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1999 Volvo Award Winner in Clinical Studies

A Randomized Clinical Trial of Three Active Therapies for Chronic Low Back Pain

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Study Design. A randomized clinical trial.

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

Summary of Background Data. There is much evidence documenting the efficacy of exercise in the conservative management of chronic low back pain, but many questions remain regarding its exact prescription and method of application. The most successful method must be identified to enable refinement of future rehabilitation programs to target the specific needs of the patient with chronic low back pain and the budget of the healthcare provider.

Methods. One hundred forty-eight patients with chronic low back pain were randomized to one of the following treatments, which they attended twice a week for 3 months: 1) modern active physiotherapy, 2) muscle reconditioning on training devices, or 3) low-impact aerobics. Pretherapy and posttherapy, objective measurements of lumbar mobility were performed, and questionnaires were administered inquiring about self-rated pain and disability, and psychosocial factors. Similar questionnaires were administered 6 months after therapy. The data were analyzed using the intention-to-treat principle.

Results. Of the 148 patients, 16 (10.8%) dropped out of the therapy. One hundred thirty-seven questionnaires (93%) were available for analysis at all three time points. After therapy, significant reductions were observed in pain intensity, frequency, and disability; Fear-Avoidance Beliefs about physical activity ($FABQ_{activity}$); and "praying/hoping," "catastrophizing," and "pain behavior" coping strategies—each with no group differences in the extent of the response. These effects were maintained over the subsequent 6 months, with the exception of disability and $FABQ_{activity}$ for the physiotherapy group. There were small but significant posttherapy increases in lumbar mobility, with aerobics and devices showing a greater response than physiotherapy.

Conclusion. The general lack of treatment specificity suggests that the main effects of the therapies were educed not through the reversal of physical weaknesses targeted by the corresponding exercise modality, but rather through some "central" effect, perhaps involving an adjustment of perception in relation to pain and disability. The direct costs associated with administering physiotherapy were three times as great, and devices four times as great, as those for aerobics. Administration of aerobics as an efficacious therapy for chronic low back pain has the potential to relieve some of the huge financial burden associated with the condition. [Key words: aerobics, chronic low back pain, costs, physiotherapy, rehabilitation, training devices/machines] **Spine 1999;24: 2435–2448**

Musculoskeletal disorders, with back pain accounting for more than half of the cases, are now the most common cause of chronic incapacity in industrialized countries.[6] Furthermore, chronic low back disability appears to be increasing faster than any other form of incapacity. Persons with chronic low back pain (CLBP) make up the minority of those experiencing back pain; yet, because of the expenditure associated with repeated treatment, long-term work absence, and social support, they account for the majority of the total costs to the economy.[16] There is therefore a pressing need to evaluate the effectiveness of interventions aimed at management of the chronic condition.

There is now considerable evidence documenting the efficacy of exercise in the conservative treatment of low back pain (LBP).[22,39] Exercise can be a relatively inexpensive, easily administered treatment method, which may prove to be the most effective solution for patients whose pain appears to be so resistant to many other treatment options. However, the usefulness of exercise has not gone entirely unchallenged, and a number of questions regarding its exact prescription and method of application still remain to be answered.[39] These are important issues to resolve, particularly from the clinical perspective, because different exercise programs will be associated with differing implementation costs in terms of capital expenditure and personnel time, and probably also with varying compliance rates.

It is important to investigate not only which exercise method is the most efficacious, but also what its possible mechanism of action might be with regard to the alleviation of symptoms. For example, if the positive effects of an exercise rehabilitation program are contingent on an improvement in muscle strength—as intimated by the repeated findings of reduced back extensor strength in patients with CLBP and by the frequently described "deconditioning syndrome" targeted by functional restoration programs[27]—then the prescription of aerobic exercise could not be expected to achieve the same results. In this case, there would be adequate justification for the use of strength training devices that apply the progressive loading levels required by the musculature to adapt and hypertrophy. However, if the effects are educed "centrally" by an antidepressive action of exercise[7,31] or from

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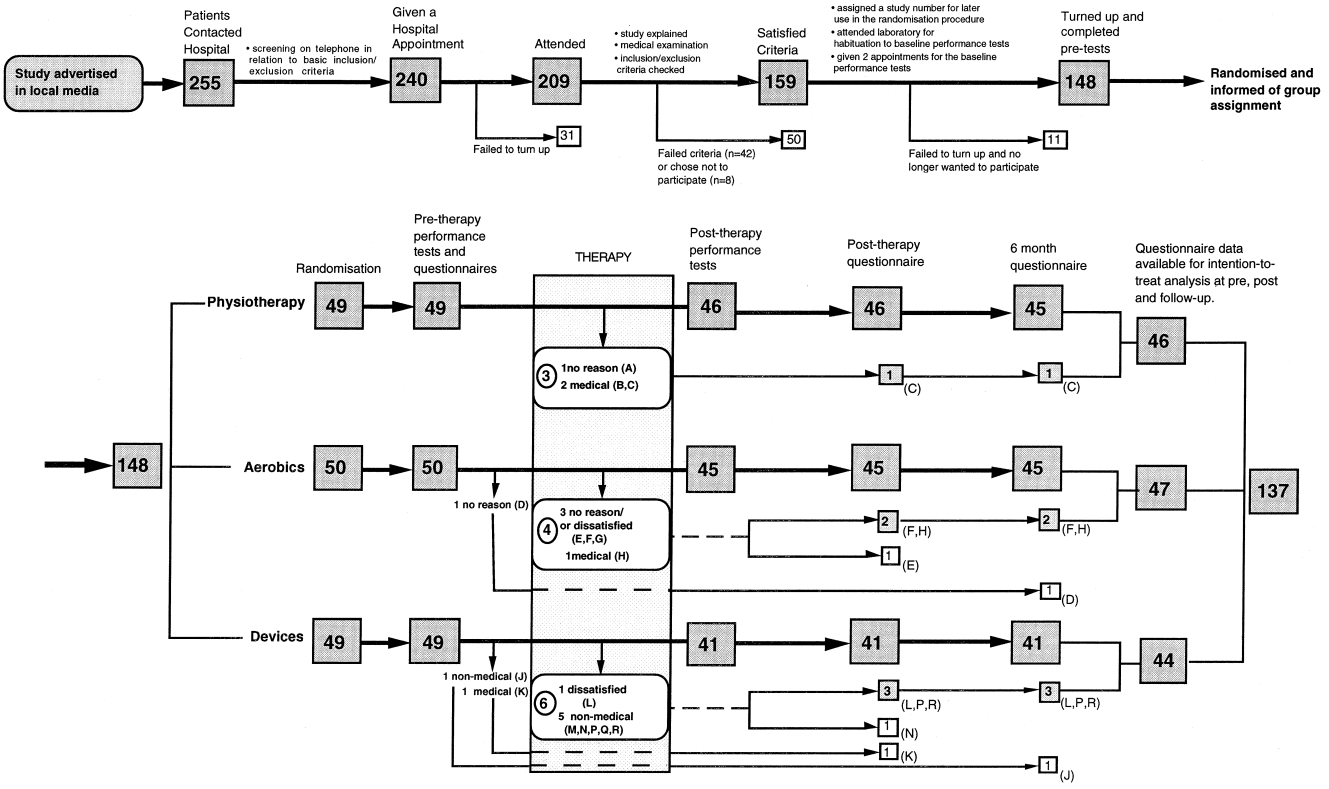

Figure 1. Flow diagram summarizing the formation of the final study group (top) and the number and group membership of dropouts throughout the course of the treatments (bottom).

Physiotherapy: A = Attended 12 sessions, kept failing to turn up to appointments and eventually ignored our attempts to make contact; B = Attended 9 sessions, had an accident for which needed physiotherapy for neck and head considered it too much to attend for LBP; C = Completed 4 sessions, experienced serious acute exacerbation of LBP contraindicating continuation with treatment.

Aerobics: D = Never began the treatment, didn't explain why; E= Attended 1 class, didn't like the exercises and decided they would not help the pain; F = Attended 6 classes, decided exercises were not helping and sometimes led to further episodes of pain; G = Attended 4 classes, kept failing to turn up and ignored our numerous attempts to make contact; H = Completed 4 classes, had serious acute exacerbation of LBP which prevented continuation with the exercises.

