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Review Article

Clinical Effectiveness of Craniosacral Therapy in Patients with Headache Disorders: A Systematic Review and Meta-analysis

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ABSTRACT

Objectives: To analyze the effectiveness of craniosacral therapy in improving pain and disability among patients with headache disorders.
Design: Systematic review and meta-analysis.
Data sources: PubMed, Physiotherapy Evidence Database, Scopus, Cochrane Library, Web of Science, and Osteopathic Medicine Digital Library databases were searched in March 2023.
Review methods: Two independent reviewers searched the databases and extracted data from randomized controlled trials comparing craniosacral therapy with control or sham interventions. The same reviewers assessed the methodological quality and the risk of bias using the PEDro scale and the Cochrane Collaboration tool, respectively. Grading of recommendations, assessment, development, and evaluations was used to rate the certainty of the evidence. Meta-analyses were conducted using random effects models using RevMan 5.4 software.
Results: The searches retrieved 735 studies, and four studies were finally included. The craniosacral therapy provided statistically significant but clinically unimportant change on pain intensity (Mean difference = −1.10; 95% CI: −1.85, −0.35; I^2: 44%), and no change on disability or headache effect (Standardized Mean Difference = −0.34; 95% CI −0.70, 0.01; I^2: 26%). The certainty of the evidence was downgraded to very low.
Conclusion: 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.

Headaches are one of the most prevalent medical issues seen in clinical practice in the 21st century (Amiri et al., 2022; Stovner et al., 2022). They are regarded as one of the top 10 most debilitating conditions, affecting nearly 50% of the global adult population. Furthermore, headaches are a significant cause of work absences and result in substantial healthcare system expenses (Gil-Gouveia and Miranda, 2022; Simić et al., 2020), ranging from €27 billion in Europe (Stovner et al. 2022) to $56 billion in United States of America (Newman et al., 2021).

Pharmacological treatment, therapeutic exercise, and manual therapy are the most commonly used treatments (Bini et al., 2022; Núñez-Cabaleiro and Leirós-Rodríguez, 2022; Olesen, 2018). However, due to the chronic nature of headaches, many patients seek complementary and alternative treatments in search of symptom relief (Nahin et al., 2016; Vickers et al., 2018).

The use of complementary and alternative medicine is common in clinical practice. Nurses are well positioned to implement these therapeutic modalities and their use of acupressure and acupuncture are common as clinical practice (Hamlin and Robertson. 2017). According to the World Health Organization (WHO), osteopathic treatment is considered as complementary and alternative medicine. Osteopathic therapy involves the use of manual contact for the diagnosis and treatment of various somatic dysfunctions. Osteopathic interventions usually involve a wide range of manual techniques, such as joint mobilizations and manipulations, myofascial release, visceral manipulations, and craniosacral therapy

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(CS) or cranial osteopathy (World Health Organization 2010). These techniques are commonly implemented by doctors, nurses, and/or physiotherapists.

The concept of CS therapy was developd by Sutherland and Upledger in the 1970s (Sutherland, 1990; Upledger and Vredevoogd, 1983), who hypothesized that movement restrictions in the cranial structures can negatively affect the CS rhythmic impulses conveyed through the cerebral spinal fluid from the cranium to the sacrum, commonly known "as the "primary respiratory m"chanism" (Green et al., 1999). Craniosacral therapy techniques involve the use of gentle manual force to address somatic dysfunctions and attempt to restore motion to restrictions within individual sutures of the skull, the skull as a whole, and the skull in relation to the sacrum. The release of these restrictions tends to normalize the CS rhythm (Greenman and McPartland, 1995).

Currently, CS therapy is included in the Benchmarks for Osteopathic Education of the WHO (World Health Organizationm 2010). However, its biological plausibility, assessment reliability, and clinical effectiveness are the subject of debate (Ernst, 2012; Green et al., 1999). Regarding biological plausibility, several studies have demonstrated that adult cranial bones are fused, with complete fusion of the cranial sutures occurring by the age of 13 to 18 years (Downey et al., 2006; Okamoto et al., 1996). Additionally, the relationship between CS dysfunction and disease has not been established (Green et al., 1999). Guillaud et al (2016) reviewed studies on intra- and inter-rater reliability and found that the results were either unusable or did not demonstrate reliability for any of the investigated parameters.

