Abstract:

Background: We report on the study design and protocols of two randomized controlled trials (Acupuncture Randomized Trials = ART) that investigate the efficacy of acupuncture in the treatment of chronic low back pain and osteoarthritis of the knee, respectively. Objective: To investigate whether acupuncture is more efficacious than (a) no treatment or (b) minimal acupuncture in the treatment of low back pain and osteoarthritis. Design: Two randomized, controlled, multicenter trials with three treatment arms and a total follow-up time of 52 weeks. Setting: 30 practitioners and outpatient units in Germany specialized in acupuncture treatment. Patients: 300 patients will be included in each study. In the low back pain trial, patients will be included according to clinical diagnosis. In the osteoarthritis pain trial, patients will be included according to the American College of Rheumatology criteria. Interventions: Patients are randomly assigned to receive either (1) semi-standardized acupuncture (150 patients), (2) minimal acupuncture at non-acupuncture points (75 patients), or (3) no treatment for two months 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: The main outcome measure is the difference between baseline and the end of the 8-week treatment period in the following parameters: pain intensity as measured by a visual analogue scale (VAS; 0–100 mm) in the low back pain trial and by the Western Ontario and McMaster Universities Osteoarthritis Score (WOMAC) in the osteoarthritis trial. 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.