

MEETING ABSTRACT

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EHMTI-0266. Validation of a sham manipulative procedure: a new protocol for conducting placebo-control clinical trials in manual therapy

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Background

Few manual therapy studies have attempted to conduct placebo-control clinical trials. Thus, quantification of alleged placebo effects consequently becomes difficult.

Aim

To investigate and validate a new placebo intervention for spinal manipulative therapy clinical trials, i.e. sham manipulation, and investigate the feasibility of a short de-blinding questionnaire.

Method

A single blinded, prospective randomized, placebo-controlled trial with 1 month baseline and 3 months treatment with 12 treatments. 104 participants diagnosed with migraine were equally randomized into 1 of 3 groups: (i) chiropractic spinal manipulative therapy (CSMT), (ii) placebo (sham manipulation), (iii) control group (continued usual management). The participants filled in questionnaire on de-blinding after each treatment session. Primary end-point was the rate of successful blinding through de-blinding questionnaires given after each treatment session.

Results

772 out of 840 individual cases were analyzed, only 8.1 % out of all cases missed their appointment. The unadjusted result shows that both the active and placebo group believed they received active treatment with odds ratio (OR) of ≥ 88.9 and ≥ 80.0 respectively. Due to strong cluster effect in our data, logistic regression model was used to

adjust for repeated measures which showed a significant OR of >10 in both the active and the placebo group.

Conclusion

This is the first study to successfully demonstrate a manipulative sham procedure over a full length treatment period, assessing the placebo group with de-blinding questionnaire after each session which thus, could be incorporated in future clinical trials.

No conflict of interest.

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