The clinical effectiveness of CS therapy has been investigated in different populations, such as patients with fibromyalgia, lateral epicondylitis, low back pain, pelvic girdle pain, neck pain, headache, or even children with cerebral palsy in several systematic reviews and meta-analyses (Ernst, 2012; Green et al., 1999; Guillaud et al., 2016; (Haller et al., 2019); Jäkel and von Hauenschild, 2012). Of these, three concluded that there is not enough high-quality evidence to suggest a positive effect of CS therapy (Ernst, 2012; Green et al., 1999; Guillaud et al., 2016). Jakel and von Hauenschild (2012) suggested that some benefits may occur, but there is a lack of evidence to support CS therapy in a variety of clinical conditions. Only Haller et al. (2019) concluded that CS therapy provides benefits for patients with chronic pain. Therefore, the clinical effectiveness of CS therapy remains unclear, and to the best of our knowledge, no systematic review or meta-analysis investigating the effectiveness of CS therapy in patients with headache disorders has been conducted. Thus, the aim of the study was to investigate the clinical effectiveness of CS therapy on pain intensity and disability in the short-term compared to sham interventions or no intervention in patients with headache disorders.

Methods

Study Design

A systematic review and meta-analysis following the PRISMA Statement and the Cochrane recommendations was carried out (Page et al., 2021). The study protocol was registered previously in PROSPERO with a unique registration number CRD42023407798.

Search strategy.

The bibliographical search was conducted in PubMed (MEDLINE), Physiotherapy Evidence Database (PEDro), Scopus, Cochrane Library, Web of Science (WOS), and Osteopathic Medicine Digital library (OSTMED) from inception to March 2023. The Population, Intervention, Comparison, Outcome, and Study design (PICOS) framework was used to define the search strategy. Medical Subjects Headings (MeSH) were used as the keywords in the search strategy: musculoskeletal manipulation, chiropractic, chiropractic manipulation, osteopathic manipulation, and headache disorders. The reference lists of the included studies were hand-searched. Searches were limited to studies in English, French, and Spanish. The search strategy used in each database is shown in Appendix I.

Eligibility criteria and study selection.

The inclusion criteria were based on the PICOS framework: Population: adults diagnosed with any type of headache disorder; Intervention: CS therapy in isolation; Comparison: control or sham techniques; Outcomes: pain intensity and/or disability or effect of the headache; Study: randomized controlled trials (RCTs). Studies were excluded if they: included patients with different pathologies than headache disorders; included CS therapy combined with other interventions; reported variables not related to the clinical effectiveness of the CS therapy (such as hearth rate); or the outcome variables reported were not measured using a valid and reliable instrument.

Once the searches were performed in each database, the reference lists were exported to Mendeley to remove duplicates. Two reviewers (L. C. L. and A. C. U.), with more than eight years of experience in the design of systematic reviews and meta-analyses, independently reviewed the title and abstract of each reference to determine potential eligibility. The same reviewers assessed the full texts of the potential studies. A third author (L. M. M.) was consulted in case of discrepancies between the reviewers.

Data extraction.

The two experienced reviewers extracted the data from the included studies using the standardized process adapted from the Cochrane Collaboration including: characteristics of the study population; type of interventions; outcome measures; and results. Data were analyzed using a qualitative and quantitative synthesis.

Risk of bias and certainty of evidence.

Two assessors assessed the quality of the studies using the PEDro scale and the Cochrane Risk of Bias tool. PEDro scale is an 11-items scale based on the study of Verhagen et al (1998). One item of the PEDro scale (eligibility criteria) is related to external validity and was not used to calculate the total score. A score of 7 or above was considered "high" quality, 5-6 was considered "fair" quality, and 4 or below was considered "poor quality" (Verhagen et al., 1998).

The risk of bias of the studies was evaluated using the Risk of Bias 2 (RoB2). This tool is used to assess the potential risk of bias in various types of studies, including randomized trials and non-randomized studies. The tool evaluates five different domains of bias, which are: 1) the randomization process, 2) deviations from intended interventions, 3) missing outcome data, 4) measurement of the outcome, and 5) selection of the reported result. The assessment of each domain is conducted based on its potential risk of bias, with three possible levels: low, some concerns, or high. The combination of the previous five items is used to determine the overall risk of bias rating for the entire study.

