

between five and 10 years after treatment. Only one trial had a sufficient duration of follow up, and this found that the failure rate was significantly lower with surgery than with radiotherapy. For the other trials recurrence rates are difficult to judge as two trials had a follow up period of two years, four trials had a follow up period of one year, and 12 trials had a follow up period of six months or less.

In general, the quality of the trials was poor. In 13 of the 18 trials the method of randomisation was not described or was unclear. Only four of the trials clearly showed that concealment of allocation was adequate. Only 12 of the 18 trials used an intention to treat analysis, and seven of those involved the therapeutic option imiquimod. Blinding of outcome assessment was done or attempted for most of the trials. In conclusion, the evidence base for the most common cancer is poor.

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Randomised controlled trial of physiotherapy compared with advice for low back pain

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Abstract

Objective To measure the effectiveness of routine physiotherapy compared with an assessment session and advice from a physiotherapist for patients with low back pain.

Design Pragmatic, multicentre, randomised controlled trial.

Setting Seven NHS physiotherapy departments.

Participants 286 patients with low back pain of more than six weeks' duration.

Intervention Routine physiotherapy or advice on remaining active from a physiotherapist.

Main outcome measures Primary outcome was scores on the Oswestry disability index at 12 months. Secondary outcomes were scores on the Oswestry disability index (2 and 6 months), scores on the Roland and Morris disability questionnaire and SF-36 (2, 6 and 12 months), and patient perceived benefit from treatment (2, 6, and 12 months).

Results 200 of 286 patients (70%) provided follow up information at 12 months. Patients in the therapy group reported enhanced perceptions of benefit, but there was no evidence of a long term effect of physiotherapy in either disease specific or generic outcome measures (mean difference in change in Oswestry disability index scores at 12 months – 1.0%, 95% confidence interval – 3.7% to 1.6%). The most common treatments were low velocity spinal joint mobilisation techniques (72%, 104 of 144 patients)

and lumbar spine mobility and abdominal strengthening exercises (94%, 136 patients).

Conclusion Routine physiotherapy seemed to be no more effective than one session of assessment and advice from a physiotherapist.

Introduction

Physiotherapists in the British NHS treat around 1.3 million people for low back pain each year, but there is only weak evidence for the effectiveness of routine physiotherapy and no evidence for the effectiveness of electrotherapy, laser treatment, ultrasound therapy, or traction.^{1 2} International guidelines vary but generally recommend advice to remain active, exercise therapy for patients with chronic low back pain (> 12 weeks' duration) and some suggest spinal manipulation for acute or subacute low back pain.³⁻⁵ We investigated the effectiveness of physiotherapy, as commonly practised in the British NHS, over a year for patients with low back pain compared with a session with advice from a physiotherapist.

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Results for patients with valid data at each assessment are on bmj.com

Table 1 Mean (SD) change in disease specific scores at 2, 6, and 12 months from baseline for patients receiving physiotherapy or advice only for low back pain, with missing data replaced using last value carried forward

Instrument	Therapy group (n=144)		Advice only group (n=142)		Mean difference (95% CI)	P value	
	Mean (SD) change	Effect size	Mean (SD) change	Effect size		t test	Analysis of covariance*
Oswestry disability index:							
2 months	-2.65 (9.34)	0.24	-1.33 (9.29)	0.12	-1.32 (-3.50 to -0.86)	0.17	0.24†
6 months	-2.89 (11.59)	0.26	-1.83 (10.61)	0.17	-1.06 (-3.66 to 1.54)	0.31	0.36
12 months	-3.27 (10.99)	0.29	-2.23 (11.47)	0.20	-1.04 (-3.70 to 1.59)	0.28	0.33
Roland and Morris disability questionnaire:							
2 months	-1.13 (3.98)	0.26	-0.56 (3.38)	0.13	-0.56 (-1.42 to 0.30)	0.32	0.20
6 months	-1.19 (4.74)	0.27	-0.79 (4.20)	0.18	-0.40 (-1.44 to 0.64)	0.61	0.45
12 months	-1.36 (4.66)	0.31	-0.99 (4.23)	0.23	-0.38 (-1.41 to 0.66)	0.62	0.48

* Adjusted for score at baseline, age, sex, smoking status, and time since first episode of back pain.

