# RobotReviewer report

## Abstract

Here are the results from 1 PDFs.

## Risk of bias table

| trial | design | Random sequence generation | Allocation concealment | Blinding of participants and personnel | Blinding of outcome assessment |
|---|---|---|---|---|---|
| Xu S, 2006 | RCT | + | + | ? | + |

## Trial summaries

| n | Participants | Interventions | Outcomes | punchline | finding |
|---|---|---|---|---|---|
| 960 | 794 patients were analysed in the intention-to-treat popoulation and 443 in the per-protocol population, 1295 patients screened, 960, Patients who had two to six migraine attacks per month, 125 patients (106 from the standard group) withdrew their consent to study participation | Manual acupuncture versus sham acupuncture and usual care, acupuncture, verum acupuncture, sham acupuncture, verum acupuncture, or standard therapy, part-standardised verum acupuncture procedure, acupuncture and standard migraine prophylaxis with beta blockers, calcium-channel blockers, or antiepileptic drugs, sham acupuncture | migraine days, mean reduction of 2 .3 days | All subscales of the Migraine-Specific Quality-of-Life Questionnaire were improved significantly more in the manual acupuncture group than in the two control groups at weeks 20. | ‚Üë sig increase |

## Characteristics of studies

### Xu S, 2006

| | |
|---|---|
| Population | 1. 21 Other inclusion criteria were age between 15 and 65 years, history of migraine without aura for more than 12 months, initial onset of migraine before the age of 50 years, between two and eight migraine attacks during the baseline phase, naivety to acupuncture, and ability to give informed consent.<br>2. Therefore, we designed a randomised clinical trial among patients with migraine who were naive to acupuncture, using non-penetrating sham control and assessment of blinding to determine the efficacy of manual acupuncture and quantify the true placebo response in the prophylaxis of episodic migraine without aura.<br>3. Exclusion criteria included all other types of primary and secondary headaches, history of a clinically significant disorder (for example, severe mental illness), pregnancy or breast feeding, and non-adherence to the baseline diary. |
| Intervention | 1. In the usual care group, patients received acupuncture for free after waiting 24 weeks.<br>2. Therefore, we designed a randomised clinical trial among patients with migraine who were naive to acupuncture, using non-penetrating sham control and assessment of |

| | |
|---|---|
| | blinding to determine the efficacy of manual acupuncture and quantify the true placebo response in the prophylaxis of episodic migraine without aura.<br>3. In case of severe pain (visual analogue score >8), diclofenac sodium enteric coated tablets (25 mg/tablet; maximal tolerated dose 200 mg/day) were allowed as a rescue medication. |
| Outcomes | 1. Secondary outcomes included the proportion of patients achieving at least a 50% reduction in the mean number of migraine days or migraine attacks during weeks 17 to 20 and changes in the severity of migraine as measured by a visual analogue scale, the Migraine-Specific Quality-of-Life Questionnaire (MSQ), 24 the Pittsburgh Sleep Quality Index (PSQI), 25 the Migraine Disability Assessment Score (MIDAS), 26 the Beck Anxiety Inventory (BAI) scale, 27 the Beck Depression Inventory II (BDI-II) scale, 28 and the mean dose of used rescue medication from baseline to week 20.<br>2. We also found no significant difference in the mean dose of rescue medication or in Beck Anxiety Inventory and Beck Depression Inventory II scores among the three groups at week 20.<br>3. Primary outcomes Secondary outcomes |

| Bias | Judgement | Support for judgement |
|---|---|---|
| Random sequence generation | low | 1. Treatments were allocated in a centralised manner via an interactive web response system with stratification by centre and a block size of five.<br>2. After the baseline assessment, an independent investigator randomised eligible patients in a 2:2:1 ratio to receive manual acupuncture, sham acupuncture, or usual care.<br>3. The baseline characteristics of all randomised patients were well balanced among the three groups (table 1). |
| Allocation concealment | low | 1. Treatments were allocated in a centralised manner via an interactive web response system with stratification by centre and a block size of five.<br>2. To maintain blinding in patients, outcome assessors, and statisticians, the allocation sequence was concealed until the end of the study.<br>3. After the baseline assessment, an independent investigator randomised eligible patients in a 2:2:1 ratio to receive manual acupuncture, sham acupuncture, or usual care. |
| Blinding of participants and personnel | high/unclear | 1. To maintain blinding in patients, outcome assessors, and statisticians, the allocation sequence was concealed until the end of the study.<br>2. To ensure successful blinding, we recruited acupuncture naive patients, used non-penetrating needles as the control, and designed the same procedures to perform the same rituals as far as possible in the manual and sham acupuncture groups.<br>3. At the end of the study, we determined the maintenance of blinding of patients by asking them whether they thought the needles had penetrated the skin. |
| Blinding of outcome assessment | low | 1. To maintain blinding in patients, outcome assessors, and statisticians, the allocation sequence was concealed until the end of the study.<br>2. The total trial period was 24 weeks, including four weeks of baseline assessment, eight weeks of treatment after randomisation, and 12 weeks of follow-up.<br>3. The primary outcomes were change in the mean number of migraine days and migraine attacks per four week cycle during |

weeks one to 20 after randomisation compared with baseline (the four weeks before randomisation).

# References

1. Xu S et al. Manual acupuncture versus sham acupuncture and usual care for prophylaxis of episodic migraine without aura: multicentre, randomised clinical trial Lancet Neurol 2006. 5(4); 310-6 PMID: 16545747