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Melissa A. Stefanosky

*Philadelphia College of Osteopathic Medicine*

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Is Craniosacral Therapy Effective in the Reduction of Pain Intensity in Individuals with Non-specific Neck and/or Back Pain?

Melissa A. Stefanosky, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

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ABSTRACT

OBJECTIVE: The objective of this selective evidence based medicine review is to determine whether or not craniosacral therapy is effective in the reduction of pain intensity in individuals with non-specific neck and/or back pain.


DATA SOURCES: Three randomized controlled trials comparing craniosacral therapy to sham treatment, classic massage and/or trigger point therapy. These data sources were found using PubMed.

OUTCOMES MEASURED: Pain intensity in the neck and/or back, measured by using a 10-point numeric pain rating scale and the visual analogue scale.

RESULTS: All three studies found craniosacral therapy to be just as effective in reducing neck and/or back pain intensity compared to the control groups receiving sham treatment, classic massage or trigger point therapy. In the study by Haller et al. the group difference at week 8 was -21.0 with a statistically significant p-value of 0.001 and a 95% confidence interval of (-32.6 to -9.4). In the study by Castro-Sánchez et al the 95% confidence interval between group difference was -1.03 (-1.94 to -0.11) with a statistically significant p-value of 0.008. The third study by Bialoszewski et al proved a change in baseline of 3.5 with a statistically significant p-value of 0.047.

CONCLUSIONS: The results of the randomized controlled trials validate that craniosacral therapy reduces pain intensity in individuals with non-specific neck and/or back pain.

KEY WORDS: Back pain, craniosacral
INTRODUCTION

Non-specific neck and/or back pain is classified as pain that is not attributable to a recognizable specific pathology. The lifetime prevalence of low back pain is about 84%. Due to the significant percentage of lifetime prevalence it is not surprising that back pain is the third most common reason for visits to the doctor’s office. There is no exact estimate of exactly how many non-specific neck and/or back pain health care visits there are each year. Although according to data, in 2007 there were over 19.1 million people reported for receiving treatment for back problems. The particular costs of health care costs associated with low back pain in the US have not been identified. However, the total costs of health care for patients with musculoskeletal conditions add up to approximately $240 billion and the total costs associated with low back pain in the US is greater than $100 billion per year.

Non-specific neck and/or back pain cannot be attributed to any specific injury or primary disease. It is impossible to identify the overuse or damage to the anatomy by diagnostic tests. This makes it difficult to confirm exactly from where the pain is coming. Overuse or damage to an intervertebral disc, ligament or paravertebral muscles is sufficient enough to aggravate a series of functional changes significantly limiting the physical function of a patient.

The usual methods used to treat non-specific neck and/or back pain are physical therapy, acupuncture, opioids and NSAIDs, fusion therapy, and osteopathic manipulative treatment. The treatment methods mentioned all have an effective role in reducing pain intensity in patients with non-specific neck and/or back pain. However, due to the unidentified cause of each patient’s pain, each treatment modality currently available exhibits a different effect on each individual. Research is warranted find a more effective way to manage non-specific neck/back pain since the current modalities are not always effective. Craniosacral therapy is being studied as a
noninvasive, mindfulness-based treatment approach using gentle manual palpation techniques to release fascial restrictions between the cranium and the sacrum. Craniosacral therapy is based on the theory that controlled movements at the cranial sutures of the skull negatively affect rhythmic impulses transported through the cerebral spinal fluid from the cranium to the sacrum.

**OBJECTIVE**

The objective of this selective evidence based medicine review is to determine whether or not craniosacral therapy is effective in the reduction of pain intensity in individuals with non-specific neck and/or back pain.

**METHODS**

All three randomized control trials were found searching PubMed with the key words “back pain” and “craniosacral”. All three articles were published in peer–reviewed journals between the years 2014 and 2016. Articles were selected based on relevance to the objective and analyzed to make sure the outcomes of the studies were patient oriented evidence that matters (POEMs). Two of the articles, Haller and Castro- Sánchez, were both written in English and the third article by Bialoszewski was written in Polish and translated to English.

In all three randomized control trials the populations studied consisted of patients greater than 18 years old with non-specific neck and/or back pain. Craniosacral therapy was the intervention analyzed in all three trials. The comparisons in each separate trial were trigger point therapy, light-touch sham treatment and classic massage. Improvement of the patient’s non-specific neck and/or back pain based on a decrease in their pain intensity was the outcome measured. The types of studies included three randomized control trials comparing craniosacral therapy to the other treatment options.
The common inclusion criteria were studies that were randomized control trials that were published after the year 2007. Exclusion criteria were RCTs that contained participants who were under the age of 18 years old. Additional inclusion and exclusion criteria of the original research studies is included in Table 1. The statistics reported and used in the studies were p-value and NNT.