Devices: J = Left Switzerland to work abroad; K = Just before attending for first session, was in a motor vehicle accident and suffered serious neck injuries preventing use of the DBC devices; L = Attended 1 session, didn't like the treatment and considered it too far to travel to attend twice per week; M = Attended 4 sessions, new family commitments, too much of a time commitment; N = Attended 1 session, too far to travel and too much time commitment; P = Attended 9 sessions, change in work hours meant too much time commitment; Q = Attended 6 sessions, stationed abroad by the workplace; R = Attended 12 sessions, change of workplace, further away from the hospital too much of a time commitment.

the feeling of social interaction and mutual support brought about by group exercise, then the use of expensive training devices and the execution of very specific movements would be questionable. In view of the limited resources available to health care providers worldwide, potential differences in the economic efficacy of such diverse treatment programs should not be disregarded.

Despite the seemingly large number of intervention studies carried out to date, one chronic LBP treatment method still cannot be advocated over another. This is believed to have resulted, at least in part, from the use of poor-quality scientific methods in many of the previous studies, leading to considerable uncertainty regarding which treatments are clinically effective and cost effective.[18,22,39] Moreover, although a similarity between the efficacy of various exercise methods has been suggested from meta-analyses, the relative efficacy of differing active treatments for patients with CLBP, particularly with the inclusion of an aerobic exercise program, has not been quantified previously within the confines of one randomized clinical trial.

The aim of the current study was to perform a randomized clinical trial to examine the relative efficacy of three different active therapy programs frequently used in the management of chronic LBP: modern individual "active" physiotherapy, specific back conditioning/ strengthening exercises using training devices, and general group aerobic exercise. Outcome was assessed in terms of changes in subjective pain intensity, pain frequency, and disability and using objective tests of functional capacity. Psychosocial factors also were investigated (using questionnaires) to examine their role as possible determinants of therapy outcome.

Methods

Study Population. Patients were recruited following local media advertisement giving details of the study and requirements for participation (Figure 1). In the original call for volunteers, the most important inclusion and exclusion criteria were presented in a simplified form to limit the response to those most suitable for participation. To control for expectation bias, patients were partly "blinded" by being informed that the research was being performed to compare three currently popular therapies for CLBP, the relative efficacy of which had not yet been established. Patients attended the hospital, where all the admission criteria were checked in detail through medical history interview/clinical examination by neurologists and the necessary documentation for the study (personal/medical history details and various questionnaires) was completed.

Inclusion criteria were: younger than 65 years; more than 3 months of continual or recurrent episodes of LBP, with or without referred pain (of a nonradicular nature), serious enough to cause absence from work, or solicitation of medical attention; ability and willingness to travel independently to the hospital; willingness to comply with the treatment randomly assigned; ability to read and write German or English; and ability to perform a preinclusion test designed to ensure a certain minimal ability to perform the planned functional outcome tests (sitting on a chair, leaning forward, and lifting a weight of 3 to 5 kg from knee height to an upright sitting position 15 times in 30 seconds).

The exclusion criteria included: constant or persistent severe pain; nonmechanical LBP; pregnancy; previous spinal surgery; current nerve root entrapment accompanied by neurologic deficit; spinal cord compression; tumors; severe structural deformity; severe instability; severe osteoporosis; fresh fracture; inflammatory disease of the spine; spinal infection; severe cardiovascular or metabolic disease; other corresponding disorders preventing active rehabilitation; acute infection; and lack of cooperation.

After receiving an oral and written explanation of what would be required of them, the patients signed an informed consent form confirming their agreement to participate. The study was approved by the local University Ethics Committee.

Assignment to the Treatments. On acceptance for inclusion in the study, patients were assigned a number (in chronological order) that later would be used in performing the randomization process. Patients were prestratified by age (those younger than 40 years and those older than 40 years) and by gender to prevent unequal distributions of these variables among the treatment groups.

Using a table of random numbers and a restricted randomization procedure (in blocks of 15),[20] patients were assigned to one of the following three treatment groups: 1) physiotherapy, 2) training with devices, or 3) aerobics/stretching classes. All patients were required to attend therapy twice per week for a total of 3 months. The treatments were administered in geographically separate areas of the hospital to avoid contact between patients in the different groups. No charge was incurred by the patient's health insurance for the treatment. The basic components of the three treatment groups are described in the following discussion.

Physiotherapy. The usual modern physiotherapeutic treatment administered in the hospital spine unit for this type of patient was applied during the study. This involved half-hour individual therapy sessions focused on improving the functional capacity of the patient and giving instruction on ergonomic principles. Isometric exercises were carried out, and exercises with Therabands (The Hygenic Corporation, Akron, OH) and general strength-training devices were performed. In addition, patients were advised on home exercises and encouraged to perform them. At times, other acute problems (not necessarily back related) representing a hindrance to the planned back therapy required treatment with passive therapies such as ultrasound, electrotherapy (TENS), short-wave, or heat/cold treatment.

A group of physiotherapists, managed by one highly experienced physiotherapist, was involved in administering the treatments. Each therapist was allowed a certain freedom to adopt what he or she considered to be the most appropriate treatment program for the individual case, but was expected to follow the guidelines drawn up by the senior physiotherapist. Eleven physiotherapists were involved in the study, although one therapist was responsible for treating 60% of the patients.

Muscle Reconditioning Using Training Devices. Of the many different types of back muscle reconditioning/functional restoration approaches available, the David Back Clinic program was chosen for inclusion in the study because it is a clearly defined, progressive program, and its effectiveness in the management of CLBP had already been established in a noncontrolled (single-group) case series study[37] and in a randomized study.[19] This treatment is marketed as a 12-week active functional restoration program, the key element of which comprises controlled, progressive exercises carried out on training devices within the patient's pain-free range of motion.

Patients attended in groups of 2 to 3, and each session lasted approximately 1 hour. The exercises applied isoinertial loading to the lumbar spine in the sagittal, frontal, and horizontal planes, in accordance with the strength-generating capacity of the trunk muscles (*i.e.,* following the force-length curve of the muscles). Relative progression of the loading was applied throughout the rehabilitation period. Individual record cards were kept, documenting the training details (*e.g.,* number of repetitions of a given exercise, weight used). Each session was preceded by a 5- to 10-minute aerobic warmup (cycling, stepping). Relaxation and stretching exercises were carried out before and after the exercises performed on each device. To secure the appropriate performance of the treatment procedure, sessions were managed by specially trained therapists.

Aerobics/Stretching Classes. The patients in this group attended small group classes (12 patients per class maximum) lasting 1 hour that included stretching and aerobic and muscle-toning exercises carried out to music with an appropriate tempo and rhythm to promote the desired level of exertion. The program, compiled from a range of previously published sources,[3,30,41] comprised a 10- to 20-minute warmup involving whole-body static stretching and low-impact aerobic exercises followed by 30 minutes of specific exercises directed predominantly at the trunk and leg muscles. The number of repetitions were increased, and more difficult variations of the exercises were incorporated, as the patients became more competent. (The full program is available on request.) The last 15 minutes of the class consisted of cool-down and relaxation exercises.

Three exercise instructors were responsible for conducting the classes.

The initial medical screening examination, the treatments, and the objective functional assessments were each administered by different groups of professionals.

Functional Assessments and Questionnaires Before and After Treatment. On entry to the study, and again directly after the 3-month treatment, the following assessments were carried out.

Lumbar Spine Range of Motion. Lumbar spine range of motion was quantified using a motion analysis device, the CA-6000 Spine Motion Analyzer (Orthopaedic Systems, Hayward, CA), which accurately monitors spinal movements in three directions: flexion–extension, lateral bending, and axial rotation.[9] Briefly, the CA-6000 is an electromechanical device consisting of six high-precision potentiometers connected in a linkage system that allows unrestricted three-dimensional motion.

The device, secured to the patient at the sacrum and the thoracolumbar junction, is interfaced to a personal computer to allow online measurement of three-dimensional lumbar spinal movements. Each exercise was demonstrated by the investigator and then practiced by the patient. Two trials each of the three major movements (flexion–extension, lateral bending, axial rotation) were then carried out. If any major inconsistencies were observed between these two trials, a third or fourth trial was allowed. The highest value generated was taken as representative for that movement.

Tests of isometric trunk strength and of erector spinae fatigability (using surface electromyography) during dynamic and isometric tests, as well as, in a subgroup of 55 patients, erector spinae muscle biopsies and magnetic resonance imaging of the paraspinal muscles in cross section were carried out. The data from these assessments will be published separately.

