SPINE Volume 32, Number 15, pp 1578–1585

Active Exercise, Education, and Cognitive Behavioral Therapy for Persistent Disabling Low Back Pain

A Randomized Controlled Trial

Ruth E. Johnson, PhD,* Gareth T. Jones, PhD,† Nicola J. Wiles, PhD,‡ Carol Chaddock, DipGrad,§ Richard G. Potter, MBBS,§ Chris Roberts, PhD,‖ Deborah P. M. Symmons, MD,‖ Paul J. Watson, PhD,¶ David J. Torgerson, PhD,** and Gary J. Macfarlane, MD†

Study Design. A randomized controlled trial.

Objectives. To determine 1) whether, among patients with persistent disabling low back pain (LBP), a group program of exercise and education using a cognitive behavioral therapy (CBT) approach, reduces pain and disability over a subsequent 12-month period; 2) the cost-effectiveness of the intervention; and 3) whether *a priori* preference for type of treatment influences outcome.

Summary of Background Data. There is evidence that both exercise and CBT delivered in specialist settings is effective in improving LBP. There is a lack of evidence on whether such interventions, delivered by trained individuals in primary care, result in improved outcomes.

Methods. The study was conducted in nine family medical practices in East Cheshire, UK. Patients 18 to 65 years of age, consulting with LBP, were recruited; those still reporting LBP 3 months after the initial consultation were randomized between the two trial arms. The intervention arm received a program of eight 2-hour group exercise session over 6 weeks comprising active exercise and education delivered by physiotherapists using a CBT approach. Both arms received an educational booklet and audio-cassette. The primary outcome measures were pain (0–100 Visual Analogue Scale) and disability (Roland and Morris Disability Scale; score 0–24).

Results. A total of 196 subjects (84%) completed follow-up 12 months after the completion of the intervention program. The intervention showed only a small and nonsignificant effect at reducing pain (−3.6 mm; 95% confidence interval, −8.5, 1.2 mm) and disability (−0.6 score; 95% confidence interval, −1.6, 0.4). The cost of the intervention was low with an incremental cost-effectiveness ratio of £5000 (U.S. $8650) per quality adjusted life year. In addition, patients allocated to the intervention that had expressed a preference for it had clinically important reductions in pain and disability.

Conclusions. This intervention program produces only modest effects in reducing LBP and disability over a 1-year period. The observation that patient preference for treatment influences outcome warrants further investigation.

Key words: randomized controlled trial, back pain, exercise, behavioral therapy, preference. **Spine 2007;32: 1578–1585**

Back pain is one of the most common and costly health complaints, with 7% of the U.K. adult population consulting their general practitioner (GP) for low back pain (LBP) each year.[1] Further, recent evidence has shown that up to half of patients consulting their GP with a new episode of LBP will continue to experience pain and disability 3 months later.[2] It is important that, when acute symptoms have not resolved, delay in intervention is avoided. However, given the magnitude of the problem and the scarcity of resources in secondary care, it is preferable that any intervention for patients with persistent LBP is delivered in a primary care setting. Further, it must be acceptable and convenient to patients and cost-effective.

Chronic LBP and associated disability is multifactorial in etiology and best understood with a biopsychosocial model.[3] Studies have demonstrated that the main determinants of disability in LBP are psychosocial and changes in psychosocial factors appear to be key in the reduction of reported disability in people undergoing physiotherapy exercise programs.[4–6] Previous studies have demonstrated that a cognitive behavioral approach to the management of musculoskeletal pain is effective in reducing disability[7,8] and reducing the time taken to return to work.[9,10] A recent Cochrane review concluded, overall, that there was evidence that behavioral therapy was superior to waiting-list-controls in terms of short-term pain relief. Most of these studies involved the delivery of care in specialist settings and were evaluated as of low methodologic quality.[11] There has been no research into the effect of such a treatment approach using trained

From the Divisions of *Clinical Psychology, Medical School, University of Manchester, Manchester, UK; †Aberdeen Pain Research Collaboration, Epidemiology Group, University of Aberdeen, Aberdeen, UK; ‡Academic Unit of Psychiatry, Department of Community Based Medicine, University of Bristol, Bristol, UK; §Eastern Cheshire Chronic Pain Management Service, Eastern Cheshire Primary Care Trust, Macclesfield, UK; ‖Epidemiology and Health Sciences, Medical School, University of Manchester, Manchester, UK; ¶University Department of Anaesthesia, Critical Care and Pain Management, University of Leicester, Leicester, UK; and **York Trials Unit, Department of Health Sciences, University of York, York, UK.

Acknowledgment date: July 20, 2006. First revision date: October 6, 2006. Acceptance date: October 10, 2006.

Supported by the Arthritis Research Campaign, Chesterfield, UK and the Epidemiology Unit at the University of Manchester, UK.

The manuscript submitted does not contain information about medical device(s)/drug(s).

Charity funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

Address correspondence and reprint requests to Gary J. Macfarlane, MD, Epidemiology Group, Department of Public Health, Medical School, University of Aberdeen, Polwarth Building, Foresterhill, Aberdeen, UK AB25 2ZD; E-mail: g.j.macfarlane@abdn.ac.uk

individuals in primary care when symptoms have proved resistant to normal management.

