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Effectiveness and Cost-Effectiveness of Three Types of Physiotherapy Used to Reduce Chronic Low Back Pain Disability

A Pragmatic Randomized Trial With Economic Evaluation

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Study Design. Pragmatic, randomized, assessor blinded, clinical trial with economic analysis.

Objective. To compare the effectiveness and cost-effectiveness of three kinds of physiotherapy commonly used to reduce disability in chronic low back pain.

Summary of Background Data. Physiotherapy reduces disability in chronic back pain, but there are several forms of physiotherapy and it is unclear which is most effective or cost effective.

Methods. A total of 212 patients referred to physiotherapy with chronic low back pain were randomized to receive usual outpatient physiotherapy, spinal stabilization classes, or physiotherapist-led pain management classes. Primary outcome was Roland Disability Questionnaire score 18 months from baseline; secondary measures were pain, health-related quality of life, and time off work. Healthcare costs associated with low back pain and quality-adjusted life years (QALYs) were also measured.

Results. A total of 71 participants were assigned to usual outpatient physiotherapy, 72 to spinal stabilization, and 69 to physiotherapist-led pain management. A total of 160 (75%) provided follow-up data at 18 months, showing similar improvements with all interventions: mean (95% confidence intervals) Roland Disability Questionnaire score improved from 11.1 (9.6–12.6) to 6.9 (5.3–8.4) with usual outpatient physiotherapy, 12.8 (11.4−14.2) to 6.8 (4.9–8.6) with spinal stabilization, and 11.5 (9.8–13.1) to 6.5 (4.5–8.6) following pain management classes. Pain, quality of life, and time off work also improved within all groups with no between-group differences. Mean (SD) healthcare costs and QALY gain were £474 (840) and 0.99 (0.27) for individual physiotherapy, £379 (1040) and 0.90 (0.37) for spinal stabilization, and £165 (202) and 1.00 (0.28) for pain management.

Conclusions. For chronic low back pain, all three physiotherapy regimens improved disability and other relevant health outcomes, regardless of their content. Physiotherapist-led pain management classes offer a cost-effective alternative to usual outpatient physiotherapy and are associated with less healthcare use. A more widespread adoption of physiotherapist-led pain management could result in considerable cost savings for healthcare providers.

Key words: low back pain, rehabilitation, physiotherapy, physical therapy, exercise, back school, economic analysis. **Spine 2007;32:1474–1481**

Throughout the industrialized world, chronic low back pain is a common, disabling, and costly problem. The annual cost of low back pain to the U.K. public healthcare provider, the National Health Service (NHS), has been estimated at £1.1 billion, with chronic problems responsible for 80% of these costs.[1]

International guidelines recommend active physiotherapy, treatment emphasizing exercise, as a key component in chronic low back pain management.[2] In the United Kingdom, around 1.3 million people per year receive NHS physiotherapy for low back pain, costing an estimated £150 million.[3] However, there are several types of physiotherapy for low back pain. Usual outpatient physiotherapy involves individual advice, exercises, and joint manipulation or mobilizations aimed at specific impairments.[4] Other treatments include physiotherapist-led outpatient pain management programs, which use education, general exercise, and a paced return to usual activities to reduce the emotional distress and unhelpful beliefs associated with back pain and aim to improve coping and self-management. Physiotherapist-led general exercise and brief education in small groups reduce disability and healthcare costs compared with primary care.[5] A third treatment, spinal stabilization training, involves very specific exercises of deeper trunk muscles that are dysfunctional in chronic low back pain and proposed to actively stabilize the lumbar spine.[6,7] Spinal stabilization reduces pain and disability in lumbar instability and recurrence following first-episode pain but, while in widespread use, its efficacy is unproven in chronic nonspecific back pain.[6,7] Whether one form of

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physiotherapy is more effective or cost-effective than another is unknown.[8]

To help inform decision makers, we compared the clinical effectiveness and costs of spinal stabilization and physiotherapist-led pain management classes with usual outpatient physiotherapy for people with chronic low back pain.

■ Materials and Methods

Design. Following Guy's Hospital Research Ethics Committee approval (reference number 01/09/05), we carried out a pragmatic, randomized, assessor-masked trial with written consent from all participants between January 2002 and June 2005. The study evaluated physiotherapy as delivered in two inner-city London public hospitals. Data were collected by a research physiotherapist using questionnaires and structured interviews.

Participants. Participants were recruited from referrals by specialist or primary care practitioner to hospitals' physiotherapy departments. Inclusion criteria were; low back pain of more than 12 weeks duration, with or without leg symptoms or neurologic signs; being 18 years of age or older; adequate command of English; ability to give informed consent; and ability to attend classes. People were excluded if they had previous spinal surgery, physiotherapy for low back pain in the last 6 months, medical conditions such as rheumatological diseases, or other disabilities rendering them unsuitable for group treatments of low back pain.

