

A Randomized Controlled Trial of Osteopathic Manipulative Therapy to Reduce Cranial Asymmetries in Young Infants with Nonsynostotic Plagiocephaly

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Abstract

Objective: This study aimed to compare the efficacy of osteopathic manipulative therapy (OMTh) versus light touch therapy (LTT) in reducing cranial asymmetries in infants with nonsynostotic plagiocephaly (NSP).

Study Design: A prospective, parallel-group, single-center, LTT-controlled randomized clinical trial was conducted in the Department of Neonatology of Sant'Anna Hospital in Turin, Italy, from September 6, 2016 to February 20, 2020. We enrolled infants of 1 to 6 months of age with NSP, who were then randomly assigned to the study group (repositioning therapy plus six sessions of OMTh) or the control group (repositioning therapy plus six sessions of LTT). The outcome was the reduction of the oblique diameter difference index (ODDI) score <104%, which was assessed at the end of the intervention protocol (at 3 months) and at 1 year of age.

Results: A total of 96 infants were randomized, 48 in the OMTh group and 48 in the LTT group, with mean ages of 3.1 versus 3.2 months, and baseline ODDI score of 110.2 versus 108.7%. In the OMTh group, a significant reduction of the ODDI score <104%, compared with the LTT group, was observed in the intention-to-treat (ITT) and per-protocol (PP) analyses. The ITT analysis revealed an ODDI score <104% in the OMTh group at 3 months (risk difference: 0.41; 95% confidence interval [CI]: 0.25–0.53; $p < 0.001$) and at the follow-up at 1 year of age (risk difference: 0.47; 95% CI: 0.31–0.64; $p < 0.001$). The PP analysis at 3 months reported a risk difference of 0.44 (95% CI: 0.27–0.60; $p < 0.001$), and at 1 year of age, a risk difference of 0.54 (95% CI: 0.36–0.72; $p < 0.001$).

Conclusion: In infants with NSP, a course of six OMTh sessions significantly reduced cranial asymmetries at both the 3-month and 1-year follow-up assessments, compared with LTT. This study is registered with ClinicalTrial.gov (identifier: NCT03970395; www.clinicaltrials.gov).