Questionnaires. A pretherapy questionnaire was administered, which inquired about the following:

- sociodemographic information (marital status, education, occupation, smoking habits, daily workload, work status)
- existing or planned compensation claims for back injury
- current fitness, regular exercise habits, and exercise self-efficacy[35]
- LBP intensity (0–10 visual analog scale [VAS] for greatest pain and for average pain over the past 6 weeks) and pain location (pain drawing), duration, and frequency (never, occasional, often, permanent)
- low back disability (Roland and Morris questionnaire[33])
- beliefs about physical/work activity being a cause of the back trouble and fears about the dangers of such activities during an episode of LBP (Fear-Avoidance Beliefs Questionnaire [FABQ][40])
- strategies for coping with pain (Coping Strategy Questionnaire[34])
- psychological disturbance[13] (determined using a combination score from the modified somatic perception questionnaire [MSPQ[24]] and the modified ZUNG Questionnaire[25])
- beliefs about back trouble (Back Beliefs Questionnaire[36]); attitudes toward job satisfaction, social support from colleagues, and mental stress of work (Psychosocial Aspects of Work Questionnaire[36])

This booklet was pilot tested initially with a group of eight patients, as recommended by Deyo et al,[8] to evaluate its wording, length, and general acceptability.

In the posttherapy questionnaire, in addition to the preceding sections, the patients were asked about their impressions of the treatment they had received: initial reaction on hearing which group they had been assigned to; changed impressions during treatment; additional problems encountered during the therapy; therapist's competence and friendliness; changes in pain and in ability to carry out daily activities compared with pretreatment experience, graded 1 (much worse) to 5 (much better); overall satisfaction with the program, and so forth.

The questions concerning variables such as the patients' perception of changes in pain experienced, disability, and fitness were included for comparison with the corresponding responses recorded by means of change on the pain scale, the disability questionnaire, and so on. The exercise self-efficacy questionnaire also was reworded to inquire about the patient's intention to continue independently with the exercises he or she had learned. Patients also were asked whether they had undertaken any other treatments for their back pain at the same time they were receiving treatment from the authors. A list with 11 options was provided, which included acupuncture, pain medication, injection, physiotherapy, traction, manipulation, chiropractic therapy, massage, corset, strength training, or other.

At the first follow-up assessment, carried out 6 months after therapy, a questionnaire similar to the aforementioned booklet was administered. It contained, in addition, questions regarding the longevity of the observed treatment effect, the patient's success in continuing independently with a similar exercise program, and any treatments (from the preceding list of options) or doctor visits that had taken place since the therapy at the hospital was finished.

Statistics. The required sample size (approximately 50 to 55 in each group after randomization) was determined on the basis of the expected clinically significant change for the most important outcome measures, assuming a Type I error probability of 5%, a Type II error probability of 15% (*i.e.,* power of 85%), and a 15% dropout rate.[1]

Because most of the continuous variables under investigation were approximately normally distributed, parametric statistics were used for the analyses. The comparability of the groups at baseline was assessed using analysis of variance. Changes in continuous variables for the three groups between 0 months (entry), 3 months (immediately after therapy), and 9 months (at 6-months follow-up) were assessed using a two-factor analysis of variance with repeated measures (group × time of assessment). Global changes over time in the entire patient cohort were identified by noting the significance of the main effects from the repeated-measures analysis of variance. The differences in before *versus* after therapy, immediately after therapy *versus* 6 months after, and before therapy *versus* 6 months after therapy were then identified by contrast analyses. Differences in the response over time among the three groups were revealed by a significant interaction, and the location of the significant differences (*i.e.,* how the groups differed in their behavior for a given variable over time) was confirmed by the performance of contrast analyses. For categorical variables, group differences were analyzed using contingency analyses.

Relations between variables were analyzed by simple and stepwise regression analysis.

One statistical analysis was performed according to the "intention-to-treat" principle. In this way, the data from all patients, including patients who had not completed the full program, were used (where such data was available). Because the total therapy dropout rate after randomization was only on the 10% borderline (see Results section), it was not considered necessary to perform a worst-case analysis.[22,28]

A second analysis was performed for only those patients who completed the therapy (*i.e.,* attended at least two thirds of the assigned treatments in the program). Only those differences between the results generated using Analysis 1 and Analysis 2 that were notable will be mentioned in this text. Significance was accepted at the 5% level, but because of the multiple univariate analyses, caution will be exercised in the interpretation of the results, especially when *P* values approach this 5% limit. When 20 measures are compared with a 5% significance level, it is expected that at least one comparison would be statistically significant by chance alone.

Results

Study Sample

Figure 1 shows a flow diagram summarizing the formation of the final study group. From a total of 255 patients who responded to the initial recruitment drive, 148 satisfied the admission criteria and were randomized into a therapy group. Of these, 16 patients (10.8%) dropped out (*i.e.,* attended less than two thirds of the therapy sessions), leaving 132 to complete the treatment (Figure 1).

The patients were requested to try to complete all 24 sessions, even if this meant spreading them over more than the 3 months. The three treatment groups did not differ significantly in their compliance rates, with 84.1% of the patients completing all 24 sessions, a further 7.6% completing 23 sessions, and the remaining 8.3% completing between 16 and 22 sessions. Furthermore, 61.4% of the patients completed their sessions in 11 to 14 weeks, 28.0% in 15 to 16 weeks, and 10.6% in 16 to 19 weeks.

All participants who completed the therapy (132 of the 148) attended for the posttests and completed their posttherapy questionnaires, and 131 of them also returned a 6-month questionnaire (Figure 1). In addition, 6 of the therapy dropouts completed both a modified postquestionnaire and a 6-month follow-up questionnaire. Thus, there were 137 of 148 (93%) data sets available for the repeated-measures analysis of the questionnaire data at pretherapy, posttherapy, and 6 month after therapy. Other questionnaires from therapy dropouts were received either posttherapy or 6 months after therapy (Figure 1), but unless a questionnaire was returned at each time point, it could not be included in the repeated-measures analyses.

Comparability of Groups at the Start

The baseline sociodemographic and some clinical characteristics of the patients, separated by original group assignment after randomization, are shown in Table 1.

Table 1. Synopsis of Baseline Sociodemographic and Physical Characteristics of the Patients in Each of the Three Treatment Groups

	Physiotherapy (n = 49)	Aerobics (n = 50)	Devices (n = 49)	*P*
Gender (% female)	61	54	55	0.74
Married (%)	69.4	72.0	63.3	0.63
Current smoker (%)	24.5	30.0	18.4	0.40
Highest education (%)				0.19
High school	59.2	50.0	58.3	
College	32.7	44.4	25.0	
University	8.1	6.0	16.7	
Work status (%)				0.80
Full time	40.8	52.0	49.0	
Part time	32.7	30.0	30.6	
Retired/unemployed/ homemaker	26.5	28.0	20.4	
Heaviness of work load (%)				0.20
Office working/sedentary	38.8	52.0	51.0	
Light manual handling	61.2	42.0	44.9	
Heavy manual handling	0.0	6.0	4.1	
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
Body mass index (kg/m^2)*	23.8 ± 4.0	24.4 ± 3.5	23.4 ± 2.9	0.40
LBP duration (yr)	10.0 ± 9.0	9.7 ± 9.1	13.0 ± 10.0	0.17
LBP disability claim (%)				0.91
No claim	84.5	89.1	91.6	
Considering claim	6.7	4.4	2.1	
Claim submitted	2.2	0.0	2.1	
Claim granted	4.4	4.3	4.2	
Claim turned down	2.2	2.2	0.0	

* Body mass index = weight (kg)/height $(m)^2$.
Note: Values are mean ± SD.

The corresponding pain, disability, psychological, and performance data at baseline are represented by the "pre-" data in Table 2. (The few dropouts from the original study data set hardly altered the mean ± SD values, and they did not alter the significance of any differences among the groups.) These characteristics were representative of the typical profile displayed by the patient with chronic back pain, and there was no significant difference among the three groups for any of these variables at baseline.

When the 16 therapy dropouts were compared with the 132 patients who completed the entire treatment program, there was no difference among the groups at baseline for any of the variables shown in Table 1, with the exception of age. The dropouts were slightly younger than those who stayed with the treatment (mean, 40.1 and 45.7 years, respectively [$P = 0.033$]).

