



A fitness programme for patients with chronic low back pain: 2-year follow-up of a randomised controlled trial

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Abstract

The aim of this study was to assess the long-term effect of a supervised fitness programme on patients with chronic low back pain. The design of the study was a single blind randomised controlled trial with follow-up, by postal questionnaire, 2 years after intervention. The Oswestry Low Back Pain Disability Index was used as the outcome measure to assess daily activity affected by back pain. Eighty-one patients with chronic low back pain, who were referred to the physiotherapy department of a National Health Service orthopaedic hospital, were randomised to either a supervised fitness programme or a control group. Patients in the intervention group and control group were taught specific exercises to be continued at home and referred to a backschool for back care education. In addition, the intervention group attended eight sessions of a supervised fitness programme. Sixty-two patients (76%) with a mean age of 37 years, returned the Oswestry Low Back Pain Disability Index questionnaire. Of these, 29 were in the intervention group and 31 in the control group. Patients in the intervention group demonstrated a mean reduction of 7.7% in the Oswestry Low Back Pain Disability Index score (95% confidence interval of mean paired difference 3.9, 11.6 $P < 0.001$), compared with only 2.4% in the control group (95% confidence interval of mean paired difference -2.0 , 6.9 $P > 0.05$). Between group comparisons demonstrated a statistically significant difference in disability scores between the treatment and control group (mean difference 5.8, 95% confidence interval 0.3, 11.4 $P < 0.04$). This study supports the current trend towards a more active treatment approach to low back pain. We have demonstrated clinical effectiveness of a fitness programme 2 years after treatment but this needs to be replicated in a larger study which should include a cost effectiveness analysis, further analysis of objective functional status and a placebo intervention group. © 1998 International Association for the Study of Pain. Published by Elsevier Science B.V.

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1. Introduction

The costs of back pain in the United Kingdom to the National Health Service are difficult to measure precisely but have recently been estimated to fall between £264.5 and £435.7 million per annum. This includes the costs of physiotherapy intervention that are thought to lie between £24 and £36 million (Klauer Moffett et al., 1995). The majority

of patients with back pain are managed non-operatively although the efficacy of standard physiotherapy treatment is questionable. A number of trials have been carried out to evaluate the efficacy of physiotherapy intervention for back pain, including manipulative therapy and exercise, but most are considered to be methodologically poor (Koes et al., 1991, 1995). A large variety of treatment modalities are used which are generally dependent on the clinician's experience and beliefs rather than evidence from the literature.

Management guidelines produced by the United Kingdom Clinical Standards Advisory Group (Clinical Standards Advisory Group, 1994) suggest more intensive vigorous

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exercise programmes for the treatment of chronic low back pain. Although these guidelines are not based on strong scientific evidence, recent systematic reviews of the literature have generally supported this recommendation (Agency for Health Care Policy and Research, 1994; Evans and Richards, 1996; van Tulder et al., 1996). More recent guidelines, produced by the Royal College of General Practitioners and distributed to GPs by the Department of Health, together with a back care booklet for patients with acute low back pain, also recommend physical activity (Roland et al., 1996). However, high quality research is necessary to provide further evidence to support these guidelines. At present, there are no published data available documenting the number of United Kingdom centres offering rehabilitation programmes for patients with low back pain and it is thought that only a small number of hospitals run fitness programmes.

Based on clinical observation and recommendations from the literature at the time (Linton, 1985; Waddell, 1987) we established, in 1988, a fitness programme for patients with chronic low back pain. The aim of this simple programme was to combat the common effects of physical and psychological deconditioning in chronic low back pain. Significant benefits of the fitness programme were demonstrated at the 6-month follow-up assessment and those results are reported elsewhere (Frost et al., 1995). We present further 2-year follow-up results of the trial comparing (1) standardised treatment plus a supervised fitness programme with (2) standardised treatment plus advice to continue with unsupervised exercise at home.