Table 1: Demographics & Characteristics of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th># Pts</th>
<th>Age (yrs)</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
<th>W/D</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haller et al., 2016 (1)</td>
<td>RCT</td>
<td>54</td>
<td>19-65</td>
<td>Patients who were 18 years or older with chronic nonspecific neck pain for 3 months or more with at least moderate pain intensity</td>
<td>Patients with degenerative, inflammatory or neurological diseases, physical trauma, neoplasms of the spine, severe comorbidities, or patients taking corticosteroids/opiates or muscle relaxants</td>
<td>9</td>
<td>Craniosacral therapy vs. light touch sham treatment</td>
</tr>
<tr>
<td>Castro-Sánchez et al., 2016 (2)</td>
<td>RCT</td>
<td>64</td>
<td>18-64</td>
<td>Patients with lower back pain for at least 3 months, age 18-65, score of 4 or greater on the RMQ, and not currently receiving PT</td>
<td>Patients with lumbar stenosis, spondylolisthesis, fibromyalgia, tx with corticosteroids or oral medication, hx of spinal surgery and disease of the central or peripheral nervous system.</td>
<td>0</td>
<td>Craniosacral therapy vs. classic massage treatment</td>
</tr>
<tr>
<td>Bialoszewski et al., 2014 (3)</td>
<td>RCT</td>
<td>55</td>
<td>24-47</td>
<td>Patients who were 25-50 years old, diagnosis of lumbar sacral spine pain due to overload and absence of other musculoskeletal conditions</td>
<td>Patients with non-overload associated lumbar sacral spine pain as confirmed by specialist, no informed consent provided, and poor compliance.</td>
<td>0</td>
<td>Craniosacral therapy vs. trigger point therapy</td>
</tr>
</tbody>
</table>

OUTCOMES MEASURED
In the article by Haller et al., the study performed measured the outcomes of pain intensity of each individual in the study during the last 7 days of week 8 by using a 100-mm visual analog scale. In the article by Castro-Sánchez et al, the study performed measured the outcomes by analyzing the pain intensity using a 10-point numerical pain scale. These were taken at baseline, after treatment and at a 1 month follow up. In the article by Bialoszewski et al., the study performed measured the outcomes by using a visual analogue scale as well. These were taken before the treatment and immediately after they completed the treatment.

RESULTS

In the article by Haller et al., the population addressed in the study were individuals 18-65 years with chronic nonspecific neck pain for 3 months or more with at least a moderate pain intensity of ≥ 45 mm on a 100-mm visual analog scale (VAS). Exclusion criteria included individuals with specific neck pain due to degenerative disease, trauma or neoplasms of the spine. Individuals with severe comorbid somatic and psychiatric disorders were also excluded from this study. There was an intervention group who received cranial sacral treatment for 8 weeks and a comparison group who received 8 weeks of light-touch sham treatment. The two groups each received 8 units of either cranial sacral therapy or sham treatment once a week for 45 minutes. The trial was conducted at the Department of Internal and Integrative Medicine, Kliniken Essen-Mitte, University of Duisburg-Essen, Essen, Germany. During the eight weeks four patients in the craniosacral group and eight patients from the sham treatment group did not attend all the treatments. At the eight-week mark only three patients had dropped out and this was due to scheduling or loss of interest in the trial. An average pain intensity during the last seven days was recorded using a 100-mm VAS at week 8. Using the results of this randomized control trial, the change in baseline (Table 2) shows that cranial sacral therapy was more
effective than sham treatment in treating the pain intensity of individuals with non-specific neck pain. With a 95% confidence interval the between – group difference at week 8 was -21.0 (-32.6 to -9.4) with a p-value of 0.001 which is statistically significant.  

Table 2: CST vs Sham Pain Intensity at Baseline and Week 8

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Week 8</th>
<th>Change in baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>CST</td>
<td>64.1 ± 12.8</td>
<td>31.7 ± 20.7</td>
<td>32.4</td>
</tr>
<tr>
<td>Sham</td>
<td>64.4 ± 13.3</td>
<td>53.5 ± 20.3</td>
<td>10.9</td>
</tr>
</tbody>
</table>

In the article by Castro-Sánchez et al., the population addressed in the study were individuals aged 18-65 with lower back pain for at least 3 months. Exclusion criteria included those currently participating in physical therapy, presence of lumbar stenosis, diagnosis of spondylolisthesis, fibromyalgia or current treatment with corticosteroids. Individuals who were referred for physical therapy to a clinic run by the Health Science School of the University of Almeria in Spain were the ones recruited for this trial. There were 64 individuals randomly assigned to either receive craniosacral therapy or classic massage. Both groups attended a physical therapy clinic once per week for 10 weeks. A 10-point numeric pain rating scale (NPRS) was used to measure each individual’s pain intensity at baseline and immediately after treatment. There was 100% compliance of both groups, at week 10 there were no individuals lost to follow up. Using the results of the randomized control trial, the change in baseline (Table 3) shows that cranial sacral therapy was more effective than classic massage in decreasing the pain intensity of individuals with chronic low back pain. With a 95% confidence interval the between group difference was -1.03 (-1.94 to -0.11) with a p-value of 0.008. Overall the results between the two groups are very similar, both prove to be effective in reducing pain intensity.

