

Randomised controlled trial of a short course of traditional acupuncture compared with usual care for persistent non-specific low back pain

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Abstract

Objective To determine whether a short course of traditional acupuncture improves longer term outcomes for patients with persistent non-specific low back pain in primary care.

Design Pragmatic, open, randomised controlled trial.

Setting Three private acupuncture clinics and 18 general practices in York, England.

Participants 241 adults aged 18-65 with non-specific low back pain of 4-52 weeks' duration.

Interventions 10 individualised acupuncture treatments from one of six qualified acupuncturists (160 patients) or usual care only (81 patients).

Main outcome measures The primary outcome was SF-36 bodily pain, measured at 12 and 24 months. Other outcomes included reported use of analgesics, scores on the Oswestry pain disability index, safety, and patient satisfaction.

Results 39 general practitioners referred 289 patients of whom 241 were randomised. At 12 months average SF-36 pain scores increased by 33.2 to 64.0 in the acupuncture group and by 27.9 to 58.3 in the control group. Adjusting for baseline score and for any clustering by acupuncturist, the estimated intervention effect was 5.6 points (95% confidence interval -0.2 to 11.4) at 12 months (n = 213) and 8.0 points (2.8 to 13.2) at 24 months (n = 182). The magnitude of the difference between the groups was about 10%-15% of the final pain score in the control group. Functional disability was not improved. No serious or life threatening events were reported.

Conclusions Weak evidence was found of an effect of acupuncture on persistent non-specific low back pain at 12 months, but stronger evidence of a small benefit at 24 months. Referral to a qualified traditional acupuncturist for a short course of treatment seems safe and acceptable to patients with low back pain.

Trial registration ISRCTN80764175.

Introduction

Acupuncture is used by about 2% of adults in the United Kingdom each year for several conditions, including back pain. We determined whether a short course of acupuncture improves longer term

outcomes for patients with non-specific low back pain in primary care. We also monitored safety and acceptability of acupuncture to patients. A cost effectiveness study was carried out alongside this trial.¹

Participants and methods

We recruited patients aged 18-65 with non-specific low back pain of 4-52 weeks' duration, assessed as suitable by their general practitioner for primary care management (see bmj.com for exclusions). Thirty nine general practitioners from 16 practices identified patients.

Our primary outcome was the bodily pain dimension of the SF-36 at 12 months. This assesses pain in the past four weeks.²⁻⁴ We subsequently amended the protocol to include economic data and an additional clinical end point at 24 months. Our secondary outcomes were scores on the Oswestry pain disability index,⁵ the McGill present pain index,⁶ and the seven remaining dimensions of the SF-36.² Each was administered at baseline and at 3, 12, and 24 months. Satisfaction with treatment was assessed at three months.⁷ We included questions on concerns about back pain⁷ and current use of analgesics at 12 and 24 months. At 24 months we collected patient reports of back pain in the past year.

We assessed safety by monitoring patient reported adverse events at each acupuncture session, and at follow-up of those not completing treatment. We also collected information on responses to treatment from patients. Acceptability was assessed through the uptake of acupuncture, dropout rates, and patient completed items on satisfaction with aspects of care and willingness to retry acupuncture.

We randomised patients to receive a short course of traditional acupuncture or usual care (see bmj.com for details of randomisation and blinding). The six participating acupuncturists were registered with the British Acupuncture Council. Acupuncture care comprised up to 10 individualised sessions over three months.

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Patients in the usual care group received NHS treatment according to their general practitioner's assessment of need. We collected information from patients at 3, 12, and 24 months on all treatments received for low back pain.

