 5 days for a week)	
Sinaki	2 y	34	—	—
Smidt	12 mo	27	—	—

For each group a homogeneity test was carried out without any significant results.

The 1st group ("aerobics") represents the most numerous [9-18] with the highest number of samples (266 subjects who underwent treatment and 295 in checks). For this type of exercise, for which there nevertheless exists an extreme heterogeneity of programs, the intensity of the load and the force is described in only one study,[11] and showed a efficacy at the level of the vertebral lumbar, not in the hip (Figure 1).

The 2nd group (resistance) is represented by 3 studies,[14, 19, 20] with a total of 53 subjects who underwent treatment and 55 checks (Figure 2). One study [19] presents the use of only one side, in a cross-shaped man-

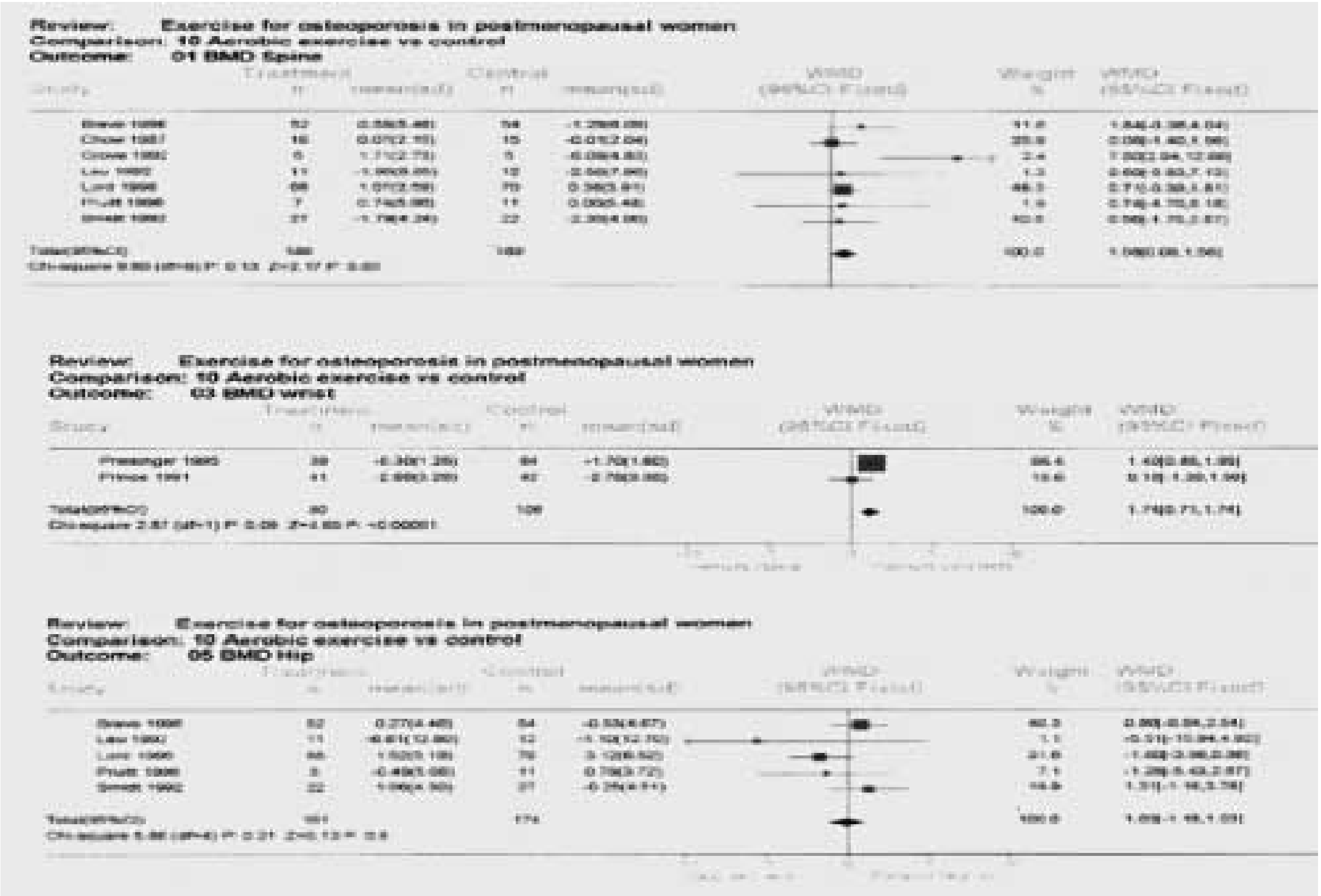

Figure 1.—Effectiveness of exercise in studies with aerobic exercises.

ner, as a check. Eliminating in this way the bias derived from the genetic condition and the environment, but on the other hand modifying the complete efficacy of the training programme.