Physiotherapists commonly treat LBP in the primary care setting where access to psychological services might be restricted. Training physiotherapists to perform cognitive behavioral therapy (CBT)-oriented programs is attractive, and there has already been research using individual therapy.[12] Enabling physiotherapists to conduct group sessions has the potential to offer improved cost-effectiveness of treatment programs.

Our main aim was therefore to evaluate the hypothesis that, among patients with persistent disabling LBP 3 months after initial GP consultation, a 6-week community-based group intervention program based on active exercise and education using a CBT approach results in a reduction in pain and disability over the subsequent 12-month period, in comparison to usual GP care supplemented with educational material. In addition, we aimed to determine the cost-effectiveness of the intervention and to examine whether *a priori* patient preference for type of treatment influenced outcome.

■ Materials and Methods

The trial was set in nine general practices in East Cheshire, UK. Ethical approval was granted by the South Cheshire Local Research Ethics Committee (LREC Number M134/01). The trial was registered on the International Standard Randomized Controlled Trial Number System (ISRCTN-89801482) and on http://www.controlled-trials.com.

Study Population. Patients, 18 to 65 years of age, consulting their GP with LBP between January 2002 and July 2003, were invited to take part in the study. Initial patient recruitment was conducted, either directly by the GP during the consultation or by identifying patients in weekly searches of practice computer records and mailing invitation letters on behalf of the GP. Criteria for exclusion were also checked in medical records, *i.e.*, consultation for LBP in past 6 months, "red flags" indicating signs of serious pathology,[13] pregnancy or recent childbirth, major rheumatologic, neurologic, neoplastic, or other conditions that may prevent full participation in the intervention, previous spinal surgery, major psychiatric illness diagnosed or such symptoms under investigation, or a history of drug or alcohol abuse in past 5 years.

Irrespective of method of recruitment, patients were given the same study information sheet and asked for their consent to be contacted again, by questionnaire, 3 months after their GP consultation. This questionnaire assessed LBP using a 100-mm visual analogue scale (VAS) and disability using the Roland and Morris Disability Questionnaire (RMDQ), which provides a scale score of 0 (no disability) to 24.[14] In addition, various demographic characteristics were assessed, as was psychologic distress using the 12-item General Health Questionnaire (GHQ),[15] general health using the EuroQol EQ-5D,[16] and healthcare usage. The GHQ has previously been demonstrated to be a powerful predictor of both the onset and outcome of an episode of LBP.[17,18] Each item is scored from 1 (low level of distress) to 4 (high level of distress), giving a total score of 12 to 48. The EQ-5D scale ranges from 1 (perfect health) to 0 (dead). Healthcare usage data included care from GPs (number of consultations), prescribed and nonprescribed medication usage, care from NHS hospitals (emergency, nonemergency admissions, outpatient visits, other visits), and private treatments (hospital admissions or visits to other healthcare professionals).

At 3 months, persons reporting persistent disabling LBP, defined as a pain score of ≥20 mm or more (100-mm VAS) and a RMDQ disability score of ≥5, were invited to attend a pretrial assessment visit, where trial eligibility was verified by a study physiotherapist. These therapists also took consent for enrollment in the trial. Participants were then randomized to one of two treatment groups at the University of Manchester, by means of a computer-generated code, by a researcher independent of the assessment process. Patients were allocated using a stochastic minimization procedure to ensure trial arms were comparable for gender, prior history of back pain (yes/no), and level of psychologic distress (>22 GHQ). This cutoff has previously been demonstrated to identify a group at high risk of persistent symptoms.[18] Patients were contacted within 48 hours of randomization to inform them of their treatment allocation and for the exercise/CBT group to book them into the next session.

Given the nature of the interventions, it was not possible to blind subjects or staff to treatment allocation. Thus, to assess the possible influence of treatment preference on LBP outcome, after an explanation of each treatment arm and before randomization, each participant was asked whether they had a preference for which intervention they may be allocated.

Interventions. Both groups were mailed an educational pack containing a booklet and audio-cassette. Both contained advice on self-management suitable for patients with persistent LBP. There were nine "leaflets" in the booklet: pain and activity; pacing; goal setting; stress; posture and body mechanics; guidelines for sleep hygiene; beds and sleeping; flare-up plans; when to see your GP. The comparison arm received no further intervention and continued to be treated as usual according to their GP.

Those randomized to the active intervention were invited to attend a community-based treatment program, consisting of eight 2-hour group sessions over a 6-week period. Each group comprised between 4 and 10 participants and was led by 2 physiotherapists. The objectives of the intervention were to:

- Introduce and develop awareness of the concept of managing back pain through focusing on resumption of activity;
- Enable the patient to achieve independent control of their back pain through the use of physical exercise and psychological self-help techniques;
- Encourage and assist patient return to normal activities/work; and
- Prepare patients to independently manage subsequent episodes of back pain and improve levels of activity.

The main features of the program included problem solving, pacing and regulation of activity, challenging distorted cognitions about activity and harm, and helping patients to identify helpful and unhelpful thoughts about pain and activity. This was achieved through group discussion, the use of case vignettes, and practical (physical) activities. Further details of how the objectives were met and an overview of the 8 treatment sessions are given in Appendix 1 (available online through Article Plus). Each session began with a review of the previous session and each included a period of exercise. The course included key features of a cognitive behavioral approach to en-

couraging the self-management of back pain.[19] In addition to the sessions, patients were required to set their own homework each week to practice skills and take part in behavioral experiments at home. Homework was individualized but typically included paced activity programs, engagement in previously avoided activities of daily living, and resumption of a ceased leisure activity or hobby. Monitoring thoughts associated with pain and recognizing helpful and unhelpful thoughts associated with these simple behavioral experiments were also included. Homework was assessed and discussed at the beginning of each session and followed up the problem solving sessions where necessary.

