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Original Article

Positive Effects of Physiotherapy on Chronic Pain and Performance in Osteoporosis

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Abstract. The aim of this placebo-controlled, randomized, single-masked study was to establish the effects of a 10-week ambulatory exercise programme for osteoporotic patients on pain, use of analgesics, functional status, quality of life, balance and muscle strength. Fifty-three ambulatory postmenopausal women with at least one spinal crush fracture and pains within the last 3 years were randomized for physiotherapeutic training twice a week for 10 weeks or no training. The training included general training of balance and muscle strength, with stabilization of the lumbar spine. The participants were tested at baseline, week 5 and week 10 with a balance test, muscle strength test and questionnaires on pain, use of analgesics, functional status and quality of life. Twelve weeks after the supervised training had finished (week 22) they answered the same questionnaires. The study groups were comparable at baseline. The training group had a significant reduction in use of analgesics ($p=0.02$) and pain level ($p=0.01$) during the training period. Distribution of functional score improved; the improvement was reduced at week 22. Quality of life score improved significantly throughout the study ($p=0.0008$), even after week 22. Balance improved non-significantly ($p=0.08$). Quadriceps muscle strength improved significantly after 5 weeks ($p=0.04$). Back extensor muscle strength improved almost significantly ($p=0.09$). In conclusion, this training programme for osteoporotic patients improved balance and level of daily function and decreased experience of pain and use of analgesics. Quality of life was improved even beyond the active training period.

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Introduction

Osteoporotic patients with spinal crush fractures are characterized by a change in posture and reduced height, back pain and some degree of change in life-style imposed by the disease. Special physiotherapeutic training is considered important for improving posture and balance, and reducing pain and fracture risk [1–4].

Few studies have described the limitations in personal and social relations of osteoporotic patients [1,5], but no studies have examined the effect of training on level of daily function, quality of life, pain level and use of analgesics in osteoporotic patients. We wanted to examine whether a physiotherapeutic training programme for osteoporotic patients could reduce pain level and use of analgesics, increase quality of life and level of daily function, and, in addition, improve balance and strength of trunk and quadriceps muscles.

Materials and Methods

Women aged 55–75 years with osteoporosis and at least one spinal crush fracture and back pain within the previous 3 years were included. All patients included had to have had chronic back pain due to vertebral fracture but no acute pain from new fracture. They also had to be able to participate in ambulatory training twice a week continuously for 10 weeks. Patients with diseases that would interfere with participation, such as severe heart or pulmonary disease, psychiatric disease, medicine or alcohol abuse, or rheumatoid disease were not included; neither were patients who had participated in this kind of training previously. The patients were recruited from the Endocrine Clinic or their general physician.

Blocks of 12 patients were randomly assigned to the training group or control group. The participants were randomized consecutively and in masked fashion by the drawing of sealed envelopes containing the name of the group. The training programme was conducted by one of two physiotherapists for 1 h twice a week for 10 consecutive weeks in groups of 6 participants. It was based on a programme devised by the physiotherapist Vibeke Vala (Gainesville, FL; personal communication) and contains an overall training of balance, muscle strength, stretching and relaxation, in lying and standing positions, to the limit of pain; spine rotation was undertaken only in a lying position. The programme contained isometric training of extensors and flexors of the trunk. Balance was trained by exercises standing on one leg. The patients learned to stabilize the lumbar spine in all exercises. For the second 5 weeks the programme was extended with more demanding exercises. A full description of the programme can be requested from authors. A home exercise programme with 10 of the exercises was given to the participants after 5 weeks. The control patients were instructed to continue their daily life as usual. They were tested in exactly the same way as the training group; the 'effect of attention' was thus evaluated.

All participants were tested before randomization (week 0), after 5 weeks and after 10 weeks. Twelve weeks after training had stopped (week 22) a questionnaire with the usual questions was posted to all participants, who answered it by mail. The tester was the same at all visits and was masked with regard to the group to which the participant was allocated. The participants were all carefully instructed not to disclose to the tester the group to which they belonged.

Questionnaires

Pain Level. An 11-point box scale on pain level [6] was filled in at baseline, weekly during the 10-week training period, and again at the 22-week questionnaire. Score 0 indicated no pain and score 10 maximal pain.

