

Comparison of physical treatments versus a brief pain-management programme for back pain in primary care: a randomised clinical trial in physiotherapy practice

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Summary

Background Recommendations for the management of low back pain in primary care emphasise the importance of recognising and addressing psychosocial factors at an early stage. We compared the effectiveness of a brief pain-management programme with physiotherapy incorporating manual therapy for the reduction of disability at 12 months in patients consulting primary care with subacute low back pain.

Methods For this pragmatic, multicentre, randomised clinical trial, eligible participants consulted primary care with non-specific low back pain of less than 12 weeks' duration. They were randomly assigned either a programme of pain management (n=201) or manual therapy (n=201). The primary outcome was change in the score on the Roland and Morris disability questionnaire at 12 months. Analysis was by intention to treat.

Findings Of 544 patients assessed for eligibility, 402 were recruited (mean age 40.6 years) and 329 (82%) reached 12-month follow-up. Mean disability scores were 13.8 (SD 4.8) for the pain-management group and 13.3 (4.9) for the manual-therapy group. The mean decreases in disability scores were 8.8 (6.4) and 8.8 (6.1) at 12 months (difference 0 [95% CI -1.3 to 1.4], p=0.99), and median numbers of physiotherapy visits per patient were three (IQR one to five) and four (two to five), respectively (p=0.001). One adverse reaction (an exacerbation of pain after the initial assessment) was recorded.

Interpretation Brief pain management techniques delivered by appropriately trained clinicians offer an alternative to physiotherapy incorporating manual therapy and could provide a more efficient first-line approach for management of non-specific subacute low back pain in primary care.

Introduction

In the UK, primary-care guidelines for the management of acute low back pain encourage early referral to a physiotherapist for patients with non-specific pain for whom first-line management by general (family) practitioners with medication, advice to stay active, and simple messages about self management has not been effective.^{1,2} Evidence from systematic reviews of the effectiveness of specific types of physiotherapy in such patients, including exercise and manual techniques, is conflicting,^{3,4} but lends support to active intervention rather than no treatment. Two systematic reviews of spinal manipulation^{5,6} showed a more beneficial outcome with this technique than with sham procedures or passive interventions.

Even early in the course of an episode of low back pain, the reasons why patients might not be recovering are complex and include more than just the pathophysiology of the spine. Psychological distress and misguided beliefs about pain seem to interfere with recovery and raise the risk of chronic disability.⁷⁻⁹ These clinical observations are lent support by epidemiological evidence, which has consistently shown that psychosocial factors are important determinants of outcome in patients with low back pain.^{10,11} Such evidence led to the strong recommendation of the UK clinical guidelines^{1,2} for a

broad approach to the primary-care management of low back pain within the biopsychosocial model of care, which emphasises the importance of early attention to psychosocial factors. In secondary care, multi-disciplinary pain-management programmes based on cognitive behavioural techniques have reduced disability and increased the likelihood that patients with chronic low back pain are able to return to work.^{12,13} Such programmes are labour intensive, expensive, and impracticable for the many patients with back pain presenting in primary care. One approach in this setting would be to take important key messages and principles from secondary-care programmes that relate to the biopsychosocial management of low back pain and incorporate them as additional or alternative approaches to the physiotherapy management for such patients.¹⁴⁻¹⁶ However, unresolved issues include what constitutes an appropriate primary-care pain-management intervention, how this intervention might be delivered, and how it can be integrated with current practice. We did a randomised clinical trial to compare the clinical effectiveness, in primary care, of a brief pain-management programme delivered by physiotherapists with that of a programme of physiotherapy including spinal management techniques in the treatment of non-specific low back pain of less than 12 weeks' duration.

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Methods

Study participants

Participants were recruited from 28 general practices in North Staffordshire, UK. All adults aged 18–64 years who consulted their general practitioners for the first or second time with an episode of non-specific low back pain (as defined by the UK Clinical Standards Advisory Group)² of less than 12 weeks' duration and who were able to give informed written consent were invited to participate. Exclusion criteria were red flags² (clinical indicators of possible serious spinal or systemic disorders); long-term sick leave (>12 weeks); a clinical diagnosis of osteoporosis or inflammatory arthritis; systemic steroid treatment for longer than 12 weeks; pregnancy; previous hip or back surgery or a fracture; abdominal surgery within the previous 3 months; and treatment by another health care professional for this episode of back pain.

The general practitioner undertook a screen for red flags, provided an information leaflet about the study, obtained written permission for further contact, and faxed contact details to the research centre. A study nurse telephoned potential participants after 48 h to arrange a home visit where eligibility was established, written informed consent to randomisation was obtained, and the baseline assessment was undertaken. The North Staffordshire local research ethics committee approved this study.