† Repeated measure analysis of covariance.

Methods

We carried out a multicentre, investigator blinded, randomised controlled trial. Participants were identified from physiotherapy referrals made by general practitioners and consultants. They were invited to participate from seven physiotherapy departments based in NHS outpatient departments in Oxfordshire and Reading, Berkshire.

Our inclusion criteria were age 18 years and over with low back pain for at least six weeks with or without leg pain or neurological signs. We excluded patients with serious conditions, those who had treatment for physical problems in the past month, and those referred for intensive functional restoration programmes.

Outcome measures

Our primary outcome measure was scores on the Oswestry disability index at 12 months: 0% (no disability) to 100% (totally disabled or bedridden).⁶ Secondary outcome measures were scores on this index at two and six months and scores on the Roland and Morris disability questionnaire at 2, 6, and 12 months.^{6,7} This questionnaire contains 24 items relating to functions commonly affected by low back pain: 0 (best health) to 24 (worst health). General health was measured with the SF-36 at 2, 6, and 12 months (higher scores indicate better health).⁸ Patient perceived benefit of treatment was measured on a scale from 0 (no benefit) to 10 (maximum benefit) and on a dichotomous scale (perceived benefit or no perceived benefit).

Intervention

Patients were randomised to receive advice to remain active (advice only group) or advice and a standard course of physiotherapy (therapy group). Both groups were given an advice book, and information from this was discussed with the physiotherapist.⁹ Advice was directed towards promoting self management and modifying beliefs and behaviour.

Patients in the advice only group received one session with a physiotherapist, who carried out a physical examination and gave general advice to remain active. The session lasted for up to an hour.

Patients in the therapy group underwent a physical examination by physiotherapists that lasted up to one hour. The physiotherapists chose a treatment strategy based on their findings but agreed to treat according to a standardised protocol reflecting routine NHS

practice.¹⁰ This included any combination of joint mobilisation and manipulation; soft tissue techniques, including stretching; spinal mobility and strengthening exercises; heat or cold treatment; and advice. The protocol specified up to five additional treatment sessions of around 30 minutes.

Randomisation and blinding

Patients were allocated to treatment by a computer generated random number sequence.¹¹ No stratification was used. The code for the grouping was known only to the physiotherapists treating the patients. The allocation was concealed from each patient until the first appointment. The baseline assessment was carried out by the research therapist before randomisation.

Statistical analysis

All analyses were performed on an intention to treat basis. To address potential biases due to incomplete follow up, we analysed patients with complete data at all time points and those with data at any time point, using the last known value carried forward to replace missing values. Outcome data for change in scores from baseline were compared between the groups. Bias due to non-response was assessed at each follow up.

We used independent *t* tests or Mann-Whitney U tests for continuous data and χ^2 tests for categorical data for unadjusted comparisons. Analysis of covariance was used to assess the effects of treatment at each time point, with baseline scores as the covariate, and adjusting for differences in age, sex, smoking status, and time since first episode of back pain. We examined the effects of treatment over all time points using repeated measures analysis of covariance. Relative risks were used to assess the differences between the groups for perceived benefit of physiotherapy, with logistic regression used for adjusted comparisons.

Results

Between October 1997 and January 2001 we randomised 144 patients with low back pain to therapy and 142 to advice only. The groups were well balanced (see bmj.com).

Table 2 Mean (SD) change in SF-36 domain scores at 2, 6 and 12 months from baseline for patients receiving physiotherapy or advice only for low back pain, with missing data replaced using last value carried forward

