| **Critique author** | **Ed Whitney** |
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| **Bibliographic Data** | |
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| Authors | Haller H, Lauche R, et al. |
| Title | Craniosacral Therapy for the Treatment of Chronic Neck Pain: A Randomized Sham-controlled Trial |
| PMID | 26340656 |
| Citation | Clin J Pain 2016;32(5):441-449. |
| Other information if relevant | |

| **Methods** | |
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| Aim of study | To investigate the efficacy of craniosacral therapy (CST) in the setting of chronic nonspecific neck pain |
| Design | Randomized clinical trial |

| **Participants** | |
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| Population from which participants are drawn | Patients with chronic neck pain who responded to advertisements inviting them to attend a clinical trial |
| Setting (location and type of facility) | A department of Integral and Integrative Medicine in a university setting in Essen, Germany |
| Age | 44 |
| Sex | 44 women, 10 men |
| Total number of participants for whom outcome data were reported | 54 |
| Inclusion criteria | Age 18 to 65 with at least 3 months of nonspecific neck pain with an intensity of at least 45 points on a 100 point scale and no prior experience with CST |

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| Exclusion criteria | - Specific neck pain (disc prolapse, scoliosis, inflammatory diseases such as arthritis or spondylitis, neurological diseases, physical trauma such a whiplash, any surgical operations on the cervical spine, or neoplasms of the spine)<br>- Recently modified drug therapy<br>- Recent manipulative treatment<br>- Taking corticosteroids, opiates, muscle relaxants, or antidepressants |
| Other information if relevant | - The informed consent process did not tell the participants that one of the interventions would be sham CST; the patients were told that alternative forms of CST would be employed, in order to try to achieve balanced expectations of treatment in the two groups |

**Intervention Groups**

| **Group 1** | |
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| Group name | CST |
| Number in group | 27 |
| Description of intervention | - Standardized treatment protocols were used in which each patient received 8 weekly sessions of 45 minutes duration, which included an initial structural CST examination which was repeated at the end of each session<br>- CST consisted of recognized techniques which were adapted to the restrictions found on the initial CST exam, including frontal and parietal lift, medial compression of the parietal bones, cranial base release, lumbosacral and sacroiliac decompression, fascial unwinding of the neck and shoulders, and similar techniques |
| Duration of treatment period | 8 weeks |
| Co-interventions if reported | Body awareness dialogue with the therapist when indicated |
| Additional information if relevant | The therapists were licensed physiotherapists with advanced CST qualification and an average of 6 years of clinical practice |

| **Group 2** | |
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| Group name | Sham CST |
| Number in group | 27 |

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| Description of intervention | - Standardized treatment protocols were used in which each patient received 8 weekly sessions of 45 minutes duration, which included an initial structural CST examination which was repeated at the end of each session, identical to the CST group<br>- In lieu of the specific CST techniques, the physiotherapists applied light touch to standardized anatomic areas, equal to those treated with CST, for 2 minutes each time |
| Duration of treatment period | 8 weeks |
| Co-interventions if reported | The same body awareness dialogues were used as in the CST group, in order to better simulate CST techniques |
| Additional information if relevant | The therapists were licensed physiotherapists with advanced CST qualification and an average of 6 years of clinical practice |

| **Primary outcome** | |
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| Outcome name and criteria for definition | - Pain intensity at 8 weeks on a 100 point scale<br>- Responder rate evidenced by the proportion of patients who reported pain reductions of 20% (minimal response) and 50% reduction (substantial response) |
| Time points measured and/or reported | 8 weeks for the primary analysis, repeated at 20 weeks of followup |
| Differences between groups | - The CST group had an average baseline pain intensity of 64.1, an average 8 week pain intensity of 31.7, and an average 20 week pain intensity of 31.6<br>- The sham CST group had an average baseline pain intensity of 64.4, an average 8 week pain intensity of 53.5, and an average 20 week pain intensity of47.8<br>- The adjusted pain intensity difference was 21.0 points in favor of CST, with 95% confidence interval 9.4 to 32.6<br>- At 8 weeks, the responder rates also favored CST<br>- Minimal response was recorded by 74.1% of the CST group and 40.7% of the sham CST group<br>- Substantial response was recorded by 44.4% of the CST group and 14.8% of the sham CST group<br>- At week 20, the 50% response rates did not reach the level of statistical difference between groups |