Treatment Fidelity. The team of therapists who delivered the intervention were trained to competencies designed to be applicable to the needs of nonpsychologists managing musculoskeletal pain conditions in the primary care setting. The training was led by a physiotherapist experienced in cognitive behavioral treatment approaches to pain management (P.J.W.) and comprised four classroom days on the principles of CBT for LBP, and reflective practice.

Treatment fidelity was assessed by an independent rating of audio-recordings of the group sessions. A purposive sample of 15 recordings was made (with the participants' consent) such that there were recordings from each of the sessions and including each of the physiotherapists. These recordings were then assessed by two external and independent examiners experienced in the field of delivering cognitive behavior therapy. A checklist of "desirable" CBT principles was developed and the audio-recordings were assessed for "no evidence," "some evidence," or "clear evidence" that these principles were being adhered to in the treatment sessions.

Outcomes. Participants were sent a postal questionnaire 3, 9, and 15 months postrandomization, approximating to the end of intervention, 6, and 12 months post-treatment. Primary clinical outcomes were pain severity (100-mm VAS) and disability (RMDQ). In addition, general health was assessed using the EQ-5D.

Sample Size. A minimum clinically important difference of 3 points in the RMDQ was used for the sample size calculation, as has been previously recommended.[20] Based on previous data among persons consulting with back pain,[18] a within-group standard deviation of 6 RMDQ points was assumed, and a correlation between baseline and follow-up scores was 0.67. A study with 84 subjects per arm would have 90% power to detect a 3-point difference using a two-tailed test and 5% significance level. This would also detect a 12-mm difference in pain score.

Statistical Methods. Treatment effect with 95% confidence interval (CI) was estimated at each of the three follow-up stages for the primary outcomes, pain VAS and RMDQ, separately, using analysis of covariance, adjusting for baseline pain, RMDQ, age, gender, LBP history, and psychological distress (GHQ). All analyses were conducted according to "intention to treat" (ITT) principles. Because of the method of delivery of the intervention, there may have been clustering within groups.[21] Random effect models were used to control for any potential "group effect," from which the intracluster correlation coefficient was estimated. In addition to the three cross-sectional analyses, a longitudinal analysis of treatment effect across the whole follow-up period was carried out. Generalized linear latent and mixed models were used: 1) to determine whether there was evidence of a random gradient (*i.e.*, whether change over time varied from one individual to another); 2) to investigate time by treatment interaction; 3) to estimate overall treatment effect; and 4) to examine whether any time trend in outcome was evident, regardless of treatment.

A preplanned subgroup analysis was carried out to investigate the influence of prior patient treatment preference on treatment effect.

Economic Analysis. The cost of health care was calculated for each patient who provided healthcare utilization data at all three follow-up stages (as detailed above). In addition, we collected information on aids or equipment purchased by the individual because of their back pain. For comparability, we costed the same health resources as a recent major U.K. back pain trial,[22] updated for 2003 to 2004 prices.[23] Private care costs were obtained from the same major insurance provider (www.bupahospitals.co.uk/asp/paying/priceguides.asp; accessed October 11, 2005). Costs of delivering the interventions were added and the mean cost per trial arm calculated. The EuroQol (EQ-5D) instrument measuring health-related quality of life was used as the health outcome for the economic analysis.[16] Quality-adjusted life years (QALYs) were estimated by calculating "area under the curve." A bootstrapping technique was used to estimate the mean difference between trial arms in both costs and QALYs using 1000 repetitions. Costs and QALYs were adjusted so they covered a 12-month and not a 15-month period. These estimates were then used to generate the cost effectiveness acceptability curve.

Because decision makers, whether they are individual clinicians or policy makers, have to choose a treatment option for a patient (even if this is no treatment), we should choose the treatment that is most likely to be cost-effective, whether or not this is statistically significant. Therefore, the economic approach does not rely on traditional tests of statistical significance. Rather, the cost-effectiveness of a treatment decision is based on average cost-effectiveness ratios. The uncertainty around our choice can be portrayed through either using confidence intervals or, using cost-effectiveness acceptability curves. A cost-effectiveness acceptability curve allows a decision maker to look at the level of uncertainty associated with a "willingness to pay" value for each increment in health gain: in this instance a QALY.

■ Results

Participant Flow

A total of 2068 potentially eligible patients consulted a GP with LBP in one of the nine participating general practices between January 2002 and July 2003 (Figure 1). A total of 61% of these individuals agreed to take part in the study, of whom 92% subsequently completed the 3-month post-GP consultation questionnaire. At this time, 39% of participants were identified as having persistent disabling LBP (≥20 mm pain VAS and ≥5 RMDQ). A total of 280 patients completed a pretrial assessment and 234 were found to be eligible, consented, and were randomized, 116 to the intervention arm. Follow-up questionnaires were returned by 95% of partici-