Procedures

The random allocation sequence was produced by a computerised random-number generator. Study participants were assigned a unique study number. Randomisation to an allocated treatment was undertaken by a trial administrator who posted participants an opaque envelope containing their appointment with one of the trial physiotherapists. Follow-up data were obtained by the study nurse at 3 months (postal self-complete questionnaire) and 12 months (home visit). Study nurses and researchers who collected, entered, and analysed data were unaware of treatment allocation. Trial participants were unaware of the study hypothesis, although by necessity the treating physiotherapists were not. The effectiveness of the concealment of treatment allocation from the study nurse was assessed at 12 months.

Patients were randomly assigned either a brief pain-management programme or a course of physiotherapy including manual therapy techniques. The brief pain management programme was designed to identify and address psychosocial risk factors for persistent or recurrent disability related to back pain. The emphasis was on return to normal activity through functional goal setting, with educational strategies to overcome psychosocial barriers to recovery. Participants were assessed with a stem and leaf interview¹⁷ (a set series of open questions that can be followed by supplementary

questions dictated by the participant's response) to develop a management plan that included general fitness and exercise, explanation about pain mechanisms, distress (about pain, iatrogenic adverse effects, limitations for work and family activities), encouragement of positive coping strategies, overcoming fear of "hurt=harm", and implementation of a graded return to usual activities (increase function, pacing, fear avoidance, treatment adherence, obstacles to recovery). Exercises, done both in clinic and at home, focused on increasing overall physical activity and spinal mobility and were tailored to individual functional needs and capabilities. No manual therapy techniques were used. Three musculoskeletal physiotherapists delivered the brief pain management programme package. They were trained to predetermined competencies in the biopsychosocial model of care before the start of the trial. The training programme included hypothetical case reports of patients with different presentations of back pain and disability, and problem-solving exercises dealing with activities of daily living, distress, and fear. The initial 2-day course was supplemented by clinical tutoring including the use of a treatment log.

The package of hands-on manual physiotherapy was primarily oriented towards spinal manual-therapy techniques and was designed to be consistent with best current manual physiotherapy practice in the UK. The emphasis was on diagnosing and treating biomechanical dysfunction of the spine by use of the skills of the physiotherapist to assess and treat the spine with manual-therapy techniques and specific exercises for the back. The manual therapy included articular mobilisation, articular manipulation, or other soft-tissue treatment approaches. This package also included an individualised home programme of specific spinal stabilisation and muscle strengthening back exercises, education about the anatomy of the spine, and ergonomic advice. The three physiotherapists who delivered the manual-therapy package had all completed postgraduate training in manual therapy. Treatment approaches were agreed and standardised before the trial.

The interventions were started within 10 days of randomisation and consisted of one 40 min assessment and treatment session and up to six subsequent 20 min treatment sessions. Details of the number and duration of treatment sessions and the techniques used were recorded on a standard proforma.

Outcomes were measured at baseline and at 3 months and 12 months after randomisation. The primary outcome was change in disability related to the back measured at 12 months, rated on the self-completed Roland and Morris disability questionnaire (RMDQ)¹⁸ 24-item scale. Self-completed secondary outcomes included: participants' overall assessment of change compared with baseline (six-point scale: completely better, much better, better, same, worse, much worse); pain location (body chart); rating of pain severity

(0–100 mm visual analogue scale) and nature of pain (short-form McGill pain questionnaire¹⁹). Depression and somatic distress were also measured with two questionnaires (the modified Zung depression inventory²⁰ and the modified somatic perception questionnaire, which can be combined to give a score of psychological distress, the DRAM);²¹ fear of movement was assessed with the Tampa scale of kinesiophobia (scale: 17–68);²² and coping strategies were measured with the coping strategies questionnaire, which contained four subscales (each 0–36) for coping self-statements, praying or hoping, catastrophising, and increasing activity level.²³ Satisfaction with treatment (0–100 mm visual analogue scale), days off work since start of current episode, and cointerventions (use of health-care services and medication) were also assessed. Cointerventions were validated by a medical record review in 10% of participants.