Statistical analysis

Allowing for a 10%-15% dropout rate, we determined that we needed 100 patients in each arm to detect a difference in outcome between the groups of 10 (SD 19.3) points for the SF-36 pain score at 12 months, at 90% power and a two sided 5% significance level. The number of patients was subsequently increased to 240, retaining the original power. Analysis was undertaken on an intention to treat basis, using analysis of covariance for outcomes at 12 and 24 months, with baseline SF-36 pain scores as a covariate. We undertook a case analysis after exploration of known characteristics. The adjusted estimated effect and 95% confidence intervals are reported. We estimated clustering by acupuncturist using robust standard errors. We undertook a sensitivity analysis using a more complex regression model comprising baseline covariates that were observed to affect outcomes at three months, and by undertaking analysis using last observation carried forward to deal with missing values. We carried out exploratory analysis using analysis of covariance to examine the interaction between the effect of acupuncture and two variables measuring patients' expectations and beliefs, assessed before randomisation.

Results

Overall, 241 patients were recruited to the trial (see [bmj.com](#)). Two patients subsequently withdrew. With the exception of inability to work because of low back pain, no significant differences were observed between the groups at baseline (see [bmj.com](#)).

All patients randomised to acupuncture accepted the referral. Pain resolved in nine patients before treatment; the remaining patients received an average of 8.1 treatments. Patients also received adjunctive care (see [bmj.com](#)). Details of the acupuncture treatments are published elsewhere.⁸ Half the patients randomised to usual care received physiotherapy or manipulation during the first three months. Other interventions included drugs and back exercises (see [bmj.com](#)).

The dropout rate was within the range expected at 12 months. The rate was higher at 24 months, but

similar in both groups. Those lost to follow-up were younger and had poorer SF-36 pain scores at three months. This pattern was observed in both groups.⁹

Clinical outcomes

Table 1 shows pain scores for patients completing follow-up at 12 and 24 months. An intervention effect of 5.6 points (95% confidence interval -0.2 to 11.4) was found on the primary outcome SF-36 pain dimension in favour of the acupuncture group at 12 months (table 2). At 24 months a statistically significant difference was found between the groups, with an estimated effect of 8.0 points (2.8 to 13.2). The acupuncture group had better scores on the Oswestry pain disability index and the McGill present pain intensity measure. These differences failed to reach statistical significance in most analyses (table 2).

Patient perceived treatment benefits, adverse events, and prior expectations and beliefs

At three months patients in the acupuncture group were significantly more likely to be "very satisfied" with their treatment and with their overall care compared with patients receiving usual care but showed no such difference in satisfaction with information received. At 24 months the acupuncture group were more likely to report fewer concerns about their back pain, less likely to report current use of analgesics, and more likely to report no pain for the past 12 months (see [bmj.com](#)).

No serious adverse events (see [bmj.com](#)) were reported by patients in the acupuncture group. Four of the 16 patients who withdrew from acupuncture care mentioned minor adverse events. In total, 23% (30/133) of patients receiving acupuncture reported a temporary worsening of low back pain during treatment that bothered them "a lot" or "a great deal." However, 86% (112/133) experienced acupuncture as relaxing, and 91% (126/139) would retry it.

Comparison of groups classified according to expectations of improvement in back pain and belief that acupuncture might help, both stated before randomisation, showed evidence that expectations of improvement had a positive treatment effect, and weak evidence of an interaction effect whereby positive belief was associated with less benefit than neutral belief (see [bmj.com](#)).

Table 1 Observed mean pain outcome scores over time by acupuncture or usual care groups

Variable	Baseline				12 months				24 months			
	Acupuncture care		Usual care		Acupuncture care		Usual care		Acupuncture care		Usual care	
	Mean (SD)	No of patients	Mean (SD)	No of patients	Mean (SD)	No of patients	Mean (SD)	No of patients	Mean (SD)	No of patients	Mean (SD)	No of patients
All cases:												
SF-36 bodily pain*	30.8 (16.2)	159	30.4 (18.0)	80	64.0 (25.6)	147	58.3 (22.2)	68	67.8 (24.1)	123	59.5 (23.4)	59
Oswestry pain disability index†	33.7 (15.4)	159	31.4 (14.2)	80	20.6 (19.3)	134	19.6 (15.4)	57	18.3 (16.5)	114	21.0 (14.2)	50
McGill present pain index‡	2.64 (1.0)	159	2.70 (1.0)	80	1.43 (1.1)	135	1.53 (0.9)	57	1.42 (1.1)	113	1.71 (1.1)	49

*Scored on a 0 to 100 (no pain) scale.