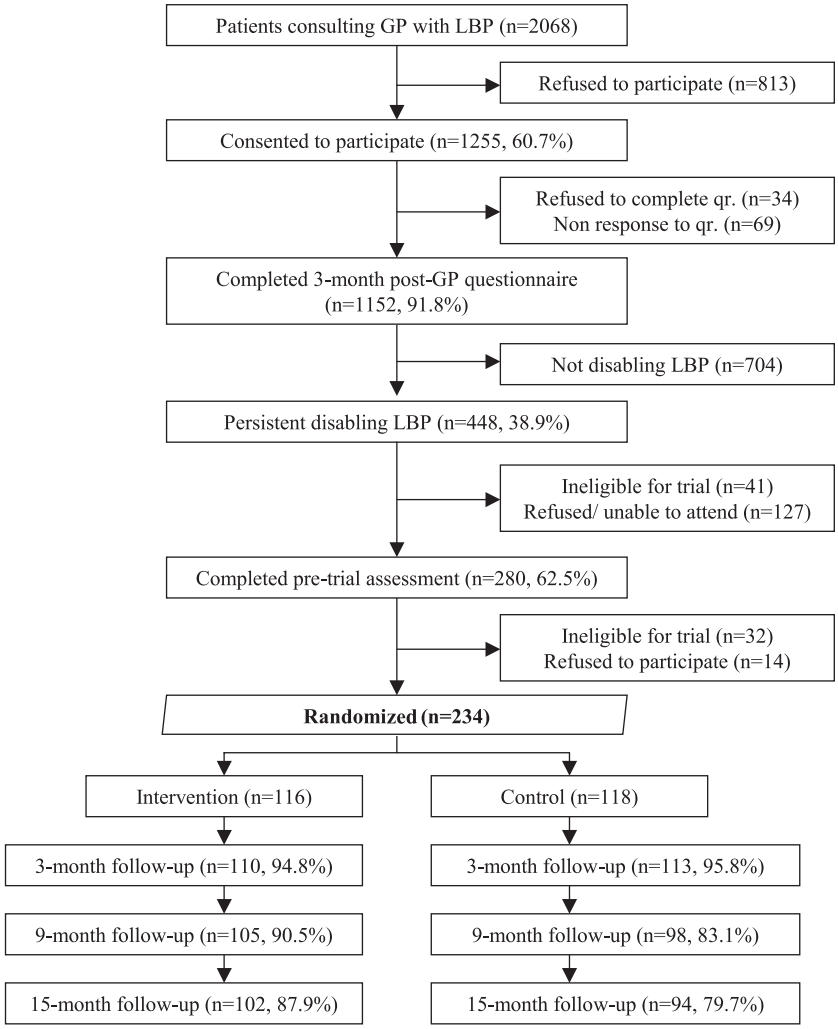

Figure 1. Flow of participants from recruitment to follow-up. Values are % followed-up of 116 and 118 randomized individuals, respectively.

pants at 3 months, 87% at 9 months, and 84% at 15 months (Figure 1).

Patients who refused to participate were compared with those who consented. Consenters at the initial GP recruitment stage (n = 1255) were older (median difference, 6 years; 95% CI, 5 to 7 years) and included more females (difference, 8%; 95% CI, 4% to 12%) than nonconsenters (n = 813). Subsequently, patients who returned the 3-month post-GP questionnaire (n = 1152) were also older and included more females than those who failed to return it (n = 103). However, females were less likely to attend a pretrial assessment. Otherwise, groups were similar with respect to age, pain, and disability. Among those attending the assessment, there were no significant differences between those who agreed to be randomized (n = 234) and those who refused (n = 14). In summary, there were a few small differences between patients who did and did not participate in the study, but there were no major threats to external validity.

For patients randomized, the demographic characteristics of the two trial arms were similar (Table 1).

Analysis of Treatment Effect

Pain and disability outcome scores for both groups can be seen in Table 2. Both groups demonstrated a substantial reduction in pain over the course of follow-up: in the intervention group pain reduced from 44.9 mm to 27.9 mm on the VAS, while in the control group pain reduced from 51.6 mm to 36.4 mm. Since adjusting for potential clustering of patients within treatment groups showed no evidence of a group effect, effect estimates are presented without such adjustment. However, there was some ev-

Table 1. Baseline Characteristics of Participants

	Intervention Arm (n = 116)	Control Arm (n = 118)
Demographics		
Age (yr) [mean (SD)]	47.3 (10.9)	48.5 (11.4)
Female gender [no. (%)]	71 (61)	69 (58%)
Married/living as married [no. (%)]	85 (73)	86 (73%)
Paid employment [no. (%)]	79 (68)	78 (66%)
Routine and manual occupations [no. (%)]	33 (28)	32 (27%)
Clinical factors		
Pain intensity (VAS) [mean (SD)]	44.9 (18.2)	51.6 (22.9)
Disability (RMDQ) [mean (SD)]	10.6 (3.9)	10.9 (4.0)
Episode duration before GP consultation <1 mo [no. (%)]	63 (54)	45 (38)
History of LBP [no. (%)]	104 (90)	103 (87)
Psychological distress (GHQ ≥22) [no. (%)]	96 (83)	96 (81)
General Health (EuroQol EQ-5D) [mean (SD)]	0.66 (0.22)	0.64 (0.22)

