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

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# **Executive** summary

Health Technology Assessment 2004; Vol. 8: No. 48

## Health Technology Assessment NHS R&D HTA Programme





## **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,  $\in$ 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 OALYs, 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**

Vickers AJ, Rees RW, Zollman CE, McCarney R, Smith CM, Ellis N, *et al.* Acupuncture of chronic headache disorders in primary care: randomised controlled trial and economic analysis. *Health Technol Assess* 2004;**8**(48).

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The research reported in this monograph was commissioned by the HTA Programme as project number 96/40/15. As 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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#### ISSN 1366-5278

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Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA. Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.