Statistical analysis

The sample-size calculation was based on change in RMDQ at 12 months after randomisation. A previous study in primary care showed a mean reduction in RMDQ score of 5.3 (SD 5.8) over 3 months.⁸ To detect a clinically significant difference of 2 points between the two treatment groups,²⁴ with a significance level of 5% (2-tailed) and 90% power, 180 patients were needed in each treatment group. To allow for a 10% dropout rate, the total sample needed was 400. Analysis was by intention to treat. Estimates of the treatment effect with 95% CIs (brief pain management minus manual physiotherapy) were calculated and statistical tests (*t* tests for numerical data, χ^2 tests for categorical data) were done for the primary and all secondary outcomes. Statistical significance was set at the 5% level (two-tailed). Exploratory sensitivity analyses of the mean differences in RMDQ change scores were undertaken. First, we did an analysis of covariance using multiple linear regression adjusting for covariates, selected according to random differences in baseline characteristics. Second, we undertook an on-treatment analysis by restricting the comparison to patients who received their allocated treatment per protocol—ie, excluding patients who were not recorded as having received their assigned treatment or who did receive treatment reserved for the other group.

We also undertook a set of preplanned subgroup analyses of the primary outcome measure using linear regression to investigate the interaction effect of treatment with the following stratified baseline factors: age (<40 years, \geq 40 years); sex; RMDQ (<14, \geq 14); and psychological distress (DRAM: normal, at risk, distressed-somatic, distressed-depressed).²¹ Statistical analyses were undertaken with SPSS for Windows version 12.0. An independent steering data monitoring and ethics committee monitored the trial every 6 months. No interim analyses were undertaken during the study period.

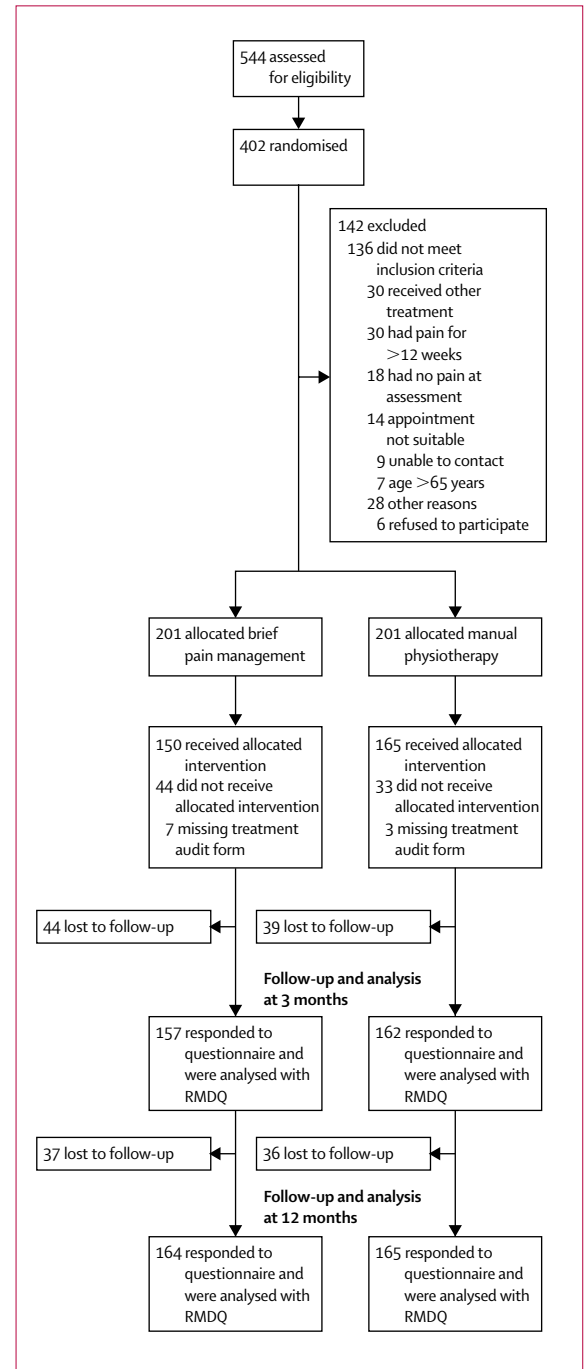


Figure: Trial profile

*RMDQ scores were available for all participants who completed and returned the questionnaire.

Role of the funding source

The sponsors of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Of the potential participants who were screened between July, 2000, and July, 2002, 74% were eligible and consented to randomisation (figure). The number of participants randomly assigned to a treatment group ranged from one to 61 patients per general practice. Treatment allocation and baseline characteristics varied little across practices that recruited 20 or more patients and those that recruited fewer than 20 patients. The mean age of participants was 40·6 years (range 18–64) and 52% (210) were women (table 1). For both intervention groups the follow-up rate was 82% at 12 months. The subgroup lost to follow-up had a higher proportion of men than the group with completed follow-up (44 [60%] vs 148 [45%]) and the mean age was lower (35·0 vs 41·9 years); the baseline RMDQ scores were 13·3 and 13·6, respectively. Treatment concealment from the study nurse was effective: treatment allocation was revealed to the nurse by 16 of 402 participants (three in the brief-pain-management group, 13 in the manual-physiotherapy group). However, treatment received was correctly identified in only seven participants.