Domain	Therapy group (n=144)		Advice only group (n=142)		Mean difference (95% CI)	P value	
	Mean (SD) change	Effect size	Mean (SD) change	Effect size		t test	Analysis of covariance*
Physical function:							0.06†
2 months	5.24 (19.99)	0.27	1.70 (16.10)	0.07	3.55 (-0.52 to 7.61)	0.037	0.09
6 months	5.43 (18.80)	0.28	2.77 (17.07)	0.12	2.66 (-1.53 to 6.86)	0.098	0.21
12 months	5.98 (20.98)	0.31	3.22 (18.87)	0.14	2.76 (-1.91 to 7.42)	0.095	0.25
Role physical:							0.97†
2 months	14.99 (39.35)	0.37	10.80 (35.77)	0.27	4.19 (-4.57 to 12.9)	0.60	0.35
6 months	15.91 (46.41)	0.39	14.26 (38.87)	0.36	1.65 (-8.31 to 11.6)	0.97	0.74
12 months	13.89 (45.11)	0.34	13.20 (42.70)	0.33	0.68 (-9.54 to 10.9)	0.83	0.90
Bodily pain:							0.16†
2 months	9.70 (20.53)	0.54	7.47 (19.33)	0.37	2.22 (-2.41 to 6.87)	0.39	0.35
6 months	13.35 (22.88)	0.74	10.49 (21.78)	0.51	2.86 (-2.34 to 8.06)	0.37	0.28
12 months	16.79 (24.34)	0.93	10.63 (24.70)	0.52	6.16 (0.45 to 11.9)	0.057	0.035
General health:							0.39†
2 months	-0.15 (14.23)	0.01	-0.24 (12.76)	0.01	0.09 (-3.05 to 3.24)	0.73	0.95
6 months	-1.36 (16.01)	0.07	0.06 (13.97)	0.00	-1.42 (-4.92 to 2.08)	0.16	0.43
12 months	-1.66 (15.92)	0.09	-1.35 (17.05)	0.07	-0.31 (-4.15 to 3.53)	0.62	0.87
Vitality:							0.57†
2 months	2.01 (16.26)	0.11	0.62 (13.74)	0.04	1.39 (-2.11 to 4.90)	0.30	0.44
6 months	1.77 (17.87)	0.09	1.17 (13.30)	0.07	0.60 (-3.07 to 4.26)	0.72	0.75
12 months	2.55 (17.85)	0.13	1.09 (15.26)	0.06	1.45 (-2.41 to 5.32)	0.43	0.46
Social functioning:							0.28†
2 months	6.25 (22.08)	0.24	1.67 (19.54)	0.07	4.58 (-0.17 to 9.43)	0.24	0.06
6 months	8.51 (25.16)	0.33	2.64 (20.02)	0.12	5.87 (0.58 to 11.2)	0.12	0.03
12 months	5.90 (25.13)	0.23	2.64 (23.39)	0.12	3.26 (-2.39 to 8.91)	0.67	0.26
Role emotional:							0.21†
2 months	6.53 (39.61)	0.17	1.41 (36.57)	0.04	5.12 (-3.77 to 14.0)	0.36	0.26
6 months	3.03 (36.02)	0.08	-0.94 (41.63)	0.02	3.97 (-5.11 to 13.0)	0.46	0.39
12 months	5.36 (40.66)	0.14	-3.29 (40.93)	0.09	8.65 (-0.87 to 18.2)	0.065	0.08
Mental health:							0.10†
2 months	2.46 (13.17)	0.15	-2.45 (13.67)	0.15	4.91 (1.79 to 8.06)	0.006	0.002
6 months	1.15 (14.46)	0.07	-1.41 (14.88)	0.09	2.55 (-0.86 to 5.97)	0.22	0.14
12 months	0.64 (15.89)	0.04	-1.55 (16.56)	0.10	2.19 (-1.59 to 5.97)	0.25	0.26

* Adjusted for score at baseline, age, sex, smoking status, and time since first episode of back pain.

†Repeated measures analysis of covariance.

The patients were treated by 76 physiotherapists. Treatment in the therapy group included joint mobilisation using low velocity thrusts (104 of 144 patients; 72%); soft tissue techniques (20; 14%); specific exercises,¹² abdominal stability or strengthening exercises, and general mobility exercises for the lumbar spine (136; 94%); and heat (9; 6%) or cold treatment (4; 3%).

Overall, 82% of patients in both groups complied with treatment. Patients in the therapy group received a median number of five (range 1-12) sessions, with 118 (82%) having six or fewer. Twenty six (18%) patients received more than six sessions as a result of decisions made by the physiotherapist. The median number of sessions in the advice only group was one (range 1-22). The number of single sessions was 116, with 26 patients receiving extra sessions either because they were unhappy with advice only (eight patients), because the physiotherapist deemed it unethical to withhold further treatment (four patients), or because the patient had been re-referred for more treatment (two patients).