Table 2. Outcomes at 3, 9, and 15 Months

	Intervention Arm		Control Arm		Treatment Effect* [difference (95% CI)]
	n	Mean (SD)	n	Mean (SD)	
Primary outcomes					
Pain (VAS)					
Baseline	116	44.9 (18.2)	118	51.6 (22.9)	—
3-mo follow-up	110	29.1 (24.5)	113	35.3 (26.7)	−2.44 (−8.43 to 3.56)
9-mo follow-up	105	26.1 (23.5)	98	35.0 (28.4)	−4.60 (−11.07 to 1.88)
15-mo follow-up	102	27.9 (26.1)	94	36.4 (27.3)	−5.49 (−12.43 to 1.44)
Longitudinal					−3.63 (−8.48 to 1.23)†
Disability (RMDQ)					
Baseline	116	10.6 (3.9)	118	10.9 (4.0)	—
3-mo follow-up	110	7.4 (5.3)	113	8.0 (5.3)	−0.31 (−1.50 to 0.88)
9-mo follow-up	105	6.5 (4.7)	98	8.0 (5.4)	−1.09 (−2.28 to 0.09)
15-mo follow-up	101	6.7 (5.6)	94	8.0 (5.5)	−0.93 (−2.30 to 0.45)
Longitudinal					−0.60 (−1.59 to 0.40)†
Secondary outcome					
General health (EQ-5D)					
Baseline	116	0.66 (0.22)	118	0.64 (0.22)	—
3-mo follow-up	98	0.75 (0.18)	87	0.70 (0.25)	0.05 (−0.01 to 0.11)
9-mo follow-up	88	0.75 (0.24)	86	0.71 (0.25)	0.03 (−0.05 to 0.10)
15-mo follow-up	89	0.75 (0.23)	81	0.71 (0.23)	0.03 (−0.04 to 0.09)
Longitudinal					0.04 (−0.01 to 0.09)†

*Effect of intervention adjusted for baseline pain, disability, age, gender, LBP history, and psychological distress estimated by analysis of covariance at each follow-up stage.
†Effect of intervention across the 15 mo follow-up period estimated by GLLAM adjusting as above.

idence that change over time in outcome varied from one individual to another; therefore, models are presented accounting for a random gradient. There was, however, no evidence of an interaction between treatment effect and time.

The intervention group experienced only a small reduction in pain and disability relative to the control group, effects that were not statistically significant (Table 2). Across the 15 months following randomization, there were no significant differences in outcome between the intervention and control arms: intervention reduced pain scores by 3.6 mm (95% CI, −8.5 to 1.2) relative to the control arm, and RMDQ by 0.6 points (−1.6 to 0.4). There was no trend in the change in pain and disability scores over the follow-up period. The intervention produced a modest improvement in general health compared with the control: EQ-5D score 0.04 (−0.01 to 0.09).

Patient Preference

Before randomization, 114 (49%) patients had stated a preference to receive the intervention, 20 (8%) the control, and 100 (43%) were indifferent. A significant interaction between patient preference and treatment effect was found at 9- and 15-month follow-up (Table 3). Patients allocated to the intervention who had a preference for it had clinically important reductions in pain and disability, whereas patients who had a preference for the control (although in the minority) had a poorer outcome if they received the intervention. For those with no preference, there was little effect of the intervention.

Economic Analysis

Patients providing healthcare utilization data (n = 149; n = 78 intervention arm) were entered in a cost-utility analysis. The mean difference in cost was £27 (U.S. $47)* higher in the intervention arm (95% CI, −159 to 213). The mean incremental cost-effectiveness ratio was £5000 (U.S. $8650) per QALY. The cost-effectiveness acceptability curve (Figure 2) shows that there was about a 90% probability that the treatment produced a cost per QALY of £30,000 (U.S. $51,900) or less.

Treatment Fidelity and Compliance

The results of the two independent assessors of treatment fidelity can be seen in Table 4. They concluded that: "CBT principles were, for the most part, applied by physiotherapists in this trial. The teaching notes prepared for each session were adhered to and the topics were covered in detail. At times, however, it was evident that the therapists found it difficult to adopt the communication style characteristic of a CBT approach and some methods, including challenging patients' beliefs and fears, were limited." It is clear from Table 4 that for most components there was "some" evidence of them being present in each session.

Regarding compliance to the interventions, 63% of participants allocated to the group sessions attended at least half of these sessions. In addition, at the time of final follow-up, among patients assigned to the intervention and control arms, 95% and 94% reported having read the educational booklet respectively, while 86% in both groups reported having listened to the audiotape.

■ Discussion

We have demonstrated that, among persons with persistent disabling LBP, an intervention comprising active ex-

*Exchange rate of £1 = $1.73 has been used.

Table 3. Treatment Effect Adjusting for Patient Preference

	Treatment Effect (95% CI)*		
	No Preference (n = 100)	Prefer Intervention (n = 114)	Prefer Control (n = 20)
Pain (VAS)			
3-mo follow-up	−0.28 (−9.63, 9.06)	−4.70 (−17.45, 8.06)	7.69 (−17.50, 32.89)
9-mo follow-up	−0.33 (−10.16, 9.50)	−12.61 (−26.01, 0.80)	16.57 (−9.24, 42.37)
15-mo follow-up	−1.24 (−11.77, 9.30)	−11.74 (−26.18, 2.70)	14.97 (−13.60, 43.54)
Disability (RMDQ)			
3-mo follow-up	0.08 (−1.78, 1.93)	−1.18 (−3.71, 1.36)	1.69 (−3.32, 6.69)
9-mo follow-up	−1.25 (−3.04, 0.55)	−0.81 (−3.25, 1.64)	5.44 (0.73, 10.14)
15-mo follow-up	0.13 (−1.96, 2.21)	−2.81 (−5.66, 0.04)	4.03 (−1.60, 9.65)

*Interaction term for trial arm and preference, modification of the treatment effect for no preference group.

ercise and education, delivered using a CBT approach, produces small nonsignificant improvements over the 15 months following randomization into the study (3.6 mm in pain and 0.6 RMDQ points) compared with education alone. A modest improvement was found in the secondary outcome of general health. However, the effect of the intervention was modified by *a priori* patient preference: the greatest improvement was evident in those who wished to receive it, no effect was seen in those who did not have a preference, and a worsening of symptoms in those who had preferred only to receive the control intervention.