Outcome Measures. The primary outcome was the Roland Disability Questionnaire, which contains 24 questions concerning activity limitations due to back pain, scored 0 (no limitation) to 24 (maximum limitation), with a minimum clinically important change being 2 or 3 points.[9] Secondary outcomes were recent pain assessed by 0 to 100 numerical analogue scale, health-related quality of life measured with EQ-5D (EuroQoL) questionnaire,[10] and work participation measured by days not working due to back pain in the previous 6 months. A simple global measure of patient satisfaction with treatment outcome and care was used, rated on a 1 (extremely dissatisfied) to 7 (extremely satisfied) point scale. Adverse effects were defined as an increase in pain or symptoms within 1 week of treatment requiring general practitioner or casualty consultation as reported to the research physiotherapist. The number and type of treatments were recorded from patient notes after unmasking. The primary endpoint was 18 months from baseline assessment; secondary endpoints were 6 and 12 months.

Economic Evaluation. Health utility was measured in quality-adjusted life years (QALY) gained for each patient by calculating the area under the EQ-5D curve for 18 months after baseline.[11] Direct medical costs were measured by collecting public health service (NHS) utilization data for the previous 6 months to each assessment from physiotherapy notes and from participants using the interview-based questionnaire Client Services Receipt Inventory.[12] Unit costs (£) were for 2003 to 2004, obtained from the Personal Social Services Research Unit Database, NHS reference costs, and British National Formulary (Table 1).[13–15] Three patients (two from spinal stabilization and one from individual physiotherapy) incurred unusually high costs because they received spinal fusion or decompression surgery. These patients were excluded in a sensitivity analysis.

Table 1. Unit Costs of Healthcare Resources Used

Healthcare Resource	Unit	Cost per Unit (£)
Trial physiotherapy		
Initial consultation[13]	60 min visit	24.00
Individual physiotherapy subsequent treatment[13]	30 min visit	12.00
Group subsequent treatment[13]	120 min visit	9.00
Public Health Service (NHS) visits		
Inpatient investigation or rehabilitation[13]	Day	273.00
Specialist[13]	Visit	68.00
Clinical physiotherapist specialist[13]	Visit	32.00
Occupational health doctor[13]	Visit	32.00
Occupational health nurse[13]	Visit	24.00
Hospital accident and emergency department[14]	Visit	65.00
General practitioner[13]	1 min of visit	1.92
Practice nurse[13]	30 min visit	11.00
Practice osteopath[13]	30 min visit	24.00
Public Health Service (NHS) procedures[14]		
Spinal fusion or decompression	Procedure	4219.35
Fluoroscopy-guided facet joint injections	Procedure	1249.22
Epidural	Procedure	848.00
MR scan	Investigation	265.00
CT scan	Investigation	176.00
Bone scan	Investigation	139.00
Nerve conduction studies	Investigation	117.00
Ultrasound scan	Investigation	90.00
Radiograph	Investigation	14.97
Blood test	Investigation	10.63

Randomization and Masking. Before the trial started, the randomization protocol was computer-generated and held by a trials unit independent of and distant from the trial setting. After clinical assessment, participants were assigned to their intervention by clinic staff telephoning the trials unit. No stratification was used.

As this was a pragmatic trial evaluating clinical practices, masking of participants or clinicians was neither possible nor desirable. We tried to ensure that participants started the trial with equal expectation of each intervention's efficacy: patient recruitment information stated that all three interventions were effective. Success of assessor blinding was evaluated by asking the assessor to suggest what each participants allocation had been following each assessment.

Interventions. All treatments were delivered in hospital physiotherapy departments alongside nontrial patients. All treating physiotherapists had at least 2 years clinical experience and were briefed about and had agreed to treat according to the trial protocol. The hospitals have their own common internal teaching program for the leaders of the pain management program and spinal stabilization training, but otherwise treating physiotherapists had no extra training for the trial.