The GRADEpro GDT was utilized to create a summary of the results. This framework categorizes the evidence as "high", "moderate", "low", or "very low" and allows researchers and clinicians to evaluate the significance of the results. The certainty of evidence for the meta-analysis was downgraded based on the presence of certain factors, including the risk of bias, inconsistency of the results, indirectness of evidence, and imprecision. The risk of bias was increased in one level or two levels when 25% or 50% of the subjects included in the present study were from clinical trials

with poor or fair methodological quality: random allocation and/or sample size calculation, participant, lack of allocation concealment, and personnel blinding (blinding of outcome assessors), inconsistency of results (if the included studies showed heterogeneity on the outcome measurement or intervention, or the I^2 value was ≥50%), the GRADEpro was devalued in one level and in two level if the I^2 was ≥75 (Guyatt, Oxman, Kunz, Woodcock, et al., 2011), indirectness of evidence (downgraded by one level if different populations, interventions, or comparators were included), and imprecision (if the number of participants in the comparison was less than 100, the evidence was devalued by one level). If the sample size was ≤30 individuals, the evidence was devalued by two levels (Guyatt, Oxman, Kunz, Brozek, et al., 2011). Single randomized trials were considered deemed inconsistent and imprecise, thus providing evidence of "low certainty". This certainly level could be further reduced to "very low" if the trial also exhibited a high risk of bias (Xie and Machado 2021).

Data synthesis and analysis.

The quantitative synthesis of the results was conducted using the RevMan 5.4 software for the outcomes pain intensity and disability/effect of headache. Separate analyses were performed for pain intensity and disability or effect of headache. When studies reported pain intensity on a scale other than 0-10 (e.g., 0-100), data were transformed into a 0-10 scale. Mean, standard deviations (SD), and sample size at each time point were extracted for each group. Outcomes were analyzed based on the post-intervention means and SDs by calculating the mean difference (MD) when studies used the same scale or standardized mean difference (SMD) when studies used different scales, with 95% coefficient intervals (CIs). Significance was set at $p < .05$.

The minimum clinically important difference (MCID) on pain intensity has been reported to range from 1.5-3.2 (Calixtre et al., 2020; Young et al., 2019). For disability, the effects size was used to classify the effect estimates as small (SMD at least 0.2 but less than 0.5), medium (SMD from 0.5 to less than 0.8), or large (SMD 0.8 or greater) (Cohen, 1988).

Data were combined for meta-analysis when at least two studies were homogeneous. Studies were considered homogeneous if they applied a common intervention and measured a common outcome. When a three-arm study was included, the data from the repeated group were divided (Higgins et al., 2011). Random-effect meta-analysis was performed when the combination of intervention effects could incorporate an assumption that the studies are not all estimating the same intervention effect (Higgins et al., 2019).

Results

Four studies were included in the qualitative and quantitative synthesis. Seven studies were excluded for different reasons. Four studies included CS therapy in a multimodal intervention (Anderson and Seniscal, 2006; Cerritelli et al., 2015; Rolle et al., 2014; Voigt et al., 2011). Two were case series (Domaranczy and Truszczynska-Baszak, 2020; Rao, 2017) and one a congressional abstract (Mann et al., 2012). The description of the selection process is shown in the PRISMA flowchart diagram (Fig. 1).

Characteristics of Included Studies

A total of four RCTs were included comprising 184 patients with headache disorders. The sample size ranged from 10-25 patients per group.

The studies included patients with tension-type headache (Hanten et al., 1999), chronic neck pain (Haller et al. 2016), or migraine (Arnadottir and Sigurdardottir, 2013; Muñoz-Gómez et al., 2022). The sociodemographic and clinical variables are presented in the Table 1.

The CS groups included several techniques, such as the fourth ventricle (CV-4) technique, frontal and parietal lift, medial compression of the parietal bones, release of the sagittal suture and the atlanto-occipital joint, compression-decompression of the sphenobasilar and the temporomandibular joints, cranial base release, release of the hyoid diaphragm and the thoracic inlet, dural tube traction, respiratory and pelvic diaphragm release, lumbosacral and sacroiliac decompression, fascial unwinding of the neck/shoulders and lower limbs, and/or still point induction (Arnadottir and Sigurdardottir, 2013; Haller et al., 2016; Hanten et al., 1999; Muñoz-Gómez et al., 2022).

