

Comparison of three active therapies for chronic low back pain: results of a randomized clinical trial with one-year follow-up

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Abstract

Objectives. To examine the relative efficacy of three active therapies for patients with chronic low back pain.

Methods. One hundred and forty-eight subjects with chronic low back pain were randomized to receive, twice weekly for 3 months, (i) active physiotherapy, (ii) muscle reconditioning on training devices, or (iii) low-impact aerobics. Questionnaires were administered to assess pain intensity, pain frequency and disability before and after therapy and at 6 and 12 months of follow-up.

Results. One hundred and thirty-two of the 148 patients (89%) completed the therapy programmes and 127 of the 148 (86%) returned a questionnaire at all four time-points. The three treatments were equally efficacious in significantly reducing pain intensity and frequency for up to 1 yr after therapy. However, the groups differed with respect to the temporal changes in self-rated disability over the study period ($P = 0.03$): all groups showed a similar reduction after therapy, but for the physiotherapy group disability increased again during the first 6 months of follow-up whilst the other two groups showed a further decline. In all groups the values then remained stable up to the 12-month follow-up. The larger group size and minimal infrastructure required for low-impact aerobics rendered it considerably less expensive to administer than the other two programmes.

Conclusions. The introduction of low-impact aerobic exercise programmes for patients with chronic low back pain may reduce the enormous costs associated with its treatment.

KEY WORDS: Chronic low back pain, Exercise, Aerobics, Back reconditioning, Physiotherapy, Disability.

Musculoskeletal disorders, of which back pain accounts for more than half the number of cases, are the most common cause of chronic incapacity in industrialized countries [1]. Chronic low back pain (cLBP), typically defined as low back pain lasting longer than 3 months, represents a particularly costly sociomedical problem because of the expenditure associated with repeated treatment and the long-term absence from work and need for social support [2]. The development of effective interventions aimed at management of the chronic problem are thus urgently required. Active treatments are increasingly advocated for the treatment of cLBP [3], although few studies have documented the relative efficacies of different types of programme [4]. A number of types of functional restoration programme for patients with cLBP have been established, many of which include exercise routines on special equipment with the aim of

reversing the compromised trunk muscle function and mobility of these patients [5–7]. However, it has also been suggested that the specific exercise modality is less important than simply encouraging normal movement and improving general fitness [3, 8]. Nonetheless, this has not been examined within the confines of a randomized clinical trial of different exercise modalities. This is an important issue to address, not least because different programmes are often associated with vastly different implementation costs. In view of the limited resources faced by health-care providers worldwide, this economic issue cannot be disregarded.

The aim of the present study was to carry out a randomized clinical trial to examine the relative efficacies of three active therapy programmes for cLBP patients: modern individual physiotherapy, specific trunk-muscle conditioning using training devices, and group low-impact aerobics. Outcome was assessed up to 1 yr later in terms of self-rated pain intensity, pain frequency and disability. The short- and medium-term results of the study have been reported previously [9].

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Methods

Study population

Participants were recruited into the study following advertisement in local media. Admission criteria were checked by medical history interview and clinical examination. The main inclusion criteria were: less than 65 yr old; more than 3 months of low back pain with or without referred pain (non-radicular) serious enough to require medical attention or absence from work; and willingness to comply with the randomly assigned treatment. The exclusion criteria were: constant or persistent severe pain; pregnancy; previous spinal surgery; current nerve root entrapment accompanied by neurological deficit; spinal cord compression; tumours; severe structural deformity; severe instability; severe osteoporosis; inflammatory disease of the spine; spinal infection; severe cardiovascular or metabolic disease; and acute infection.

The patients gave their signed, informed consent to participation and the study was approved by the University Ethics Committee (University of Zürich).

Assignment to the treatments

Before the start of the study, a randomization schedule was drawn up for prestratified groups [stratified by age (less than 40 yr or greater than 40 yr) and sex], using a table of random numbers and a restricted randomization procedure (blocks of 15) [10]. After medical examination and upon agreeing to participate in the study, each patient was assigned a number (in chronological order of acceptance into the study) which would determine their later group membership, according to the randomization table. Once all baseline assessments and questionnaires had been completed, these consecutive numbers were entered into the random numbers table to determine group membership. Patients were assigned to one of the following three treatment groups.