2. Method

Patients referred to a hospital orthopaedic outpatient department between 1991 and 1993, were invited to take part in the study. They were included in the trial if they were between 18 and 55 years old, diagnosed with mechanical low back pain for at least 6 months (with or without referred pain), able to travel independently to the hospital and declared medically fit by their general practitioner. They were excluded if they had constant or persistent severe back pain judged on clinical grounds to be due to nerve root irritation, other musculoskeletal disabilities that would affect their ability to cope with the fitness programme, systemic conditions, major surgery within the last year, fractures, spondylolisthesis, had physiotherapy previously within the last 3 months, were engaged in moderately strenuous sporting activities (e.g. squash, swimming, fitness training, cycling) at least twice a week for the last 6 months or were pregnant.

Patients were randomly allocated to one of two groups; (1) treatment group – backschool and advice to carry out specified exercises at home plus an invitation to attend the fitness programme or, (2) control group – backschool and advice to carry out specified exercises at home.

The minimisation method of randomisation (Pocock, 1983) was used and patients were stratified by computer programme according to duration of symptoms (6 months–1 year or >1 year), previous episodes of low back pain (none, or 1–5 episodes, or >5 episodes), age (18–40 or >40) and sex. Computer allocation was generated for each patient, once they had consented to participate, by a person not involved in patient assessment.

2.1. Assessment

The Oswestry Low Back Pain Disability Index was used to assess limitations of daily activities prior to the intervention (baseline), and 2 years after intervention. It is a questionnaire designed to assess the impact of back pain on daily functioning which has been shown to be a reliable, valid and responsive measure of functional disability (Baker et al., 1989; Beurskens et al., 1995; Fischer and Johnston, 1997). The questionnaire was administered at baseline, together with a battery of outcome measures, during an interview by an investigator who was blind to the treatment assignment. Two years after randomisation, the Oswestry Low Back Pain Disability Index was sent by post to all randomised patients by a research assistant who was also blind to the treatment allocation. No further assessment was carried out at this time. Information on the age, sex, duration of symptoms and baseline pain levels (recorded on a numerical scale 0–100, 0 = no pain, 100 = maximum) were recorded.

2.2. Intervention

2.2.1. The fitness programme

The fitness programme consisted of eight sessions of 1 h extending over 4 weeks. Participants were given written advice before the first class. Cognitive behavioural principles were used throughout the programme by the physiotherapists taking the exercise classes (Harding and Williams, 1995). The programme was based on a normal model of human behaviour rather than the disease model. Participants were encouraged to compare themselves with sportsmen and women who had been laid off their training for a long time and needed to get back to their previous activities. They were given maximum encouragement and positive reinforcement where appropriate but pain behaviour (e.g. inappropriate distorted posture or facial expression) was not rewarded with attention. They were informed that the exercises were progressive and they should start slowly and gently to avoid over-activity. They were also advised not to compete with other participants and that unaccustomed exercise may make muscles ache in all parts of their bodies, including their backs, but this was nothing to worry about. A distinction was made between hurt and harm. Each session included a warm-up, aiming to gradually increase the patients' heart rate, and general stretching exercises. A circuit of 15 progressive exercises,

which worked all large muscle groups, followed the warm-up. Participants spent one minute on each exercise either increasing the repetition or progressing the difficulty of the exercise over the four weeks. All exercises were demonstrated and checked throughout by a physiotherapist who supervised the class and participated when time permitted. Patients were given exercise sheets to record the number of repetitions achieved in each session, providing immediate

feedback. They were encouraged to improve their own record but not to compete with each other as participants' levels of physical ability were variable. The class finished with low impact aerobic exercise and further stretching and relaxation exercises. Participants were encouraged, from the beginning, to incorporate exercise into their daily routine and increase their regular levels of activity, taking up activities that they would find enjoy-