The control group consisted of no intervention (Arnadottir and Sigurdardottir, 2013; Hanten et al., 1999) or a sham technique based on light superficial contact (Haller et al., 2016; Muñoz-Gómez et al., 2022). Information about the interventions, the duration of the session, frequency, and total number of sessions is shown in Table 2.

Outcome measures.

The outcomes considered in this meta-analysis were pain intensity, and disability or effect of the headache. Three studies assessed pain intensity using the visual analogue scale (VAS) (Haller et al., 2016; Hanten et al., 1999; Muñoz-Gómez et al., 2022). All the studies assessed disability or effect using a VAS scale (Hanten et al., 1999), the headache impact test (HIT-6) (Arnadottir and Sigurdardottir 2013), the neck disability index (NDI) (Haller et al., 2016), or the headache disability index (Muñoz-Gómez et al., 2022). All the studies assessed the outcome variables at baseline and after the intervention.

Study quality and risk of bias.

The methodological quality of the studies was assessed with the PEDro scale. Considering this scale, one study presented low quality (Hanten et al., 1999), two studies were categorized as fair quality (Arnadottir and Sigurdardottir, 2013; Muñoz-Gómez et al., 2022), and the study of Haller et al. was rated as high quality (Haller et al., 2016) (Table 3).

Three studies showed an unclear randomization process (Arnadottir and Sigurdardottir, 2013; Hanten et al., 1999; Muñoz-Gómez et al., 2022). Two studies presented a high risk of bias and two, an unclear risk of bias with deviations from the intended interventions (Arnadottir and Sigurdardottir, 2013; Haller et al., 2016; Hanten et al., 1999; Muñoz-Gómez et al., 2022). Only one study showed an unclear risk of bias due to missing outcome data (Hanten et al., 1999). Two studies reported a high risk for the process of the measurement of the outcome (Haller et al., 2016; Hanten et al., 1999). Three studies showed a high risk for the selection of the reported results (Arnadottir and Sigurdardottir, 2013; Haller et al., 2016; Muñoz-Gómez et al., 2022). The Cochrane RoB2 results are shown in Figure 2.

Synthesis of results.

Very low certainty of evidence suggested that CS therapy provides statistically significant but clinically unimportant change on pain intensity after intervention compared to a sham or control group (MD = −1.10; 95% CI: −1.85, −0.35; I^2: 44%; 3 studies; 164 participants) (Fig. 3A).

Very low certainty of evidence suggested that CS therapy provides no statistically significant change on disability or impact of the headache after intervention compared to a sham or control group (SMD = −0.34; 95% CI −0.70, 0.01; I^2: 26%; 4 studies, 184 participants) (Fig. 3B).

