Acupuncture of chronic headache disorders in primary care: randomised controlled trial and economic analysis

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Executive summary

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Objectives
The primary objective was to determine the effects of a policy of ‘use acupuncture’, compared with a policy of ‘avoid acupuncture’, on headache in primary care patients with chronic headache disorders. Secondary objectives were to determine the effects of using acupuncture compared with avoiding acupuncture on medication use, quality of life, resource use and days off sick in this population and to determine the cost-effectiveness of acupuncture.

Methods
Design
This study was conducted as a randomised, controlled trial.

Setting
General practices in England and Wales.

Participants
The study included 401 patients with chronic headache disorder, predominantly migraine.

Interventions
Patients were randomly allocated to receive up to 12 acupuncture treatments over 3 months or to a control intervention offering usual care.

Main outcome measures
The outcome measures included headache score, assessment of Short Form 36 (SF-36) health status and use of medication at baseline, 3 months and 12 months; use of resources was assessed every 3 months; and assessment of incremental cost per quality-adjusted life-year (QALY) gained for the purposes of economic evaluation.

Results
Headache score at 12 months, the primary endpoint, was lower in the acupuncture group (mean 16.2, SD 13.7, n = 161, 34% reduction from baseline) than in controls (22.3, SD 17.0, n = 140, 16% reduction from baseline). The adjusted difference between means was 4.6 (95% confidence interval 2.2 to 7.0, \( p = 0.0002 \)). This result is robust to sensitivity analysis incorporating imputation for missing data. Patients in the acupuncture group experienced the equivalent of 22 fewer days of headache per year (8 to 38). SF-36 data favoured acupuncture, although differences reached significance only for physical role functioning, energy and change in health. Compared with controls, patients randomised to acupuncture used 15% less medication (\( p = 0.02 \)), made 25% fewer visits to GPs (\( p = 0.10 \)) and took 15% fewer days off sick (\( p = 0.2 \)). Total costs during the 1-year period of the study were on average higher for the acupuncture group (£403, $768, €598) than for controls (£217) because of the acupuncture practitioners' costs. The mean health gain from acupuncture during the year of the trial was 0.021 QALYs, leading to a base-case estimate of £9180 per QALY gained. This result was robust to sensitivity analysis. Cost per QALY dropped substantially when the analysis incorporated likely QALY differences for the years after the trial.

Conclusions
Implications for healthcare
The results of the study suggest that acupuncture leads to persisting, clinically relevant benefits for primary care patients with chronic headache, particularly migraine. It is relatively cost-effective compared with a number of other interventions provided by the NHS.
Implications for research
The optimal methods of acupuncture remain unknown and require systematic research. Further studies could examine the duration of acupuncture effects beyond 1 year and the relative benefit to patients with migraine compared with tension-type headache. Trials are also warranted examining the effectiveness and cost-effectiveness of acupuncture in patients with headache receiving more aggressive pharmacological management.

Publication
NHS R&D HTA Programme

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