Table 1

Fitness programme circuit of exercises

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1. Static cycling
Start on low resistance (25–50 W) and approximately 65–70 rev/min. Record resistance.
Increase resistance, not speed.
 2. Free arm weights
Lying on your back with your arms by your side, lift right arm to left shoulder. Repeat with left arm.
Repeat above with weight. Increase and record weight for progression. This exercise should be done slowly.
 3. Alternate knee raising
Stand straight. Lift right knee to touch left hand and repeat lifting opposite knee. Record number of lifts.
Repeat the above, lifting knee higher to touch left elbow.
Increase speed of the exercise.
 4. Sit and stand
Sit on chair with arms crossed and stand up straight. Sit down again and repeat as often as possible. Record number of times you stand up.
Repeat the above with a medicine ball.
 5. Press ups
Stand with shoulders facing the wall with feet approximately 2 feet from it. Lean towards the wall and then push away keeping your back straight.
Record number.
Half press-up on the mat, on your knees keeping your back straight. Progress to full press up.
 6. Bridging
Lie flat on your back with your knees bent. Tighten stomach muscles, tilt your pelvis backwards by pressing your lower back onto the mat.
Hold this position and *slowly* lift hips off. Lower body *slowly* onto the mat.
 7. Step-ups
Step up and down onto shallow step. Record number of step-ups.
Progress onto deeper step and increase number of steps.
 8. Medicine ball lifts
Lie flat on your back with knees bent. Lift a small medicine ball up from your chest until your arms are straight and lower. Record number of lifts.
Repeat above with heavier ball and increase repetitions.
 9. Jogging on bouncer
Stand on bouncer and lift alternate feet slowly.
Increase speed until jogging on the bouncer.
 10. Rounding and hollowing
Start on the mat on your hands and knees. Tighten your stomach muscles and lower your head which should make your back flex or round.
Lift your head up and slowly let your back hollow and extend.
 11. Shuttle walking
Walk between markers on the floor. Record number of times you walk up and down.
Increase your speed.
 12. Arm raising
Standing with your arms by your side, raise alternate arms above your head. Record number of times you raise your arms.
Repeat above with weights and increase speed.
 13. Leg lifting
Lying with your upper body supported on the plinth (adjust plinth as necessary for your height), with feet on the floor, lift alternate legs off the ground.
Do not swing your legs.
Lift both legs together *slowly* so that both feet *just* lift off the ground.
 14. Stomach exercise
Lie on your back with your knees bent and arms by your side. Tighten stomach muscles, tilt your pelvis backwards by pressing your lower back onto the mat. Hold this position for 5 s and slowly relax.
Tighten stomach muscles, tilt your pelvis backwards by pressing your lower back onto the mat. Lift your head and shoulders and reach towards your knees with your hands. Slowly return to the starting position.
 15. Skipping rope exercise
Place the rope stretched out on the floor. Step over it from side to side.
Repeat above and increase speed
Skip using the rope. Try not to land heavily on your heels.
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able and satisfying. Instructions given to patients describing the circuit of exercises carried out in the class are given in Table 1.

2.3. Common treatment for control and fitness group

2.3.1. Specific exercises

Four individual exercises, judged to be clinically appropriate, were taught to all patients in the study and included a selection of the following: isometric abdominal strengthening exercises, spinal extensor strengthening exercises, passive flexion in supine, passive extension in prone lying, hamstring, iliopsoas, and quadriceps stretching and lower limb strengthening exercises. Patients were advised to remain active and continue with the exercises twice daily until their follow-up appointment 6 weeks later. They were seen briefly within 2–3 days to check that no problems had arisen and that they were carrying out the exercises as instructed.

2.3.2. Backschool

Patients in both groups attended the backschool programme which involved two 90-min sessions. These 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 entitled *Backfire* and practical workshops. The aim was to encourage a positive attitude and a return to normal activities. At the time the trial commenced this was thought to be an effective treatment for patients with chronic low back pain (Klaber et al., 1986). Further details of the backschool are described elsewhere (Klaber Moffett, 1990).

2.3.3. Statistical analysis

First, the differences between characteristics of the respondents and non-respondents were analysed using a *t*-test (adjusted for inequality of variance between the two groups if needed). Then an intention-to-treat analysis was carried out using all the data that were available from the respondents at the 2-year follow-up. Within group compar-

isons for change in disability in the treatment and control group were by paired *t*-test. Tests for differences in disability at the 2-year follow-up were by analysis of variance adjusted for the baseline scores (Snedecor and Cochran, 1980). Residual values were plotted against the predicted values to check for normal distribution, and only models with adequate fit are presented. Analysis was carried out using the statistical package SPSS for Windows version 6. Statistical significance was at the $P < 0.05$ level. Data are the mean and one standard deviation unless otherwise stated, and include 95% confidence intervals for treatment effect where appropriate.

