Randomised controlled trial for evaluation of fitness programme for patients with chronic low back pain

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Abstract

***Objective*—To evaluate a progressive fitness programme for patients with chronic low back pain.**

***Design*—Single blind randomised controlled trial. Assessments were carried out before and after treatment by an observer blinded to the study and included a battery of validated measures. All patients were followed up by postal questionnaire six months after treatment.**

***Setting*—Physiotherapy department of orthopaedic hospital.**

***Subjects*—81 patients with chronic low back pain referred from orthopaedic consultants for physiotherapy. The patients were randomly allocated to a fitness programme or control group.**

***Intervention*—Both groups were taught specific exercises to carry out at home and referred to a backschool for education in back care. Patients allocated to the fitness class attended eight exercise classes over four weeks in addition to the home programme and backschool.**

***Results*—Significant differences between the groups were shown in the changes before and after treatment in scores on the Oswestry low back pain disability index ($P<0.005$), pain reports (sensory $P<0.05$ and affective $P<0.005$), self efficacy reports ($P<0.05$), and walking distance ($P<0.005$). No significant differences between the groups were found by the general health questionnaire or questionnaire on pain locus of control. A benefit of about 6 percentage points on the disability index was maintained by patients in the fitness group at six months.**

***Conclusion*—There is a role for supervised fitness programmes in the management of moderately disabled patients with chronic low back pain. Further clinical trials, however, need to be established in other centres to confirm these findings.**

Introduction

Recent research suggests a need for a more active approach to the management of patients with low back pain to reduce disability.[1-3] Most clinical trials investigating the effectiveness of exercise programmes on patients with low back pain, however, have been carried out in the United States or Scandinavia.[4-11] Fitness programmes aimed at restoring function in patients with chronic low back pain are not routinely available in the United Kingdom and have not previously been evaluated by means of a randomised controlled trial. We aimed to evaluate the effectiveness of an outpatient fitness programme designed for patients with chronic low back pain. Our hypothesis was that attendance at a supervised fitness programme aimed at gradually increasing physical activity in patients with chronic low back pain is more effective than a home exercise programme in reducing functional disability; decreasing pain; increasing a feeling of control over pain; increasing confidence in ability to carry out normal activities; and increasing endurance.

Patients and methods

Approval was obtained from the Central Oxford Research Ethics Committee. The design of the study was a single blind randomised controlled trial, the assessor being unaware of the allocation of treatment. Patients referred to the physiotherapy department of the Nuffield Orthopaedic Centre between 1991-3 were invited to take part in the study if they fitted the study criteria (see appendix). Patients were seen by the assessor and given information about the study, an explanatory letter for their general practitioner, and a pain diary, which they were asked to complete before starting the treatment. The first assessment was carried out a week later. Four individual exercises judged to be clinically appropriate for each patient were taught, and patients were advised to continue with the exercises twice daily until their follow up appointment. They were seen briefly within two to three days to check that no problems had arisen and that they were carrying out the exercises as instructed. No further attempt was made to improve compliance in the control group as the study aimed to reproduce normal clinical practice.

The patients were then randomly allocated to the backschool or the backschool and fitness programme. The minimisation method of randomisation[12] was used, and patients were stratified according to duration of symptoms, previous episodes of low back pain, age, and sex. Assessments were carried out by a single blinded observer before and after treatment and at six months after treatment by postal questionnaire. A two year follow up assessment is currently in progress.

Backschool intervention—The educational programme included discussion of the patient's main problem, functional anatomy, simple applied body mechanics, advice regarding functional activities and exercise, relaxation techniques, ergonomic advice, a video titled *Prevention of back injury*, and practical workshops.