Treatments were in line with the study protocols (table 2). 33 (17%) participants assigned brief pain management and 20 (10%) of those assigned manual physiotherapy did not attend for their treatment. The median number of physiotherapy visits was significantly lower in the brief pain management group than in the manual physiotherapy group for both the intention-to-treat analysis ($p=0\cdot001$) and for the per-protocol analysis ($p=0\cdot006$). 77% of the participants assigned pain-management techniques and 93% of those who actually attended were recorded as having received the techniques defined a priori as relevant to this intervention (table 2). Of those assigned manual physiotherapy, 83% of the complete cohort and 93% of attendees were recorded as receiving manual-therapy techniques. Median satisfaction with treatment at 3 months was the same for both interventions.

The RMDQ change scores did not differ between groups at 3 months and 12 months (table 3). The sensitivity analyses also showed no significant differences in outcome between the two treatment groups. There were no significant differences in mean RMDQ change scores between subgroups stratified according to age, sex, RMDQ, and DRAM categories at 3 months' and 12 months' follow-up. Participants' overall assessment of improvement did not differ between groups at 12 months (table 4). 129 (84%) in the pain-management group and 132 (84%) in the manual physiotherapy group rated themselves as completely better, much better, or better (difference 0·2% [-7·9 to 8·4, $p=0\cdot954$). Interventions did not differ with respect to outcomes for back pain or function and psychological measures. There were significantly fewer contacts with secondary care in

	Brief pain management (n=201)	Manual physiotherapy (n=201)
Demographics		
Age (years)*	40·4 (12·0)	40·9 (11·6)
Women	100 (50%)	110 (55%)
Routine and manual occupations	105 (54%)	130 (66%)
Currently in paid employment	142 (71%)	152 (76%)
Time off work for current episode†	97 (48%)	108 (54%)
Back pain and function		
RMDQ score*	13·8 (4·8)	13·3 (4·9)
Severity of pain today (VAS)*	55·8 (23·3)	55·5 (22·9)
Pain in past week (SF McGill VAS)*	68·3 (21·2)	69·9 (20·3)
Severity of main complaint (VAS)*	60·9 (20·0)	61·3 (19·4)
Radiating pain below the knee	60 (30%)	67 (33%)
Using painkillers	185 (92%)	189 (94%)
Duration of current episode of pain <1 month	150 (75%)	149 (74%)
Previous episode of low back pain	157 (78%)	139 (69%)
Psychological measures		
MSPQ score*	5·6 (4·3)	5·3 (5·0)
Zung score*	24·9 (7·9)	24·4 (8·1)
CS-CSS score*	25·2 (6·7)	25·1 (6·2)
CS-PH score*	15·8 (8·1)	15·1 (7·7)
CS-CAT score*	8·4 (6·7)	7·9 (6·7)
CS-IAL score*	22·4 (6·3)	22·7 (5·9)
TSK score*	40·7 (6·2)	41·0 (7·2)
General health		
Widespread pain‡	25 (12%)	27 (13%)
Longstanding illness present	64 (32%)	59 (30%)

Numbers do not add up to totals in all cases because of missing data. At least 90% of all questions were completed. Data are number of participants unless otherwise indicated. *Data are mean (SD). †Time off work: work relates to current paid employment. ‡Based on the ACR definition; VAS=visual analogue scale; SF McGill=short form McGill pain questionnaire; MSPQ=modified somatic perception questionnaire; Zung=modified Zung depression scale; CS=coping strategies questionnaire (CS=coping self-statements, PH=praying or hoping, CAT=catastrophising, IAL=increasing activity level); TSK=Tampa scale for kinesiophobia.