Use of Analgesics. A questionnaire on weekly use of analgesics, devised by the authors from a questionnaire by Mannicke et al. [7], was filled in at baseline, weekly during the 10 weeks of the programme, and again at the 22-week questionnaire. The question asked was: 'For how many days during the last week have you used analgesics?': score 20 = none, score 15 = mild analgesics (aspirins, NSAID) 1–4 days, score 10 = mild analgesics 5–7 days, score 5 = opiates 1–4 days, score 0 = opiates 5–7 days.

Daily Level of Function. A questionnaire regarding level of daily functioning was filled in at baseline, week 10, and after 22 weeks. The questionnaire was the validated and well-established Oswestry questionnaire [8], modified by authors for osteoporotic patients (Table 1). The

Table 1. Questionnaire related to level of daily function (translated from Danish)

1. Daily function	*Score*
Independent/no difficulties	20
Independent with some troubles	15
Help is needed sometimes	10
Help is needed often	5
Dependent on help	0
2. Time spent in the bed	
Less than 10 h daily	20
10 to 12 h daily	15
12 to 16 h daily	5
More than 16 h daily	0
3. Use of analgesics	
No daily use	20
Daily use, mild analgesics only	10
Some days use of opiates	5
Daily use of opiates	0
4. Back pains	
No pain or need for analgesics	20
Pain but no use of analgesics	15
No pain when using analgesics	10
Analgesics have only partial effect	5
Analgesics have (almost) no effect	0
5. Personal care	
I can manage without having (more) pain	20
I can manage slowly, but gets more pain	15
I can manage with a little help	10
I need daily help for most of my personal care	5
I am confined to my bed and cannot manage personal care	0
6. Walking	
I can walk a long distance	20
I cannot walk more than 1000 m because of pain	15
I cannot walk more than 200–300 m because of pain	10
I can only walk if I use a stick	5
I lie in bed most of the time and must crawl to the toilet	0
7. Sitting	
I can sit in any chair for a long time	20
I can sit in my best chair for a long time	15
I cannot sit for more than 1 h because of pain	10
I cannot sit for more than 10 min because of pain	5
I cannot sit at all because of pain	0
8. Standing	
I can stand for as long as I wish	20
I can stand as long as I wish to, but it gives me pain	15
I cannot stand for more than 1 h because of pain	10
I cannot stand for more than 10 min because of pain	5
I cannot stand because of pain	0
9. Sleeping	
Pains do not change my sleep	20
I can only sleep if I use analgesics	15
I sleep less than 6 h even though I use analgesics	10
I sleep less than 2 h even though I use analgesics	5
I cannot sleep because of pain	0
10. Social life	
My social life is normal and unaffected by the disease	20
My social life is normal but affected by the disease	15
The disease has not changed my social life, except that I avoid physical activities as dance or sport	10
The disease has restricted my social life to my home	5
I have no social life because of the disease	0

modification consisted of replacing questions about sex life and travelling ability with questions about daily function and use of analgesics, and a reduction in scoring possibilities from 6 to mainly 5. For each test a total score was calculated as the sum of scores, given as a percentage of maximum possible scores.

Effect on Quality of Life. A questionnaire on quality of life was designed by the authors (Table 2), as no such questionnaire exists for Danish osteoporotic patients. Questionnaires on *changes compared with baseline* in quality of life were filled in at the end of week 5 and week 10, and at week 22. For each test a total score of change was calculated as the actual score sum as a percentage of neutral score sum (= 120).

Table 2. Questionnaire for testing changes in quality of life

Compared with your condition at the start of the study:
1. Has your tiredness changed?
2. Can you walk longer distances?
3. Can you walk faster?
4. Can you sit for a longer time?
5. Can you stand for a longer time?
6. Are you more confident when walking up a staircase?
7. How do you manage daily affairs in the home?
8. How do you manage daily personal care?
9. How do you sleep?
10. Has your social life changed?
11. Do you find your posture has changed?
12. Has your general well-being changed?

Each question had five scoring possibilities: score 20 = great improvement, score 15 = slight inprovement, score 10 = no change, score 5 = slight worsening, score 0 = significant worsening since the start of the study.