The fitness programme—included eight sessions lasting for an hour over a period of four weeks. Each session included warm up and stretching followed by a circuit of 15 progressive exercises. The sessions finished with a stretching routine and light aerobic exercise. Psychological principles were used throughout the programme by the physiotherapist supervising the class. Participants were encouraged to think of themselves as sports people who needed to improve their fitness rather than disabled patients. They were warned at the beginning of the first session that unaccustomed exercise may cause muscle aches and pains but that these were not harmful. They were advised to inform the therapist if they experienced

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BMJ 1995;310:151-4

an increase in leg pain or change in neurological symptoms—for instance, sensory or motor changes. Otherwise pain was not discussed in the class. All patients were advised not to compete with each other, and repetitions of the exercises were recorded by the patient on their personal charts, encouraging them to better their own achievements.

OUTCOME MEASURES

Revised Oswestry low back pain disability index—This questionnaire was used as the main subjective measure of functional disability. It is a 10 section questionnaire including six statements in each section designed to assess limitations of various activities of daily living. It is scored on a 0-100% scale (0=no disability, 100=totally disabled).[13]

Pain diaries—Patients were asked to record the sensory and affective components of pain by using a 101 point numerical scale four times daily for one week before and after treatment. A number was chosen by the patient between 0 and 100 for both components of pain (0=no pain and no distress caused by pain, 100=pain as bad as it could be and pain as distressing as it could be). Multiple measures of pain intensity over time have been shown to maximise the reliability and validity of pain assessment.[14]

The pain locus of control questionnaire was used to investigate the patients' control over their pain. Two scores relating to cognitive control and pain responsibility are incorporated within the questionnaire.[15]

The pain self efficacy questionnaire is a 10 part questionnaire and was used to assess the patients' confidence in their ability to carry out normal activities of daily living (0=no confidence in carrying out normal activities of daily living, 60=complete confidence in carrying out normal activities of daily living).[16]

The general health questionnaire is a well validated questionnaire that was used as a measure of general psychological state. It is scored on a 0-90 scale. A high score of over 39 is considered to be associated with psychological symptoms.[17]

The shuttle walking test was developed from a running test now widely used to assess functional capacity in sportsmen and women. The reliability of the shuttle walking test has been assessed in patients with chronic airways obstruction and shown to be a superior method of measuring walking capacity in comparison with other tests.[18] The reliability of the test in patients with low back pain was investigated before we started the trial and considered to be satisfactory according to recommendations outlined by Bland and Altman.[19] The test required the patients to walk up and down a 10 m course identified at each end by two cones inset 0·5 m from either end to avoid the need for abrupt changes in direction. The explanation to the patient was standardised and played from a tape at the beginning of the test. Accuracy of the timed signal was ensured by the inclusion on the tape recording of a calibration period of one minute. The speed at which the patient walked was dictated by an audiosignal played on a tape recorder. In the first minute the patient was required to walk up and down the walkway three times, amounting to a distance of 30 m. The next minute required the patient to walk faster and complete 40 m within the time dictated by the audiosignal from the tape recorder. The speed and distance was therefore increased each minute until the end of the test. Heart rate was recorded with a short range telemetry device throughout the test. The only verbal contact was advice given each minute to increase the walking speed slightly, otherwise no form of encouragement was given throughout the test. The end of the test was determined by the patient stopping because of fatigue or by the operator if the patient failed to complete a shuttle in the time allocated.

Results

A total of 116 patients were asked to take part in the study over a period of 18 months; 81 patients (70%) agreed. Five patients dropped out of each group for various reasons. The remaining 71 patients were included in the analysis. Pain diaries were completed surprisingly well by most patients, with only three diaries from each group missing in the final analysis. The number of sessions attended by the patients who were randomised to the fitness group varied from three to eight, with an overall percentage attendance of 86%. Table I shows the baseline data.

