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## Efficacy of acupuncture for the prophylaxis of migraine: a multicentre randomised controlled clinical trial

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### Summary

#### Background

Our aim was to assess the efficacy of a part-standardised verum acupuncture procedure, in accordance with the rules of traditional Chinese medicine, compared with that of part-standardised sham acupuncture and standard migraine prophylaxis with beta blockers, calcium-channel blockers, or antiepileptic drugs in the reduction of migraine days 26 weeks after the start of treatment.

#### Methods

This study was a prospective, randomised, multicentre, double-blind, parallel-group, controlled, clinical trial, undertaken between April 2002 and July 2005. Patients who had

two to six migraine attacks per month were randomly assigned verum acupuncture (n=313), sham acupuncture (n=339), or standard therapy (n=308). Patients received ten sessions of acupuncture treatment in 6 weeks or continuous prophylaxis with drugs. Primary outcome was the difference in migraine days between 4 weeks before randomisation and weeks 23–26 after randomisation. This study is registered as an International Standard Randomised Controlled Trial, number ISRCTN52683557.

## Findings

Of 1295 patients screened, 960 were randomly assigned to a treatment group. Immediately after randomisation, 125 patients (106 from the standard group) withdrew their consent to study participation. 794 patients were analysed in the intention-to-treat population and 443 in the per-protocol population. The primary outcome showed a mean reduction of 2.3 days (95% CI 1.9–2.7) in the verum acupuncture group, 1.5 days (1.1–2.0) in the sham acupuncture group, and 2.1 days (1.5–2.7) in the standard therapy group. These differences were statistically significant compared with baseline ( $p < 0.0001$ ), but not across the treatment groups ( $p = 0.09$ ). The proportion of responders, defined as patients with a reduction of migraine days by at least 50%, 26 weeks after randomisation, was 47% in the verum group, 39% in the sham acupuncture group, and 40% in the standard group ( $p = 0.133$ ).

## Interpretation

Treatment outcomes for migraine do not differ between patients treated with sham acupuncture, verum acupuncture, or standard therapy.



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