Balance–Muscle Strength Tests

Balance. A Chattecx Balance System (Chattecx Corporation) was used for testing balance. A platform, 59 × 43 cm, was placed on strain gauge pressure sensors, which were situated on top of the original movable platform. The machine registered the tested person's mean centre of balance by means of the strain gauge sensors, 1000 registrations per test. Balance was tested in four different situations: standing on both feet with the eyes open or with the eyes closed for 25 s each, standing in the tandem position for 10 s, and standing on both feet with the platform tilting for 10 s. The best result of three was recorded for each situation. Balance was described by a Sway Index (Dispersion Index) that was calculated by the standard deviation of the 1000 x- and y-coordinates gathered during a test. A 'balance sum' was calculated for patients who performed all tests, as the sum of the four indices. A good balance gives a low Sway Index.

Isometric Muscle Strength of Back Extensors and Abdominal Flexors. A strain gauge dynamometer (Tr Testi Oy, Jyväskylä, Finland) was used [9,10] to test the isometric strength of back extensors and abdominal flexors. The patient was tested while standing, with the hip fixated. The best result of three was recorded.

Strength of Femoral Quadriceps Muscle. A strain gauge instrument (Tr Testi Oy, Jyväskylä) was used to test the strength of the femoral quadriceps muscle, with the patient sitting in a special chair. A superimposed twitch was applied to ensure maximal voluntary isometric contraction [11,12]. The best result of three was used.

Statistical Analysis

The results were described by median (25;75 percentile) value. Between-group differences were evaluated by Mann–Whitney test. This test was also used for within group comparisons of percentage change. To these analyses were added results of repeated measures variance analysis to obtain an overall evaluation of group differences throughout the study. Level of significance was chosen at $p = 0.05$.

Results

Fifty-three patients were randomized. Mean age in the training group was 65 years (62;70), in the control group 68 years (64;71). During the study 3 patients in the training group and 2 patients in the control group were excluded due to adverse events not related to the training. Two patients did not return the questionnaire at week 22.

The participation in the training sessions was high (100% (90;100)).

Questionnaires

Pain Level. At baseline the median pain scores in the two groups were comparable. In order to elucidate the changes in distribution of pain score between each registration, the data are presented graphically as the distribution of all pain score values instead of one mean score value, as the mean value camouflages the opportunity to illustrate these changes in the study groups. Figure 1 shows the distribution (%) of patients in the two study groups related to their individual pain score during the study period, with pain score divided into five subgroups. For the training group, the group scoring 4–6 was reduced at week 10 as well as week 22, and the groups with lower scores increased simultaneously, especially the middle group (score 2–3) but also the lower two groups. The distribution in the control group was nearly unchanged during the study. By

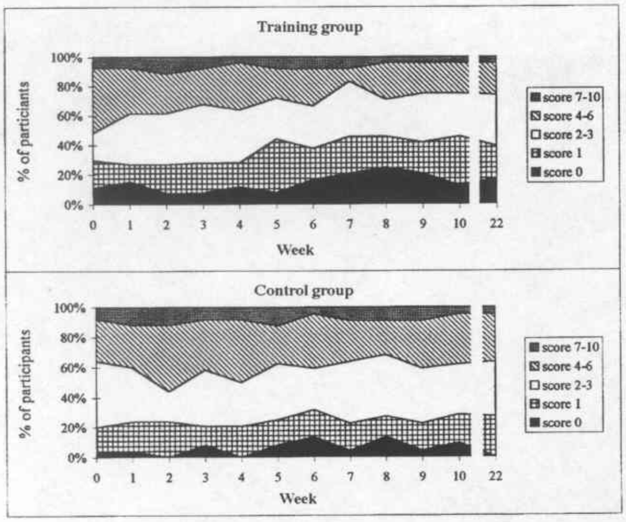

Fig. 1. Distribution (%) of participants related to weekly pain score during the study period. Participants were divided into five subgroups according to score as shown in the figure. Score 10 = maximal pain, score 0 = no pain.

analysis of variance using all values, a significant difference was found between the course of values from the two study groups ($p = 0.02$).