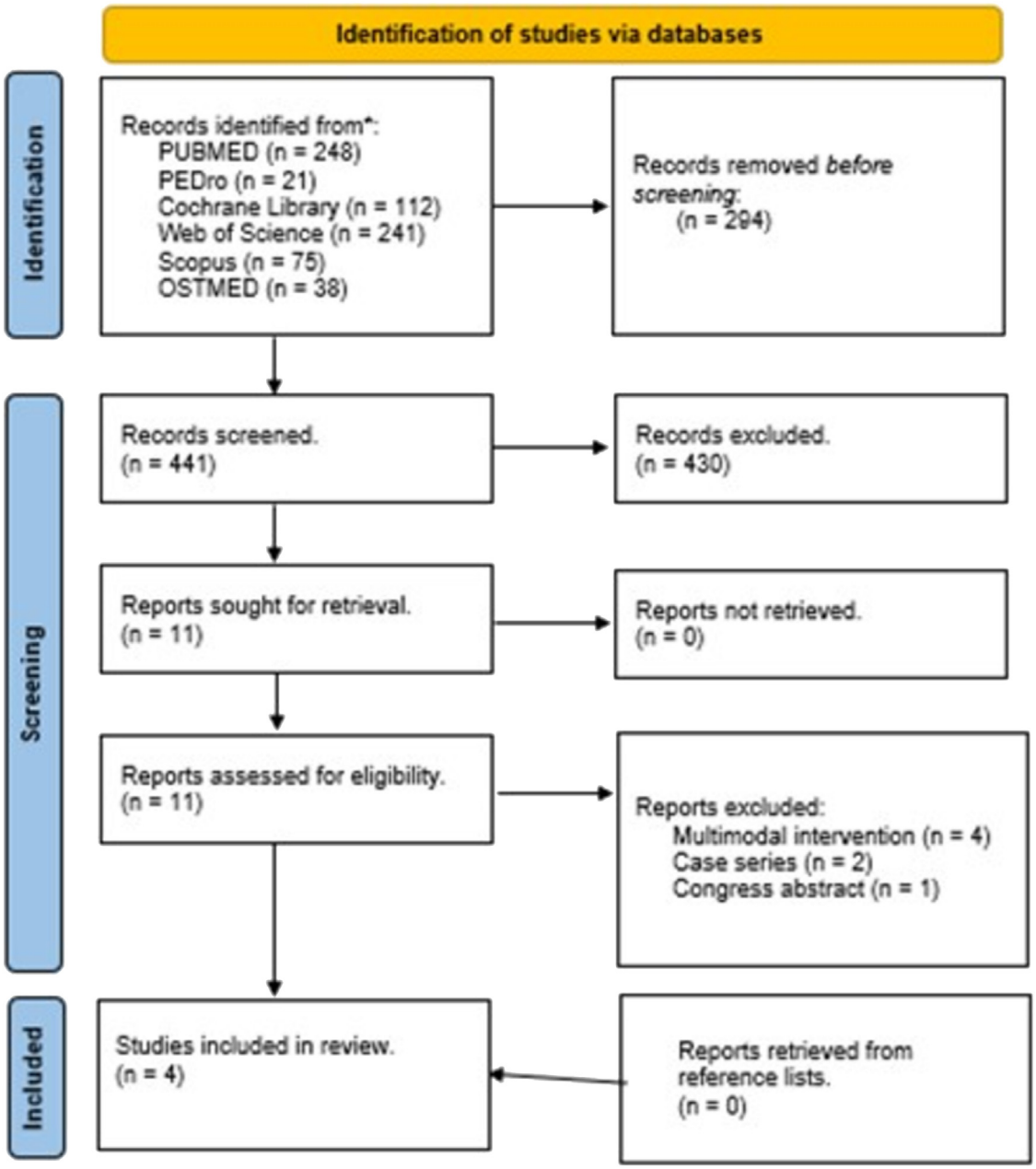

Figure 1. PRISMA flowchart diagram.

Table 1
Sociodemographic and Clinical Characteristics of the Participants

Autor (year)	N (sex ratio)	Participants		Intervention		Outcome (tool)	Main Results
		Mean age (SD)	Diagnosis	CST	CG		
Hanten et al. 1999 A	20	36 (12)	TTH	CST (n=20)	Resting position (n=20)	-Pain (VAS) -Impact (VAS)	No statistically significant differences between groups
Hanten et al. 1999 B	20	36 (12)	TTH	CST (n=20)	Control (n=20)	-Pain (VAS) -Impact (VAS)	↑Pain and impact in CST vs CG
Arnadottir et al. 2013	20 (2M/18F)	37.6 (9.3)	Migraine	CST (n=10)	Control (n=10)	-Headache impact (HIT-6)	No statistically significant differences between groups
Haller et al. 2016	54 (11M/43F)	CST: 44.2 (9.7) CG: 45.0 (10.5)	CNP	CST (n=27)	Sham intervention (n=27)	-Pain (VAS) -Neck disability (NDI)	↑Pain and disability in CST vs CG
Muñoz-Gómez et al. 2022	50 (10M/40F)	CST: 40.92 (7.95) CG: 37.64 (9.42)	Migraine	CST (n=25)	Sham intervention (n=25)	-Pain (VAS) -Migraine severity (HDI)	↑Pain and migraine severity in CST vs CG

M = male; F = female; SD = standard deviation; CST = craniosacral therapy; CG = control group; TTH = tension-type headache; CNP = chronic neck pain; VAS = visual analogue scale; NDI = neck disability index; HDI = headache disability index; HIT-6 = headache impact test questionnaire.