†Scored on a 0 (no pain) to 100 scale.

‡Scored on a 0 (no pain) to 5 scale.

Table 2 Difference in outcome scores between acupuncture and usual care groups at 12 and 24 months

Variable	12 months			24 months		
	No of patients	Difference* (95% CI)	P value	No of patients	Difference* (95% CI)	P value
SF-36 bodily pain score:						
Unadjusted difference	215	5.7 (-1.4 to 12.8)	0.11	182	8.2 (0.8 to 15.7)	0.031
Difference adjusted for baseline pain score and clustering by acupuncturist	213	5.6 (-0.2 to 11.4)	0.06	182	8.0 (2.8 to 13.2)	0.003
Difference adjusted for baseline pain score and other baseline covariates†	212	6.0 (-0.6 to 12.6)	0.07	179	9.0 (1.8 to 16.2)	0.015
Oswestry pain disability index:						
Unadjusted scores	191	0.9 (-3.8 to 5.8)	0.68	164	-2.7 (-7.1 to 1.6)	0.22
Difference adjusted for baseline pain score and clustering by acupuncturist	191	-0.5 (-5.1 to 4.2)	0.85	164	-3.4 (-7.8 to 1.0)	0.21
McGill present pain index:						
Unadjusted scores	192	-0.1 (-0.4 to 0.2)	0.55	162	-0.3 (-0.7 to 0.1)	0.1
Difference adjusted for baseline pain score and clustering by acupuncturist	192	-0.1 (-0.4 to 0.3)	0.67	162	-0.2 (-0.6 to 0.1)	0.21

*Improvement is indicated by negative change for Oswestry and McGill present pain index and by positive change on SF-36.

†Baseline covariates include duration of current episode of low back pain in weeks, expectation of back pain in six months, SF-36 physical functioning, and reported pain in legs.

Discussion

Weak evidence was found of an effect of acupuncture care on non-specific low back pain at 12 months, but stronger evidence of a small benefit at 24 months.

Our study was designed to detect a larger difference of 10 points, which was not achieved at either 12 or 24 months. A difference of at least five points in the mean score of the SF-36 bodily pain dimension is, however, considered a clinically worthwhile benefit² and a difference of between five and nine points a moderate benefit.^{10,11} In this study the magnitude of the effect extends to eight points at 24 months, a difference between groups of about 10%-15% of the final pain score in the control group, and achieves statistical significance. We found no evidence of functional improvement. Other outcomes included patient satisfaction with acupuncture care, reduced concerns about back pain, and reduced use of analgesics.

One limitation of our study is the possibility of an effect of clustering by practitioner on the statistical significance of the outcome. Cluster analysis made little difference to the primary outcome of bodily pain. Sensitivity analysis taking into account baseline covariates increased the intervention effect but did not alter the main results. Groups were well balanced at baseline with the exception of 11 patients who described themselves as permanently unable to work because of low back pain, all of whom were in the acupuncture arm. Excluding these patients increased the estimated effect of acupuncture at 12 months.⁹

Secondary outcome measures showed mixed effects. Those measuring the effect of pain on daily living did not show a significant acupuncture effect at 12 or 24 months. Patients in the acupuncture group reported a substantial reduction in concerns about their back pain that was not observed in the usual care group.

We evaluated a package of care and cannot isolate the components of acupuncture treatment that are associated with the outcomes observed in the acupuncture group. Beyond the needling itself, several aspects of acupuncture care in this trial could contribute to its observed effectiveness (see bmj.com).

