

## **Efficacy, effectiveness and efficiency of acupuncture in patients with osteoarthritis of the knee or the hip – the acupuncture randomized trial (ART) and the acupuncture routine care study (ARC)**

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**Objective:** The aim of our studies was to evaluate: 1) the efficacy of acupuncture compared to minimal acupuncture and compared to a waiting list control in patients with osteoarthritis of the knee and 2) the effectiveness and cost-effectiveness of acupuncture (in addition to routine medical care) in patients with osteoarthritis of the hip or knee.

**Methods:** 1) In the Acupuncture Randomised Trial (ART) patients with pain due to osteoarthritis of the knee 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 consisted each of 12 sessions per patient over 2 months. The primary outcome parameter in the osteoarthritis trial was the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index after 2 months.

2) In the Acupuncture in Routine Care Study (ARC) patients with chronic arthritis of the hip and the knee were randomly allocated to: receive up to 15 acupuncture sessions over three months (ACU), or to a control group (CON) receiving no acupuncture. Study participants were allowed to receive additional usual medical care covered by social health insurance funds. Primary outcome parameter was the WOMAC Index after 3 months. Data for direct costs and sick leave were provided by the social health insurance funds. The cost-effectiveness-analysis was performed from an overall cost perspective. Incremental cost-effectiveness-ratios (ICER) were calculated using quality adjusted life years (QALYs) after 3 months.

**Results:** 1) In ART, 294 patients (66% female, 64±7 years (mean±sd)) were enrolled. The mean baseline-adjusted WOMAC Index at 2 months was 26.9±1.4 (mean±SE) in the AC, 35.8±1.9 in MA group and 49.6±2.0 in the WL group. The difference for the AC vs. MA group was -8.8 (95% CI -13.5 to -4.2, p<0.001) and for the AC vs. WL group was -22.7 (27.5. to -17.9, p<0.001). 2) In ARC, 632 patients were included (61% female, mean age 61.8±10.8 years (mean±sd)). At three months, the WOMAC index improved by 17.6±1.0 (mean±SE) to 30.5±1.0 in the ACU group and by 0.9±1.0 to 47.3±1.0 in the CON group, difference 16.7±1.4, p<0.001. Additional acupuncture treatment was associated with higher overall costs during 3 months compared to routine care alone (€ 1,218 vs. € 706 p<0.001). There were more QALYs gained in the ACU compared to the CON (ACU-CON: 0.02±0.01). The incremental cost effectiveness ratio was € 17,845 per QALY gained.

**Conclusion:** Acupuncture treatment was superior to minimal acupuncture and to waiting list control in patients with osteoarthritis of the knee. In addition routine medical care plus acupuncture was more effective than routine care alone but resulted in additional costs. However, according to international health economics benchmarks it can be regarded as cost-effective.