

Linde K, Streng A, Reitmayr S, Hoppe A, Brinkhaus B, Becker-Witt C, Wagenpfeil St, Weidenhammer W, Willich SN, Melchart D. Efficacy of acupuncture in patients with migraine – the Acupuncture Randomised Trials (ART). *Biometrical Journal*. 2004 (Suppl.); 46: 34.

### **Efficacy of acupuncture in patients with migraine – the Acupuncture Randomised Trials (ART)**

**Objective:** In a randomised controlled multicenter clinical trial we investigated whether acupuncture is more effective compared to no acupuncture or minimal acupuncture in patients with migraine.

**Materials and methods:** Patients with migraine (according to the criteria of the International Headache Society) were randomised to treatment with semi-standardised acupuncture (AC), minimal acupuncture (MA, superficial needling at non-acupuncture points) or to waiting list control (WL). AC and MA was administered by specialised acupuncture physicians in 18 outpatient centers and consisted of 12 sessions per patient over 8 weeks. Patients completed headache diaries for 4 weeks before randomisation, for 12 weeks after randomisation, and from week 21 to 24 after randomisation. Main outcome measure was the difference in headache days with at least moderate headache between the 4 weeks before and weeks 9 to 12 after randomisation.

**Results:** A total of 302 patients (88% female, 43±11 years) were included from April 2002 to January 2003. The number of days with headache of moderate or severe intensity decreased by  $2.5 \pm 2.7$  days (mean  $\pm$  sd, baseline  $5.2 \pm 2.5$ ) in the AC group compared to  $0.9 \pm 2.2$  days (baseline  $5.4 \pm 3.0$ ) in the WL group (difference AC - WL 1.5 days, 95% CI 0.8 to 2.3 days,  $p < 0.001$ , one-sided t-test), and to  $2.4 \pm 2.7$  days (baseline  $5.0 \pm 2.4$ ) in the MA group (difference AC - MA 0.1 days, 95% CI  $-0.7$  to 0.9 days,  $p = 0.405$ ). The proportion of responders (reduction of headache days by at least 50%) was 51% in the acupuncture group, 53% in the minimal acupuncture group, and 14% in the waiting list group.

**Conclusion:** Compared to a waiting list control the acupuncture intervention investigated in this trial proved highly effective in reducing migraine headaches. However, the same clinically relevant effect was also achieved with the minimal acupuncture intervention.