

Longer term clinical and economic benefits of offering acupuncture care to patients with chronic low back pain

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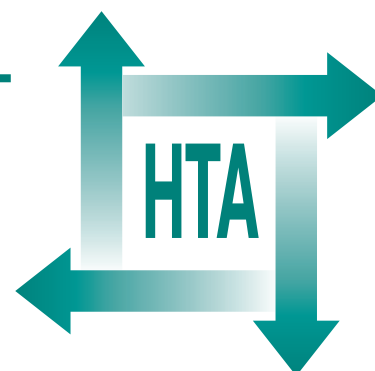
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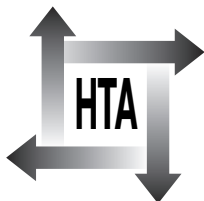


Executive summary

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Executive summary

Objectives

The primary objective was to test the hypothesis that a population of patients with persistent non-specific low back pain, when offered access to traditional acupuncture care alongside conventional primary care, gained more long-term relief from pain than those offered conventional care only, for equal or less cost. Secondary objectives were to monitor the safety and acceptability of acupuncture care to patients, and to assess the evidence for an ‘acupuncturist effect’ by testing the heterogeneity of outcomes for the six acupuncturists participating in the trial.

Methods

Design

The study was a pragmatic, two parallel group, randomised controlled trial ($n = 241$). Patients in the experimental arm were offered the option of referral to the acupuncture service comprising six acupuncturists. The control group received usual care from their general practitioner (GP). Eligible patients were randomised in a ratio of 2:1 to the offer of acupuncture to allow between-acupuncturist effects to be tested.

Setting

The study was conducted in three non-NHS acupuncture clinics, with referrals from 39 GPs working in 16 practices in York, UK.

Subjects

The subjects were patients aged 18–65 years with non-specific low back pain of 4–52 weeks’ duration, assessed as suitable for primary care management by their GP.

Interventions

The trial protocol allowed up to ten individualised acupuncture treatments per patient. The acupuncturist determined the content and the number of treatments according to patient need. Acupuncture patients received needling using disposable acupuncture needles, and adjunctive treatments including massage and advice on diet,

rest and exercise. Usual care commonly entailed a mixture of physiotherapy, medication and recommended back exercises. Patients receiving acupuncture care continued to have access to usual care for their back pain at the discretion of their GP.

Main outcome measures

The primary outcome measure was the Short Form 36 (SF-36) Bodily Pain dimension (range 0–100 points), assessed at baseline, and 3, 12 and 24 months. The study was powered to detect a 10-point difference between groups at 12 months post-randomisation. Cost–utility analysis was conducted at 24 months using the EuroQoL 5 Dimensions (EQ-5D) and a preference-based single index measure derived from the SF-36 (SF-6D). Secondary outcomes included the McGill Present Pain Index (PPI), Oswestry Pain Disability Index (ODI), all other SF-36 dimensions, medication use, pain-free months in the past year, worry about back pain, satisfaction with care received, and safety and acceptability of acupuncture care.

Results

The trial successfully recruited 241 patients via referrals from 39 GPs. Two patients withdrew immediately, leaving 159 in the ‘acupuncture offer’ arm and 80 in the ‘usual care’ arm. All 159 patients randomised to the offer of acupuncture care chose to receive acupuncture treatment, and received an average of eight acupuncture treatments within the trial.

Analysis of covariance, adjusting for baseline score, found an intervention effect of 5.6 points on the SF-36 Pain dimension [95% confidence interval (CI) –1.3 to 12.5] in favour of the acupuncture group at 12 months, and 8 points (95% CI 0.7 to 15.3) at 24 months. No evidence of heterogeneity of effect was found for the different acupuncturists. Patients receiving acupuncture care did not report any serious or life-threatening events. Sixteen patients dropped out of acupuncture treatment, four of whom mentioned specific minor adverse events, such as pain at the site of needling. ▶

No treatment effect was found for any of the SF-36 dimensions other than Pain, or for the ODI. Patients receiving acupuncture care reported a significantly greater reduction in worry about their back pain at 12 and 24 months compared with the usual care group. At 24 months, the acupuncture care group was significantly more likely to report 12 months pain free and less likely to report the use of medication for pain relief.

The acupuncture service was found to be cost-effective at 24 months; the estimated cost per quality-adjusted (QALY) was £4241 (95% CI £191 to £28,026) using the SF-6D scoring algorithm based on responses to the SF-36, and £3598 (95% CI £189 to £22,035) using the EQ-5D health status instrument. The NHS costs were greater in the acupuncture care group than in the usual care group. However, the additional resource use was less than the costs of the acupuncture treatment itself, suggesting that some usual care resource use was offset.

Conclusions

Traditional acupuncture care delivered in a primary care setting was safe and acceptable to patients with non-specific low back pain. Acupuncture care and usual care were both associated with clinically significant improvement at 12- and 24-month follow-up. Acupuncture care was significantly more effective in reducing bodily pain than usual care at 24-month follow-up. No benefits relating to function or disability were identified. GP referral to a service providing traditional acupuncture care offers a cost-effective intervention for reducing low back pain over a 2-year period.

Implications for healthcare

Based on the study's findings, commissioners of musculoskeletal services would be justified in considering making GP referral to a short course of traditional acupuncture care available for a typical population of primary care attendees with persistent non-specific low back pain.

Recommendations for research

The following recommendations are suggested for further research.

- Trials are needed to assess the impact of traditional acupuncture on the persistence and

recurrence of low back pain compared with other possible short-term packages of care (such as massage, chiropractic or physiotherapy), delivered in an episode of non-acute low back pain.

- The cost-effectiveness of different types of acupuncture offered as short-term packages of care, delivered in an episode of non-acute low back pain, could be assessed.
- Research is needed into the optimum timing for an acupuncture treatment package in a patient episode of low back pain, and to assess the value of repeated courses of acupuncture for patients experiencing recurrent episodes of low back pain.
- Further studies with more patients per acupuncturist are warranted to explore differences between acupuncturists. No significant difference between acupuncturists was found in this study. However, this lack of evidence of heterogeneity does not mean that there is no heterogeneity.
- Exploration is needed of the underlying causes and mechanisms involved in the continued improvement over time of patients with low back pain receiving a short course of traditional acupuncture.
- Qualitative investigation is needed into the meaning to patients of the substantial reported reduction in worry about back pain found in the acupuncture care group, but not in the usual care group, its relationship to patient coping strategies and its implications for the care and management of this group of patients.
- There is a need for the distillation of a protocol for traditional acupuncture treatment for low back pain that allows individualised treatment to be delivered while defining a package of care that represents value for money, which can be commissioned reliably and safely.
- Acupuncture may be delivered in a number of different ways. This trial examined traditional acupuncture delivered by qualified practitioners. There is a case for research to look at the comparative cost-effectiveness of different modes of acupuncture offered as short-term packages of care, delivered in an episode of non-acute low back pain, for example acupuncture care delivered by physiotherapists in a primary care setting.
- Qualitative work is indicated to assess the relative value placed on process utilities by patients, such as feelings of relaxation and support during treatment, and the possibility of trade-off between these and conventional

pain outcomes should be explored using standard methods for preference elicitation such as conjoint analysis.

- Methodological work is needed to guide the research community about the best way to proceed with missing data in clinical trials with longer term outcomes.

Publication

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NHS R&D HTA Programme

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The research reported in this monograph was commissioned by the HTA Programme as project number 96/40/07. The contractual start date was in April 1999. The draft report began editorial review in October 2003 and was accepted for publication in January 2005. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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