In the individual physiotherapy protocol, patients were assessed and treated according to assessment findings. Treatment consisted of a combination of joint mobilizations, joint manipulation, and massage. Exercises were taught individually to be performed at home and included specific trunk muscle retraining, stretches, and general spinal mobility. Patients usually also received back-care advice. Up to 12 sessions of around 30 minutes each were permitted in the protocol and according to de-

partmental policy. The spinal stabilization physiotherapy consisted of individual transversus abdominis and lumbar multifidus muscle training followed by group exercises that challenged spinal stability. Exercises were tailored to assessment findings and progressed within participants' ability to maintain a stable and minimally painful spine. The exercise program aimed to improve trunk muscle motor control to provide dynamic segmental stability for the lumbar spine. Participants attended a maximum of 8 sessions of 90 minutes supervised by a senior physiotherapist and physiotherapy assistant. The pain management program consisted of a combination of structured back pain education with group general strengthening, stretching, and light aerobic exercises progressed according to pacing principles. A cognitive-behavioral approach was used: the program aimed to reduce fear of movement and reinjury and encourage self-management by introducing modern knowledge of back pain (hurt does not equate to harm), a graded return to usual activities with goal-setting, and use of positive coping strategies. The program consisted of a maximum of 8 sessions of 90 minutes supervised by a senior physiotherapist and physiotherapy assistant. Fidelity to protocol was assessed by recording treatments from physiotherapy notes after treatment allocation had been revealed.

Sample Size. *A priori* sample size calculation assuming a power of 90%, $\alpha = 0.05$, Roland disability score mean (SD) of 12 (5) and a minimally clinically important change of 3 points[9] gave a sample size of 59 per group in a three equal groups design. We aimed to recruit a total of 240 participants to allow for 25% attrition.

Statistical Analysis. Clinical outcomes were analyzed on both intention to treat and complete case bases according to a previously prepared data analysis plan. We used analysis of covariance with baseline data as covariate to compare the effects of treatment at each time point. Cross-sectional comparisons, where appropriate, were made using ANOVA. For the intention-to-treat analysis, missing values were imputed using the last known value carried forward and a sensitivity analysis compared results with and without imputation. To address potential bias due to attrition, baseline values from participants with complete data were compared with those from participants with any data. Actual attrition from each arm was compared with the number expected if attrition was equal across all three arms using the χ^2 goodness of fit test to determine if rates of attrition were unequal. Distributions were checked to ensure that parametric assumptions were met; and if they were not, nonparametric analyses were undertaken. Security of masking was evaluated by comparing number of correct treatment suggestions with that expected by chance using the χ^2 test.

For the economic evaluation, we analyzed results from participants with complete EQ-5D and direct medical NHS cost data at all time points on an available case basis (cases with complete cost data only). Results for all participants with endpoint clinical data, imputing missing EQ5D and cost data with last value carried forward, were analyzed as a sensitivity analysis. Costs and outcomes occurring during the 12- to 18-month period were each discounted at 3.5%, the current recommended rate for public sector projects.[16] Arithmetic mean and standard one way ANOVA test-based confidence intervals are considered appropriate for comparing mean costs between three groups and relevant statistics for informing decision-making, despite the potential skewness of cost data.[17] Incremental cost effectiveness ratios, the difference in cost of two interventions divided by the difference in their effect, were estimated giving a cost per QALY that can be compared with the maximum the U.K. public health service is willing to pay for such an improvement in health implied by recent National Institute of Clinical Excellence decisions.[18,19] The validity of the results was confirmed using bootstrapping where the original data were used to provide an empirical estimate of the sampling distribution through repeated resampling from the observed data.[20] Results are presented as cost-effectiveness acceptability curves, a graphic representation of the probability that a particular intervention is cost-effective over a range of possible values for the maximum willingness to pay for a QALY.[20]

All data were double entered. Data were analyzed using SPSS 12.0 (SPSS Inc., Chicago, IL). Results are presented as mean (SD) unless otherwise stated.

■ Results

Participant Retention

We randomized 212 participants between March 2002 and September 2003, reassessed 169 (80%) participants at 6 months, 154 (73%) at 12 months and 160 (75%) at 18 months following baseline. Retention tended to be lowest in pain management (47 of 69, 68%) and highest in individual physiotherapy (59 of 71, 83%), not significantly (Pearson's $\chi^2 = 4.256$, $P = 0.12$); participants reported difficulty in attending classes twice weekly and some sought other treatment rather than waiting for a class space to become available (Figure 1).

Sixty-two (25%) participants did not provide data at 18 months. Those remaining on the trial tended to be older, age 45 (12) *versus* 43 (12); more likely to be female, 66% *versus* 57%; and less disabled, Roland Disability Questionnaire score 11.8 (5.8) *versus* 12.6 (5.6). Differences in socioeconomic characteristics were more pronounced, with nonresponders being more likely to be off-work due to back problems, 18 of 52 (35%) *versus* 35 of 160 (22%); in social housing, 39 of 52 (75%) *versus* 86 of 160 (54%); and receiving state benefit 22 of 52 (43%) *versus* 52 of 160 (32%).

