Abstract

Background: Sham intervention is often used as a control in manual therapy RCTs to test the efficacy of a certain manual treatment. This is true for osteopathy as well. Sham control treatments may have an important effect beyond placebo effect, but there is currently low evidence on that. These effects of unspecific physical contact must be further evaluated.

Aim: We expect to present evidence and if so, the size of that effect.

Study Design: This study is a systematic review of RCTs.

Methods: We searched RCTs in PubMed and ISI Web of Science with a search string based on keywords related to manual therapy, sham treatment, no treatment, pain, mobility, RCT. We analysed the RCTs based on the Cochrane Risk of Bias tool and the Cochrane GRADE tool for level of evidence.

Results: In total, we included 5 RCTs (230 participants) in this systematic review. All studies had only participants without any anatomopathological substrates. Two studies controlled their intervention with detuned ultrasound therapy, one with light touch and deep inspiration, one with replication of a scapular mobilization with reversed hand placement and less intensity, and the last with fake cranial osteopathy. The most common high risk of bias in these studies was blinding of personnel and the most common unclear risk of bias was selective outcome reporting. We judged the quality of the evidence to be “high” to “low,” and the main reason for downgrading the evidence was risk of bias. The baseline measurements were significantly different between groups within two studies for one outcome each ($p=0.03$ and $p=0.0015$). Some sham interventions were found to have a statistically significant effect, others had no effect on any one of our outcomes. Paired sample t-tests within the sham group have shown a statistically significant effect on pain on VAS within one study ($p=0.01$), no statistically significant effect on PPT and a statistically significant negative effect on ROM within one study for one of two measured sides ($p<0.01$). The post-intervention over time across group comparison was statistically significant once for pain on VAS for one study ($p=0.0016$), thrice for PPT for two studies ($p=0.0016$, $p=0.0141$ and $p=0.0239$), once for ROM for one study ($p=0.0489$). No serious adverse events were reported in any of these RCTs.

Conclusion: Light touch with deep inspiration was the only sham intervention to have no statistically significant effect at any point, when compared to the group’s baseline measure and compared to the observation group. It was not possible to conclude whether the interventions actually had a significant effect or not, because of the low amount of studies, the high variability of the baseline measurements, the variability of the post-intervention measurements and the low effect size of the interventions that had an effect. Further research is required.