Patients' Satisfaction With the Therapy Received

Figure 2 shows the patients' satisfaction with the treatment that they received during their participation in the study, as assessed directly after the therapy. The majority of the patients declared their satisfaction on hearing which group they had been assigned to (Figure 2A), and

Table 2. Changes in Self-Rated Pain and Disability, Pretherapy (1), Posttherapy (2), and at 6-month Follow-up (3) and in Spinal Mobility Pre- and Posttherapy

		Global (n = 137)	*P* (main effect)	Physiotherapy (n = 46)	Aerobics (n = 47)	Devices (n = 44)	*P* (interaction)
Pain* (highest)	Pre	6.5 ± 2.0	0.0001	6.7 ± 2.0	6.4 ± 1.8	6.5 ± 2.1	0.99
	Post	5.0 ± 2.7	(1>2=3	5.1 ± 2.7	5.0 ± 2.7	4.9 ± 2.8	
	6 mo	4.7 ± 2.8	1>3)	4.8 ± 2.6	4.5 ± 2.7	4.6 ± 3.1	
Pain* (average)	Pre	4.3 ± 1.8	0.0001	4.4 ± 1.8	4.1 ± 1.8	4.2 ± 1.8	0.50
	Post	3.3 ± 2.2	(1>2=3	3.2 ± 2.2	3.6 ± 2.5	3.1 ± 2.1	
	6 mo	3.1 ± 2.1	1>3)	3.2 ± 2.0	3.1 ± 2.3	2.8 ± 2.1	
Average pain frequency†							
	Pre	3.4 ± 0.7	0.0001	3.4 ± 0.6	3.4 ± 0.7	3.4 ± 0.8	0.77
	Post	3.0 ± 0.9	(1>2>3)	3.1 ± 0.8	3.1 ± 0.9	2.9 ± 0.9	
	6 mo	2.9 ± 0.9		3.0 ± 0.9	2.9 ± 0.9	2.8 ± 0.9	
Roland & Morris disability‡							
	Pre	7.9 ± 4.6	0.0001	7.9 ± 4.0	7.7 ± 4.7	8.0 ± 5.1	0.08
	Post	6.6 ± 5.0	(1>2=3	6.8 ± 4.9	6.3 ± 5.1	6.7 ± 5.0	(P v A&D;
	6 mo	6.3 ± 4.9	1>3)	7.7 ± 5.3	5.4 ± 4.4	5.7 ± 4.8	0.02)
Lumbar spinal range of motion							
Flexion/extension	Pre	79.2 ± 14.1	0.005	79.1 ± 14.4	78.3 ± 13.9	80.1 ± 14.3	0.48
	Post	81.3 ± 13.8		80.2 ± 13.3	80.5 ± 13.7	83.6 ± 15.0	
Lateral bending	Pre	58.2 ± 10.6	0.001	58.8 ± 10.6	56.2 ± 11.7	59.8 ± 9.2	0.04
	Post	60.5 ± 10.1		59.0 ± 10.8	60.8 ± 10.2	61.9 ± 9.4	(PvA&D;0.04)
Axial rotation	Pre	44.0 ± 9.5	0.056	45.6 ± 10.5	42.0 ± 10.0	44.3 ± 7.7	0.02
	Post	45.3 ± 8.5		44.9 ± 9.1	45.8 ± 9.4	45.1 ± 6.9	(PvA&D;0.04)

* Visual Analogue Scale (VAS; score 0–10).
† Pain-free = 1; sporadic = 2; often = 3; continuous = 4.
‡ Possible score 0–24; higher score = more disabled.
Note: Values are mean ± SD. After the *P* value for the main effect, locations of significant differences between assessment times (1), (2), and (3) are shown in parentheses. After the *P* value for the interaction, locations of significant differences in the behavior of the three groups over time are shown in parentheses (e.g., *P* vs. A&D: physiotherapy group significantly different in response over time compared with aerobics and device groups).

few of them changed their impression for the worse during the course of the treatment (Figure 2B). This was true for all three groups alike.

The majority of the patients declared that they enjoyed attending for therapy (Figure 2C), and that they would recommend it to other patients with problems similar to their own (Figure 2D). In these two respects, the results were more satisfactory for the aerobics and physiotherapy groups than for the devices group ($P = 0.045$). More than 70% of the patients would have continued with the therapy given the chance, with no difference among the groups (Figure 2E). More than 92% declared their therapist to be competent, with the physiotherapy group projecting a higher overall rating than the other two groups (Figure 2F; $P = 0.02$), and more than 94% reported their therapist to be friendly, with no intergroup differences (Figure 2G). Regarding the therapist's provision of advice for performing everyday activities (Figure 2H) and interest in the patients and their back problems (Figure 2I), the ratings of the physiotherapy group were significantly higher than those of the aerobic and devices groups ($P = 0.001$ for each factor).

Co-treatments

According to self-reports, 61% of the patients received no additional treatments for their LBP during the course of the treatment administered for the study, with no differences among the three groups. Those who reported having received supplementary treatments underwent an average of 1.5 (range, 1–3) options from the list of 11 readily available treatments described in the Methods section. There were no significant differences among the three groups in this respect ($P = 0.78$).

Outcome Measurements

Self-Rated Pain and Disability. *Pain Score.* Considering the patient group as a whole, there was a significant reduction in the greatest and the average pain recorded after therapy, as compared with the pretherapy values, with no significant differences found among the three groups in the extent of this reduction (Table 2). Significant positive relations were observed between the pretherapy pain score and the reduction in pain after therapy, such that those who had the greatest pain at the start showed the most impressive reductions after therapy ($r = 0.48$; $P = 0.0001$ for greatest pain; $r = 0.36$; $P = 0.0001$ for average pain).

When patients were questioned directly about the reduction in their self-rated pain (*e.g.,* "Has your pain decreased since the start of the study?"), results similar to those obtained after analysis of the pre- and postscores on the pain scale were obtained. As a group, the patients reported an average response equivalent to 3.6 on a scale of 1 to 5 (1 = much worse, 3 = unchanged, 5 = much better), with no significant differences among the groups. This direct grading showed a significant positive correlation with the data obtained from the pre- and postrat-

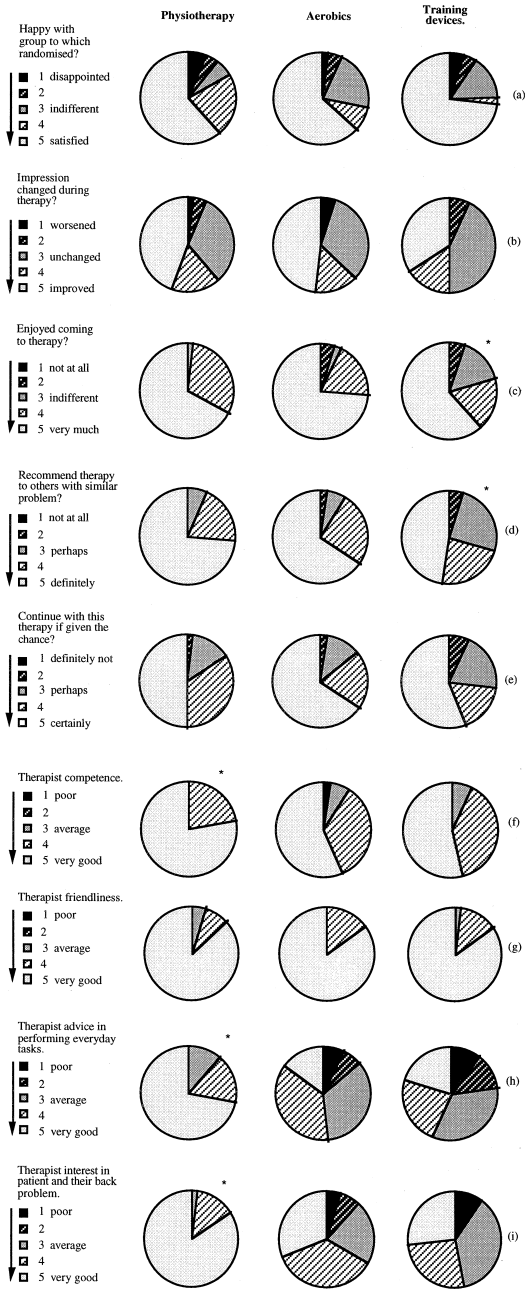

Figure 2. Results of patient satisfaction with treatment received during participation in the study, as assessed directly after the therapy. *Significantly different from the other two groups.

ings on the pain scale (r = 0.47; $P = 0.0001$ for greatest pain; r = 0.48; $P = 0.0001$ for average pain), but, on an individual basis, there were contradictory results in a number of instances (*e.g.,* a declared reduction in pain, but a marked increase in the pain indicated on the pain scale compared with the pretreatment value, and *vice versa*).