Table 1: Baseline characteristics of participants, by treatment group

	Brief pain management (n=194)	Manual physiotherapy (n=198)
Frequency of physiotherapy visits*	3 (1–5)	4 (2–5·25)
Number who did not attend for assessment	33 (17%)	20 (10%)
Number who attended for assessment	161 (83%)	178 (90%)
Frequency of physiotherapy visits*†	3 (2–5)	4 (3–6)
Duration of treatment in days*†	27·5 (8·75–49·75)	28 (14–45)
Number who received pain management techniques specified on proforma	150	12
Proportion of each group	150/194 (77%)	12/198 (6%)
Proportion of those who attended for assessment†	150/161 (93%)	12/178 (7%)
Number who received manual physiotherapy techniques specified on proforma	38	165
Proportion of each group	38/194 (20%)	165/198 (83%)
Proportion of those who attended for assessment†	38/161 (24%)	165/178 (93%)
Number who received other specified techniques‡	157	169
Proportion of each group	157/194 (81%)	169/198 (85%)
Proportion of those who attended for assessment†	157/161 (98%)	169/178 (95%)
Satisfaction with treatment*¶	93 (68–97)	93 (80–98)

*Data are median (IQR); †Based on the 161 patients in the brief pain management group and 178 patients in the manual physiotherapy group who did attend for assessment—ie, had at least one physiotherapy visit recorded in the case notes; ‡Other specified techniques refers to the following modality techniques specified on the treatment proforma: specific spinal mobilisation exercise; neurodynamic exercise; postural exercise; advice about posture, ergonomics, lifting; advice about activities of daily living, sport/leisure; pain control (medication, heat/cold, positions of comfort). ¶Based on 126 pain-management and 135 manual-therapy patient responses to the visual analogue scale self-complete question "Overall, how satisfied are you with your physiotherapy treatment?" on the 3-month follow-up questionnaire.

Table 2: Summary of interventions from 392 case notes audited, by treatment group

	Brief pain management	Manual physiotherapy	Mean difference (95% CI)*	p†
3-months				
Number analysed‡	157	162		
Absolute score	6.0 (5.9)	5.1 (5.8)	0.8 (-0.5 to 2.1)	0.203
Change score§	7.8 (6.6)	8.1 (6.0)	-0.2 (-1.6 to 1.2)	0.755
Sensitivity analyses				
ANCOVA	-	-	-0.6 (-1.8 to 0.6)	0.337
Additional adjustment	-	-	-0.5 (-1.8 to 0.9)	0.492
Per-protocol analysis	-	-	-0.7 (-2.3 to 0.9)	0.407
12-months				
Number analysed‡	164	165		
Absolute score	5.2 (5.7)	4.4 (5.5)	0.8 (-0.5 to 2.0)	0.222
Change score§	8.8 (6.4)	8.8 (6.1)	0 (-1.3 to 1.4)	0.994
Sensitivity analyses				
ANCOVA	-	-	-0.5 (-1.7 to 0.7)	0.405
Additional adjustment	-	-	-0.9 (-2.2 to 0.4)	0.175
Per-protocol analysis	-	-	-0.2 (-1.8 to 1.5)	0.820

Data are mean (SD) unless otherwise stated. *Difference in mean scores (pain management group - physiotherapy group); †Derived by t test; ‡Values presented are those for the main analyses and also apply to sensitivity analysis (mean difference adjusted for RMDQ change score by ANCOVA). The numbers in the analysis for the additional adjustment (baseline age, sex, occupational classification, time off work, RMDQ score, and previous low-back pain) were 109 for the pain-management group and 122 for the physiotherapy group at 3 months, and 114 and 126, respectively, at 12 months. The numbers analysed for the per-protocol analysis were 96 and 132 at 3 months, and 99 and 135 at 12 months; § Mean change (SD) in RMDQ score from baseline.

Table 3: RMDQ scores at 3 months and 12 months follow-up

participants in the pain-management group than in the manual-physiotherapy group (table 5). One adverse reaction (an exacerbation of pain after the initial assessment) was recorded. This was reported to the data monitoring and ethics committee as specified in the protocol.

Discussion

Clinical outcome was the same at 3 months and 12 months for participants randomised to either a brief pain-management programme or to a package of physiotherapy incorporating spinal manual-therapy techniques. This pragmatic, randomised clinical trial had high internal validity, shown by the adequate recruitment, remote system of randomisation, and effective masking of assessors and analysts. Although we expected our follow-up rate to be very high since our previous trials achieved over 90% long-term follow-up,^{25,26} such rates are optimistic compared with other published trials of low back pain.²⁷ Our actual follow-up rate of 82% at 12 months gave us 88% power to detect a 2 point difference in RMDQ change scores between groups. The interventions were delivered according to

the study protocol, and the higher rate of non-attendance for the pain management than for the manual therapy intervention should not be interpreted as an indicator of the acceptability of either treatment package because trial participants were not aware of the specific content of the interventions or the study hypothesis. We chose disability related to back pain as our primary outcome measure¹⁸ in line with other primary-care studies of low pack pain.^{27,28} However, because a particular focus of our trial was to reduce disability by tackling psychosocial issues, we also included outcome measures to assess the effect of our interventions on pain, coping, psychological distress, and fear of movement, although the trial was not powered to provide precise estimates in these domains.