Physiotherapy group. The patients had half-hour individual physiotherapy sessions focused on improving functional capacity using strengthening, co-ordination and aerobic exercises, and with instruction on ergonomic principles and home exercises.

Devices group. Patients had 1-h sessions for muscle reconditioning using training machines/devices, in groups of two or three. Four exercise devices (DBC International, Finland) provided progressive, isoinertial loading to the trunk in the three cardinal planes. Each session was preceded by 5–10 min of aerobic warm-up (e.g. cycling), and relaxation/stretching exercises were carried out before and after the use of each device.

Aerobics group. Patients took part in low-impact aerobics classes lasting 1 h, comprising exercises to music, with a maximum of 12 patients per group. A warm-up of 10–20 min, involving whole-body stretching and low-impact aerobic exercises, was followed by 20–30 min of specific trunk and leg muscle exercises. The last 15 min of the class comprised cool-down and stretching/relaxation exercises.

The three types of treatment were administered in geographically separate areas of the hospital so as to avoid contact between patients in the different groups. No charge was incurred by the patient or their health insurance provider for receiving the treatment.

Assessments before and after treatment

Upon entry to the study (before randomization), after the 3-month treatment period and at 6 and 12 months of follow-up, a questionnaire booklet was administered to the patients to complete in their own time, enquiring amongst other things about the following: (i) sociodemographic information; (ii) low back pain intensity [Visual Analogue Scale (VAS) with a score range of 0–10], duration (in months) and frequency (pain-free, sporadic, often, permanent); (iii) low back disability (Roland and Morris questionnaire [11]); (iv) beliefs about physical activity/work being a cause of back trouble and fears about the dangers of such activities when experiencing low back pain {Fear-Avoidance Beliefs Questionnaire (FABQ) [12]}; and (v) psychological disturbance [13], using a combined score from the Modified Somatic Perception Questionnaire (MSPQ [14]) and the modified Zung questionnaire [15].

Immediately after therapy, the questionnaire also enquired about any other treatments for back pain undertaken at the same time as the treatment was received in the study hospital. A list with 11 options was provided: acupuncture, pain medication, injection, physiotherapy, traction, manipulation, chiropractic, massage, corset, strength training, other.

At the 6- and 12-month follow-ups, additional questions concerned the duration of the treatment effect and the patient's success in continuing independently with exercises similar to those learnt during the study.

Statistical analysis

The required sample size (approximately 54 per group) was determined, assuming a type I error probability of 5%, a type II error probability of 15% (i.e. power of 85%) and 15% dropout, based on the expected change in the clinical measures of pain and disability (determined from other similar exercise programs with similar patients [e.g. 5, 8]) [16]. Calculations were done for a medium effect size (0.55) for group differences after therapy. For the examination of treatment efficacy in low back pain, a sample of 50 volunteers per group after randomization has been considered methodologically adequate [4]. This number is also a manageable quota of additional patients that can be treated simultaneously for the purposes of the study with the resources and space available in the hospital.

Changes in continuous variables over the four assessment periods were assessed by analysis of variance with repeated measures (group \times time of assessment). Contrast analyses were used to identify differences (i) between the various time-points and (ii) amongst the three groups in their pattern of change over

time. Associations between categorical variables were analysed by contingency analysis and group differences in ordinal data were examined with the Wilcoxon rank sum test.

The data were analysed using the intention-to-treat principle, whereby the data from all patients returning a questionnaire at the requested time, including patients who had not completed the full programme, were included. Significance was accepted at the 5% level.

Results

Study sample

A flow diagram summarizing the formation of the final study group is given in Fig.1. From a total of 255 volunteers who responded to the initial recruitment drive, 159 satisfied the admission criteria; 148 of these chose to take part in the study and underwent randomization. One hundred and thirty-two of the 148 (89.2%) completed the full programme. The majority of dropouts discontinued the programme because of changed work or family commitments or other medical problems and only rarely because they were dissatisfied with the treatment (Fig. 1). There were 127/148 (86%) data sets available for the repeated-measures analysis of the questionnaire data at all four time-points (Fig.1). The proportions of participants in each group whose data contributed to this final analysis were as follows: devices 77%, physiotherapy 88%, aerobics 84% ($P = 0.39$).

Table 1 shows some of the demographic characteristics of the patients; there were no significant differences

amongst the three groups for any variable. The dropouts did not differ significantly from those who stayed with the treatment, other than that they were younger (40.1 vs 45.7 yr; $P = 0.033$).