Baseline Data

The three treatment groups had similar characteristics (Table 2) and baseline values of outcome measures (Table 3), suggesting randomization was effective.

Success of Masking

At 6 months, 59% (91 of 155) participants' treatment was guessed correctly by the assessor against 33% (52 of 155) expected by chance ($P < 0.001$). At 12 months, 38% (56 of 147) and 18 months 36% (57 of 157) correct guesses were not significant. Participants presumed to have individual physiotherapy tended to have lower Roland disability scores; but this was nonsignificant, suggesting that unmasking did not influence primary outcome.

Treatments

Details of treatment received were available for 190 of 212 (90%) participants. Eight (4%) participants re-

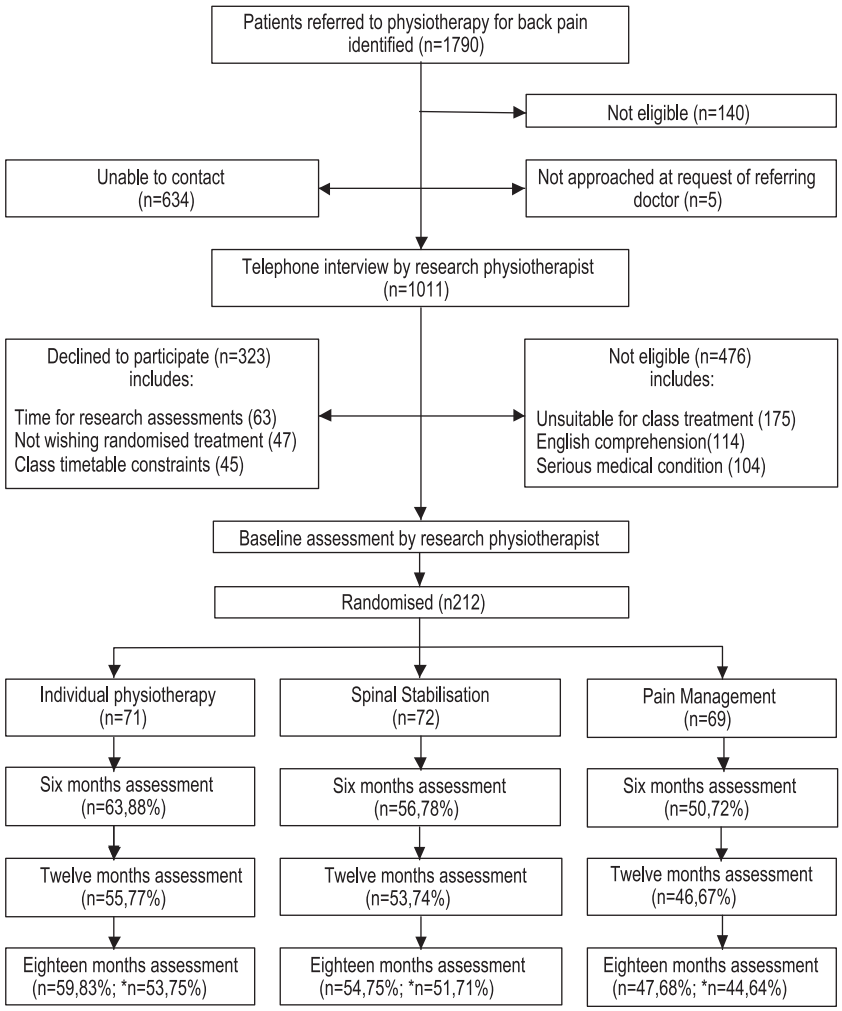

Figure 1. Progress of participants through trial.

ceived nonprotocol treatments such as manipulation in the spinal stabilization arm. All others received treatment per protocol. All participants were taught some form of exercise.

Outcomes

Primary Outcome. Eighteen months following randomization, all three forms of physiotherapy resulted in reduction in Roland Disability Questionnaire score (Table 3). Mean (CI) Roland disability score improved from 11.1 (9.6–12.6) to 6.9 (5.3–8.4) in the individual physiotherapy group, 12.8 (11.4−14.2) to 6.8 (4.9–8.6) in the spinal stabilization group, and 11.5 (9.8–13.1) to 6.5 (4.5–8.6) in the pain management group ($P < 0.001$). There were no differences between arms in Roland Disability Questionnaire score ($P = 0.46$).

Secondary Outcomes. Pain, health-related quality of life (EQ-5D score) improved and number of days off work over the previous 6 months decreased, but there were no differences between arms (Table 3). Interim results at 6 and 12 months were similar to those of 18 months. The majority of participants (108 of 168, 64%) were "very" or "extremely" satisfied with the care received; 75 of 168 (45%) were "very" or "extremely" satisfied with treatment outcome at 6 months and 80 of 160 (50%) at 18 months. Differences in satisfaction were nonsignificant for outcome ($P = 0.4125$) and care ($P = 0.3375$).