Our trial took place in North Staffordshire, mainly within the conurbation of Stoke on Trent, a mixed urban and semi-rural area. 60% of participants graded their occupation as routine or manual. The results of our trial are applicable to a defined subset of all patients consulting primary care practitioners with non-specific low back pain of less than 12 weeks' duration. Patients with pain for this duration account for roughly one in five of those presenting to primary care with low back pain.²⁹ Disability related to back pain at baseline was greater in our trial than in several primary-care observational²⁹ and intervention studies.^{14,16,27} We chose this group of patients with subacute low back pain so that we could specifically investigate the effectiveness of an intervention aimed at identifying and tackling psychosocial barriers to recovery at an early stage of persistent low back pain and at outcomes over a period of 12 months when recurrence rates in such patients can be substantial. Although roughly 75% of participants reported a current episode duration of less than 4 weeks of back pain, most reported previous episodes and were not, therefore, new consulters.

The low level of psychological distress in our trial participants could have reduced the ability of the trial to show a beneficial effect of a pain-management package specifically aimed at targeting psychological risk factors for persistence or recurrence. Subgroup analysis to investigate differences in effectiveness between interventions in participants with high levels of distress was limited by small numbers (n=31) and consequent lack of statistical power. This analysis showed a mean reduction in RMDQ at 12 months of 9.2 in participants categorised as "distressed-depressed" according to their baseline DRAM and assigned brief pain management, compared with 6.8 in those assigned manual therapy. This finding merits further investigation to assess whether selective targeting of interventions (such as brief pain management delivered specifically to those with greater distress) leads to better clinical improvement.

The overall similarity in clinical effectiveness between the physiotherapy packages raises the

	Brief pain management	Manual physiotherapy
Number of completed items	153	157
Completely better	28 (18%)	35 (22%)
Much better	76 (50%)	73 (47%)
Better	25 (16%)	24 (15%)
Same	13 (9%)	19 (12%)
Worse	8 (5%)	6 (4%)
Much worse	3 (2%)	0

Table 4: Participants' assessment of overall change at 12 months' follow-up, by treatment group

	Endpoint	Brief pain management		Manual physiotherapy		Difference‡ (95% CI)	P§
		n*	Summary†	n*	Summary†		
Back pain and function							
Back pain today	12 months	163	78 (48%)	162	70 (43%)	4.6% (-6.2 to 15.5)	0.401
Severity of pain today (VAS)	3 months	152	19.8 (23.2)	153	17.6 (24.9)	2.2 (-3.2 to 7.7)	0.418
Pain in past week (SF McGill VAS)	12 months	163	19.0 (24.3)	164	17.2 (24.2)	1.8 (-3.5 to 7.1)	0.503
	3 months	152	21.9 (23.8)	157	21.6 (25.7)	0.4 (-5.2 to 5.9)	0.900
Severity of main complaint (VAS)	12 months	163	22.6 (25.9)	163	19.7 (24.9)	2.9 (-2.7 to 8.4)	0.306
Time off work¶	12 months	148	16.6 (22.0)	152	17.0 (22.5)	-0.4 (-5.4 to 4.7)	0.879
Time off work¶	12 months	110	59 (54%)	130	76 (58%)	-4.8% (-17.5 to 7.9)	0.453
Psychological measures							
MSPQ	3 months	143	4.1 (4.8)	139	3.5 (4.6)	0.5 (-0.6 to 1.6)	0.354
	12 months	159	3.9 (5.0)	159	3.1 (4.4)	0.8 (-0.2 to 1.9)	0.112
Zung	3 months	136	25.1 (7.1)	136	24.3 (8.0)	0.8 (-1.0 to 2.6)	0.380
	12 months	157	24.9 (7.4)	157	24.8 (7.2)	0.1 (-1.5 to 1.7)	0.922
CS-CSS	12 months	105	25.6 (7.4)	103	25.1 (6.8)	0.4 (-1.5 to 2.4)	0.683
CS-PH	12 months	104	11.1 (7.8)	103	10.5 (6.8)	0.6 (-1.4 to 2.6)	0.536
CS-CAT	12 months	106	6.3 (6.2)	103	6.4 (7.1)	-0.1 (-1.9 to 1.7)	0.888
CS-IAL	12 months	105	20.7 (6.6)	102	20.4 (7.5)	0.2 (-1.7 to 2.2)	0.826
TSK score	3 months	138	46.7 (7.6)	138	46.8 (8.5)	-0.1 (-2.0 to 1.8)	0.933
	12 months	150	45.0 (6.6)	154	44.7 (7.5)	0.3 (-1.3 to 1.9)	0.713
Cointerventions for back pain over 12 months							
Primary-care consultation	12 months	152	45 (30%)	158	46 (29%)	0.5% (-9.7 to 10.7)	0.924
Secondary-care consultation	12 months	153	2 (1%)	157	11 (7%)	-5.7% (-10.1 to -1.2)	0.012
Received prescribed medicines	12 months	152	51 (34%)	157	43 (27%)	6.2% (-4.1 to 16.5)	0.239

