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Original paper

Validation of a simplified sham acupuncture technique for its use in clinical research: a randomised, single blind, crossover study

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Contributors MK was the Principal Investigator and contributed to the study concept and design, needles preparation, experimental acupuncture procedures, interpretation of the data, drafting of the manuscript and critical revision of the article. AZ contributed to the experimental set-up of the study including randomisation, needles preparation, drafting of the manuscript and critical revision of the article. RA contributed to the study design, made the randomisation program, statistical analyses and critical review of the manuscript. GC contributed to the study concept and design, made sample size calculations, interpretation of the data, drafting of the manuscript and critical revision of the article.

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Abstract

Objectives The validity of a new sham acupuncture technique was tested on acupuncture naïve healthy subjects.

Methods The procedure was tested in accupoints L14 and ST6 in a randomised, single blind and crossover study. The participants were blind to which technique they received. 32 healthy volunteers (15 men, 17 women, aged between 20 and 62 years, mean age 34 years) were recruited at the Universidad de la República, Uruguay. Interventions Participants were randomly assigned to one of two groups: (1) real acupuncture or (2) sham acupuncture. After 30 min, the patients were 'needled' again in a crossover design. Main outcome measures A yes/no questionnaire was used to assess the credibility and characteristics of the procedure.

Results For the credibility question (do you think you received real acupuncture?) no statistically significant group differences were evident before or after the crossover. Subjects who answered yes to this question ranged from 14/16 (87.5%) before crossover to 10/16 (62.5%) after crossover for the sham and 12/16 (75%) before crossover to 15/16 (93.8%) after crossover for the real acupuncture. The question that showed a significant difference (only after crossover) was the question, "did you feel the needle penetrating the skin?"; after crossover 12/16 (75%) subjects in the real acupuncture group said yes and 2/16 (12%) subjects in the sham group said yes to this question (p<0.01).

Conclusions These data suggests that this method is credible and constitutes a simple and inexpensive technique for use as a control in clinical research in acupuncture naïve subjects.

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