

13. Diseases of the Musculoskeletal and Connective Tissue

Reference

Nabeta T, Furuta T, Kitakouji H, et al. Randomized controlled pilot study of acupuncture on neck stiffness. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 1997; 47(3): 173–81 (in Japanese with English abstract). Ichushi Web ID: 1998092691

1. Objectives

To investigate the problems associated with conducting clinical trials of acupuncture.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT: envelope).

3. Setting

Meiji School of Oriental Medicine, Osaka, Japan.

4. Participants

Thirty-two student volunteers who were identified as having neck stiffness by questionnaire prior to the intervention, and who gave informed consent by signature (mean age in the two groups: 32.8 and 30.4 years).

5. Intervention

Arm 1: Acupuncture group. A needle (0.2×50 mm) was inserted to a depth of 20 mm at the BL10 (天柱) point and was retained for 10 minutes after the sparrow-pecking technique was repeated 5 times (n=16).

Arm 2: Control group. A needle was used to pierce the skin at the BL10 (天柱) point but was removed after simulating insertion and sparrow pecking. Subsequent needle removal was also simulated (by deliberately making a sound when replacing the needle in the needle receptacle) (n=16).

The treatment period continued for three weeks. The volunteers received a weekly-intervention (3 in total). Two participants were dropped from Arm 1 (one due to herpes, and one due to needle pain), data were unavailable for four participants.

In Arm 2, data were unavailable for two participants (reasons unknown).

6. Main outcome measures

Stiffness was measured on a visual analogue scale (VAS) before treatment, immediately after treatment, and 1, 3, 5, and 7 days after treatment. Participants were asked about neck stiffness in the stimulation region, and stiffness in the whole shoulder. Subjects were also asked after the trial what kind of acupuncture they received.

7. Main results

There was no significant between-group difference in VAS change. In response to the question after the trial “What kind of acupuncture did you feel you received?,” 66.7% of participants in Arm 1 and 35.7% in Arm 2 replied “They inserted needles.” The difference was significant ($\chi^2=7.843$, $P=0.02$).

8. Conclusions

Acupuncture has no effect on neck stiffness.

9. From acupuncture and moxibustion medicine perspective

Not mentioned.

10. Safety assessment in the article

One participant complained of needle pain in Arm 1.

11. Abstractor's comments

This study was intended to clarify the problems associated with the conduct of clinical trials of acupuncture and moxibustion by actually conducting an RCT of acupuncture. The aim of the study was not to evaluate the effect of acupuncture on neck stiffness. The authors mention that many problems result from the clinical trial design. Specifically, they discuss interventions, control group interventions, selection of disorders, recruitment bias, masking, statistical power, and intent-to-treat analysis. For researchers intending to conduct a study, the study has greater value as a reference for study design than as an evaluation of the therapeutic effect of acupuncture on neck stiffness. There were problems with the authors' intentions and ethics, and the value of the study may have been increased by selection of a disorder and acupuncture intervention that could be applied in the clinic.

12. Abstractor and date

Takahashi N, 6 December 2011.