TABLE I—*Baseline data of patients in fitness and control groups*

Detail	Fitness group (n=36)	Control group (n=35)
Mean (SD) age year	34·2 (9·4)	38·5 (9·3)
Women	19	18
Men	17	17
Mean (SD) time since first episode (months)	102·2 (92·6)	101·8 (90·7)
Mean (SD) duration of present symptoms (months)	26·3 (27·4)	18·7 (15·4)
Smokers	8	6

Table II shows the mean (SD) and median scores for measures before and after treatment. The Mann-Whitney U test was used to compare the differences between the fitness and control groups. There were no significant differences between any of the baselines measures before treatment. Significant differences between the groups were shown in the changes before and after treatment in disability, pain (sensory and affective), self efficacy, and walking distance. Both groups reported considerable improvements in their general health, although differences between the groups were not significant. Neither scales of the questionnaire on pain locus of control changed significantly over time.

Patients' subjective appraisal—Immediately after treatment all patients were asked how much benefit (on a scale of 0-100) they had gained from attending for treatment. Patients in the fitness group scored significantly higher than the control group, although benefits were also perceived by the patients in the control group (mean (SD) 65·6 (25·8) *v* 45·0 (25·0); median (range) 67·5 (0-100) *v* 50·0 (0-90); Mann-Whitney U test $P<0·001$).

Six month follow up—There was an 86% response rate to the follow up questionnaires from the 71 patients who attended for the second assessment. An intention to treat analysis was carried out on the data, although 12 patients in the control group crossed over to the fitness group after the second assessment (table III, figure 1). The results were also analysed by separating the patients who crossed over from the control group to the fitness group (table IV, figure 2). At six months there was a significant difference in the change in the scores on the Oswestry low back pain disability index when we compared the fitness group with those patients who remained in the control group (Mann-Whitney U test, $P<0·03$). Patients who crossed over from the control group to the fitness group after the second assessment reported reduced disability at the six month follow up, although the improvement was not significant.

Discussion

Most patients included in our study were moderately disabled by pain as measured by the Oswestry low back pain disability index, although many had a long history of low back pain. Scores were significantly reduced in patients who attended the fitness programme compared with those who were in the control group, and a benefit of about 6 percentage points on the Oswestry

TABLE II—*Mean (SD) and median scores for all data before and after treatment. Mann-Whitney U test used to analyse differences in changes between groups*

Outcome measure	Fitness group			Control group			P value for difference between groups
	Before	After	P value for difference	Before	After	P value for difference	
Disability:							
Mean (SD)	23·6 (9·7)	17·6 (10·9)	<0·005	23·6 (12·3)	21·7 (13·6)	0·53	<0·005
Median (range)	22 (2-48)	16 (2-48)		22 (4-52)	20 (4-48)		
Sensory pain:							
Mean (SD)	20·9 (12·3)	12·1 (9·9)	<0·005	25·6 (17·9)	22·1 (20·1)	0·25	<0·05
Median (range)	19 (1-58)	10 (1-34)		21 (2-63)	16 (1-71)		
Affective pain:							
Mean (SD)	15·4 (12·8)	8·56 (9·5)	<0·05	16·8 (15·8)	16·4 (15·4)	0·61	<0·005
Median (range)	11·8 (1-48)	5 (1-34)		14·5 (1-67)	12 (1-48)		
Self efficacy:							
Mean (SD)	43·3 (10·5)	48·8 (9·8)	<0·05	41·1 (11·4)	42·4 (10·5)	0·55	<0·05
Median (range)	46 (16-58)	50 (25-60)		42 (14-59)	44 (26-60)		
General health:							
Mean (SD)	31·7 (13·9)	23·2 (11·8)	<0·005	26·7 (7·3)	22·6 (10·1)	<0·05	0·11
Median (range)	29 (14-65)	19·5 (9-68)		26 (17-46)	21 (6-52)		
Cognitive control:							
Mean (SD)	8·8 (5·8)	11·1 (5·6)	0·10	7·9 (3·8)	8·9 (4·5)	0·59	0·06
Median (range)	8·5 (0-22)	10·5 (2-21)		8·5 (2–19)	9 (0-18)		
Pain responsibility:							
Mean (SD)	10·1 (2·9)	9·8 (2·7)	0·89	7·4 (3·2)	7·9 (3·2)	NS	0·52
Median (range)	9·5 (4-16)	9 (6-16)		7·5 (2-14)	8·5 (1·12)		
Walking distance (m):							
Mean (SD)	445 (140·8)	553·7 (154·5)	<0·005	408·9 (166·4)	421·4 (167·4)	0·80	<0·005
Median (range)	440 (180-170)	540 (260-880)		440 (80-780)	430 (100-760)		