Table 2
Techniques Applied in Each Group

Autor (year)	CST	CG	Session duration	Frequency (sessions/week)	Total number of sessions
Hanten et al. 1999	CV-4 technique	Resting position technique	CST: 10m CG: 10m	1s/w	1
Hanten et al. 1999 B	CV-4 technique	No intervention	CST: 10m CG: 10m	1s/w	1
Arnadottir et al. 2013	No techniques reported Treated areas: Pelvic area, diaphragm, inlet of the upper thoracic cavity, muscles around the hyoid and the upper muscles in the back of the neck.	No intervention	NR	1.5s/w	6
Haller et al. 2016	Frontal and parietal lift Medial compression of the parietal bones Release of the sagittal suture and the atlanto-occipital joint Compression-decompression of the sphenobasilar and the temporomandibular joints Cranial base release Release of the hyoid diaphragm and the thoracic inlet Dural tube traction Respiratory and pelvic diaphragm release Lumbosacral and sacroiliac decompression Fascial unwinding of the neck/shoulders and lower limbs Still point induction Dialog techniques	Light touch on standardized anatomic aeras	45m	1s/w	8
Muñoz-Gómez et al. 2022	Suboccipital inhibition technique Frontal technique Sphenoid technique CV-4 technique Lumbosacral technique	Hands-on placebo superficial contact under the occiput	CST: 35m CG: 10m	1s/w	4

NR = no reported; CST = craniosacral therapy; CG = control group.

Table 3
PEDro Scale Total Score

Author	Items											Total score	
	1	2	3	4	5	6	7	8	9	10	11		
Hanten et al. 1999	Y	Y	N	Y	N	N	N	N	N	Y	Y	4/10	low
Arnadottir et al. 2013	Y	Y	N	Y	N	N	N	Y	Y	Y	N	5/10	Fair
Haller et al. 2016	Y	Y	Y	Y	Y	N	Y	N	Y	Y	Y	8/10	High
Muñoz-Gómez et al 2022	Y	Y	N	Y	Y	N	N	Y	N	Y	Y	6/10	Fair

*1: Elegibility criteria was not considered in overall score.
2: Subjects randomly allocated to groups.
3: Allocation was concealed.
4: Groups similar at baseline regarding most important prognostic indicators.
5: Blinding of subjects.
6: Blinding of all therapists.
7: Blinding of all assessors who measured at least one key outcome.
8: Measures of key outcomes obtained from more than 85% of those initially allocated to groups.
9: All subjects for whom outcome measures were available received the treatment or control condition as allocated or where this was not the case, data was analysed by "intention to treat".
10: Results of between group statistical comparisons are reported for at least one key outcome.
11: Study provides both point measures and measures of variability for at least one key outcome.
Y = criterion satisfied; N = criterion not satisfied.

According to GRADE, the overall certainty of evidence for all comparisons were rated as very low for pain intensity and disability (Appendix II).

Discussion

The aim of this systematic review and meta-analysis was to investigate the clinical effectiveness of CS therapy in patients with headaches disorders. The results showed that CS therapy, when administered in isolation, produced statistically significant but clinically unimportant changes on pain intensity, and no statistically significant changes on disability or headache impact compared to sham or control interventions in patients with headache disorders. The certainty of evidence was downgraded to very low for both dependent variables, which means that there is little confidence in the effect estimate. The true effect is likely to differ substantially from the estimated effect.

Concerning the methodological aspects, several flaws need to be considered. The randomization process was not performed correctly in three studies (Arnadottir and Sigurdardottir, 2013; Muñoz-Gómez et al., 2022). Examiners and/or patients were not blinded in three studies (Arnadottir and Sigurdardottir, 2013). None of the studies registered the study protocol to clarify the risk of selection bias (Arnadottir and Sigurdardottir 2013; Haller et al. 2016; Muñoz-Gómez et al. 2022). The outcome measurement process was reported as having a high risk of bias in two studies (Haller et al. 2016).

The quantitative synthesis of this systematic review and meta-analysis found a statistically significant improvement on pain intensity (−1.10 [−1.85; −0.35]) but not on disability and impact