Sixty-one per cent of the patients declared they had received no additional treatments for their low back pain during the course of the treatment administered for the study, with no difference between the three groups. Those who declared they had undergone supplementary treatments undertook an average of 1.5 (range 1–3) options from the list of 11 readily available treatments (see Methods). There was no significant difference between the three groups in this respect ($P = 0.71$).

Outcome measurements

Pain score. Changes in pain intensity (highest and average VAS score in the last 2 weeks) recorded over the four time-points for each therapy group are shown in Table 2. For the whole group of patients there was a significant reduction in mean pain intensity immediately after therapy, which was retained 12 months later, with no significant difference amongst the three groups in the extent of the change (Table 2).

Cut-off scores were established to categorize clinically significant changes in highest pain intensity (VAS) on the basis of the results of a reliability study in a similar patient group (R. Stärkle *et al.*, unpublished data) as follows: improvement = value reduced by more than 2.8 points; unchanged = values 2.8 higher or 2.8 lower than the pretherapy score; worse = value 2.8 points or more than before therapy. According to this classification, 12 months after therapy 46 patients (36.2%) were

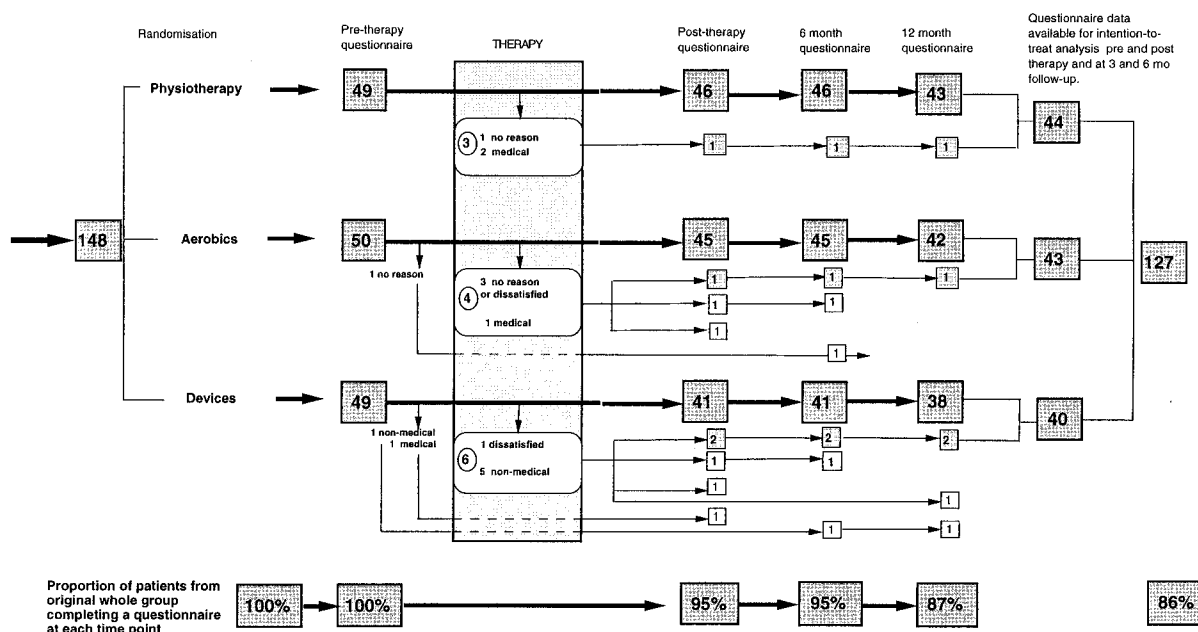


FIG. 1. Flow diagram showing how the study group was formed and the number and group membership of dropouts throughout the course of the study. Shaded boxes represent patients who returned a questionnaire at every time-point (large boxes represent those completing treatment; small boxes represent treatment dropouts) and whose data were included in the final intention-to-treat repeated measures analysis of variance. Open boxes represent patients who returned a questionnaire at any other time-point.