At the follow-up assessment 6 months after therapy, further reductions, on the average, of 0.3 points for the greatest pain and 0.2 points for the average pain were observed for the whole patient group, with no significant differences among the groups in the extent of the decline (Table 2). These 6-month values were not significantly different from the posttherapy values, but remained significantly lower than the pretherapy values. When asked to grade directly how their pain had changed in the 6 months since the end of therapy (on a 1 to 5 basis as described earlier), an average value of 3.4 was scored (*i.e.,* between "unchanged" and "better," again with no significant group differences in the response.

Pain Frequency. Before therapy, 52% of the patients declared that they experienced LBP "continuously," 38% "often," and 10% "sporadically." After treatment, there was a significant reduction in the regularity of pain episodes (Table 2): only 35% had pain "continuously," 36% "often," 25% "sporadically," and 4% were totally pain-free. The groups did not differ significantly from each other in relation to this reduction in their frequency of pain episodes (Table 2). A further slight, but significant, reduction in pain frequency was observed after 6 months (Table 2), such that only 30% had pain "continuously," 34% "often," 31% "sporadically," and 5% were pain-free. Again, there were no significant group differences in the extent of these reductions at 6 months.

Disability. Self-rated disability on the Roland and Morris scale showed a significant decrease from pre- to posttherapy (Table 2), with no unique effect of group membership. The same was true in relation to a single direct question inquiring as to whether their ability to perform everyday tasks was improved by the therapy (average response = 3.6 on a scale of 1 to 5, wherein 1 = much worse, 3 = unchanged, 5 = much better). The patients who were most disabled at the start showed the greatest improvement after therapy (r = 0.34; $P = 0.0001$).

At the follow-up assessment 6 months after therapy, Roland and Morris disability scores for the devices and aerobics groups showed a further significant decline from the posttherapy values, whereas in the physiotherapy group the scores increased, such that they were no longer significantly different from the pretherapy values (Table 2). In answer to the direct question concerning how the patients' thought their ability to perform everyday tasks had changed in the past 6 months, the average response was 3.5, with the devices and aerobics groups scoring slightly, but not significantly, higher than the physiotherapy group: 3.6, 3.6, and 3.4, respectively.

Longevity of the Observed Treatment Effect. In answer to a question concerning how long the treatment received in the hospital had alleviated their symptoms during the past 6 months, 51% of the patients replied "until now"; 28% described the effects as lasting only a short time; and 21% reported that the therapy had not had any effect in the first place. According to self-reports, 58% of the patients had attempted to continue independently with exercises similar to those they had learned in the hospital. There were no group differences in either of these parameters.

There was a significant positive association between

continuation with the exercises and longevity of the effect ($P = 0.016$). Over the 6-month follow-up period, the patients undertook an average of 1.3 treatments (range, 0–9 treatments) for their back pain, from a list of 13 possible options (including the 11 "readily available" treatments described in the Methods section, in addition to "doctors' visit" and "surgery"). The differences among the groups were not significant (aerobics 1.3, devices 1.1, physiotherapy 1.4; $P = 0.64$).

Objective Measures of Function: Lumbar Spinal Mobility. The effects of the three therapy regimens on lumbar spinal range of motion are shown in Table 2. In considering the patient group as a whole, there was a small but significant posttherapy increase (2–3%) in the range of motion in the sagittal plane (*i.e.,* flexion and extension), with no difference among the groups in the extent of the increase. The ranges of lateral bending and axial rotation showed the greatest improvements in the aerobics group (relative increases of 8.2% and 9.0%, respectively), a modest increase in the devices group (relative increases of 3.5% and 1.8%, respectively), and little change in the physiotherapy group. The difference between the extent of change in the aerobics and devices groups compared with that in the physiotherapy group was significant (Table 2).

General Fitness. Patients were questioned about improvements in self-rated general fitness in two ways: 1) by means of a question appearing in both the pre- and postquestionnaires asking them to grade their fitness on a scale of 1 to 5 (1 = poor, 3 = average, 5 = excellent) and 2) with a direct question ("Do you think your fitness has improved since the start of the study?") graded on a scale of 1 to 5 (1 = much worse, 3 = unchanged, 5 = much better). In relation to the first assessment method, there was a significant increase in fitness after therapy ($P = 0.003$), but there was no significant difference among the groups ($P = 0.91$). However, when asked directly about their estimated change in fitness, the physiotherapy and aerobics groups each reported significantly greater improvements than did the devices group ($P < 0.05$).

Psychological Parameters

The change in scores recorded on the various psychological and beliefs questionnaires before therapy, after therapy, and 6 months thereafter are shown in Table 3. (As a result of the multiple univariate testing required to examine this data set, caution must be exercised in interpreting some of the changes when the P value is close to the established 5% cutoff.)

For the ZUNG depression score and also for the ZUNG and MSPQ scores combined, there were no significant whole-group changes over the three assessment times. However, the tendency of the aerobics and devices groups to retain their posttraining reduction in depression scores was significantly different from the behavior of the physiotherapy group, which showed an increase in scores after 6 months to above pretherapy values.

Fear-avoidance beliefs about physical activity were significantly reduced in all the groups after treatment. After 6 months, further reductions were observed in the aerobics and devices groups, but not in the physiotherapy group. Fear-avoidance beliefs about work showed a significant main effect of a reduction between pretherapy and 6-months follow-up.

Two of the cognitive coping strategies, "praying/hoping" and "catastrophizing," were used to a significantly lesser extent after therapy, with no differences among the groups in the extent of the change displayed. Over the following 6 months, "catastrophizing" significantly decreased further, whereas "praying/hoping" remained stable, again without group differences.

Another cognitive coping strategy, diverting attention, was reduced directly after therapy in the physiotherapy and aerobics groups and then remained stable at 6 months, whereas in the devices group, no change was seen after therapy, but a reduction was observed after 6 months. The pattern of change in this parameter in the devices group was significantly different from that of the physiotherapy and aerobics groups. Coping "self-statements" were significantly reduced from pretherapy to the 6-month follow-up, with no group differences in the extent of the reduction. Between pretherapy and the follow-up assessment 6 months after therapy, the coping strategy of "ignoring pain" was increased in the aerobics group; the pattern of change in this parameter over time in the aerobics group was different from that displayed by the other two groups.

Two behavioral coping strategies, increasing activity level and increasing pain behavior, showed reductions after therapy that were maintained at the follow-up assessment 6 months after therapy. No group differences existed in the pattern of change in these strategies over time. In relation to how patients rated their overall effectiveness in using the coping strategies, no significant differences were observed from pre- to posttherapy in any of the groups. However, 6 months later, scores for control over pain and ability to decrease pain were significantly higher than the pretherapy values.

No main effects for differences in psychosocial aspects of work were observed at any of the three time points when the group was considered as a whole. However, significant interactions revealed that whereas the aerobics and physiotherapy groups tended to increase their ratings of "social support received from colleagues/managers" over the three periods, the devices group showed a reduction after therapy, which remained the same at 6 months. Similarly, the devices group differed in terms of changes in their ratings of "mental stress at work," showing a decrease over the three periods, as opposed to a tendency to increase shown by the other two groups.

No significant changes in the Back Beliefs Questionnaire were observed for the whole patient group over

Table 3. Changes in Various Psychological Attributes and Beliefs Pretherapy (1), Posttherapy (2), and at 6-month Follow-up (3)