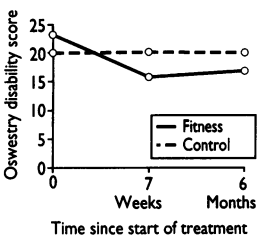

FIG 1—*Scores on low back pain disability index for all patients included in intention to treat analysis. Higher scores on index correspond to greater disability*

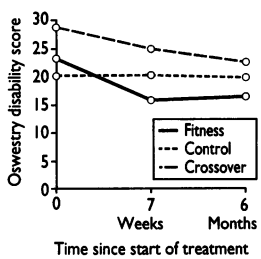

FIG 2—*Scores on Oswestry low back pain disability index, including crossover data. Higher scores correspond to greater disability*

TABLE III—*Scores on Oswestry low back pain disability index for all patients included in intention to treat analysis*

Time	Fitness group (n=29)		Control group (n=32)	
	Mean (SD)	Median (range)	Mean (SD)	Median (range)
Before treatment	23·1 (9·4)	23 (2-46)	24·2 (12·4)	20 (4-52)
After treatment	16·3 (10·3)	16 (2-46)	21·2 (14·2)	20 (3-58)
At 6 month follow up	15·1 (8·3)	17 (0-30)	23·4 (15·2)	20 (0-54)

index was maintained at six months by patients in the fitness group. These findings are comparable with results of a two year follow up study of patients with low back pain who were assessed by using the Oswestry index and benefited from chiropractic treatment compared with hospital outpatient treatment.[20] In this study the mean number of individual sessions of treatment that were necessary to show the benefit of the chiropractic treatment was 9·1, which is considerably more than the 10 group sessions of education and exercise carried out by a single physiotherapist.

The number of patients who crossed over from the control group after the second assessment limits the validity of the long term follow up, although it has been suggested that a change in treatment indicates the superiority of one treatment group over another and should be used as an outcome measure.[21]

Motivation and compliance is a major problem with any treatment that requires patients to maintain improvement by continuing with their own exercise regimen after discharge from hospital. Although there was no evidence for an improvement in control over pain or responsibility for pain, it was encouraging that at the six month follow up assessment many patients who had attended the fitness programme reported that they were continuing with exercise as it helped them to cope with their back problem and remain active. Some patients who hoped to join exercise groups outside the hospital, however, suggested that community exercise facilities for people with back problems are inadequate.

TABLE IV—*Scores on Oswestry low back pain disability index, including patients who crossed over from control group to fitness group. Crossover group includes patients originally in control group who were transferred to fitness programme after second assessment*

Time	Fitness group (n=29)		Control group (n=20)		Crossover group (n=12)	
	Mean (SD)	Median (range)	Mean (SD)	Median (range)	Mean (SD)	Median (range)
Before treatment	23·1 (9·4)	23 (2-46)	21·6 (11·9)	20 (4-46)	28·4 (12·6)	29 (6-52)
After treatment	16·3 (10·3)	16 (2-46)	18·1 (12·6)	20 (4-56)	28·4 (13·9)	25 (10-58)
At 6 month follow up	15·1 (8·3)	17 (0-30)	22·3 (14·6)	20 (0-54)	25·1 (16·7)	23 (2-48)