3. Results

A total of 81 patients were recruited over a period of 18 months. Of these, ten patients (five from each group) did not comply with the protocol during the intervention phase and failed to return for the short term follow-up assessment. In the control group, two patients complained of increased pain following randomisation, one had an exacerbation of a chronic chest complaint, one sought chiropractic treatment, and one failed to attend the second assessment for unknown reasons. In the fitness group, two complained of increased pain after the first fitness session and did not return for the short term follow-up assessment, one patient was unable to attend due to family bereavement and two patients were unable to attend due to an unexpected increase in work commitments. There was an 86% attendance rate for patients who were randomised to the fitness group. Following the first post treatment blinded assessment (6 weeks after randomisation), 12 patients changed from the control group to the fitness group. The effect of this was to weaken the power of the sample but the results of intention-to-treat analysis still demonstrated statistically significant results in favour of the fitness programme at 6 weeks and at 6 months (Frost et al., 1995).

At the 2-year follow-up, of the 81 patients included in the trial, four patients (university members) had moved out of the area and were not traceable, and 15 failed to respond to

Table 2

Baseline characteristics of patients in the respondent and non-respondent group

	Respondents (<i>n</i> = 62)	Non-respondents (<i>n</i> = 19)
Number in fitness group	31	10
Number in control group	31	9
Age (mean ± SD)	37.7 ± 9.3	34.6 ± 10.6
Females	34	8
Males	28	11
Baseline pain score (0 = no pain, 100 = maximum pain) (mean ± SD)	22.4 ± 20.2	24.9 ± 22.6
Duration since initial onset of LBP (months, mean ± SD)	112.4 ± 91.0	98.2 ± 94.5
Baseline Oswestry Disability Index (mean ± SD)	23.5 ± 11.5	21.9 ± 11.0

LBP, lower back pain.

Table 3

Difference in baseline characteristics of patients in the fitness and control group who returned the 24-month follow-up questionnaire

	Fitness	Control
Age	35.4 ± 9.1 (20–53)	40.2 ± 9.2 (22–57)
Females	17	17
Males	14	14
Duration of LBP since initial onset (months)	114.0 ± 91.7 (7–300)	110.0 ± 94.0 (7–360)
Baseline Oswestry Low Back Pain Disability Index	23.1 ± 9.5 (2–46)	24.6 ± 12.8 (4–52)
Baseline pain score (0 = no pain, 100 = maximum pain)	22.2 ± 17.9 (0–55)	22.5 ± 22.2 (0–90)

LBP, lower back pain. Scores are presented as the mean ± SD and range (in parentheses).

further contact for unknown reasons. The response rate at 2 years was 76% resulting in 62 respondents (31 treatment, 31 control) and 19 non-respondents (10 treatment, 9 control). Non-respondents were on average younger, slightly less disabled and had a shorter duration of low back pain. The differences between respondents and non-respondents are given in Table 2. None of the differences were statistically significant. The characteristics of the respondents in the treatment and control group are given in Table 3. There were no significant differences between the treatment and control groups in distribution of sex, age and duration of symptoms and pain at initial assessment. Also, there were no differences between the baseline scores on the Oswestry Low Back Pain Disability index. The Oswestry Low Back Pain Disability scores for the treatment and control group at the two year follow-up are shown in Table 4. Within group comparisons are reported first. Patients in the intervention group demonstrated a mean reduction of 7.7% (95% confidence interval of mean paired difference 3.9, 11.6 $P < 0.001$), whereas the reduction was only 2.4% in the control group (95% confidence interval of mean paired difference –2.0, 6.9 $P > 0.05$). Between group comparisons demonstrated a statistically significant difference in the Oswestry Low Back Pain Disability scores between the treatment and control group at the $P < 0.04$ level (mean difference 5.8, 95% confidence interval 0.3, 11.4).