There are a number of methodologic issues that need to be addressed in interpreting the findings of this study. First, one must consider whether there was any bias due to loss to follow-up; this is a possibility, but unlikely, since response rates to the follow-up questionnaires were high (95%, 87%, and 84% at 3, 9, and 15 months, respectively). Pain and disability in the control arm at 3-month follow-up were lower for patients who subsequently dropped out at 9 months; this may explain the slight increase in effect at 9 months.

Second, compliance to the intervention was modest: 63% of subjects allocated to the intervention attended at least half (4 of 8) of the sessions. The effect of noncompliance is a dilution of the treatment effect shown by an ITT analysis, such that the effect in true compliers is a multiple of this effect. Only a small effect was shown by ITT; even if this were multiplied to give an estimate of the effect in compliers alone, the effect would still be relatively small.

Third, patients in the trial had relatively mild LBP at baseline; ≥20 mm pain and ≥5 RMDQ points. It may have been unrealistic to expect the intervention to yield substantial reductions in these patients. However, although the trial entry criteria, above, were fairly low, the mean pain and disability was considerably greater than this: 45 and 52 mm, and 10.6 and 10.9 points in the intervention and control groups, respectively. Further, additional analysis showed that treatment effect was no different in patients with more severe LBP within the participating group (data not shown).

Fourth, this was a pragmatic trial and evaluated an intervention delivered in a primary care setting by existing staff. A team of physiotherapists were trained in the principles and techniques of CBT to enable them to conduct the intervention. However, the question remains as to whether brief training in these techniques is sufficient to bring about clinically significant change. A recent study by Jellema *et al*[24] demonstrated that brief training in psychosocial assessment and treatment of back pain delivered to GPs did not improve outcome over usual care for back pain. The authors postulated that this might be attributed to ineffective implementation of the intervention, but further work is necessary. Similarly, although an independent review of treatment fidelity in the current study concluded that the main elements of a cognitive behavioral management program were adhered to in the treatment sessions, it is clear that these elements were not delivered optimally. It may be, therefore, that expecting nonbehavioral therapists to incorpo-

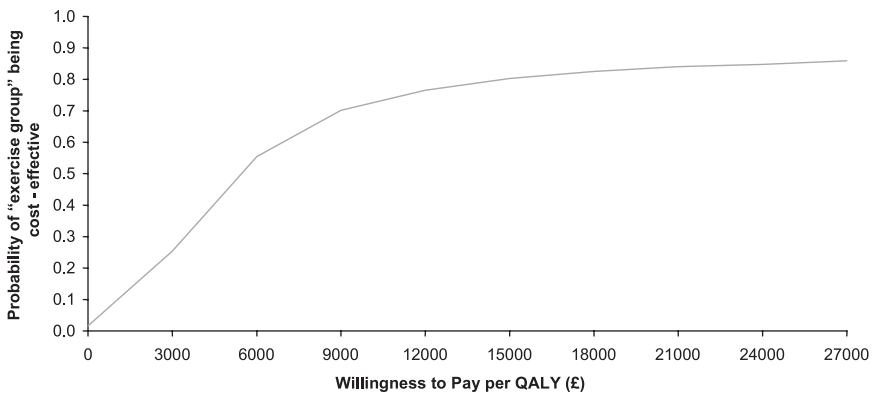

Figure 2. Cost-effectiveness acceptability curve.

Table 4. Assessment of Intervention CBT Content

Checklist of CBT Content	Level of Evidence (no. of sessions*) None	Some	Clear
Patients expectation of treatment	15	0	0
Explanation of CBT	4	11	0
Exploration of beliefs	8	5	2
Challenging evidence presented	4	10	1
Reinforcement	7	6	2
Coping strategies	6	2	7
Techniques for changing behavior	0	1	14
Identifying anxieties/fears	11	4	0
Reducing catastrophizing thoughts and feelings	5	5	5
Information given by physiotherapists	0	8	7
Homework	3	12	0
Regular progress reports	0	7	8
Pain diaries/self-reported measures	9	5	1
Planning, prioritizing and pacing activities	1	11	3
Goal setting	4	4	7
Flare-ups	9	1	5
Problem solving	3	8	4
Principles of collaboration	0	11	4

*Fifteen sessions assessed in total.

rate such aspects into their treatment delivery with only a brief training program is not realistic.

Finally, despite the limited clinical effectiveness, the intervention was found to have a relatively low cost: approximately £5000 (U.S. $8650) per QALY. We did not evaluate costs from a societal perspective, *i.e.*, indirect costs.