Use of Analgesics. At baseline the median score were comparable between the two groups. For the same reasons as explained above the changes in use of analgesics are shown as the distribution (%) of patients related to their individual analgesic score during the study period for the two study groups (Fig. 2). In the training group the subgroup scoring 20 (no use of analgesics) increased throughout the study, with a corresponding reduction in the other subgroups. At week 22, the subgroup scoring 20 was slightly reduced

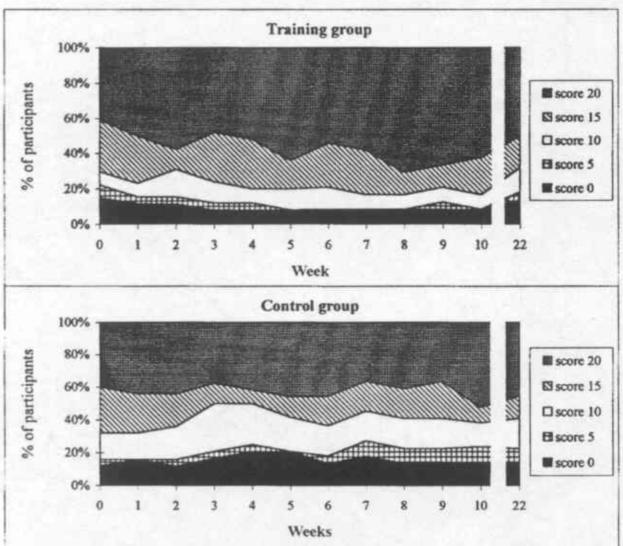

Fig. 2. Distribution (%) of participants related to score on weekly use of analgesics during the study period. Score 20 = no use of analgesics, score 0 = using opiates 5–7 days a week.

compared with week 10, but still increased compared with baseline. For the control group almost no changes between the subgroups were found during the study. By analysis of variance a significant difference was found between the course of values in the two groups when testing from week 0 to week 10 ($p = 0.01$), but if past intervention values (week 22) were included, the significance of differences disappeared.

Level of Daily Function. At baseline, median levels of daily function were comparable in the two groups. Figure 3 shows the distribution (%) of participants related to total score sum in the two study groups at week 0, week 10 and week 22. In the training group there was a general shift towards the higher-scoring subgroups during the active training period, as the proportion scoring 0–74 was reduced from 50% to around 15%. When active training stopped there was a small drop-back for some patients, but in general the

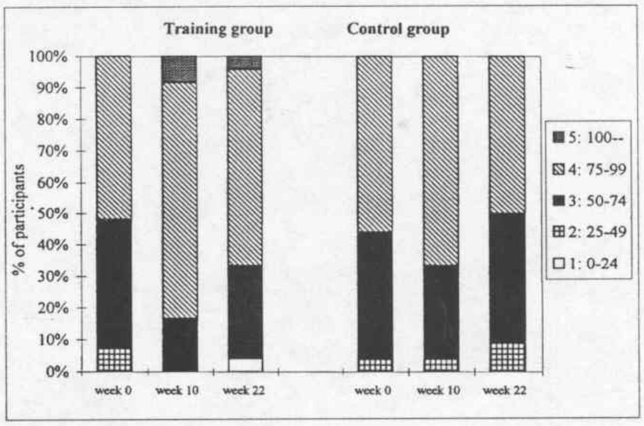

Fig. 3. Distribution (%) of participants related to total score of daily function during the study period. Score 100 = highest possible level of daily function, score 0 = lowest possible level of daily function. Participants were divided into five groups according to five scoring possibilities.

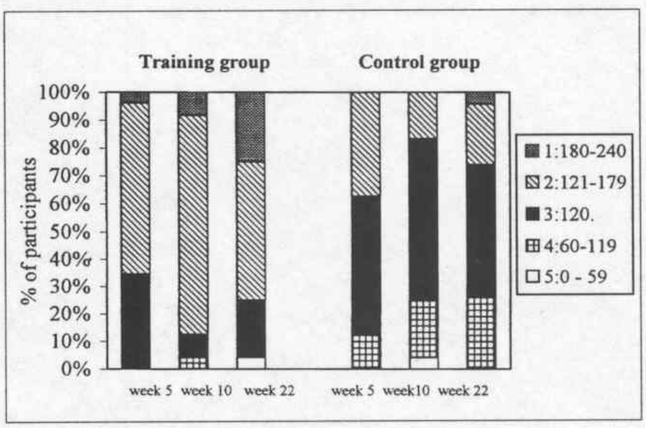

Fig. 4. Distribution (%) of participants related to total quality of life score during the study period. Total score 120 = no change compared with time of inclusion, total score >120 = improvement compared with time of inclusion, total score <120 = worsening compared with time of inclusion. Total score was divided into five subgroups according to five scoring possibilities.

score were higher than at baseline. In the control group the distribution showed no major changes during the study. By analysis of variance no significant differences were found in the course of total score median values between the two groups.

