

**Clinical Practice Guideline:                      CranioSacral Therapy (CST)**

**Date of Implementation:                      February 9, 2006**

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**Product:    Specialty**

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## **GUIDELINES**

American Specialty Health – Specialty (ASH) considers CranioSacral Therapy (CST) to be unproven due to insufficient scientific evidence. There may be some risk of substitution harm or labeling effects if used to the exclusion of more established therapeutic or diagnostic procedures with known clinical effectiveness or diagnostic utility.

Patients must be informed verbally and in writing of the nature of any procedure or treatment technique that is considered experimental/investigational or unproven, poses a significant health and safety risk, and/or is scientifically implausible. If the patient decides to receive such services, they must sign a Member Billing Acknowledgment Form (for Medicare use Advance Beneficiary Notice of Non-Coverage form) indicating they understand they are assuming financial responsibility for any service-related fees. Further, the patient must sign an attestation indicating that they understand what is known and unknown about, and the possible risks associated with such techniques prior to receiving these services. All procedures, including those considered here, must be documented in the medical record. Finally, prior to using experimental/investigational or unproven procedures, those that pose a significant health and safety risk, and/or those considered scientifically implausible, it is incumbent on the practitioner to confirm that their professional liability insurance covers the use of these techniques or procedures in the event of an adverse outcome.

## **DESCRIPTION/BACKGROUND**

CranioSacral Therapy (CST) has been described as a manual method of evaluating and enhancing the functioning of a proposed physiological body system called the “craniosacral system (CSS)”, which is comprised of the membranes and cerebrospinal fluid that surround and protect the brain and spinal cord.

CST advocates believe this system influences the entire body by affecting the brain and spinal cord as well as the pituitary and pineal glands. As such, the CSS serves as a core function in that the entire body’s health depends on its well-being. Practitioners claim CST can treat a wide range of disorders and physical disabilities, including spinal cord injuries.

CST began as an osteopathic technique. This therapy is said to work with the rhythm and flow of the cerebrospinal fluid as it pulses through the system at a rate of about 10 cycles per minute. The fluid barrier of the CSS is the dura mater, which also composes the interior lining of the skull. The membrane is also attached to the upper neck vertebrae, the lower back sacrum, the tailbone, and the openings in the spinal column where nerves exit. The skull bones are believed to continuously move in a subtle manner to accommodate fluid pressure changes within this system. Anything that interferes with the membrane's ability to accommodate the rhythmically fluctuating fluid pressures and volumes is thought to be a potential cause of illness.

CST's purpose is to find areas of restricted movement that compromise function and re-establish normal movement. During treatment, a trained CST therapist uses a light touch to feel the rhythmic motion of the cerebrospinal fluid within the CSS. The therapist checks the rate, amplitude, symmetry, and quality of this subtle wave-like motion in places where the craniosacral membrane barrier attaches to bones such as the skull, sacrum, and tailbone. Any restrictions or blockages are treated with light-touch adjustments. These gentle corrections are said to assist the hydraulic forces in the CSS and improve the central nervous system functioning, which is believed to facilitate the body's innate self-healing mechanisms.

## EVIDENCE REVIEW

Cooperstein and Gleberzon (2004) reported on studies with the research objective of providing direct evidence of an association between craniosacral dysfunction and poor health outcomes. They observed a few studies with design flaws and that the literature reviewed was not of the highest quality based on the hierarchy of evidence. Green et al. (1999) concluded that there is no "significant strength of association, experimental confirmation, specificity of relationship and/or consistency of observed evidence" between craniosacral dysfunction and health in their systematic review and critical appraisal. Research methods that could conclusively evaluate effectiveness have not been applied to date.

Controversy about cranial bone motion affects the general acceptance of some intervention methods such as cranial osteopathic and CST techniques. Core to these intervention techniques is the belief that cranial bone mobility provides a compliant system where somatic dysfunction can occur and therapeutic techniques can be applied. Diversity of opinion over the truth of this concept characterizes differing viewpoints on the anatomy and physiology of the cranial complex. Literature on cranial bone motion was reviewed for the purpose of better understanding this topic. Published research overall was scant and inconclusive.