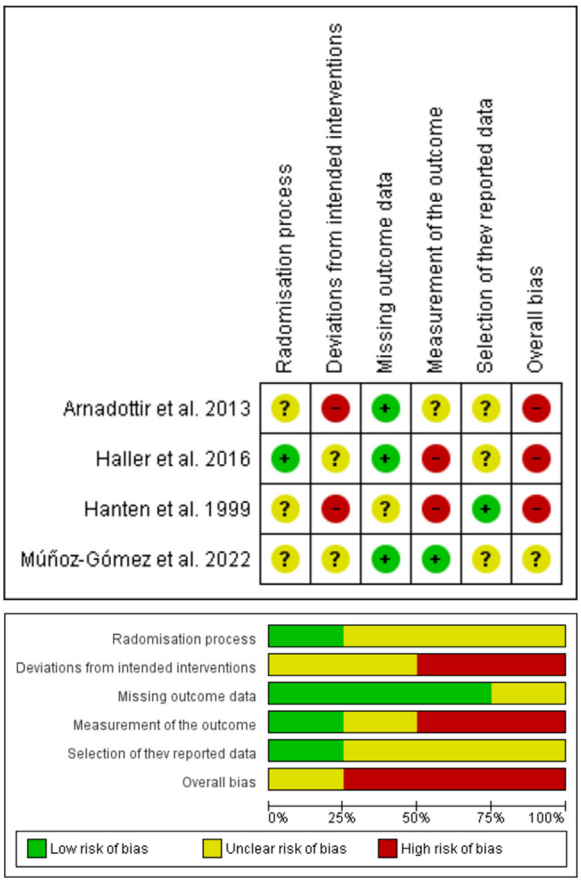

Figure 2. Cochrane risk-of-bias tool.

(–0.34 [–0.79; 0.01]). The results achieved on pain intensity were clinically unimportant because they were not higher than the MCID stated for pain intensity (1.5-3.2) (Calixtre et al., 2020; Young et al., 2019). These results are in accordance with previous systematic reviews that found no robust evidence supporting the clinical effectiveness of CS therapy (Ernst, 2012; Green et al., 1999; Guillaud et al., 2016). The systematic review and meta-analysis conducted by Haller et al. (2019) found benefits after the application of CS therapy. However, this study presented several flaws, such as the inclusion of data from abstracts in the meta-analysis and carrying out the meta-analyses regardless of the population of each study.

The assessment and treatment of patients varied significantly across the studies. In one study, the treatment was applied by a nurse and a physiotherapist (Arnadottir and Sigurdardottir 2013), in two studies the treatment was applied by the physiotherapist (Haller et al. 2016; Muñoz-Gómez et al., 2022), and one study did not specify who applied the treatment (Hanten et al. 1999). In addition, only one study specified that the techniques applied were based on restrictions found by manual palpation (Arnadottir and Sigurdardottir, 2013), and a striking lack of clarity was observed in the three other studies regarding patient assessment (Haller et al., 2016; Muñoz-Gómez et al., 2022). It must be emphasized that the reliability of CS assessment, both intra- and inter-rater, was found to be inaccurate (Guillaud et al., 2016). In addition, Seffigner et al. (2004) concluded that spinal palpatory diagnostic procedures were unreliable.

Regarding the interventions, all the studies included in the analysis used CS therapy, although with a diversity of techniques implemented in each individual study. Hanten et al. (1999) used the CV-4 technique, and Muñoz-Gómez et al. used frontal technique, sphenoid technique, CV-4 technique, lumbosacral technique, and suboccipital inhibition technique (Muñoz-Gómez et al., 2022). Haller et al. (2016) described multiple techniques that were applied according to the therapist's perception, including dialog