TABLE 1. Baseline characteristics of the study participants

Characteristic	Physiotherapy (n=49)	Aerobics (n=50)	Devices (n=49)	P
Sex: no. (%) female	30 (61)	27 (54)	27 (55)	0.74
Married: no. (%)	34 (69)	36 (72)	31 (63)	0.63
Current smoker: no. (%)	12 (25)	15 (30)	9 (18)	0.40
High school education: no. (%)	29 (59)	25 (50)	28 (58)	0.19
Work status: no. (%)				0.80
Full time	20 (41)	26 (52)	24 (49)	
Part time	16 (33)	15 (30)	15 (31)	
Retired/unemployed/homemaker	13 (26)	9 (18)	10 (20)	
Type of work: no. (%)				0.20
Office working/sedentary	19 (39)	26 (52)	25 (51)	
Light manual handling	30 (61)	21 (42)	22 (45)	
Heavy manual handling	0 (0)	3 (6)	2 (4)	
Age (yr)	46.3 ± 10.1	45.2 ± 9.7	43.7 ± 10.1	0.44
Weight (kg)	71.4 ± 11.0	68.0 ± 12.3	70.3 ± 13.4	0.38
Height (cm)	171 ± 9	170 ± 11	172 ± 9	0.70
LBP duration (yr)	10.0 ± 9.0	9.7 ± 9.1	13.0 ± 10.0	0.17

Values for continuous variable are mean ± s.d.

LBP, low back pain.

TABLE 2. Changes in self-rated pain, disability, fear-avoidance beliefs and psychological disturbance before therapy (1), after therapy (2) and at 6 and 12 months of follow-up (3 and 4 respectively) (mean ± s.d.) (see footnote for maximum and minimum scores achievable for each questionnaire)

		Global (n=127)	P (main effect)	Physiotherapy (n=44)	Aerobics (n=43)	Devices (n=40)	P (interaction)
Pain ^a (highest)	Before	6.5 ± 2.0	0.0001 (1 > 2, 3, 4)	6.5 ± 2.0	6.4 ± 1.7	6.6 ± 2.6	0.99
	After	4.9 ± 2.7		5.0 ± 2.7	4.9 ± 2.6	4.9 ± 2.8	
	6 months	4.6 ± 2.8		4.8 ± 2.6	4.4 ± 2.6	4.5 ± 3.1	
	12 months	4.7 ± 2.7		4.8 ± 2.7	4.7 ± 2.8	4.5 ± 2.8	
Pain ^a (average)	Before	4.2 ± 1.8	0.0001 (1 > 2, 3, 4)	4.4 ± 1.8	4.1 ± 1.8	4.2 ± 1.9	0.90
	After	3.2 ± 2.2		3.2 ± 2.2	3.4 ± 2.2	3.1 ± 2.1	
	6 months	3.0 ± 2.1		3.2 ± 2.1	3.0 ± 2.1	2.8 ± 2.2	
	12 months	3.1 ± 2.1		3.2 ± 2.0	3.2 ± 2.2	2.9 ± 2.2	
Average pain frequency ^b	Before	3.4 ± 0.7	0.0001 (1 > 2 > 3, 4)	3.4 ± 0.6	3.4 ± 0.7	3.4 ± 0.8	0.82
	After	3.0 ± 0.9		3.1 ± 0.8	3.1 ± 0.9	2.9 ± 0.9	
	6 months	2.9 ± 0.9		3.0 ± 0.9	2.9 ± 0.9	2.8 ± 0.9	
	12 months	2.8 ± 0.9		3.0 ± 0.9	2.9 ± 0.9	2.8 ± 0.9	
Roland and Morris disability ^c	Before	7.9 ± 4.6	0.0001 (1 > 2, 3, 4)	8.0 ± 4.0	7.6 ± 4.7	8.3 ± 5.2	0.10 0.03 (P vs A&D)
	After	6.6 ± 5.0		6.7 ± 4.9	6.3 ± 4.8	6.8 ± 5.0	
	6 months	6.3 ± 4.9		7.6 ± 5.2	5.5 ± 4.4	5.7 ± 4.9	
	12 months	6.3 ± 4.9		7.4 ± 4.9	6.2 ± 4.6	5.8 ± 4.8	
FABQ physical activity ^d	Before	14.0 ± 5.3	0.0001 (1 > 2, 3, 4)	14.6 ± 4.9	13.7 ± 6.2	13.7 ± 4.7	0.67
	After	11.7 ± 5.7		11.6 ± 5.9	12.0 ± 5.7	11.4 ± 5.5	
	6 months	11.0 ± 6.2		12.0 ± 6.5	10.1 ± 6.5	10.7 ± 5.3	
	12 months	10.8 ± 5.9		11.3 ± 6.2	10.9 ± 6.0	9.9 ± 5.5	
FABQ work ^e	Before	15.9 ± 11.0	0.0001 (1 > 2, 3, 4)	15.8 ± 10.9	17.5 ± 10.7	14.5 ± 11.6	0.61
	After	13.7 ± 10.3		13.9 ± 10.5	16.2 ± 11.0	11.1 ± 8.7	
	6 months	13.4 ± 11.9		15.1 ± 11.5	14.4 ± 11.8	10.5 ± 9.0	
	12 months	12.2 ± 9.9		12.3 ± 9.9	14.3 ± 10.6	9.9 ± 8.8	
MSPQ and ZUNG ^f	Before	17.9 ± 10.0	0.22	17.9 ± 9.8	16.7 ± 8.0	19.3 ± 12.2	0.05 0.01 (P vs A, D)
	After	16.5 ± 10.7		18.1 ± 10.5	15.5 ± 10.4	15.8 ± 11.4	
	6 months	17.7 ± 11.0		20.3 ± 10.9	15.3 ± 9.7	17.4 ± 12.0	
	12 months	17.5 ± 11.6		17.3 ± 11.4	17.2 ± 11.6	18.0 ± 12.1	