Overall, 30% of patients failed to provide data for the main outcome at 12 months. Only minor differences were found in the characteristics of people completing or not completing the Oswestry disability

index at all follow up points: responders were older (mean age 43 (SD 15) *v* 37 (13); $P < 0.001$), less likely to smoke (39 (22%) *v* 50 (47%); $P < 0.001$), and more likely to have a first episode of back pain or a history of chronic back pain (39 (23%) *v* 14 (15%) and 43 (25%) *v* 14 (15%), respectively; $P = 0.009$).

We found no differences between the groups in change in scores on the Oswestry disability index at 12 months (mean difference -1.04, 95% confidence interval -3.7 to 1.59). Tables 1 and 2 show the results derived from the last value carried forward analysis.

At 12 months the mean difference in domain scores on the SF-36 were: physical function (2.76, 95% confidence interval -1.91 to 7.42), role physical (0.68, -9.54 to 10.9), bodily pain (6.16, 0.45 to 11.9), general health (-0.31, -4.15 to 3.53), vitality (1.45, -2.41 to 5.32), social functioning (3.26, -2.39 to 8.91), role emotional (8.65, -0.87 to 18.2), and mental health (2.19, -1.59 to 5.97). Patients in the therapy group reported greater improvements for mental health and physical functioning at two months than the advice only group. Results from both methods of analysis were similar.

Patients in the therapy group were more likely to report benefits from treatment at both two and six months and also more benefit on the 0-10 rating scale

at all time points than patients in the advice only group (see bmj.com).

Discussion

Routine physiotherapy for mild to moderate low back pain generally practised in the United Kingdom is no more effective than a session with a physiotherapist that includes advice to remain active. Patients' perception of treatment benefit was, however, in conflict with the validated outcome measures, and the clinical importance of this finding needs further investigation.

Our trial does not provide information on the effectiveness of advice compared with no intervention, but other trials suggest that advice supported by a booklet is a useful intervention when compared with usual care given by a general practitioner.^{13 14} Although physiotherapists usually give advice, the book we chose is not used as standard practice in most physiotherapy departments. Spinal manipulation, which physiotherapists can provide after specialist postgraduate training, was negligible in our trial, although some international guidelines say that it can be helpful for acute or subacute low back pain.

There were only a few minor differences in baseline characteristics between patients who did or did not provide complete data, but the internal validity of our study is limited because 30% of patients failed to provide data for the main outcomes at 12 months.

We addressed potential bias by replacing missing data with the last value carried forward. Estimates of the effect of treatment were similar with both methods of analysis.

Compliance with treatment is rarely assessed or adequately reported in randomised controlled trials.¹⁵ We encouraged only physiotherapists who reported clinical equipoise to be involved in the trial, but the reasons for non-compliance are complex and we could not control for clinical decisions made on the basis of patients' fluctuating symptoms and physiotherapists' beliefs about the effectiveness of treatment.

Comparison with related research

According to disease specific outcomes, our participants had mild to moderate low back pain. SF-36 scores in our trial population were similar to those of patients with back pain in the general population consulting physiotherapists and worse than those of non-consulting patients with back pain.¹⁶

Similar baseline disease specific disability scores have been reported in only one other British study of patients with subacute low back pain.¹⁷ This trial found larger health gains in patients who attended a fitness programme to increase confidence in the use of their spine and to overcome fear of exercise. This suggests that exercise programmes with good compliance that are graded to ensure improvements in cardiovascular or muscular strength are more beneficial than routine physiotherapy as carried out in this trial and generally practised in the United Kingdom.¹⁰

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What is already known on this topic

International guidelines for patients with low back pain vary

All agree that patients should be advised to stay active; some suggest spinal manipulation for acute and subacute low back pain, and most advise exercise therapy for chronic low back pain

It is unclear which type or intensity of exercise is most effective and strong evidence is lacking for the effectiveness of other treatments

What this study adds

Routine physiotherapy for patients with mild to moderate low back pain is no more effective in the long term than advice given by a physiotherapist

patients; and the participants. This trial was begun and implemented while HF and SEL were working in the Physiotherapy Research Unit, Nuffield Orthopaedic Centre, Oxford, and we thank the staff for their help. We thank Oliver Rivero-Arias for his comments on the early drafts.

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