*Numbers analysed; †Summary data are mean (SD) or number (%); ‡Difference (pain management group - physiotherapy group) is mean difference for analysis of numerical outcomes or percentage difference for analysis of dichotomous outcomes; §P values were derived by t tests for numerical outcomes and χ^2 tests for categorical outcomes; ¶Time off work relates to those currently employed who had time off work during the previous 12 months because of back pain; ||Scores for the coping Strategies questionnaire at 12 months were based on those respondents reporting having had back pain in the past month.

Table 5: Secondary outcome measures at 3 months' and 12 months' follow-up, by treatment group

question of whether either of these interventions is superior to no active intervention. We decided not to include a no treatment or a minimum treatment group for practical, ethical, and methodological reasons. The presence of a no treatment group is difficult to justify because many clinical guidelines^{1,2} support early physical intervention, and evidence-based reviews and recent trials consistently show active intervention to be better than sham or placebo procedures.^{5,6,27} Recruitment to primary care trials is notoriously difficult and early discussions with participating general practitioners drew attention to the practical advantages of including two active interventions. The inclusion of a usual care group could have led to the justifiable criticism that the amount of attention and intervention was different in the respective groups of the trial.

Physiotherapists have the potential to shift the model of care for patients with low back pain from a narrow biomedical approach to a broad approach that incorporates psychosocial factors. We trained a group of physiotherapists to deliver a package of care that, as well as including conventional physical approaches to pain management, incorporated psychosocial elements.³⁰ Both the training package received by the physiotherapists and the intervention they delivered were brief and appropriate for implementation in primary care. Other primary-care studies of cognitive behavioural approaches delivered by clinical psychologists^{18,19} have shown encouraging short-term

benefit, but effect sizes were small. Two UK trials showed a small beneficial short-term effect on disability of a group exercise class that incorporated cognitive behavioural therapy principles compared with management in a general practice in patients with simple low back pain.^{16,27} We now need to develop and assess training programmes and competency levels for practitioners who deliver pain-management programmes in primary care.

Our findings provide a choice of approach for physiotherapists and suggest that manual therapy is not essential as an initial treatment for patients with subacute low back pain. The pain-management package was delivered in fewer treatment sessions, resulted in fewer referrals to secondary care than the traditional approach, and might be an efficient first-line approach to care of patients with low back pain presenting in primary-care practice.

Contributors

All authors contributed to the interpretation of the results and drafting and revision of the article. Additionally: E M Hay contributed to the design, funding application, and management of the trial; R Mullis contributed to the design and management of the trial, data collection, and analysis; M Lewis contributed to the design of the trial and data analysis; K Vohora contributed to the recruitment procedures, data collection, and management; C J Main and P Watson contributed to the design of the treatment interventions and training of the therapists; K S Dziedzic, J Sim, and C Minns Lowe contributed to the design, funding application, and management of the trial; and P Croft contributed to the design and funding application.

Conflict of interest statement

We declare that we have no conflict of interest.