Effect on Quality of Life. Figure 4 shows the distribution of participants related to change in total score at week 5, week 10 and week 22 compared with baseline. There was a continuous improvement of scores in the training group, whereas no improvement was found at any visit in values of the control subjects. The improvement in the training group was significantly better compared with controls at week 5 ($p=0.01$) as well as at week 10 ($p<0.0001$) and this persisted at week 22 ($p=0.0008$).

Balance–Muscle Strength Tests

Table 3 shows median values at baseline, week 5 and week 10 as well as percentage change from baseline values for balance tests and tests of muscle strength. All baseline values were comparable. Both groups had an almost significant improvement of balance ($p=0.08$) at weeks 5 and 10. Balance improved by 19.6% during the 10 weeks for the training group compared with an improvement of only 6.9% in the control group. This difference was not significant due to a large dispersion of values.

For isometric muscle strength of back extensors no significant difference was found between the groups at week 5. At week 10 a non-significant improvement of extensor muscle strength was found in the training group compared with the controls ($p=0.09$). No significant differences in change in isometric muscle strength of abdominal flexors was seen between the groups at weeks 5 and 10. Baseline values for quadriceps muscle strength were comparable in the two study groups. A significant difference was found between median values in the two groups at week 5 ($p=0.046$), but at week 10 the significant difference had disappeared ($p=0.08$). By repeated measures analysis of variance no significant difference was found between the course of values for any muscle strength tests in the two groups during the study. For all results of balance and muscle tests we found a very large inter-individual dispersion of values.

Discussion

This study examined the effect of a short training program, which is accessible and acceptable to osteoporotic patients, with emphasis on the effect on qualitative measurements, as most studies have focused on the effect of training on bone mineral content [13–18]. This parameter is not in itself a predictor of any improvement of the patients' disabilities and symptoms in daily life. By using qualitative parameters the aim was to examine the effect on the patients' own interpretation of their condition, as this is the most important endpoint in any treatment. Some of the effect might be due to a 'social effect' of training in classes. However, this element cannot be separated from the total effect. An important issue was to use questionnaires that were both specific for osteoporotic patients and related to Danish lifestyle. Therefore it was not possible to use existing questionnaires on quality of life, and new ones had to be developed. We were not able to perform further validation of the questionnaire. However, the importance of validation of this questionnaire was minor as the questions related the actual status to the status at baseline and thereby the score was not compared with a standard normal scale. The questionnaire for level of daily function was validated in its original form in patients with low back pain [8], and as only a few modifications were made new validations were not performed.

Table 3. Baseline values for balance test and the muscle strength tests, and percentage difference between baseline and week 5 and week 10 values, respectively

	Week 0			Week 5			Week 10		
	Trainers	Controls	*p*	Trainers	Controls	*p*	Trainers	Controls	*p*
n	27	25		26	23		24	24	
Balance	20.6 (17.9; 23.5)	22.0 (20.7; 25.0)	0.22	17.6 (15.6; 20.1)	20.4 (17.4; 25.4)	0.08	17.8 (14.9; 19.3)	21.1 (16.4; 25.5)	0.08
Back extensors (kg)	19.3 (13.2; 31.2)	19.8 (14.0; 26.2)	0.50	28.7 (18.1; 36.6)	21.3 (17.1; 29.8)	0.19	31.7 (19.8; 38.0)	24.8 (14.6; 32.0)	0.09
Abdominal flexors (kg)	21.3 (16.3; 24.5)	18.5 (14.4; 24.7)	0.63	22.0 (17.0; 29.3)	19.2 (15.3; 28.3)	0.83	25.9 (20.3; 30.4)	20.9 (18.1; 28.8)	0.29
Quadriceps (kg)	24.1 (22.1; 29.2)	23.1 (17.7; 28.3)	0.22	26.2 (23.9; 29.1)	23.2 (19.1; 27.3)	0.05	26.7 (23.7; 28.9)	22.6 (20.2; 28.2)	0.08