A small "within-subjects, repeated-measures" study by Moran and Gibbons (2001) failed to support the construct validity of the "core-link" hypothesis as it is traditionally held by

proponents of CST and osteopathy in the cranial field. A 2012 systematic review by Jäkel and von Hauenschild concluded that given the paucity of high-quality research, further research is needed.

Liddle and Pennick (2015) completed a Cochrane review on interventions for preventing and treating low back pain and pelvic pain during pregnancy. Thirty-four RCTs examining 5,121 pregnant women, aged 16 to 45 years and, when reported, from 12 to 38 weeks' gestation were included. Fifteen RCTs examined women with low-back pain (participants = 1,847); 6 examined pelvic pain (participants = 889); and 13 examined women with both low-back and pelvic pain (participants = 2,385). Two studies also investigated low-back pain prevention and four, low-back and pelvic pain prevention. Diagnoses ranged from self-reported symptoms to clinicians' interpretation of specific tests. All interventions were added to usual prenatal care and, unless noted, were compared with usual prenatal care. The results from a number of individual studies, incorporating various other interventions, could not be pooled due to clinical heterogeneity. There was moderate-quality evidence (study design limitations or imprecision) from individual studies suggesting that osteomanipulative therapy significantly reduced low-back pain and functional disability, and acupuncture or craniosacral therapy improved pelvic pain more than usual prenatal care.

Haller et al. (2016) completed a randomized sham-controlled trial on CST for treatment of chronic neck pain. Fifty-four blinded patients were randomized to either 8 weekly units of CST or light touch sham treatment. Outcomes were assessed before and after treatment at week 8 and week 20. The primary outcome was pain intensity on a visual analogue scale; secondary outcomes included pain on movement, pressure pain sensitivity, functional disability, health-related quality of life, well-being, anxiety, depression, stress perception, pain acceptance, body awareness, patients' global impression of improvement and safety. In comparison to sham, CST patients reported significant and clinically relevant effects on pain intensity at weeks 8 and 20. Minimal clinically important differences in pain intensity at week 20 were reported by 78% of the CST patients, while 48% even had substantial clinical benefit. Significant differences at weeks 8 and 20 were also found for pain on movement, functional disability, physical quality of life and patients' global improvement. Pressure pain sensitivity and body awareness were significantly improved only at week 8; anxiety only at week 20. No serious adverse events were reported. Authors conclude that CST was both specifically effective and safe in reducing neck pain intensity and may improve functional disability and quality of life up to 3 months post intervention. The study stated that "Further studies with strict methodological designs and long-term follow-ups are needed to confirm CST efficacy in neck pain treatment."

Haller et al. (2019) systematically assessed the evidence of Craniosacral Therapy (CST) for the treatment of chronic pain. Ten RCTs of 681 patients with neck and back pain, migraine, headache, fibromyalgia, epicondylitis, and pelvic girdle pain were included. In

comparison to the usual treatment, this meta-analysis found significant small to medium size pooled effects of CST directly after the end of the intervention for: pain intensity, functional disability, and physical quality of life, which were however based mainly on one RCT for patients with pelvic girdle pain. At 6 months, CST showed greater positive effects on pain intensity and disability versus sham. Five of the 10 RCTs reported safety data. No serious adverse events occurred. Minor adverse events were equally distributed between the groups. In patients with chronic pain, this meta-analysis suggests significant and robust effects of CST on pain and function lasting up to six months. More RCTs strictly following CONSORT are needed to further corroborate the effects and safety of CST on chronic pain. A major limitation is the small number of studies included in the meta-analysis. Conclusions drawn, especially those from analyses that included only 2 RCTs, remain preliminary.