After the *P* value for the main effect, locations of significant differences between assessment times 1, 2, 3 and 4 are shown in parentheses. For example, (1 > 2 > 3, 4) means 1 significantly higher than 2, 2 significantly higher than 3 and 4 (3 and 4 not significantly different from each other).

After the *P* value for the interaction, locations of significant differences in the pattern of change for the three groups over time are shown in parentheses; P vs A, D = physiotherapy group significantly different from aerobics and devices groups.

^aVAS; score 0–10.

^bPain-free = 1, sporadic = 2, often = 3, continuous = 4. Non-parametric statistical analysis was also carried out on frequency distributions of pain frequencies. Results were essentially the same as for parametric analysis; the latter are presented for clarity.

^cPossible score 0–24; higher score = more disabled [reference 11].

^dFear-avoidance beliefs about physical activity (12); score 0–24.

^eFear-avoidance beliefs about work (12); score 0–42.

^fPsychological disturbance (13); score 0–99.

improved, 73 (57.5%) unchanged and four (3.15%) worse, with no differences amongst the groups ($P = 0.91$) [four patients (3.15%) had pretherapy scores of less than 2.8 and therefore could not be categorized].

Pain frequency. Before therapy, 63 patients (49.6%) suffered from low back pain permanently, 53 (41.7%) often and 11 (8.7%) sporadically. There was a significant reduction in pain frequency in all groups after therapy (Table 2). This was further improved upon during the next 6 months and remained stable up to the 12-month follow-up (no significant group differences in the pattern of change over time). At the 12-month follow-up, 36 patients (28.35%) suffered from low back pain permanently, 36 (28.35%) often and 46 (36.2%) sporadically; nine patients (7.1%) were pain-free.

Disability. When the whole group of patients was considered, there was a significant reduction in self-rated disability immediately after therapy, which was retained 12 months later (Table 2). However, a significant interaction suggested that the groups had behaved differently with respect to their patterns of change in disability over time; contrast analyses identified a slight but significant ($P = 0.03$) difference between the physiotherapy group and the other two groups (aerobics and devices; the latter did not differ significantly from one another). This was the result of an increase in disability in the physiotherapy group between the end of therapy and the 6-month follow-up; in contrast, during this same period the aerobics and devices groups showed a further reduction. During the final 6 months of the study (months 6–12), the values remained stable at their 6-month follow-up levels.

Working on the same principle as described above for pain intensity, cut-off scores for the clinically significant change in disability were also calculated: improvement = value reduced by more than 4 points; unchanged = value 4 higher or 4 lower than the pretherapy score; worse = value 4 points or more than before therapy. Twelve months after the therapy, 43 patients (33.9%) were improved, 54 (42.5%) unchanged and nine (7.1%) worse, with no significant differences amongst the groups ($P = 0.14$). Twenty-one patients (16.5%) had a pretherapy score of less than 4 and therefore could not be categorized.