Imputing missing data using the last value carried forward method did not change any of these conclusions: Mean (CI) Roland disability scores at 18 months were 7.4 (6.0–8.9) in the individual physiotherapy group, 8.3 (7.7–8.9) in the spinal stabilization group, and 8.3 (6.6–10.0) in the pain management group ($P < 0.001$). There were no differences between arms in Roland disability score ($P = 0.66$). Results at 6 and 12 months were similar. No serious adverse events were reported by any participants.

Economic Analysis

Complete data were available for 53 participants in the individual physiotherapy group, 51 in spinal stabilization, and 44 in pain management. Information on resource use and cost only was available for 53 spinal stabilization participants and for these variables, statistics for all responding participants are presented (Table 4). Participants in the pain management arm had fewer secondary care visits, inpatient procedures, and investigations compared with patients in the individual physiotherapy and spinal stabilization arms

Table 2. Patient Characteristics at Randomization by Treatment Group

Characteristic	Individual Physiotherapy	Spinal Stabilization	Pain Management
Female sex	42/71 (59)	51/72 (71)	43/69 (62)
Age (yr)*	45 (12)	44 (13)	44 (12)
Time since first episode (mo)*	68 (81)	86 (90)	86 (90)
Leg pain	37/70 (53)	35/71 (49)	34/69 (49)
Consultant referred	34/71 (49)	30/72 (42)	30/69 (43)
Consultant visits in last 6 mo*	0.67 (0.86)	0.56 (0.87)	0.58 (0.84)
GP visits in last 6 mo*	2.73 (2.27)	3.46 (3.19)	2.64 (2.79)
Ethnic origin white	36/71 (51)	39/72 (54)	35/69 (51)
Black African	9/71 (13)	15/72 (22)	12/69 (17)
Black Afro-Caribbean	15/71 (21)	10/72 (14)	12/69 (17)
Married or cohabiting	31/71 (44)	36/72 (50)	25/68 (37)
Social housing	41/71 (58)	41/72 (57)	41/69 (59)
Household income <£127 per week	31/68 (46)	26/70 (37)	33/68 (49)
All types of work	44/71 (62)	46/72 (64)	39/68 (57)
Full-time work	31/71 (44)	34/72 (47)	25/68 (37)
State benefit recipient	24/71 (34)	19/72 (26)	31/68 (46)
Back-related benefit recipient	6/71 (8)	7/72 (10)	9/68 (13)
Off-work due to back pain	16/71 (23)	19/72 (26)	18/69 (26)

Summary measures are no. (%) unless otherwise indicated; denominator varies according to no. of valid responses.
*Summary measures are mean (SD).

(Table 4) contributing to markedly lower costs in "other health care visits" (Table 5). Individual physiotherapy in-trial treatment costs were significantly higher. The total healthcare costs of treatment were higher for individual physiotherapy and spinal stabilization relative to pain management, but not significantly so ($P = 0.16$).

Table 4. Public Health Service (NHS) Resource Use Over 18-Month Duration of Trial

Resource Use	Individual Physiotherapy (n = 53)	Spinal Stabilization (n = 53)	Pain Management (n = 44)
Physiotherapy			
Trial individual session	5.36 (2.27)	0.98 (2.27)	0.00 (0.00)
Trial class session	0.19 (1.11)	4.94 (3.32)	5.66 (2.84)
Nontrial individual session	1.19 (3.06)	0.51 (2.02)	1.05 (5.33)
Other healthcare visits			
General practitioner	1.98 (3.17)	2.15 (3.62)	1.68 (4.89)
Consultant	0.79 (1.65)	0.55 (1.62)	0.18 (0.69)
Investigations and other visits	0.55 (1.68)	1.32 (5.99)	0.02 (0.15)

Overall, pain management is less costly and marginally more effective than the other interventions. Relative to spinal stabilization, individual physiotherapy is marginally more expensive and slightly more effective with a mean incremental cost effectiveness ratio of £1055.