		Global (n = 137)	*P* (main effect)	Physiotherapy (P) (n = 46)	Aerobics (A) (n = 47)	Devices (D) (n = 44)	*P* (interaction)
MSPQ	Pre	4.5 ± 4.2	0.12	5.1 ± 4.6	4.5 ± 4.4	3.9 ± 3.5	0.72
	Post	4.5 ± 4.1		5.3 ± 4.7	4.4 ± 4.2	3.8 ± 3.1	
	6 mo	5.1 ± 4.3		6.2 ± 4.4	4.6 ± 4.4	4.4 ± 3.8	
ZUNG	Pre	13.5 ± 7.8	0.12	13.5 ± 7.4	12.1 ± 6.0	14.9 ± 9.5	0.09
	Post	12.4 ± 8.2		13.7 ± 7.8	11.2 ± 7.6	12.3 ± 9.2	(P vs. A&D;
	6 mo	13.2 ± 8.6		15.2 ± 8.8	11.4 ± 7.7	13.0 ± 8.9	0.04)
MSPQ+ZUNG*	Pre	18.0 ± 10.3	0.12	18.6 ± 10.5	16.6 ± 8.3	18.8 ± 11.8	0.12
	Post	16.9 ± 11.4		19.0 ± 11.7	15.6 ± 10.7	16.1 ± 11.5	(P vs. A&D;
	6 mo	18.3 ± 11.4		21.4 ± 11.9	16.0 ± 10.1	17.4 ± 11.7	0.04)
FABQ† (physical activities)	Pre	13.8 ± 5.3	0.0001	14.4 ± 4.7	13.8 ± 6.2	13.0 ± 5.1	0.12
	Post	11.9 ± 5.8	(1>2>3)	11.6 ± 5.8	12.3 ± 5.9	11.7 ± 5.7	(P vs. A&D;
	6 mo	10.9 ± 6.0		12.4 ± 6.2	10.0 ± 6.3	10.4 ± 5.2	0.04)
FABQ‡ (work)	Pre	15.7 ± 11.3	0.03	16.9 ± 11.6	16.3 ± 11.1	13.8 ± 11.1	0.22
	Post	13.6 ± 10.7	(1>2&3	14.8 ± 11.0	15.8 ± 11.4	10.2 ± 8.7	
	6 mo	13.2 ± 10.9	1>3)	16.9 ± 11.5	13.5 ± 11.6	9.9 ± 8.8	
Coping§							
Diverting attention	Pre	2.8 ± 1.2	0.007	2.9 ± 1.2	2.8 ± 1.3	2.8 ± 1.1	0.12
	Post	2.6 ± 1.1	(1>2=3	2.6 ± 1.1	2.5 ± 1.3	2.8 ± 0.9	(D vs. P&A;
	6 mo	2.6 ± 1.2	1>3)	2.7 ± 1.2	2.6 ± 1.1	2.4 ± 1.2	0.03)
Reinterpreting pain sensations	Pre	1.5 ± 1.0	0.56	1.6 ± 1.0	1.4 ± 1.0	1.4 ± 1.1	0.76
	Post	1.4 ± 1.1		1.5 ± 1.2	1.3 ± 1.1	1.3 ± 1.0	
	6 mo	1.4 ± 1.2		1.6 ± 1.2	1.5 ± 1.3	1.3 ± 1.1	
Coping self-statements	Pre	3.9 ± 1.1	0.002	3.8 ± 1.1	4.0 ± 1.1	3.9 ± 1.0	0.67
	Post	3.8 ± 1.1	(1>2&3	3.8 ± 1.1	3.8 ± 1.3	3.8 ± 1.2	
	6 mo	3.7 ± 1.2	1>3)	3.7 ± 1.3	3.8 ± 1.3	3.5 ± 1.0	
Ignoring pain sensation	Pre	3.1 ± 1.1	0.66	3.1 ± 1.1	3.1 ± 1.2	3.1 ± 1.1	0.06
	Post	3.1 ± 1.2		2.9 ± 1.1	3.1 ± 1.1	3.1 ± 1.3	(A vs. P&D;
	6 mo	3.1 ± 1.1		3.0 ± 1.2	3.4 ± 1.1	3.0 ± 1.1	0.032)
Praying/hoping	Pre	2.8 ± 1.1	0.0001	2.8 ± 1.1	2.8 ± 1.3	2.8 ± 1.1	0.71
	Post	2.5 ± 1.1	(1>2=3	2.5 ± 1.1	2.4 ± 1.2	2.5 ± 1.1	
	6 mo	2.4 ± 1.3	1>3)	2.5 ± 1.3	2.3 ± 1.3	2.2 ± 1.2	
Catastrophizing	Pre	2.0 ± 1.1	0.0001	2.0 ± 1.0	1.7 ± 1.1	2.1 ± 1.1	0.67
	Post	1.7 ± 1.1	(1>2>3)	1.9 ± 1.1	1.4 ± 1.1	1.9 ± 1.2	
	6 mo	1.5 ± 1.0		1.7 ± 1.0	1.2 ± 1.0	1.7 ± 1.1	
Increasing activity level	Pre	3.5 ± 1.0	0.03	3.5 ± 1.0	3.6 ± 1.0	3.6 ± 1.0	0.42
	Post	3.4 ± 1.0	(1>2=3	3.3 ± 0.8	3.3 ± 1.1	3.6 ± 1.1	
	6 mo	3.4 ± 1.1	1>3)	3.4 ± 1.0	3.4 ± 1.1	3.3 ± 1.0	
Increasing pain behavior	Pre	3.2 ± 0.8	0.01	3.3 ± 0.7	3.2 ± 0.6	3.2 ± 1.0	0.75
	Post	3.1 ± 0.9	(1>2=3	3.1 ± 0.9	3.1 ± 0.7	3.0 ± 1.1	
	6 mo	3.1 ± 0.8	1>3)	3.2 ± 0.9	3.0 ± 0.9	3.1 ± 0.7	
Control over pain	Pre	3.2 ± 1.5	0.03	3.2 ± 1.5	3.2 ± 1.5	3.1 ± 1.6	0.49
	Post	3.3 ± 1.3	(1=2>3	3.4 ± 1.1	3.2 ± 1.4	3.1 ± 1.4	
	6 mo	3.5 ± 1.3	1>3)	3.8 ± 1.0	3.6 ± 1.4	3.1 ± 1.4	
Ability to decrease pain	Pre	2.8 ± 1.3	0.003	2.8 ± 1.4	2.8 ± 1.3	2.9 ± 1.3	0.76
	Post	3.0 ± 1.3	(1=2>3	3.2 ± 1.2	2.8 ± 1.3	3.0 ± 1.4	
	6 mo	3.2 ± 1.2	1>3)	3.3 ± 1.1	3.1 ± 1.3	3.3 ± 1.1	
PAW satisfaction‖	Pre	29.8 ± 4.8	0.93	30.1 ± 3.9	29.6 ± 5.4	29.6 ± 5.0	0.47
	Post	29.7 ± 5.5		30.1 ± 4.2	30.0 ± 6.2	28.9 ± 5.9	
	6 mo	29.8 ± 5.2		29.8 ± 3.9	30.6 ± 5.2	29.1 ± 6.2	
PAW support‖	Pre	16.3 ± 3.3	0.57	15.9 ± 3.1	16.3 ± 3.8	16.8 ± 2.8	0.04
	Post	16.2 ± 3.1		16.4 ± 2.6	16.3 ± 3.0	16.0 ± 3.6	(D vs. A&P;
	6 mo	16.5 ± 2.9		16.3 ± 2.8	17.3 ± 2.3	16.0 ± 3.3	0.02)
PAW stress‖	Pre	14.5 ± 2.7	0.26	14.7 ± 2.1	13.6 ± 3.5	15.0 ± 2.2	0.02
	Post	14.7 ± 2.5		15.4 ± 1.8	14.2 ± 3.2	14.6 ± 2.4	(D vs. A&P;
	6 mo	14.7 ± 2.5		14.9 ± 2.1	14.6 ± 2.9	14.7 ± 2.5	0.02)
BBQ¶	Pre	28.7 ± 6.1	0.32	28.6 ± 5.4	28.8 ± 6.5	28.6 ± 6.4	0.08
	Post	29.1 ± 6.5		29.7 ± 6.5	28.2 ± 6.3	29.4 ± 6.6	(A vs. P&S;
	6 mo	29.3 ± 5.9		28.7 ± 5.5	30.3 ± 5.7	29.0 ± 6.5	0.02)

* Psychological "disturbance," according to score achieved on sum of MSPQ and ZUNG ([13]), score 0–99.
† Fear Avoidance Beliefs Questionnaire ([40]), score 0–24.
‡ Fear Avoidance Beliefs Questionnaire ([40]), score 0–42.
§ Coping Strategy Questionnaire ([34]), score 0–2 for each strategy.
‖ Psychological Aspects of Work questionnaire ([36]) (satisfaction = general job satisfaction, score 7–35; support = social support from colleagues/managers, score 4–20; stress = mental stress of work, score 4–20. (Answered by 35 patients in physiotherapy, 35 patients in aerobics, and 40 patients in devices; many patients had no "workplace" as such.)
¶ Back Beliefs Questionnaire ([36]), score 9–45; the lower the number, the higher the "inevitability" beliefs about the future as a consequence of having back pain.
MSPQ = Modified Somatic Perception Questionnaire ([24]), score 0–39; ZUNG = Modified ZUNG questionnaire ([25]), score 0–60.
Note: Values are mean ± SD. After the *P* value for the main effect, locations of significant differences between assessment times (1), (2), and (3) are shown in parentheses. After the *P* value for the interaction, locations of significant differences in the behavior of the three groups over time are shown in parentheses (e.g., P vs. A&D: physiotherapy group significantly different in response over time compared with aerobics and device groups).

time, although there was a tendency for ratings of the "inevitability" of aspects of the future as a consequence of back pain to be reduced (*i.e.*, higher scores on the Back Beliefs Questionnaire).