These types of exercises showed a significant effect of the strain on the bone in the vertebral lumbar, and on the hip in the limits of (p=0.04). The measurements of the 2 levels concern only 2 studies at a time, further reducing the number of samples.

The 3rd group (walking) concerns only 3 studies,[21-23] consisting of 77 subjects who underwent treatment and 79 checks (Figure 3). In only one of the studies is the strain of the exercise calculate:[22] this however extends itself to a somewhat short follow-up period (7 months) and does not describe the level of compliance. The significance of the efficacy was shown only at the level of the backbone, the measurement on the hip was carried out in only one study with success but only on 49 subjects and 48 checks.

From these groups we excluded the studies on programs of specific side exercises: Sinaki,[24] who studied the effect of the extension exercises on spine; Revel who studied the effect of the one side hip flexion exercises.[25]

Discussion

The results of this revision leads to conclusions with extreme caution, given the low points in the quality score of the selected studies, the brevity of the follow-up, given also the low numbers of samples and excessive use, in the same studies, of mixed treatment (medicine and exercise). Moreover, the description of the exercise programmes being generally insuf-

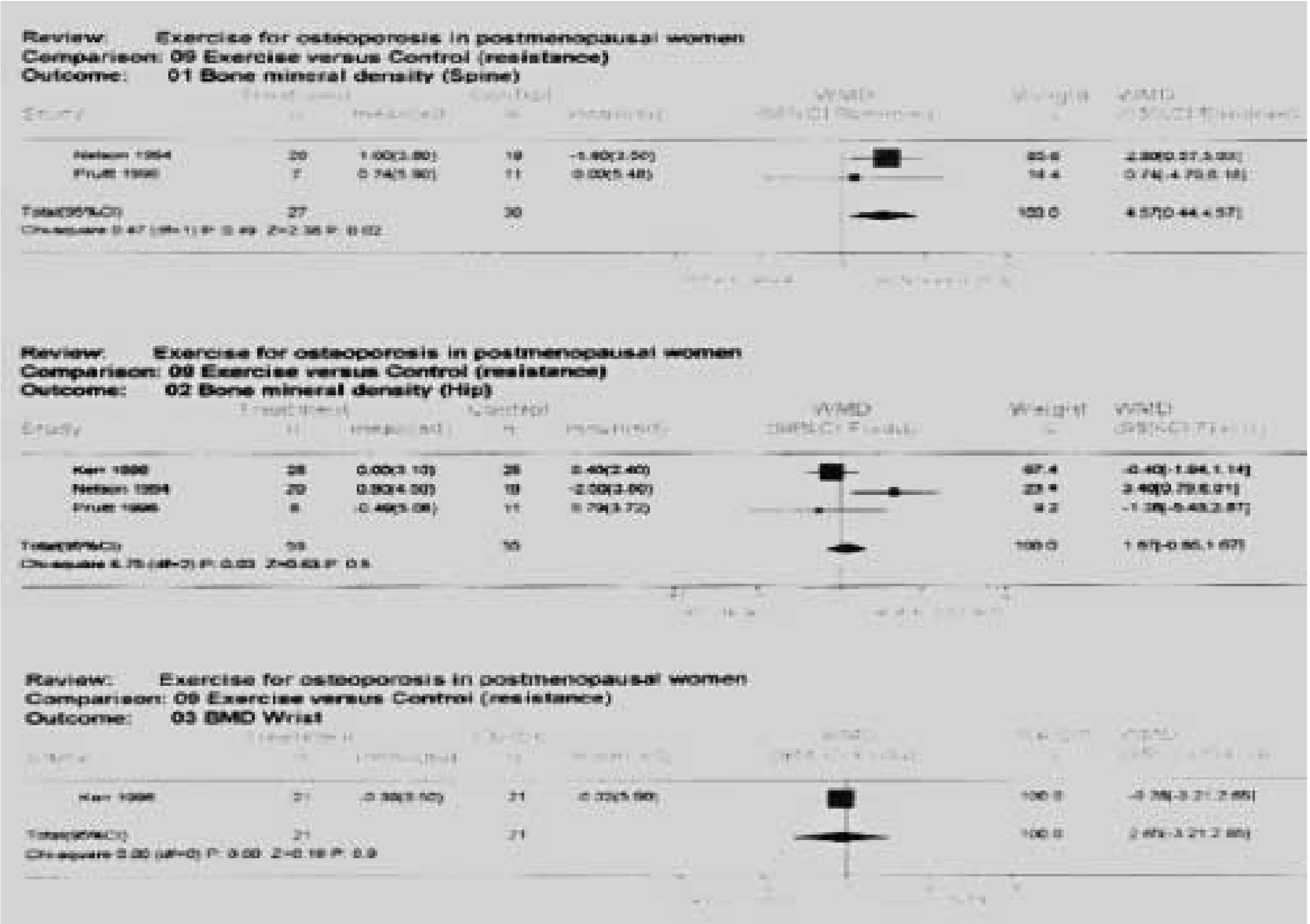

Figure 2.—Effectiveness of exercise in studies with exercises against resistance.

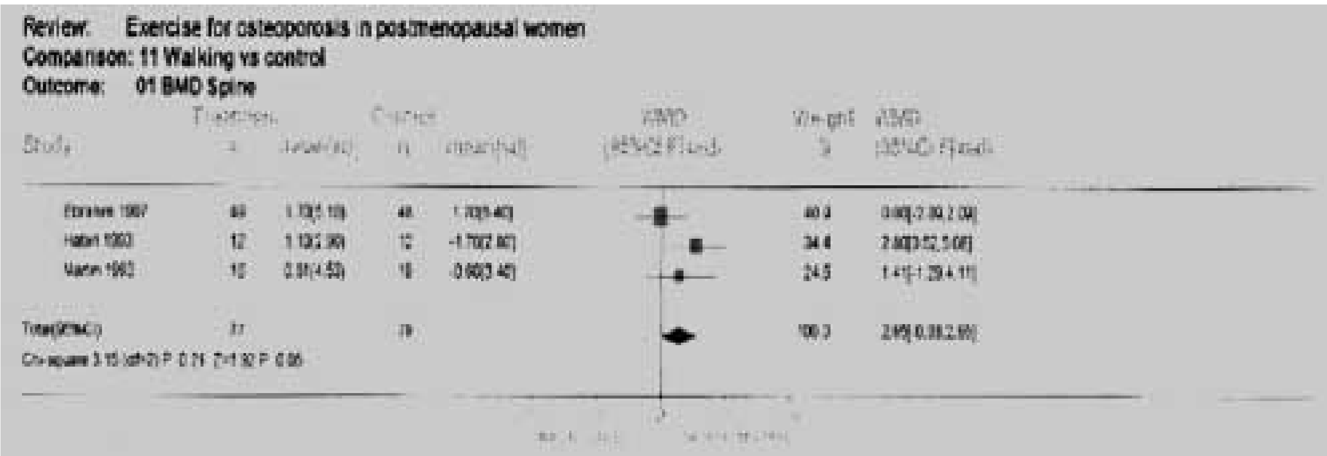

Figure 3.—Effectiveness of studies using walking as exercise.

ficient, it is difficult to establish the "posology" of the treatment in the study, and the results of the same exercises are often not sufficiently highlighted because the measurement of bone density is not carried out in effective specific load site.

Nevertheless it is possible to reach some conclusions: knowing that, after the period of rapid loss in the first few years of postmenopause, the rate of loss returns to 1% per year, we can affirm that at this level physical exercise may be a prevention, while not compensating for the loss in the first phase of rapid bone loss. Also with all the limits due to methodology problems, this meta-analysis confirms that which has emerged in recent revisions,[26, 27] or rather that the efficacy of exercise exists, but it is relatively small, and obviously, connected to its continuation in the life women.

This is the actual challenge: in the first place to have the elements to establish a program which is really effective and to be able to implement it, with a satisfying level of compliance in such a manner as to keep the results for life.

At the present time both exercise programmes above the stimulus threshold, site specific with individually defined loads, limited in time but repeated every 5 to 10 years, and long term programmes with greater compliance, as could be the case of speed walking, of which its efficacy has been proven, seem proposable.

However, beyond these simplifications, it is necessary to remember that exercises have a wider action than what is measurable at the level of the variation in bone density, or rather they work by improving muscle mass, strength, balance and co-ordination. Therefore, unlike treatment with medicine, exercises work simultaneously on various factors,[26] which really allow for a prevention of falls and therefore of fractures.

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