The cost-effectiveness acceptability curves (Figure 2) show the probability of cost-effectiveness for the three interventions for a range of prices a health commissioner might be prepared to pay per QALY. As pain management is marginally most effective and is associated with lowest healthcare costs, it is most likely to be cost-effective at all costs per QALY. The curve for pain management slopes downwards, as the greater cost-effectiveness of this treatment is largely due to its cost advantage, the relative importance of which diminishes as one is prepared to pay more for each QALY. The low, flat curve for spinal stabilization shows this intervention is very unlikely to be cost-effective compared with pain management because it is no more effective but is associated with higher healthcare costs. Usual individual physiotherapy has higher associated costs but is more effective than spinal stabilization, so at very low costs per QALY spinal sta-

Table 3. Activity Limitation, Pain, Health-Related Quality of Life, and Work Limitation Over the Course of the Trial

Outcome Measure	Assessment Point	Intervention		
		Individual Treatment (n = 71)	Spinal Stabilization (n = 72)	Pain Management (n = 69)
Roland Disability Questionnaire score (0–24; 0 = best)	Baseline	11.1 (9.6–12.6)	12.8 (11.4–14.2)	11.5 (9.8–13.1)
	6 mo	8.0 (6.4–9.7)	7.0 (5.6–8.5)	6.2 (4.6–7.7)
	12 mo	8.1 (6.5–9.8)	7.6 (5.9–9.2)	5.8 (4.2–7.4)
	18 mo	6.9 (5.3–8.4)	6.8 (4.9–8.6)	6.5 (4.5–8.6)
Pain (0–100; 0 = best)	Baseline	60 (54–66)	67 (61–73)	59 (52–65)
	6 mo	42 (35–48)	39 (32–46)	42 (34–50)
	12 mo	42 (35–49)	42 (35–49)	38 (29–46)
	18 mo	39 (31–46)	32 (24–40)	38 (29–47)
Quality of life EQ-5D (−0.5 to 1.0; 1 = best)	Baseline	0.57 (0.50–0.64)	0.48 (0.40–0.55)	0.54 (0.45–0.63)
	6 mo	0.66 (0.61–0.72)	0.66 (0.60–0.72)	0.66 (0.58–0.74)
	12 mo	0.72 (0.66–0.77)	0.61 (0.53–0.69)	0.72 (0.63–0.81)
	18 mo	0.67 (0.60–0.74)	0.63 (0.54–0.72)	0.68 (0.60–0.76)
Work limitation (days off in last 6/12)	Baseline	27 (16–38)	29 (17–41)	21 (9–33)
	6 mo	26 (14–37)	24 (11–37)	15 (4–26)
	12 mo	21 (9–32)	21 (9–32)	14 (4–25)
	18 mo	19 (8–30)	15 (5–26)	14 (4–25)

Summary measures are mean (95% confidence intervals).

Table 5. Discounted Costs (£) of Public Health Service (NHS) Resource Use and QALY Gain Over 18 Months

Resource Use	Individual Physiotherapy (n = 53)	Spinal Stabilization (n = 53)	Pain Management (n = 44)
Physiotherapy			
Trial*	90 (29)	80 (30)	75 (26)
Nontrial	11 (28)	6 (24)	12 (63)
Other healthcare visits			
General practitioner	49 (87)	53 (94)	45 (138)
Consultant	56 (123)	33 (101)	11 (43)
Other NHS, including inpatient procedures and investigations	221 (688)	196 (916)	0 (0)
Investigations	21 (65)	18 (104)	0 (0)
Inpatient procedures	201 (690)	178 (914)	0 (0)
Medication			
Free prescriptions	45 (105)	7 (20)	19 (74)
Paid-for prescriptions	2 (6)	3. (23)	0 (0)
Total NHS costs	474 (840)	379 (1040)	165 (202)
QALY gain (EQ-5D years)	0.99 (0.27)	0.90 (0.37)†	1.00 (0.28)

*$P < 0.05$ (ANOVA).
†Complete data sets available for 51 participants for EQ-5D values.

bilization likely to be more cost-effective than individual physiotherapy; as the monetary amount that society is prepared to pay per QALY rises, the likelihood that individual physiotherapy is more cost-effective than spinal stabilization training increases. If a healthcare commissioner were willing to pay £30,000 for one QALY, there is ~65% probability physiotherapist-led pain management will be cost-effective, ~35% probability usual physiotherapy will be cost effective, but the probability that spinal stabilization will be cost-effective is negligible.

The following sensitivity analyses were conducted to investigate effects of missing data and high-cost outliers. Including all participants who provided primary endpoint data, imputing missing data from 6 and 12 months of follow-up using last value carried forward made little difference to the results (Table 6). Excluding the three participants who received spinal surgery during the trial markedly reduces the associated costs of the spinal stabilization arm to £187.54 (198.65), increases the incremental cost effectiveness ratio for individual physiotherapy relative to this (£3543), and the differences in total mean public health service costs across the three groups become significant ($P = 0.007$) (Table 6.). However, the "base case" conclusion that physiotherapist-led pain management is most cost-effective remains unchanged.