Interrelations Between Changes in Outcome Measures and Changes in Psychological Factors

Using simple correlation analyses, changes in the following factors revealed a significant association with the change in disability (Roland and Morris disability scale) before to after therapy: greatest pain ($r = 0.40$; $P = 0.0001$), average pain ($r = 0.38$; $p = 0.0001$), lumbar range of flexion ($r = 0.18$; $P = 0.04$), fear-avoidance beliefs concerning physical activity ($r = 0.19$; $P = 0.029$), fear-avoidance beliefs concerning work ($r = 0.18$; $P = 0.036$), catastrophizing coping strategy ($r = 0.32$; $p = 0.0001$), and psychological disturbance (ZUNG and MSPQ) ($r = 0.36$; $P = 0.0001$). These factors were used to guide selection in a stepwise multiple regression analysis, in which 21% of the variance in disability reduction could be accounted for by a reduction in the greatest pain recorded and psychological disturbance ($P = 0.0001$).

When a similar analysis was applied to the difference in greatest pain before to after therapy, in addition to disability the following factors were important on an individual basis: lumbar range of flexion ($r = 0.30$; $P = 0.0006$), fear-avoidance beliefs concerning work ($r = 0.25$; $P = 0.004$), catastrophizing coping strategy ($r = 0.28$; $P = 0.0008$), and psychological disturbance (ZUNG and MSPQ) ($r = 0.20$; $P = 0.02$). Again, using these variables to guide entry into a stepwise regression analysis, 23% of the variance in the reduction of greatest pain experienced could be accounted for by a reduction in disability, an increase in lumbar range of flexion, and a decrease in the use of catastrophizing as a coping strategy ($P = 0.001$).

Significant relationships with the change in the average pain were displayed by changes in the following factors (in addition to disability): fear-avoidance beliefs concerning work ($r = 0.25$; $P = 0.004$) and catastrophizing coping strategy ($r = 0.24$; $P = 0.004$). Stepwise regression revealed that 10% of the variance in the reduction of average pain could be accounted for by the reduction in both disability and fear-avoidance beliefs concerning work ($P = 0.001$).

■ Discussion

General Discussion and Main Findings

The current study was a randomized clinical trial assessing the efficacy of three popular conservative therapies for CLBP, with particular emphasis on the role and specificity of different exercise modalities. The study was performed as far as practicable in accordance with previous recommendations[8,18,22,39] to ensure that it was scientifically robust and that the findings were statistically and clinically relevant. It was not considered ethically or practically feasible to use a control/no treatment group in this type of study design, which relied on voluntary participation by the patients. Similarly, it was not possible to blind the patients to the treatment they received, although special emphasis was placed on blinding them from any expectation bias with regard to the efficacy of the different treatments.

Although these factors are considered to threaten the overall methodologic quality of a randomized clinical trial, it is not uncommon to encounter such limitations in studies seeking to evaluate differing exercise/physical therapies.[39] The patients involved in the study were recruited voluntarily from the local community and therefore represented a group with good self-motivation to alleviate their prevailing symptoms. Of these patients, 12% had made or currently were involved in a disability claim, and the majority were (potential) participants in working life. They displayed pain and disability characteristics similar to those of the typical patient with CLBP described in many previous intervention studies: average pain duration of 11.0 years; greatest and average pain intensities of 6.1 and 4.3, respectively, on a 0–10-point visual analog scale (VAS); and pain experienced mostly "often" or "permanently".[14,17,26]

No attempt was made to measure return to work as an outcome variable because it is so strongly influenced by factors unrelated to the patient's health and treatment[8] and its validity and sensitivity as an outcome measure is reputedly questionable.[15] Moreover, many of patients in this study were self-employed, retired, students, or homemakers, for whom the issue of capacity to work would have been irrelevant.

The main finding of the current study was that the three treatments administered to the CLBP patients—individual modern (active) physiotherapy, muscle strengthening/coordination using training devices, and group aerobic/stretching exercises—proved to be equally efficacious in their ability to reduce pain intensity, pain frequency, and disability in tasks of daily living immediately after therapy. Moreover, the effects observed were well maintained, sometimes even improved, over the following 6-month follow-up period, with the exception of disability for the physiotherapy group, which regressed back toward its pretherapy value. This is the first randomized clinical trial to compare these different forms of active treatment directly, and the results have far-reaching implications for the future management of CLBP, particularly in relation to the associated socioeconomic costs (discussed later).

Comparison of Treatment Effect Size With Previously Published Data

To examine whether the outcome responses in the patient groups were representative of those expected for the therapies used, the magnitude of the improvements observed can be compared with those previously reported in the literature for these treatments. As long as similar outcome variables are used and the mean and standard deviation for the pre- and posttherapy values of the vari-

able are reported, the effect size can be calculated and compared across studies (effect size = (postmean − premean)/pre-SD) for different parameters.

Two previous studies evaluated the effectiveness of the David Back Clinic program as a treatment for CLBP. The first was a case series study[37] for which a combined outcome measure, pain reduction, was used, formulated on the basis of changes in pain intensity and pain frequency. The current continuous data was recoded into categorical data in an attempt to make a comparable classification system for the proportion of patients showing a decrease, no change, or an increase in pain after therapy. The proportions were 80%, 13%, and 7%, respectively, in the previous study[37] and 50%, 19%, and 30%, respectively, in the current study. As such, the current overall outcome appeared to be somewhat poorer. However, the therapy in the previous study was not administered as part of a randomized controlled trial, so there may have been certain selection biases that allowed for a more favorable outcome.

The second study was a randomized trial performed to compare the 3-month David Back Clinic program with a short period of passive physiotherapy.[19] Pain intensity was measured with a VAS and disability index by a questionnaire. The effect size was 0.86 for the decrease in average pain intensity and 0.23 for the decrease in disability. These values compare favorably with the current values of 0.61 and 0.25, respectively. It should be noted, in addition, that the effect sizes recorded in the current study were at least as good as those previously reported for similar device training aimed at "back muscle reconditioning" (*e.g.*,[32]) or those for other intensive back exercise programs,[14,26] suggesting that the findings are generalizable beyond the specific device-training program used in the current study.

The current aerobics program was developed "in house" based on a number of different sources and the personal experience of the staff running the classes (see the Methods section). Therefore, it was designed on the common principles of low-impact aerobic exercise, but was unique in terms of its precise content.

Purely aerobic/general-fitness exercise programs have not been widely evaluated in the literature, especially in the context of randomized clinical trials that have been assigned a good methodologic rating.[39] Frost et al[11] carried out a randomized controlled trial assessing the efficacy of a progressive fitness program in a group of patients moderately disabled, having pain characteristics similar to those of patients in the current study. These researchers reported a significantly better outcome in their fitness group than in a control group who received only back school education. Their effect sizes for changes in pain intensity and disability in the treatment group were 0.71 and 0.62, respectively. The pain intensity changes were similar to those obtained for the changes in greatest pain reported by the aerobics group in the current study (0.77), but the current effect size for disability was considerably smaller (0.30). Consistent with current midterm results, they also were able to demonstrate a lasting effect of their program, with the fitness group showing significantly lower disability scores at the follow-up assessment at 2 years after therapy.[12]

More recently, the preliminary results of a randomized trial performed to investigate the efficacy of a low-impact aerobics program as compared with a traditional back-care program were presented.[4] However, the patient population was not clearly described ("some LBP in the past 3 years"), and individual values for the most relevant outcome parameters before and after therapy were not detailed. It is therefore difficult to draw meaningful comparisons with this study.

Another study that used an 8-week program of aerobic exercise (not aerobics as such, but rather walking/jogging exercise)[38] showed a smaller effect size for the change in self-rated pain (0.18) and a slightly greater effect size for disability (0.36) than did the current study. When the exercise program was supplemented with behavioral therapy, the results were more impressive, although at follow-up assessment 6 months after therapy there was no longer any difference between the groups, each retaining or slightly improving on their posttreatment results.