Duration of the observed treatment effect. At the 12-month follow-up, the patients were asked to grade the period during which their complaint had been alleviated after the treatment: 1 = treatment had no effect in the first place; 2 = only a short time; 3 = until now. The ratings for each group did not differ significantly (physiotherapy, 16, 49 and 35% respectively; aerobics, 29, 33 and 38%; devices, 34, 24 and 42%; $P = 0.16$). The majority of the patients declared that they had continued independently, at least in part, with exercises similar to those taught in the hospital. There were no group differences [physiotherapy, 81%; aerobics, 86%; devices, 79% ($P = 0.72$)]. There was a low but significant association between continuing with the exercises

and the duration of positive effect after 6 months (contingency coefficient = 0.25; $P = 0.016$), but this failed to reach significance at 12 months. Those patients who continued with the exercises were more likely, at 12 months, to show a reduction in disability (65% showed a reduction compared with 41% in the group who did not continue exercising; contingency coefficient = 0.19, $P = 0.03$) and a reduction in pain intensity (78% showed a reduction compared with 55% in the group who did not continue exercising; contingency coefficient = 0.20, $P = 0.02$).

Psychological parameters. Fear-avoidance beliefs about physical activity and about work were significantly reduced in all groups after the treatment ($P = 0.009$), and the values remained significantly lower than those before therapy at both the 6- and the 12-month follow-up. There was no significant unique group effect regarding the pattern of change.

There was a slight but significant difference between the pattern of change in psychological disturbance (scores from MSPQ and ZUNG questionnaires combined) for the physiotherapy group compared with that of the other two groups ($P = 0.015$); in the aerobics and device groups these scores declined after therapy, then increased towards pretherapy values over the following 12 months, whilst the physiotherapy group showed no change after therapy, an increase at 6 months and then a reduction to pretherapy values after 12 months.

Discussion

The present study is the first clinical trial carried out to examine the relative efficacies of three active therapies for cLBP patients: individual modern physiotherapy, training on machines/devices and low-impact aerobics. One-to-one physiotherapy and device-training are both considered to be established therapies for cLBP, in that they are recognized and remunerable by health-care systems, whereas low-impact aerobics does not at present enjoy this status. The study was carried out as far as was practicable in accordance with previous recommendations [11, 17–19], but certain limitations need to be discussed. The study would naturally have been stronger with the inclusion of a no-treatment (control) group. However, this was not considered ethical or practicable with the study design chosen. A recent systematic review has provided good evidence of the effectiveness of exercise for cLBP patients [4] and the superiority of an active intervention over a control treatment has also been proved in a randomized controlled trial [5]. The main focus of the present study was therefore to examine whether there were differences in the effectiveness of the different active therapies, and their possible modes of action [20, 21]. Participation was encouraged through media advertisement and was voluntary; as such it would most certainly have been threatened by the inclusion of a no-treatment group. If the patients had been recruited following general practitioner referral to the hospital and had the waiting lists for treatment been known to be long, the inclusion of a 'waiting list

control group' would have been facilitated. However, this was not the case. Furthermore, as the majority of the patients had a long history of back pain (over 3 yr in 76% of patients), it was considered unlikely that the observed results simply reflected the natural history of back pain *per se* rather than the effect of the interventions. The patients displayed pain and disability characteristics comparable to those of the typical cLBP patient described in many previous intervention studies [22–24]. However, as voluntary recruits into the study, they were well-motivated to undertake one of the active therapies in an attempt to alleviate their prevailing symptoms and were mostly (potential) participants of working life. Whether similar results would have been observed for more severely disabled patients or those with confounding psychosocial problems, who often seek help in the tertiary care setting, remains to be shown.

The three active treatments proved to be equally efficacious in their ability to reduce pain intensity, pain frequency and disability in tasks of daily living immediately after therapy, even in those patients whose initial values for these three variables were very high. With respect to pain characteristics, these positive effects were well maintained and sometimes even improved upon in all groups over the subsequent 12 months. The mean decrease in highest pain intensity for the whole group after 12 months was 1.8 points on the VAS (effect size 0.9) and, with a quite stringent cut-off criterion, approximately 36% of the whole group also showed a significant clinical change in pain intensity (reduction of more than 2.8 points on the VAS). Furthermore, when the patients were asked directly after the therapy whether their pain and their ability to perform their everyday functions had worsened, stayed the same or improved, compared with levels before therapy, 57% (pain) and 49% (function) declared some or great improvement [9]. Perhaps, in this sense, the cut-off criterion was too strict, as individuals appeared capable of detecting a change in their clinical symptoms which was not registered as a clinical improvement by the VAS cut-off score. The whole issue of statistical and clinical significance is a complicated one, and many methods used previously for the identification of a clinically important difference appear to have been somewhat arbitrary [25].