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References

- Royal College of General Practitioners. Guidelines for the management of acute low back pain. London: RCGP, 1996.
- Clinical Standards Advisory Group on Back Pain. Back pain. London: HMSO Stationery Office, 1994.
- Cherkin D, Sherman K, Deyo R, Shekelle P. A review of the evidence for the effectiveness, safety, and cost of acupuncture, massage therapy and spinal manipulation for back pain. *Ann Intern Med* 2003; **138**: 898–906.
- Koes BW, Bouter LM, Beckerman H, Heijden GJMG van der, Knipschild PG. Physiotherapy exercises and back pain: a blinded review. *BMJ* 1991; **302**: 1572–76.
- Bronfort G, Haas M, Evans RL, Bouter LM. Efficacy of spinal manipulation and mobilization for low back pain and neck pain: a systematic review and best evidence synthesis. *Spine J* 2004; **4**: 335–56.
- Assendelft WJJ, Morton SC, Yu EI, Suttrop MJ, Shekelle PG. Spinal manipulative therapy for low back pain. *Ann Intern Med* 2003; **138**: 871–900.
- Kendall NA, Linton SJ, Main CJ. Guide to assessing psychosocial yellow flags in acute low back pain: risk factors for long-term disability and work loss. Wellington, New Zealand: Accident Rehabilitation and Compensation Insurance Corporation of New Zealand and the National Health Committee.
- Burton AK, Tillotson M, Main CJ, Hollis S. Psychosocial predictors of outcome in acute and subchronic low back trouble. *Spine* 1995; **20**: 722–28.
- Main CJ, Wood PLR, Hollis S, Spanswick CC, Waddell G. The distress risk and assessment method. *Spine* 1991; **17**: 42–52.
- Croft PR, Papageorgiou AC, Ferry S, Thomas E, Jayson MIV, Silman AJ. Psychologic distress and low back pain. *Spine* 1995; **20**: 2731–37.
- Klenerman L, Slade PD, Stanley IM, et al. The prediction of chronicity in patients with an acute attack of low back pain in a general practice setting. *Spine* 1995; **20**: 478–84.
- Karjalainen K, Malmivaara A, Pohjolainen T, et al. Mini intervention for subacute low back pain. *Spine* 2003; **28**: 533–41.
- Guzman J, Esmail R, Karjalainen K, Malmivaara A, Irvin E, Bombardier C. Multidisciplinary biopsychosocial rehabilitation for chronic low back pain. *Cochrane Database Syst Rev* 2002; **1**: CD000963.
- Moore JE, Von Korff M, Cherkin D, Saunders K, Lorig K. A randomised trial of a cognitive-behavioural program for enhancing back pain self care in a primary care setting. *Pain* 2000; **88**: 145–53.
- Linton SJ, Andersson T. Can chronic disability be prevented? A randomised trial of cognitive-behavioural intervention and two forms of information for patients with spinal pain. *Spine* 2000; **25**: 2825–31.
- Frost H, Lamb SE, Klaber Moffett JA, Fairbank JC, Moser JS. A fitness programme for patients with chronic low back pain: 2-year follow-up of a randomised controlled trial. *Pain* 1998; **75**: 273–79.
- Main CJ, Williams A. ABC of psychological medicine musculoskeletal pain. *BMJ* 2002; **325**: 534–37.
- Roland M, Morris R. A study of the natural history of back pain—part 1: development of a reliable and sensitive measure of disability in low back pain. *Spine* 1983; **8**: 141–44.
- Melzack R. The short-form McGill pain questionnaire. *Pain* 1987; **30**: 191–97.
- Main CJ, Waddell G. The detection of psychological abnormality in chronic low back pain using four simple scales. *Curr Concepts Pain* 1984; **2**: 10–15.
- Main CJ, Wood PLR, Hollis S, Spanswick CC, Waddell G. The distress risk and assessment method. *Spine* 1991; **17**: 42–52.
- Kori SH, Miller RP, Todd DD. Kinesiophobia: a new view of chronic pain behaviour. *Pain Manag* 1990; Jan/Feb: 35–43.
- Rosenstiel AK, Keefe F. The use of coping strategies in chronic low back pain patients; relationship to patient characteristics and current adjustment. *Pain* 1983; **17**: 33–44.
- Bombardier C, Hayden J, Beaton DE. Minimal clinically important difference. low back pain: outcome measures. *J Rheum* 2001; **28**: 431–38.
- Hay EM, Thomas E, Paterson SM, Dziedzic K, Croft PR. A pragmatic randomised controlled trial of local corticosteroid injection and physiotherapy for the treatment of new episodes of unilateral shoulder pain in primary care. *Ann Rheum Dis* 2003; **62**: 394–99.
- Hay EM, Paterson S, Lewis M, Hosie G, Croft P. A randomised controlled trial of local corticosteroid injection and naproxen for the treatment of lateral epicondylitis in primary care. *BMJ* 1999; **319**: 964–68.
- BEAM Trial Team. United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial; effectiveness of physical treatments for back pain in primary care. *BMJ* 2004; **329**: 1377–85.
- Damush TM, Weinberger M, Perkins SM, et al. The long-term effects of a self-management program for inner-city primary care patients with acute low back pain. *Arch Intern Med* 2003; **163**: 2632–38.
- Dunn KM, Croft PR. Classification of low back pain in primary care: using bothersomeness to identify the most severe patients. *Spine* (in press).
- Mullis R, Dziedzic K, Lewis M, et al. Is video analysis of clinical interventions in treatment trials valuable? Experiences from a low back pain study. *Rheumatology* 2004; **43** (suppl 2): ii86.