Table 3: CST vs Classic Massage Pain Intensity at Baseline and Week 10

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Week 10</th>
<th>Change in baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>CST</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sham</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
In the article by Bialoszewski et al., the population addressed in the study contained individuals aged 24-47 years with a diagnosis of lumbosacral pain due to overload. Each individual had to be ruled out by a specialist for not having a more specific cause of back pain. The intervention addressed in this study was craniosacral therapy versus trigger point therapy in the reduction of pain intensity in individuals with back pain. The patients were randomly assigned to the two groups and participated in three sessions at 3-4 day intervals, each session lasting 30 minutes. Both the craniosacral therapy and trigger point therapy were performed by a physiotherapist who was certified in both craniosacral therapy and trigger point therapy. The individuals were asked to assess their pain severity at baseline before the treatment and immediately after. Their pain intensity was measured by using the visual analog scale. Using the results of the randomized control trial, the change in baseline (Table 4) shows that cranial sacral therapy was more effective than trigger point therapy in decreasing the pain intensity of the patients with low back pain. Overall the results between the two groups were very similar in their effectiveness in reducing pain intensity in individuals with low back pain.

Table 4: TPT vs CST Pain Intensity at Baseline and After Treatment

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>After Treatment</th>
<th>Change in baseline</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CST</td>
<td>5.4 ± 1.4</td>
<td>1.9 ± 1.2</td>
<td>3.5</td>
<td>0.047</td>
</tr>
<tr>
<td>TPT</td>
<td>4.6 ± 1.5</td>
<td>2.1 ± 1.3</td>
<td>2.5</td>
<td>0.573</td>
</tr>
</tbody>
</table>

In all three randomized control trials the interventions used were all noninvasive therapies. Due to this there were no significant adverse events reported in any of the three trials. The article by Haller et al. was the only article out of the three that included specific details pertaining to the adverse effects which included minor side effects such as increased neck pain,
emotional effects, headaches, dizziness, jaw pain, fatigue, tiredness, tingling sensations, and shivering.

Table 5: Adverse Effects of Therapy (CST and Sham)

<table>
<thead>
<tr>
<th></th>
<th>Increased neck pain</th>
<th>Emotional</th>
<th>HA</th>
<th>Dizziness</th>
<th>Jaw Pain</th>
<th>Tiredness</th>
<th>Tingling Sensations</th>
<th>Shivering</th>
</tr>
</thead>
<tbody>
<tr>
<td>CST</td>
<td>6 pts</td>
<td>3 pts</td>
<td>0</td>
<td>0</td>
<td>2 pts</td>
<td>2 pts</td>
<td>0</td>
<td>2 pts</td>
</tr>
<tr>
<td>Sham</td>
<td>3 pts</td>
<td>0</td>
<td>7 pts</td>
<td>2 pts</td>
<td>0</td>
<td>2 pts</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**DISCUSSION**

Craniosacral therapy is based on the theory that controlled movements at the cranial sutures of the skull negatively affect rhythmic impulses transported through the cerebral spinal fluid from the cranium to the sacrum. Craniosacral therapy is not only recommended for individuals with chronic pain but also in individuals with chronic stress, depression, TMJ and headaches. It is not recommended in individuals who have an intracranial hemorrhage, recent skull fracture, or a systemic infection. Individuals can receive craniosacral therapy from massage therapists, osteopathic doctors, chiropractors, dentists and physical therapists. The therapy may or may not be covered by healthcare insurance.

In the article by Haller et al., the randomized controlled trial included a significantly larger proportion of females than males in the study. The age range was nineteen to sixty-five and all of the patients were Caucasian. Most were employed and had a normal body mass index. The female to male ratio placed a limit on the study results due to generalizability. The trial evaluated by Castro-Sánchez et al. also had significantly higher female to male ratio. All three randomized control trials had a small sample size which affects the reliability of the results. These trials also did not contain a control group of individuals who were receiving no form of intervention. This is predominantly important because it could not be determined whether the
interventional therapies the patients received exclusively attributed to the results or if the course of time affected the results as well.

CONCLUSION

Craniosacral therapy is effective in the reduction of pain intensity in individuals with non-specific neck and/or back pain. Craniosacral therapy was founded by an osteopath, John Upledger, and is generally practiced by osteopaths, chiropractors and massage therapists. The provider needs to be licensed in either massage therapy, physical therapy or chiropractic for the therapy to be covered under insurance. Craniosacral therapy requires minimal resources and is able to be performed in an outpatient office setting which makes it marketable to patients as well as healthcare providers. Due to the noninvasiveness of the therapy there are very few adverse side effects, making this treatment in reduction of back pain highly appealing to individuals who suffer from chronic pain.

With all of the different treatment options of back pain being analyzed in evidence-based medicine review, patients still seem to experience similar outcomes despite variation in provider, treatment and cost of treatments. In future trials combination therapy involving craniosacral therapy with other commonly utilized interventions, such as physical therapy or cognitive behavior therapy, would be beneficial.
References