This trial is complementary to recent trials that have evaluated similar interventions. The U.K. BEAM study was a large multicenter factorial trial that compared exercise, manipulation, and "best care" in general practice for back pain that does not resolve spontaneously.[25] The comparison of exercise and best care in U.K. BEAM (648 subjects) relates to the comparison in our trial. An eight-session program of exercise led by physiotherapists trained in the use of CBT principles produced a 1.4-point improvement in RMDQ score relative to best care at the 3-month follow-up, although this reduced to 0.4 points by 12 months. The cost-effectiveness of this intervention was also very close to the current trial.[22] The York Back Pain trial has shown that a very similar intervention program reduced disability by 1.4 RMDQ points relative to usual GP care at the 6- and 12-month follow-up.[26] More recently, a trial attempting to replicate the York trial in a more deprived area found small, not statistically significant, gains in RMDQ of 0.87 and 0.77 at 3 and 12 months, respectively.[27] The current trial demonstrated effects of comparable size, 1.1 and 0.9 RMDQ points at approximately 9 and 15 months following randomization (6 and 12 months after the end of the intervention).

Other studies evaluating interventions in primary care have also shown little clear benefit for alternative management strategies. A trial conducted in Dutch general practices compared an intervention aimed at addressing identified adverse psychosocial factors among back pain consulters with usual care and demonstrated no difference in disability outcome (again, using the RMDQ) over 12 months.[24] A study in the United Kingdom among back pain consulters to primary care found no difference in functional outcome measured by the RMDQ between a pain management program and manipulation. It is not known, however, whether these approaches would have been superior to no active intervention.[12]

The results of several studies suggest that the effect of delivering programs in primary care, which are based on CBT or include a CBT element, but not delivered by behavioral therapists, result in only modest improvements. However, before we conclude that these treatments are not effective in this setting, it will be necessary for future trials to pay particular attention to the training of nonbehavioral therapists and in particular evaluating whether short training programs can impart the necessary skills, and second, as with the current study, to monitor the delivery. We will be able to determine whether the problem is with the management itself or its delivery. An alternative strategy, given an insufficient number of behavioral therapists, is to consider new ways of delivering care such as internet-based programs which have shown promise in the treatment of disorders such as depression.[28]

The results according to patient preference are intriguing: the benefit of the intervention being strongest in those who expressed a preference for it, *a priori*. Although only a very small proportion of subjects reported a preference for the control (educational) intervention, the effects of preference were in the expected direction. Such effects of patient preference or expectation have been noted previously in trials of physiotherapy[29] and CBT.[30] Further, in a trial of acupuncture or massage, an effect of patient expectations was observed irrespective of the treatment received. However, preference for treatment may be a marker for some unmeasured factors, which themselves influence outcome of an episode of LBP (such illness attitudes and behaviors).[31] The mechanism by which patient preference appears to influence treatment outcome and the types of treatments on which it may have an effect will require investigation in future studies.

■ Conclusion

We have shown that an intervention, based on active exercise and education and delivered by community physiotherapists with brief training in cognitive behavioral management techniques, has, at most, a small additional benefit in the reduction of LBP and disability. However, we have also shown that small improvements in general health can be achieved, which, because the interventions are relatively inexpensive, prove to be cost-effective. It is still unknown, however, whether more extensive training and practice by the physiotherapists in CBT techniques could generate larger effects. It may be that the most effective approach to managing LBP is the administration of tailored interventions, either by risk factor load or by beliefs. Meanwhile, evidence is accruing from various randomized controlled trials to support the results of Carey *et al*, who observed that functional recovery at 6 months was similar (and pos-

itive) in back pain patients irrespective of which healthcare professional they attended.[32] It may be, therefore, that if patients receive treatment they believe is beneficial or are satisfied with treatment, then their outcome can be optimized.

■ Key Points

- A randomized trial in which physiotherapists delivered a group exercise program incorporating CBT principles to primary care patients with subacute low back pain resulted in only a very small improvement in pain and disability.
- The physiotherapists delivered some but not all the key components of CBT.
- Patients who expressed, before the trial, a preference for the active intervention had clinically important improvements in symptoms and function.


document

Appendix available online through Article Plus.

Acknowledgments

The authors thank the Trial Steering Committee: Chair, Paul Dieppe, University of Bristol, UK; Caroline Watkins, University of Central Lancashire, UK; Martin Roland, University of Manchester; and Trial Steering Committee statistician Caroline Doré, for their input and helpful suggestions during the trial; as well as the Data Monitoring Committee (Ernest Choy, Ian Harvey, and Vern Farewell). In particular, the authors thank the staff of the general practices in East Cheshire, UK who participated in the study and the team of physiotherapists who conducted the active intervention program as well as Jennifer Klaber-Moffet and Jane Carr who undertook the evaluation of the interventions delivered, Alison Littlewood (University of Manchester) who was responsible for day-to-day study administration, and Cynthia Iglesias for her advice on the economic analysis.