Costs for all participants for 6 months before baseline were £169.29 (349.71) and were significantly lower for each 6-month period of the trial: 0 to 6 months = £70.49 (452.74) ($P < 0.001$), 6 to 12 months = £92.14 (502.11) ($P = 0.003$), and 12 to 18 months = £103.03 (535.90) ($P = 0.036$).

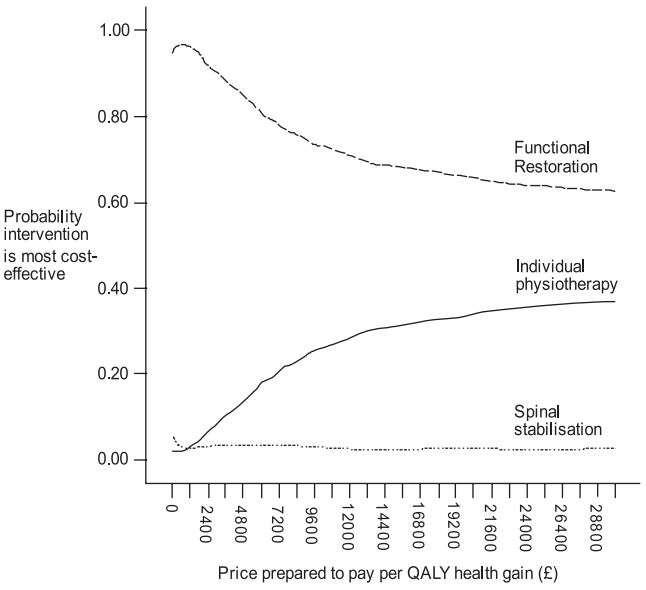

Figure 2. Cost-effectiveness acceptability curves for the three interventions: probability intervention is most cost-effective for different prices per QALY.

■ Discussion

All three physiotherapy regimens reduced disability in a moderately disabled population with chronic low back pain, with concurrent improvement in pain, health-related quality of life, time off work, and health service utilization. The content and delivery of the interventions made no difference to clinical outcome, but the pain management program was associated with lower healthcare costs and so is more likely to be the most cost-effective form of physiotherapy.

Strengths and Limitations

An important strength of this trial is its generalizability. Participants were recruited from an inner city location, and many were socioeconomically deprived and moderately disabled. The interventions were carried out in hospital physiotherapy departments by physiotherapists who were not members of the research team and had not had special training for the study. Therefore, the interventions could easily be replicated in clinical departments and the findings replicated in people who frequently consult primary care physicians.

We used a pragmatic control group usual individual physiotherapy because given the evidence of the benefits of physiotherapy compared with primary care[5,6,8]; we considered it unethical to have a "nonintervention" control group. Absence of a "nonintervention" control arm means improvements might be attributed to the natural history of condition or regression to the mean. However, once low back pain becomes chronic, pain, activity limitation, and work handicap remain almost constant, making it is more probable that improvements are due to the interventions.[21]

The class-based interventions, particularly pain management, tended to have higher attrition than individual physiotherapy, but this was not significant. This could have influenced the economic evaluation, although sensitivity analysis suggested it did not affect results. Participants in class-based interventions were no less satisfied with their care or outcome. Differences in attrition rates

Table 6. Sensitivity Analyses

	Category	Individual Physiotherapy	Spinal Stabilization	Pain Management
Base case (available case analysis)	Sample size	53	53	44
	Total NHS costs (£)	474 (840)	379 (1040)	165 (202)
	QALY gain (EQ-5D Years)	0.99 (0.27)	0.90 (0.37)	1.00 (0.28)
Base case without 3 spinal surgery patients	Sample size	52	51	44
	Total NHS costs (£)	401 (615)	188 (199)	165 (202)
	QALY gain (EQ-5D Years)	0.99 (0.27)	0.93 (0.36)	1.00 (0.28)
Imputation of missing costs and QALYs (completing participants)	Sample size	59	54	47
	Total NHS costs (£)	473 (820)	382 (1030)	174 (200)
	QALY gain (EQ-5D Years)	1.00 (0.29)	0.95 (0.39)	1.00 (0.34)

Summary measures are mean (SD).

may be due to the time inflexibility of classes and delay starting classes following assessment. Many participants, particularly those socioeconomically disadvantaged, were unable to participate or withdrew early due to difficulties with attending classes. Offering physiotherapist-delivered, flexibly timetabled classes in the community would allow more equitable health service provision. Additionally, physiotherapist-led pain management challenges participants' beliefs about back pain and their expectations about its management and prognosis.