PAIN AND SELF EFFICACY

There was a 42% (sensory) and 49% (affective) reduction in pain reported by patients attending the fitness programme compared with a 21% (sensory) and 0·02% (affective) reduction in the control group. These differences were larger than expected and may be because of various factors such as the increased production of endogenous opioid peptides in response to aerobic exercise or improvement in overall sense of wellbeing.[22-24] A common problem for patients who suffer long periods of pain is the resulting lack of confidence and fear in carrying out their normal activities of daily living and hobbies.[2] Patients' participation in the fitness class led to an improvement in self efficacy and functional ability. In previous work self efficacy has been found to be both a useful predictor and outcome measure for chronic pain programmes.[25,26] Performance based accomplishments such as the experience of carrying out physical activities, which the patients did not previously believe possible, may help to reshape attitudes about their condition.[27] There is also evidence to show that patients who attribute their improvements to their own efforts are less likely to relapse.[25]

FUNCTIONAL CAPACITY AND ENDURANCE

Walking was chosen as an objective measure instead of range of movement as it was considered to be a more valid measure of function and endurance. Although it measures only one aspect of functional ability, walking is a necessary part of every day activity, and patients with low back pain often complain of problems when walking. Patients who attended the fitness class increased their walking capacity by 25% compared with no change in the control group. The change indicated an increase in speed of walking and distance which may have been because of increased general fitness or reduced pain. The shuttle walking test used in this study is simple and quick to carry out and is a useful outcome measure of treatment for back pain.

EFFECTIVENESS OF BACKSCHOOLS

The results of this study question the effectiveness of

Key messages

- Incidence of disability caused by low back pain has increased over the past decade, and currently there is no universal cure or treatment for the problem
- Recent research suggests a need for a more dynamic approach with a move away from long term rest towards progressive activity and exercise
- This study shows that a supervised fitness programme can help to reduce pain and disability and improve patients' confidence
- Beneficial effects of treatment were maintained six months after treatment when compared with a control group who were advised to exercise independently
- Simply advising patients with low back pain to exercise is not effective in reducing disability and pain

backschools. Although a previous study carried out in the same centre on a similar population of patients with low back pain showed a reduction in disability,[28] some other studies have reported less convincing results.[29] Patients in the control group reported significant improvements in their general health scores but otherwise remained unchanged, indicating that to change other problems associated with low back pain a more active approach is necessary.

POTENTIAL COST SAVINGS

Cost effectiveness has become an increasingly important issue to consider in the management of all patients. This method of managing patients in groups has been shown to be beneficial and is cheaper than individual treatment. While it is recognised that manipulative techniques can also be affective,[21] a study to compare manual treatment with fitness programmes would be useful to assess the most beneficial and cost effective treatment for patients with chronic low back pain.

CONCLUSION

We have shown that moderately disabled patients with chronic low back pain who attend a backschool and fitness programme benefit more in the short and long term than patients who attend a backschool and exercise independently at home. Simply advising patients to become more active is not effective and additional support is necessary to change pain, disability, beliefs of self efficacy, and functional capacity. On the basis of our results education on back care alone is not recommended if the aim is to reduce pain and disability and restore the patients' confidence. The fitness programme we have described does not require expensive equipment and could be established in any physiotherapy department with access to a gymnasium in or out of the hospital setting.

We thank the National Back Pain Association and Oxfordshire locally organised research scheme for their financial support.

Appendix

CRITERIA FOR INCLUSION

- Somatic low back pain for at least six months (with or without referred pain)
- Age between 18 and 55 years old
- Patients able to travel independently to hospital
- Patients declared medically fit by their general practitioners
- Plain *x* ray examination of the lumbar spine within the past year

CRITERIA FOR EXCLUSION

- Constant or persistent severe pain judged on clinical grounds to be due to irritation of nerve root
- Other musculoskeletal disbilities that would affect patients' ability to cope with the fitness programme
- Inflammatory arthritis
- Major surgery within the past year
- Patients already involved in regular and frequent sporting activities (for example, squash, swimming, fitness training, cycling) at least twice a week for the past six months
- Previous physiotherapy within the past three months
- Spinal infection, fractures, spondylolisthesis, or malignancy
- Pregnancy
- Patients unable to walk without a walking aid

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(Accepted 8 November 1994)