Acupuncture Randomized Trials (ART) in Patients with Migraine or Tension-Type Headache -- Design and Protocols

Abstract:

Background and Objective: We report the design and essentials of the protocols of two Acupuncture Randomized Trials (ART) investigating whether acupuncture is more efficacious than no treatment and minimal acupuncture in the interval treatment of migraine and tension-type headache. Design: Randomized controlled multicenter trials with three treatment arms and a total observation period of 28 weeks. Setting: 30 practitioners and outpatient units in Germany specialized in acupuncture treatment. Patients: Per study 300 patients with migraine and episodic or chronic tension-type headache, respectively (diagnosis according to the criteria of the International Headache Society). Interventions: Patients are randomly assigned to receive either (1) semi-standardized acupuncture (150 patients), (2) standardized minimal acupuncture (75 patients), or (3) no interval treatment for 12 weeks followed by semi-standardized acupuncture (75 patients, waiting list control). Acupuncture treatment consists of 12 sessions per patient over a period of 8 weeks. Main Outcome Measure: Main outcome measure in the migraine trial is the difference between the number of days with headache of moderate or severe intensity during the 4 weeks before randomization and weeks 9 to
12 after randomization. In the study on tension-type headache the main outcome measure is similar to that described above, but for the number of headache days regardless of intensity. Outlook: The results of these two studies (available in 2004) will provide health care providers and policy makers with the information needed to make scientifically sound assessments of acupuncture therapy.