With regard to self-rated disability, the groups showed differences in their course of change in the year after therapy: during the first 6 months the devices and aerobics groups displayed a further decline in disability, whilst the physiotherapy group showed a regression towards pretherapy levels. This divergent behaviour of the groups with regard to disability, but not pain, suggests that the patients' interpretation of the disabling effects of the pain or adjustment to the pain may have played an important role during this time. It has been shown that fear-avoidance beliefs [26] and self-efficacy [27] are significant contributors to the extent that people consider themselves disabled by their chronic pain. In the present study, fear-avoidance

beliefs tended to follow the pattern of change described for disability, especially with respect to the first 6 months after discharge from therapy. In modifying fear-avoidance beliefs, the manner in which the patients were forced to confront their apprehensions may have played a pivotal role. One-to-one physiotherapy perhaps promotes a sense of dependence of the patient on the therapist to guide and govern the most appropriate activity level for them in accordance with their declared level of pain. In contrast, with a group-exercise approach, this responsibility is rather more centred upon the patient himself or herself: when patients experience themselves behaving differently from their expectations, this can be expected to reduce fear and improve self-efficacy. Thus, the difference in the behaviour of the groups in the first 6 months after therapy may have, in part, reflected a type of withdrawal effect from the individual guidance given during the one-to-one therapy. The corresponding increases in psychological disturbance seen in this group over the first 6 months after therapy tend to support this hypothesis. Nevertheless, when the changes in disability from pretherapy levels to the 12-month follow-up were determined using a more stringent criterion based on clinically significant change, the group differences no longer reached significance.

There was a slight but significant association between continuing with the exercises learnt during the treatment in the hospital and sustained improvement of clinical function, suggesting that the interventions may have provided the necessary impetus to encourage the patients to become more physically active in their daily lives in an attempt to alleviate their pain and disability. This phenomenon has been reported previously [28].

The costs of administering the different programmes varied widely. The larger group size and minimal investment with regard to infrastructure rendered aerobics considerably less expensive than either one-to-one physiotherapy or small-group device-training. The charges that would have been made to the patient's health insurance for the different therapy programmes undertaken in the present study were as follows: aerobics, 288 Swiss francs (SFr) (determined from local commercial centres, as they are not at present financed by the insurance companies); physiotherapy 960SFr; devices 1120SFr. This gives a cost ratio of 1 : 3.3 : 3.9. In the present study, the respective cost ratio for personnel alone for 1 h of treatment was 1 : 5 : 6. Epidemiological studies carried out in the UK have shown that 3–7% of the population report their back problems as being chronic [1], and a significant proportion of these people will seek medical attention continually for their condition. The most common treatments currently employed for cLBP patients are physiotherapy and—with increasing popularity—'reconditioning' programmes carried out on training machines. If the results of the present randomized study can be verified by further studies in which the treatment is prescribed rather than undertaken voluntarily, the introduction of low-impact

aerobic exercise programmes for patients with cLBP should allow considerable savings in the direct costs associated with its treatment.