References

1. McCormick A. *Morbidity Statistics From General Practice*. Fourth national study 1991–92/a study carried out by the Royal College of General Practitioners, the Office of Population Censuses and Surveys, and the Department of Health. London: HMSO; 1995.
2. Croft PR, Macfarlane GJ, Papageorgiou AC, et al. Outcome of low back pain in general practice: a prospective study. *BMJ* 1998;316:1356–9.
3. Waddell G. *The Back Pain Revolution*. London: Churchill Livingstone; 1998.
4. Woby SR, Watson PJ, Roach NK, et al. Adjustment to chronic low back pain: the relative influence of fear-avoidance beliefs, catastrophizing, and appraisals of control. *Behav Res Ther* 2004;42:761–74.
5. Woby SR, Watson PJ, Roach NK, et al. Are changes in fear-avoidance beliefs, catastrophizing, and appraisals of control, predictive of changes in chronic low back pain and disability? *Eur J Pain* 2004;8:201–10.
6. Mannion AF, Junge A, Taimela S, et al. Active therapy for chronic low back pain: 3. Factors influencing self-rated disability and its change following therapy. *Spine* 2001;26:920–9.
7. Marhold C, Linton SJ, Melin L. A cognitive-behavioral return-to-work program: effects on pain patients with a history of long-term versus short-term sick leave. *Pain* 2001;91:155–63.
8. Linton S, Andersson T. Can chronic disability be prevented? A randomized trial of a cognitive-behavior intervention and two forms of information for patients with spinal pain. *Spine* 2000;5:2825–31.
9. Sullivan MJ, Ward LC, Tripp D, et al. Secondary prevention of work disability: community-based psychosocial intervention for musculoskeletal disorders. *J Occup Rehabil* 2005;15:377–92.
10. Sullivan MJ, Stanish WD. Psychologically based occupational rehabilitation: the Pain-Disability Prevention Program. *Clin J Pain* 2003;19:97–104.
11. Ostelo RWJG, van Tulder MW, Vlaeyen JWS, et al. Behavioural treatment for chronic low-back pain. *Cochrane Database of Systematic Reviews* 2005; 1:CD002014.
12. Hay EM, Mullis R, Lewis M, et al. Comparison of physical treatments versus a brief pain-management programme for back pain in primary care: a randomised clinical trial in physiotherapy practice. *Lancet* 2005;365:2024–30.
13. Clinical Standards Advisory Group. *Back Pain*. London: HMSO; 1994.
14. Roland M, Morris R. A study of the natural history of back pain: I. Development of a reliable and sensitive measure of disability in low-back pain. *Spine* 1983;8:141–4.
15. Goldberg DP, Williams P. *A User's Guide to the General Health Questionnaire*. Windsor: Nfer-Nelson; 1988.
16. EuroQol Group. EuroQol—a new facility for the measurement of health-related quality of life: the EuroQol Group. *Health Policy* 1990;16:199–208.
17. Croft PR, Papageorgiou AC, Ferry S, et al. Psychologic distress and low back pain: evidence from a prospective study in the general population. *Spine* 1995;20:2731–7.
18. Thomas E, Silman AJ, Croft PR, et al. Predicting who develops chronic low back pain in primary care: a prospective study. *BMJ* 1999;318:1662–7.
19. Main C, Spanswick C. *Pain Management: An Interdisciplinary Approach*. Edinburgh: Churchill-Livingstone; 2000.
20. Roland M, Fairbank J. The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. *Spine* 2000;25:3115–24.
21. Roberts C. The implications of variation in outcome between health professionals for the design and analysis of randomised controlled trials. *Stat Med* 1999;18:2605–15.
22. U.K. BEAM Trial Team. United Kingdom back pain exercise and manipulation (U.K. BEAM) randomised trial: cost effectiveness of physical treatments for back pain in primary care. *BMJ* 2004;329:1381.
23. Netten A, Dennett J, Knight J. *Unit Costs of Health and Social Care*. Canterbury: Personal Social Services Research Unit, University of Kent; 2002.
24. Jellema P, Van der Windt DAWM, van der Horst HE, et al. Should treatment of (sub)acute low back pain be aimed at psychosocial prognostic factors? Cluster randomised clinical trial in general practice. *BMJ* 2005;331:84.
25. U.K. BEAM Trial Team. United Kingdom back pain exercise and manipulation (U.K. BEAM) randomised trial: effectiveness of physical treatments for back pain in primary care. *BMJ* 2004;329:1377.
26. Klaber Moffett JA, Torgerson D, et al. Randomised controlled trial of exercise for low back pain: clinical outcomes, costs, and preferences. *BMJ* 1999; 319:279–83.
27. Carr JL, Klaber Moffett JA, et al. A randomised trial comparing a group exercise programme for back pain patients with individual physiotherapy in a severely deprived area. *Disabil Rehabil* 2005;27:929–37.
28. Christensen H, Griffiths KM, Jorm AF. Delivering interventions for depression by using the internet: randomised controlled trial. *BMJ* 2004;328:265.
29. Klaber Moffett JA, Jackson DA, Richmond S, et al. Randomised trial of brief physiotherapy intervention compared with usual physiotherapy for neck pain patients: outcomes and patients preferences. *BMJ* 2005;330:75.
30. Goossens ME, Vlaeyen JW, Hidding A, et al. Treatment expectancy affects the outcome of cognitive-behavioral interventions in chronic pain. *Clin J Pain* 2005;21:18–26.
31. Kalauokalani D, Cherkin DC, Sherman KJ, et al. Lessons from a trial of acupuncture and massage for low back pain: patient expectations and treatment effects. *Spine* 2001;26:1418–24.
32. Carey TS, Garrett J, Jackman A, et al. The outcomes and costs of care for acute low back pain among patients seen by primary care practitioners, chiropractors, and orthopaedic surgeons. *N Engl J Med* 1995;333:913–7.