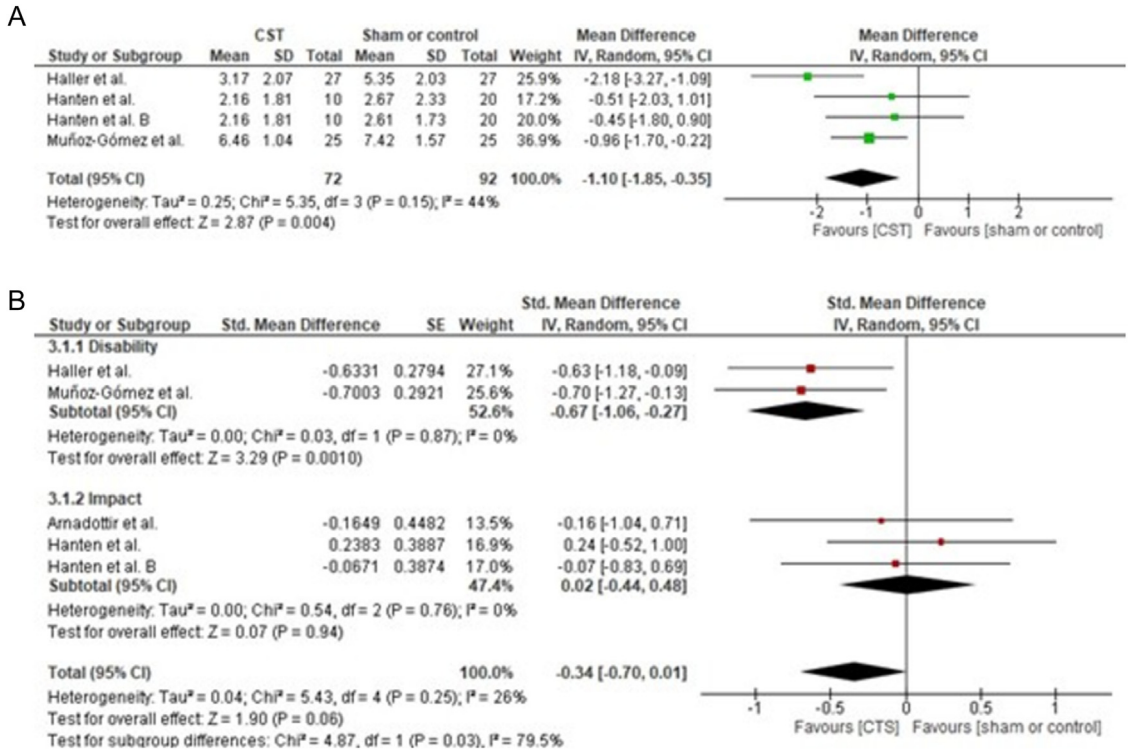

Figure 3. (A.) Forest plot of pain intensity. (B.) Forest plot of Disability and impact.

techniques. Arnadottir et al. did not explain the techniques used, but described the treated areas (Arnadottir and Sigurdardottir, 2013). It is worth noting that, despite being described as CS therapy, some of the studies incorporated techniques that deviated from the fundamental principles of CS therapy, such as dialog techniques or other forms of manual therapy techniques. A clear example is that Muñoz-Gómez et al. (2022) used the suboccipital inhibition technique, which has been shown to relieve cervical pain, improve cervical range of motion (Carrasco-Uribarren et al., 2021; González-Rueda et al., 2018), and improve flexibility of the hamstring muscles (Jiang et al., 2023).

Haller et al. (2016) included dialog techniques, but neither this study nor the rest of the included studies assessed the interaction between the therapist and the patient. Currently, it is known that contextual factors have an important influence in pain interventions (Rossettini et al., 2020). In this way, patients included in the sham or control groups may not be in a real therapeutic situation, putting the credibility of the treatment at risk. This is an important factor to consider for the interpretation of the between-groups results (Curtis et al., 2011).

The duration, frequency, and total number of sessions exhibited remarkable heterogeneity, which challenges the interpretation of results. However, it is important to highlight that the study which reported positive results employed a 35-minute session for the CS therapy group, in contrast to the 10-minute session utilized for the sham group (Muñoz-Gómez et al., 2022).

From a clinical perspective, headache disorders are the second most common complaint treated by osteopaths, with CS therapy being used often or always in 77.4% of cases (Alvarez et al., 2020). Taking into consideration data retrieved from a national survey, CS therapy is applied in many patients (World Health Organization 2010). However, the biological plausibility, assessment reliability, and clinical effectiveness do not support its use in clinical practice. Moreover, the inclusion of CS therapy in the educational framework (benchmarks for training in osteopathy, World Health Organization, 2010) and healthcare systems should be based on high quality evidence. Therefore, based on the current and previous evidence, there is no robust evidence supporting the use of CS therapy in patients with headache disorders.

Implications for Nursing and/or Health Policy

This systematic review and meta-analysis had several limitations. Some databases were omitted, so our search strategy may have missed potential studies. The interventions applied in the study were heterogeneous, which complicates the interpretation of the results. Additionally, the lack of high-quality studies may have affected the results. Future research should follow the CONSORT reporting guidelines for RCTs and standardize the assessment and treatment protocols.

Conclusion

This systematic review and meta-analysis showed very low certainty of evidence, suggesting that craniosacral therapy provided statistically significant but clinically unimportant changes on pain intensity, while no significant changes were observed on disability or headache impact compared with sham or control interventions in patients with headache disorders.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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