	Difference in values week 0–5 (%)			Difference in values week 0–10 (%)		
	Trainers	Controls	*p*	Trainers	Controls	*p*
Balance	7.62 (−1.96; 26.48)	2.63 (−1.84; 17.96)	0.42	19.64 (2.78; 24.17)	6.99 (−3.44; 16.39)	0.58
Back extensors (kg)	22.9 (8.1; 44.0)	11.1 (−2.23; 5.8)	0.28	24.9 (15.4; 53.7)	18.4 (−0.9; 61.6)	0.36
Abdominal flexors (kg)	9.4 (−3.9; 35.1)	7.9 (−6.9; 9.6)	0.98	17.7 (3.7; 34.9)	10.0 (−12.8; 55.1)	0.92
Quadriceps (kg)	8.1 (−4.2; 15.3)	−3.0 (−4.1; 7.2)	0.04	6.3 (−4.5; 12.6)	(−1.1) (−9.7; 13.4)	0.33

Values are given as median (25;75 percentile). *n* = number of participants in the two groups. *p* indicates differences between groups (Mann–Whitney test).

In general, none of the differences between groups were due to differences between the two study groups as all baseline values were comparable. As the attendance at training and tests were very high, any possible effect of the training should be measurable.

Questionnaires

Pain Level. It is an important finding that the training programme reduced pain in a large group of patients, as this proves that physiotherapeutic training is an important part of treatment in osteoporosis. The groups with most benefit from the training programme were those with medium to low pain scores, and it will probably be these groups of osteoporotic patients who wish to and will be able to participate in a training programme in practice.

Use of Analgesics. The group with daily use of opiates was unchanged during the study. This might be due to the fact that the patients did not want to make changes by themselves in dosing of this kind of analgesic. However, it could also be explained by a minor effect of the training in these patients, supported by the unchanged size of the group with high pain score during the study. Clearly, a positive effect was obtained, as a reduction in use of milder analgesics was seen during the study, and an increasing number of the patients could manage without use of analgesics. The fact that use of analgesics increased again after the supervised training had stopped suggests that the patients should continue supervised training for as long as possible, for at least once a week.

Level of Daily Function. Half of all the patients improved their score as regards level of daily function during active training; the score in the other half remained unchanged, but none worsened. It was found that this benefit was partially reduced after the end of the supervised training, suggesting that the training should continue. However, these improvements were found among the lowest/worst scoring groups, in contrast to the improvements in pain and use of analgesics.

Effect on Quality of Life. It is interesting that by using these quite simple questionnaires it was possible to register the patients' opinion about the effect – something that is usually quite difficult to examine. Quality of life is a complex concept and the individual aspects are difficult to specify. The questions used in this study represent items which, in our clinical experience, are the most important for osteoporotic patients. The question on change in posture might not have been the optimal one. One suggestion could be a question related to a statement made by some of the participants: that after the training they were able to reach the top shelf in a cupboard, their posture was straighter and they felt more stable. However, change in height during the study was not used as a measure of change in posture, as the measurement error would probably exceed the size of a possible effect from training.

A continuous improvement in quality of life was obtained and the majority maintained the gain in quality of life obtained during the supervised training period. This suggests great benefit even from a relative short programme as this.

Balance–Muscle Strength Tests

The facts that both study groups improved their balance as well as muscle strength was probably due to a certain degree of habituation to the instruments. It was only for the quadriceps muscle test, by the use of a superimposed twitch technique, that we had the possibility of ensuring that patients did their best from the beginning. The unexpected large dispersion of values made it difficult to reach statistically significant differences in these tests, but several showed positive tendencies towards improvement in the training group. Thus, if training has a positive effect on balance and muscle strength, a larger number of participants is needed to prove such an effect.

Balance. A sample of balance tests was used which gives an estimate on the total balance capacity of the patient – static as well as dynamic. The nearly significant difference between the groups could be the result of a general improvement of the participants' muscle conditioning ability.

Strength of Quadriceps Muscles. The improvement found after week 5 in the strength of quadriceps muscles was reduced after week 10, probably because the maximal effect of training was obtained after 5 weeks. The training of this muscle was mainly a functional part of the balance training exercises.

Conclusion

In conclusion, osteoporotic patients with back pain from vertebral fracture found that this training programme improved quality of life, increased level of daily function and reduced pain level and use of analgesics (except opiates). No adverse effects of the programme were found. The programme is beneficial and applicable to supervised training of moderately disabled osteoporotic patients, but not necessarily to osteoporotic patients without symptoms from their fracture or patients with fresh vertebral fracture. We recommend that supervised training at least once a week is continued beyond 10 weeks, to maintain the positive effect.

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