Despite the widespread use of physiotherapy in the management of CLBP, relatively few highly rated studies have been performed to examine its efficacy.[21] In an attempt to redress the situation, Koes et al[23] carried out a randomized controlled trial to compare the relative efficacy of active physiotherapy (similar to that used in the current study), manual therapy, general practitioner treatment, and a placebo therapy. The effect size pertaining to the response of the physiotherapy group was somewhat difficult to calculate because no standard deviation values were presented with the means. However, their absolute difference of 0.9 points on a pain VAS of 1 to 6 points compares favorably with the mean difference of 1.6 points observed in the current study using a VAS of 0 to 10 points for pain intensity (Table 3). Their corresponding disability scores reduced by 1.9 points on a 100-point VAS, which is less than the reduction of 1.1 points on a 24-point scale in the current study.

Another randomized study on the efficacy of a short period of conventional physiotherapy showed a post-therapy decrease in the median pain scale rating from 4 to 3 on a 1- to 9-point scale.[14] The physiotherapy group in the current study showed a reduction from a median value of 7 to 5 on a 1- to 10-point scale. It appears, therefore, that the current physiotherapy program was at least as efficacious as those previously described in the literature.

Possible Mechanisms of Action in Alleviating Pain and Disability

The three treatments administered in the current study were equally efficacious in relation to the most important outcome variables examined and showed effect sizes immediately after therapy that were comparable with those

previously reported in the literature for similar treatments. This confirms, experimentally, the conclusion reached by van Tulder et al,[39] after a systematic review of randomized controlled trials assessing common interventions for chronic LBP, that there is strong evidence to substantiate exercise therapy as one of the leading treatments, but that it is not possible to advocate one specific exercise method over another. At first sight, this may seem to be something of a paradox because the concept of training specificity dictates that the mode in which one trains is crucial in governing the accompanying adaptation: if increases in muscular strength are desired, then specific resistance training is required for the overload necessary to produce muscular hypertrophy. Likewise, if the desired end point is improved cardiovascular fitness or endurance, then this must be accomplished through repetitive low-intensity aerobic exercise.

In the current study, each therapy used had a substantial exercise component but placed quite differing demands on the type of adaptation expected. The finding that all groups performed equally well in relation to the most important outcome variables tends to suggest that the main effect was educed not through specific physiologic adaptations, but rather through some "central" effect. Challenging the misconception that physical activity is contraindicated in LBP may have been an important starting point in effecting this result, perhaps leading to an alteration in the patients' perception of what constitutes disability.

It was interesting to note that a highly significant reduction in fear-avoidance beliefs about physical activity was observed in all the groups after treatment, and also that the extent of the change in this measure correlated with the reduction in self-rated disability. Furthermore, in the aerobics and devices groups, the two groups in which this score was reduced further after 6 months, disability was correspondingly reduced. It is possible also that the observed effects arose as a consequence of modifications in pain perception,[10] the antidepressive action of exercise,[7,31] or simply the enhanced feeling of well-being and accomplishment associated with achieving an increase in physical fitness.[29] If this were so, then the precise form of exercise prescribed would perhaps be less important than simply finding a way to encourage patients to move confidently again despite existing pain.

The positive nature of the outcome at the follow-up assessment 6 months after therapy suggests that the treatments also were successful in the midterm, perhaps by encouraging the patients to continue independently with exercise after the treatment at the hospital was completed. Interesting, in this respect, was the finding that the aerobics and devices groups, whose sessions focused most predominantly only on exercise, retained their posttherapy results more effectively than the physiotherapy group, particularly in relation to self-rated disability and certain fundamental psychological attributes.

In attempting to assess objectively impairment caused by LBP, there is little universal agreement as to which measures should be used. Range of motion, considered to be an objective and reproducible measure, currently is the only measure included in popular published guidelines for assessing impairment.[2] In the current study, small but significant increases in spinal mobility were observed after therapy, particularly in the aerobics and devices groups. Furthermore, for the group as a whole, changes in spinal sagittal mobility showed a correlation with changes in pain intensity and self-rated disability. It is therefore possible that the success of the treatment was in part attributable to real changes in physical performance capacity, and it certainly was measurable by these changes.

A highly significant correlation was observed between pretreatment pain and disability and the extent of their reduction after therapy (*i.e.,* the patients with the greatest pain and disability showed the greatest improvements). This finding has been reported before,[37] although its interpretation is not immediately clear. Perhaps those with greater pain have a greater motivation to improve, or maybe it is just a reflection of the well-known statistical feature of "regression toward the mean" (*i.e.,* large deviations from the population mean tend to regress closer to the mean after any intervention).

Whatever the explanation, the implication is that the effects of the treatments might have been even more impressive if the current study had targeted for inclusion patients whose pain was initially more severe and disabling. Interestingly, a subgroup analysis of patients with average pain levels higher than 4 on a 0- to 10-point VAS at entry to the study showed much greater effect sizes for the most important outcome variables, again, without significant difference among the treatment groups. It therefore appears that the success of these therapies is not limited to patients who are moderately impaired, but extends also to those whose pain is quite severe. In this sense, it appears that high pain levels are no barrier to active rehabilitation, and, to the contrary, may even predispose the patient to a more successful outcome.

Financial Implications of Administering the Three Treatments

The results concerning the relative efficacy of the three treatments have many important socioeconomic implications because the costs of administering these different types of programs vary greatly. The charges that would have been made to the patients' health insurance for the different therapy programs undertaken in the current study are as follows: 288 Swiss Francs (SFr) for aerobics, 960 SFr for physiotherapy, and 1120 SFr for devices, giving a cost ratio of 1:3.3:3.9.

Epidemiologic studies performed in the United Kingdom have shown that 3% to 7% of the population report their back problems as chronic.[6] Assuming that similar figures apply in Switzerland, it can be estimated that approximately 0.4 million people (5% of a population of 7.3 million) experience a chronic back problem. The di-

rect medical costs associated with these people undertaking one of the 3-month programs in a year would thus be 115 million SFr for the aerobics, 384 million SFr for the physiotherapy, and 448 million SFr for the devices training. The most common treatments currently used for these patients are physiotherapy and, with ever-increasing popularity, programs carried out on training devices. The costs associated with differing device training programs, and even with the same program in different countries, appear to vary greatly (400 to 5000 SFr for a 3-month program); whether these varying costs reflect differing efficacies remains to be known. What appears clear, however, is that the introduction of aerobic exercise programs as an efficacious alternative should have the potential to save millions in direct costs. The current study was not able to assess the corresponding indirect costs, which can often be much more substantial than the costs of treatment. However, it could be expected that the longer-lasting positive effects of the more active programs would translate into lower costs associated with work loss and disability.

Implementation of Aerobic Exercise Classes as a Treatment for Chronic Low Back Pain

The aerobics classes were well enjoyed by the majority of the patients. Most were happy to recommend this as a treatment for patients with similar problems, reporting that they would have continued with the treatment had they been given the opportunity. Although the feedback from the patients concerning the therapists' provision of ergonomic advice and their interest in individual problems was not as satisfactory as it was, for example, in the physiotherapy group (as might be expected for group exercise classes), this appeared not to detract from the overall efficacy of the program. If these components are indeed important in the recovery/adjustment process, then the aerobics classes could naturally be supplemented with this type of support to provide for a more complete, and possibly even more successful, therapy.

A final factor, with considerable ramifications extending into the domains of health promotion and secondary prevention, involves the additional health benefits to be accrued from performing regular aerobic exercise. Many of these benefits are particularly pertinent to this same age group. Aerobic exercise has been shown to be beneficial in both the prevention and management of many prevalent disease states such as cardiovascular disease, obesity, hyperlipidemia, hypertension, and osteoporosis.[5]

■ Conclusion

In summary, the three treatments administered in the current study of patients with CLBP—individual modern (active) physiotherapy, muscle strengthening/coordination using training devices, and group aerobic/stretching exercises—were equally efficacious in their ability to effect significant reductions in pain intensity, pain frequency, and disability in tasks of daily living immediately after therapy. These treatments also effected a change in fear-avoidance beliefs about physical activity. Moreover, the effects observed after treatment were well maintained, and sometimes even improved, over the following 6 months, with the exception of disability in the physiotherapy group.

The patients volunteered their participation in the study, and the majority were still employed. However, their initial pain and disability characteristics resembled those of the typical patient with CLBP described in many previous intervention studies. It is therefore likely that the findings in this study can be extrapolated to other populations of patients with CLBP, perhaps with even greater expectations for patients whose pain is initially more severe and disabling.

The costs of administering the three treatments in the current study varied greatly, with the aerobics program costing just a fraction of the costs for the other two programs. The results should have important socioeconomic implications for rehabilitation of the patient with CLBP.

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