Muñoz-Gómez et al. (2022) evaluated the effectiveness of a craniosacral therapy protocol on different features in migraine patients. Fifty individuals with migraine were randomly divided into two groups ( $n = 25$  per group): (i) craniosacral therapy group (CTG), following a craniosacral therapy protocol, and (ii) sham control group (SCG), with a sham treatment. The analyzed variables were pain, migraine severity and frequency of episodes, functional, emotional, and overall disability, medication intake, and self-reported perceived changes, at baseline, after a 4-week intervention, and at 8-week follow-up. After the intervention, the CTG significantly reduced pain ( $p = 0.01$ ), frequency of episodes ( $p = 0.001$ ), functional ( $p = 0.001$ ) and overall disability ( $p = 0.02$ ), and medication intake ( $p = 0.01$ ), as well as led to a significantly higher self-reported perception of change ( $p = 0.01$ ), when compared to SCG. In addition, the results were maintained at follow-up evaluation in all variables. Authors concluded that this protocol based on craniosacral therapy is effective in improving pain, frequency of episodes, functional and overall disability, and medication intake in migraineurs. This protocol may be considered as a therapeutic approach in migraine patients.

Buffone et al. (2022) evaluated the effectiveness of osteopathic manipulative treatment (OMT) for gastrointestinal disorders in term and preterm infants in a systematic review and meta-analysis. Nine articles met the eligibility criteria, investigating OMT compared with no intervention, 5 involving term infants, and the remaining treating preterm infants. In the meta-analysis, 2 studies were included to analyze the hours of crying due to infantile colic, showing statistically significant results. The quality of evidence was “moderate.” The other outcomes, such as time to oral feeding, meconium excretion, weight gain, and sucking, were presented in a qualitative synthesis. OMT was substantially safe, and showed efficacy in some cases, but the conflicting evidence and lack of high-quality replication studies prevent generalization. High-quality RCTs are recommended to produce better-quality evidence.

Bordoni and Escher (2023) reviewed the most recent information on the maturation of the sutures of the spheno-occipital synchondrosis (SOS) and cranial bones, the behavior of the CSF, the maturation of the cranial meninges, and the evolution of the sacroiliac joint. Authors strongly advised abandoning the absolute certainty of the validity of the mechanisms devised by proponents of craniosacral therapy and related techniques and looking for new motivations and new methods of palpation, with respect to what is palpated by expert operators.

Jiang et al. (2023) assessed the efficacy and safety of Craniosacral therapy (CST) in the treatment of migraine, using a rigorous and innovative randomized controlled study design involving complementary light-touch sham treatments (CLST) as an attention control intervention. This was a single-center, randomized, cross-over placebo-controlled experimental design. A total of 87 participants who suffered migraine attacks from 4 to 9 per month were randomly assigned into either 2 weekly units of CST or CLST for 4 weeks. And then the 2 groups were crossed and continued treatment for 4 weeks plus a follow-up observation for 4 weeks. As the primary outcome measures, Headache Impact Test-6 (HIT-6) and headache frequency were assessed every 4 weeks (at baseline, week 4, week 8 and week 12). The secondary outcome was the scores of Headache Disability inventory (HDI) and the Hamilton Anxiety Scale (HAMA) as well as the adverse events. All 87 individuals had been screened for eligibility, of which 60 were licensed for the study. The difference of HIT-6 and headache frequency between the 2 groups was not significant at the baseline. But the headache frequency and HIT-6 of 2 groups were all declined respectively after the CST at week 4 (group A) and week 8 (group B) than before while the changes were not obvious after CLST with previous treatment. The scores and frequency of fourth evaluation showed that there was no significant increase or decrease in both the 2 groups. Besides, we found that the mean scores of HIT-6 for all participants, compared with the baseline, were decreased significantly after the 3 round treatments. We also showed the similar result in the scores of HDI and HAMA. Authors concluded that these results indicated that standardized CST was both effective and safe in alleviating the migraine intensity and frequency as well as the headache-related disability. However, as noted in the results, these results were not maintained.

Carrasco-Uribarren et al. (2024) analyzed the effectiveness of craniosacral therapy in improving pain and disability among patients with headache disorders. The searches retrieved 735 studies, and 4 studies were finally included. The craniosacral therapy provided statistically significant but clinically unimportant change on pain intensity and no change on disability or headache effect. The certainty of the evidence was downgraded to very low. Authors concluded that very low certainty of evidence suggests that craniosacral therapy produces clinically unimportant effects on pain intensity, whereas no significant effects were observed in disability or headache effect.

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