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| Additional information if relevant | - The statistical analysis was done with analysis of covariance (ANCOVA), in which the 8 week pain scores were compared and were adjusted using treatment group, baseline pain scores, and treatment expectations as covariates<br>- Treatment expectancy, assessed by the Credibility/Expectancy Questionnaire, was balanced between treatment groups |

| **Secondary outcomes** | |
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| Outcome name and criteria for definition | - Numerous secondary outcomes were measured, all of which were treated by the authors as exploratory only, and from which no conclusions were intended to be drawn |
| Time points measured | Baseline, 8 weeks, and 20 weeks |
| Differences between groups | - Group differences favoring CST were measured for pain on movement, pressure pain thresholds using a digital algometer, functional disability on the Neck Disability Index, and a variety of quality of life measures<br>- The Neck Disability Index for CST and sham CST had baseline scores of 32.4 and 29.3 respectively; at 8 weeks the scores were 17.6 and 24.8 respectively |
| Additional information if relevant | - All followup assessments were done by a blinded assessor<br>- No serious adverse events were reported during treatment, but transient post-treatment session exacerbations of symptoms such as headache were reported by 8 sham CST patients, while 6 patients in the CST group had transient neck pain, jaw pain, tiredness, and strong emotional reactions, which included weeping in one patient |

| **Conclusions** | |
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| Key conclusions of study authors | - CST was more advantageous than sham CST for the primary outcome of pain intensity at 8 weeks, and was also more advantageous on a variety of secondary outcomes<br>- There was a potential limitation of the study in the fact that CST was done by 3 physiotherapists and sham CST was done by only one PT<br>- The outcomes were subjective in nature, and it is not clear whether CST affects the structures of fascia and joints<br>- CSTG may be a worthwhile treatment option for chronic or recurrent neck pain |

| **Risk of bias assessment** | | |
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| Domain | Risk of bias<br>Low High Unclear | Comments |
| Random sequence generation *(selection bias)* | Low | |
| Allocation concealment *(selection bias)* | Low | |
| Blinding of participants and personnel *(performance bias)* | Unclear | The patients were blinded and their treatment expectations were equal<br>It is possible that there was an element of performance bias arising from the fact that there were 3 PTs doing CST and only one doing sham CST<br>It is also possible that some degree of unconsciously transmitted information was given to the patients by the unblinded therapists |
| Blinding of outcome assessment *(detection bias)* | Low | The followup information was obtained by a blinded assessor, who took the questionnaire information and was not aware of treatment group when applying the digital algometer for the pain threshold readings |
| Incomplete outcome data *(attrition bias)* | Low | |
| Selective outcome reporting? *(reporting bias)* | Low | The study protocol was registered at clinicaltrials.gov, and the primary outcome in the protocol was the primary outcome reported by the study |
| Other bias | | |

| **Sponsorship if reported** | | |
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| Study funding sources if reported | The Craniosacral Association of Germany and the Upledger Association of Germany helped to defray the open access fee for publication | |

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| Possible conflicts of interest for study authors | None declared | |
| Notes: | | |

**Comments by DOWC staff**

- Many features of a well-designed and well-conducted clinical trial were evident, and many risks of bias were controlled
- The weakest feature of the study involves the fact that the physical therapists were aware of treatment assignment
- Since much of the CST model involves the concept that there is nonverbal communication between therapist and patient, mediated through the palpating hands of the therapist, it is possible that some unintentional cueing of the patients could have occurred
- The choice to tell both groups of patients that the study was comparing two CST techniques, rather than comparing CST with sham CST, is a potentially helpful way to balance treatment expectations between groups and control that aspect of the placebo response, as discussed by Bialosky et al 2011

| **Assessment by DOWC staff** | |
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| Overall assessment as suitability of evidence for the guideline<br>☐ High quality<br>☒ Adequate<br>☐ Inadequate | The study is adequate for some evidence that in the setting of chronic nonspecific neck pain, craniosacral therapy by a physical therapist trained in the technique, is superior to sham treatment in reducing neck pain intensity at 8 weeks and probably at 20 weeks |
| If inadequate, main reasons for recommending that the article not be cited as evidence | |

**Additional references if relevant**


- Bialosky JE, Bishop MD, George SZ, et al. Placebo response to manual therapy: something out of nothing? J Man Manip Ther. 2011;19:11–19.