The study reports direct medical costs from an U.K. public health service (NHS) perspective as this is of importance to healthcare providers and policy-makers. Total U.K. low back pain related costs, including private medical and indirect costs such as informal care and lost productivity, are between 4.7 and 10 times greater than public health service costs, mostly due to employment-related items.[3] As pain management had fewest participants off work following intervention, it is likely that this arm would also show least indirect costs (from a societal perspective). However, as noncompleting participants tended to be more economically deprived, the greater attrition from pain management may affect results of any indirect cost analysis.

Inadvertent unmasking occurred frequently at 6-month follow-up as participants tended to talk about their recent treatment. This may be a disadvantage of face-to-face assessment. At 12 and 18 months, participants' treatments were identified correctly no more frequently than expected at random. As disability scores were similar for masked and unmasked participants, unmasking does not seem to have affected the trial outcome.

Study in Context With Other Findings

A recent comparison of a brief physiotherapist-led pain-management program with a similar rationale to ours concluded that it was as effective as usual physiotherapy in acute back pain.[22] Our study demonstrates that this is also true in chronic back pain and confirms physiotherapist-supervised exercise improves disability and pain in chronic low back pain.[8,23] Group treatments are not suitable for everyone with low back pain, such as those with multiple or complex problems or language difficulties, so these results should not be interpreted as meaning all chronic patients with low back pain should receive pain management. The specificity of spinal stabilization limits its use to patients with low back pain only, whereas more general exercise programs, such as in pain management, may have wider health benefit for people likely to have other chronic health conditions.

Pain management programs aimed at people with highly disabled, chronic syndromes are usually medically directed, interdisciplinary and frequently delivered as an intensive inpatient program with consequent high cost. Our physiotherapist-led outpatient program is similar in philosophy but might be termed a back school,[23] with a cognitive-behavioral approach and additional education in modern understanding of back pain and its management. We recommend that physiotherapy departments should routinely offer pain management programs as a first-line intervention rather than regarding it as a last resort as is currently frequently the case.

There are few other economic evaluations of different kinds of physiotherapy for low back pain. In contrast to our results, the U.K. BEAM study found manipulation, similar to our individual physiotherapy intervention, slightly more effective and cost-effective than general exercise and brief education.[5,24] Compared with their exercise intervention, our pain management program had a larger, structured, educational component specifically aimed at improving self-management, which may explain the markedly lower health service utilization of this arm in our study. Additionally, our participants had longer duration low back pain; and, as psychological factors become increasingly important with chronicity, an intervention specifically addressing distress and unhelpful beliefs may be of greater benefit.

Economic analysis is still unusual in rehabilitation studies; yet in this trial, it reveals important differences between interventions that are not apparent from clinical outcome measures. Promoting self-help is an important aim in back pain management and economic analysis is a means of quantifying how successfully this has been achieved. Because low back pain has such high societal and health service costs, we recommend including an economic analysis in future rehabilitation trials so policy-makers can best decide how to spend limited healthcare resources.

Currently in the United Kingdom, almost all physiotherapy for chronic low back pain is delivered individually.[4] However, group physiotherapist-led pain management is associated with fewer public health service costs due to the smaller number of secondary consultations, investigations, and procedures: mean public health service costs were £206 per patient per year less in pain management compared with usual individual physiotherapy. In the United Kingdom, 1.23 million people received public health service physiotherapy per year.[3] From recruitment data (Figure 1), conservatively 50% of referred patients were suitable for a pain management program. Extrapolating our results, changing physiotherapy practice in 50% of patients with low back pain from individual treatment to physiotherapist-led outpatient pain management programs would result in savings to the U.K. public health service of £126 million per year (2003–2004 prices).

We were surprised that reported disability remained reduced at 18-month follow-up. This indicates that physiotherapy has sustained medium-term effects on chronic back pain disability. Health service consumption tended to rise over this time, although still remaining lower than preintervention levels, suggesting that maintenance of clinical improvement was not solely due to trial interventions.

■ Conclusion

Three different types of active physiotherapy produced clinically important improvements in health state in this challenging patient group. Physiotherapist-led pain management, combining simple exercises requiring no special equipment with structured back education aimed at improving self-management, was associated with markedly less health-service consumption and was most cost effective. Given the prevalence of chronic low back pain and its personal and socioeconomic costs, these findings may have important implications for primary care management.

■ Key Points

- Usual, individual physiotherapy, spinal stabilization training, and physiotherapist-led pain management were all safe and effective at reducing disability, pain, time off work, and improving quality of life in chronic back pain.
- There were no differences in effectiveness between the different types of physiotherapy.
- Physiotherapist-led pain management was associated with least health service consumption and costs and was most cost-effective.
- A more widespread adoption of physiotherapist-led pain management could result in considerable cost-savings for healthcare providers.

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