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References

1. Clinical Standards Advisory Group. Epidemiology review: The epidemiology and cost of back pain. Annex to the Clinical Standards Advisory Group's Report on Back Pain. London: HMSO, 1994.
2. Hazard RG. Chronic low back pain and disability: The efficacy of functional restoration. *Bull Hosp Joint Dis* 1996;55:213-6.
3. Abenhaim L, Rossignol M, Valat JP *et al.* The role of activity in the therapeutic management of back pain. Report of the International Paris Task Force on Back Pain. *Spine* 2000;25 (4 Suppl.):1S-33S.
4. van Tulder MW, Koes BW, Bouter LM. Conservative treatment of acute and chronic nonspecific low back pain. A systematic review of randomized controlled trials of the most common interventions. *Spine* 1997;22:2128-56.
5. Kankaanpää M, Taimela S, Airaksinen O, Hanninen O. The efficacy of active rehabilitation in chronic low back pain. Effect on pain intensity, self-experienced disability and lumbar fatigability. *Spine* 1999;24:1034-42.
6. Manniche C, Lundberg E, Christensen I, Bentzen L, Hesselsoe G. Intensive dynamic back exercises with or without hyperextension in chronic back pain after surgery for lumbar disc protrusion: A clinical trial. *Spine* 1993;18:560-7.
7. Denner A. The trainability of the trunk and neck musculature of deconditioned back pain patients. *Manuelle Med* 1999;37:34-9.
8. Frost H, Lamb SE, Klaber Moffett JA, Fairbank JC, Moser JS. A fitness programme for patients with chronic low back pain: 2-year follow-up of a randomised controlled trial. *Pain* 1998;75:273-9.
9. Mannion AF, Müntener M, Taimela S, Dvorak J. A randomized clinical trial of three active therapies for chronic low back pain. *Spine* 1999;24:2435-48.
10. Kirkwood B. Essentials of medical statistics. Oxford: Blackwell Science, 1988.
11. Roland M, Morris R. A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low-back pain. *Spine* 1983a;8:1414.
12. Waddell G, Newton M, Henderson I, Somerville D, Main CJ. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain* 1993;52:157-68.
13. Greenough CG, Fraser RD. Comparison of eight psychometric instruments in unselected patients with back pain. *Spine* 1991;16:1068-74.
14. Main CJ. The Modified Somatic Perception Questionnaire (MSPQ). *J Psychosom Res* 1983;27:503-14.
15. Main CJ, Waddell G. The detection of psychological abnormality in chronic low back pain using four simple scales. *Curr Concepts Pain* 1984;2:10-15.
16. Altman DG. Statistics and ethics in medical research: III. How large a sample. *Br Med J* 1980;281:1336-8.
17. Deyo RA, Andersson G, Bombardier C *et al.* Outcome measures for studying patients with low back pain. *Spine* 1994;19(Suppl. 18):2032S-6S.
18. Hoffman RM, Turner JA, Cherkin DC, Deyo RA, Herron LD. Therapeutic trials for low back pain. *Spine* 1994;19(Suppl. 18):2068S-75S.
19. Koes BW, Bouter LM, van der Heijden GJMG. Methodological quality of randomized clinical trials on treatment efficacy in low back pain. *Spine* 1995;20:228-35.
20. Mannion AF, Taimela S, Müntener M, Dvorak J. Active therapy for chronic low back pain. Part 1. Effects on back muscle activation, fatigability and strength. *Spine* 2001;26:897-908.
21. Käser L, Mannion AF, Rhyner A, Weber E, Dvorak J, Müntener M. Active therapy for chronic low back pain. Part 2. Effects on paraspinal muscle cross-sectional area, fibre type size and distribution. *Spine* 2001;26:909-19.
22. Hansen FR, Bendix T, Skov P *et al.* Intensive, dynamic back-muscle exercises, conventional physiotherapy, or placebo-control treatment of low-back pain. A randomized, observer-blind trial. *Spine* 1993;18:98-108.
23. Hildebrandt J, Pflingsten M, Saur P, Jansen J. Prediction of success from a multidisciplinary treatment program for chronic low back pain. *Spine* 1997;22:990-1001.
24. Manniche C, Lundberg E, Christensen I, Bentzen L, Hesselsoe G. Intensive dynamic back exercises for chronic low back pain: a clinical trial. *Pain* 1991;47:53-63.
25. van Walraven C, Mahon JL, Moher D, Bohm C, Laupacis A. Surveying physicians to determine the minimal important difference: implications for sample-size calculation. *J Clin Epidemiol* 1999;52:717-23.
26. Crombez G, Vlaeyen JW, Heuts PH, Lysens R. Pain-related fear is more disabling than pain itself: evidence on the role of pain-related fear in chronic back pain disability. *Pain* 1999;80:329-39.
27. Estlander AM, Vanharanta H, Moneta GB, Kaivanto K. Anthropometric variables, self-efficacy beliefs and pain and disability ratings on the isokinetic performance of low back pain patients. *Spine* 1994;19:941-7.
28. Taimela S, Diederich C, Hubsch M, Heinrich M. The role of physical exercise and inactivity in pain recurrence and absenteeism from work after active outpatient rehabilitation for recurrent or chronic low back pain: a follow-up study. *Spine* 2000;25:1809-16.