An open pragmatic trial avoids the potential problems of using sham acupuncture as the control.¹² Such a design may, however, be vulnerable to confounding or bias owing to prior patients' beliefs, especially when

using subjectively assessed outcome measures, such as perceived pain. Positive patient beliefs about acupuncture have been cited as a possible mechanism for non-specific effects observed in acupuncture trials.^{13,14} Our exploratory analysis on belief does not seem to support this hypothesis. Patients in the acupuncture group with a prior positive belief in the effectiveness of acupuncture fared little better than those randomised to usual care. In contrast, patients with neutral prior belief gained more benefit from acupuncture. In addition, positive expectations of improvement in back pain seem to reinforce the effect of acupuncture care.

Overall, 76% of participants were followed up at 24 months. The strengths of our study were its pragmatic randomised design, patient recruitment, wide eligibility criteria, and a non-restrictive treatment protocol that allowed acupuncturists to treat patients as usual.¹⁵ The acupuncturists were selected through reproducible criteria, and the ratio of six practitioners to 16 general practices is similar to the national ratio of acupuncturists registered with the British Acupuncture Council to general practices.

Studies of interventions for low back pain are susceptible to effects arising from a regression to the mean; patients will tend to seek help when pain is worst or least bearable, and the pain will reduce substantially for most, with or without treatment. Our study contributes evidence for a short term acupuncture intervention compared with usual general practitioner care for non-specific low back pain.

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Competing interests: None declared.

What is already known on this topic

Non-specific low back pain is typically a recurrent condition associated with high health and social costs

Many people with back pain seek acupuncture treatment; however, evidence for long term effectiveness is sparse

What this study adds

Weak evidence was found of an effect of acupuncture care on non-specific low back pain at 12 months, but stronger evidence of a small benefit at 24 months

Referral to a qualified acupuncturist seems safe and acceptable to patients with low back pain

Ethical approval: This study was approved by York research ethics committee.

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A randomised controlled trial of acupuncture care for persistent low back pain: cost effectiveness analysis

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Abstract

Objective To evaluate the cost effectiveness of acupuncture in the management of persistent non-specific low back pain.

Design Cost effectiveness analysis of a randomised controlled trial.

Setting Three private acupuncture clinics and 18 general practices in York, England.

Participants 241 adults aged 18-65 with non-specific low back pain of 4-52 weeks' duration.

Interventions Ten individualised acupuncture treatments over three months from acupuncturists trained in traditional Chinese medicine (n = 160) or usual care only (n = 81).

Main outcome measure Incremental cost per quality adjusted life year (QALY) gained over two years.

Results Total costs to the United Kingdom's health service during the two year study period were higher on average for the acupuncture group (£460; £673; \$859) than for the usual care group (£345) because of the costs associated with initial treatment. The mean incremental health gain from acupuncture at 12 months was 0.012 QALYs (95% confidence interval -0.033 to 0.058) and at 24 months was 0.027 QALYs (-0.056 to 0.110), leading to a base case estimate of £4241 per QALY gained. This result was robust to sensitivity analysis. The probabilistic sensitivity analysis showed acupuncture to have a more than 90% chance of being cost effective at a £20 000 cost per QALY threshold.

Conclusion A short course of traditional acupuncture for persistent non-specific low back pain in primary care confers a modest health benefit for minor extra cost to the NHS compared with usual care.

Acupuncture care for low back pain seems to be cost effective in the longer term.

Trial registration ISRCTN80764175.

Introduction

The annual cost of low back pain to the United Kingdom's health service has been estimated at £480m (€703m; \$901m).¹ The use of acupuncture as an approach for the management of chronic pain, including low back pain, is receiving increasing recognition. We assessed the cost effectiveness of acupuncture for the treatment of low back pain.

Methods

Patients (n = 241) with persistent non-specific low back pain of 4-52 weeks' duration, diagnosed as suitable for management in primary care, were recruited to the trial by 43 general practitioners. Patients were randomly allocated to receive either up to 10 acupuncture treatments over three months (n = 161) or usual care only (n = 81). The primary clinical outcome was

ELPS This is the abridged version of an article that was posted on *bmj.com* on 15 September 2006: <http://bmj.com/cgi/doi/10.1136/bmj.38932.806134.7C>