4. Discussion

Long-term results of randomised controlled trials, of intervention aiming to reduce disability associated with low back pain, are rarely reported. A difference of 5.8% between the control and intervention group was shown in this study which has been considered to be a clinically significant difference in a previous study (Meade et al., 1990). A difference of 4% on a single item of the ten-section questionnaire could be as follows: no pain compared with moderate pain; or moderate pain compared with very severe pain; or able to sit for 'up to 1 h' compared with 'less than 10 min'. The patients were, on average, moderately disabled by their back pain with scores ranging from 2 to 58% on the Oswestry Low Back Pain Disability Scale at baseline. A larger treatment effect may have been noted

with an alternative outcome measure more sensitive to minor disability (Beurskens et al., 1995).

A number of limitations of the study should be noted. It would have been preferable to include all the outcome measures taken at the baseline assessment but this was not possible. This was due mainly to financial constraints as no funds were available to assess the patients in hospital or in their own homes at the long-term follow-up.

The statistical power of the study was limited by the sample size and the attrition rate, although this would make it more likely that a type II statistical error occurred. Every attempt was made to reduce any potential bias caused by the assessor and data collector. At the short-term follow-up, all data collection was carried out by a single assessor blinded to the treatment allocation. At the long-term follow-up the data were collected by post after the patients had completed the questionnaires at home, which reduced any potential assessment bias. An intention-to-treat analysis was chosen to reduce bias that may be caused by selectively excluding data (Pocock, 1983).

Adherence to the home exercise programme was not measured at the short or long-term follow-up although it is known to be poor in unsupervised exercise (Deyo et al., 1990). Compliance with exercise is difficult to obtain but could have been improved with the use of behavioural techniques which may have enhanced the intervention in both groups (Sluijus and Knibbe, 1991).

The results could be attributed to the supervised exercise attended by patients in the fitness group or simply due to a placebo affect of additional treatment sessions. Inclusion of a third placebo group would have been interesting but finan-

Table 4

Oswestry disability index of patients who returned questionnaires 24 months after treatment

	Pre-treatment % score	After 6 months % score	After 2 years % score
Fitness (<i>n</i> = 31)	23.1 ± 9.5 (2–46)	16.0 ± 9.2 (0–38)	15.4 ± 11.3 (0–52)
Control (<i>n</i> = 31)	24.9 ± 12.8 (4–48)	21.7 ± 14.2 (0–50)	22.5 ± 15.4 (2–64)

Lower scores represent less disability. Scores are presented as the mean ± SD and range (in parentheses).

cially impractical in this study. Finally, the confidence interval of the differences between the groups was wide, indicating large variations in the treatment effect and consequently conclusions are drawn with caution.

Exercise can take many forms and we have demonstrated benefits of a general non-specific fitness programme designed for patients with chronic low back pain. The patients were supervised and exercising in groups which were likely to help improve their motivation and compliance with the exercises. The intervention may have encouraged behavioural changes resulting in patients becoming more active although this theory would need to be assessed in a further study taking into account adherence to exercise following the supervised programme. Two recently published trials (Faas et al., 1993; Malmivaara et al., 1995) concluded that gentle non-specific exercise had no benefit for patients with acute low back pain. Faas et al. (1993) evaluated a programme consisting of a set of eight exercises which were non-specific gentle bed exercises, including two resting positions. This exercise programme differs significantly from that reported in our study with regard to the philosophy of treatment and type of back pain. Malmivaara et al. (1995) evaluated an exercise programme in which patients were advised to perform gentle exercises in the form of back extension and lateral flexion ten times every day. Gentle exercise, as evaluated in these other studies, may encourage the individual to be cautious or think of themselves as disabled and do not encourage patients to be more generally active. Often psychological processes are overlooked when treating low back pain although they are known to play a major role in the patients' recovery (Rose et al., 1992; Burton et al., 1994). In contrast, the fitness programme we have described enables participants to rediscover normal movement and aims at improving the individual's confidence in their spine. It utilised cognitive behavioural principles and encouraged patients to improve their general fitness in order to return to their normal activities.

The fitness programme was cheap and simple to establish and could be adapted depending on facilities and equipment available. It is most likely that the specific exercises themselves are not as important as the general philosophy of encouraging normal movement with an aim to increase general fitness without unduly stressing the spine. We have provided some evidence for clinical effectiveness in the long-term but a full cost effectiveness analysis is necessary to confirm the benefits of this treatment approach.

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