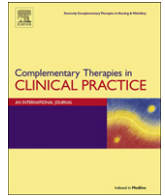


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Complementary Therapies in Clinical Practice

journal homepage: www.elsevier.com/locate/ctcp

Is craniosacral therapy effective for migraine? Tested with HIT-6 Questionnaire

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A B S T R A C T

Keywords:

Migraine
Craniosacral therapy
Short-Form Headache
Impact Test (HIT-6)
Randomized controlled study

Objective: To determine whether or not craniosacral therapy alleviates migraine symptoms.**Methods:** A cross-over experimental design was used with twenty participants, aged between 20 and 50 years, who suffered from at least two migraine attacks per month. Participants were randomly assigned to two equal-sized groups, A and B. All received six craniosacral treatments over four weeks and the groups answered the "HIT-6" Questionnaire four times; every four weeks (Times 1, 2, 3 and 4). Group A, received treatment after answering the questionnaire the first time, but Group B, answered the questionnaire twice before receiving treatment.**Results:** Immediately after treatments and one month afterwards there was significant lowering in HIT-6 scorings compared with prior to treatment. There was also significant difference in HIT-6 scorings between Times 1 and 4 ($p = 0.004$). The effect size was 0.43–0.55.**Conclusion:** The results indicate that craniosacral treatment can alleviate migraine symptoms. Further research is suggested.

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1. Introduction

Migraine has been defined as debilitating headache disorder that severely affects the day-to-day lives of people.¹ Migraines are common, and the prevalence has been found to be about 12% in the United States and 15% in Europe.^{1,2} Those suffering from migraines are likely to be absent from work and an epidemiological study by Lipton et al.¹ demonstrated that migraine severely affects peoples' lives. Of all Lipton's subjects ($n = 18,968$) who said they suffered from migraines, 54% were bedridden during migraine attacks. Sixty three percent of migraine sufferers (or 11,481 patients) experienced one to four attacks per month.

Some researchers now believe that migraine occurs because of a disturbance in the brain, where both nerve impulses and chemicals play a part.³ The International Headache Society (IHS) has published a diagnosis standard for migraine, defined as a pulsating or stinging pain in one or both sides of the head, lasting 4–74 h. The intensity of the pain is average or extreme, accompanied by nausea, vomiting, sensitivity to light and sound, and the symptoms are

aggravated by movement.³ The treatment of migraines can be difficult, despite the availability of over 100 types of medication for both acute and preventative treatments.⁴ The epidemiological study by Lipton et al.¹ found some persons' frequency of attacks and related impairments were so severe that they would benefit from migraine prevention. Therapies other than medication include to prevent migraine have been recommended, such as biofeedback, relaxation therapy, acupuncture and exercise.⁴

The effectiveness of a variety of alternative migraine treatments has been evaluated. Most of these studies have been performed on acupuncture,^{5–9} but relatively few studies exist on other alternative therapies. Four studies evaluated acupuncture,^{5–9} but only one study evaluated each of the following: biofeedback,¹⁰ massage,¹¹ and yoga.¹² The results were significantly positive. However, since so few studies have been conducted, validity of the results may be limited. The authors are not aware of any study evaluating the effects of craniosacral therapy (CST) on migraine.

A survey was conducted in one headache clinic in the UK to determine how often people suffering from headaches use complementary and alternative medicine (CAM).¹³ Out of 84 patients, 32% had used CAM, and no user perceived this as having made their headache worse.¹³ The Headache Impact Test (HIT-6) was used to measure the impact of headaches on daily life, yielding a median score of 63. According to the authors of the HIT-6 Questionnaire,^{14,15} this score on the HIT-6 Questionnaire indicates the headache seriously

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affects the lives of the responders. The HIT-6 score was the only variable found to be a significant predictor of CAM use.¹³

Upledger¹⁶ pointed out that craniosacral therapy is suitable for migraine treatment. However, a systematic review of craniosacral therapy did not demonstrate sufficient evidence to support the effects of craniosacral therapy.¹⁷ Many health practitioners have studied craniosacral therapy and use it as a supplementary therapy for their clients, without firm evidence.^{18,19} The first author of this paper, a physical therapist has completed several post graduate courses in craniosacral therapy, was eager to investigate craniosacral therapy to see if it had therapeutic impact against migraines. It was decided to study the effects of craniosacral therapy on migraines with the prime question being: Does CST alleviate migraine headaches?

2. Methodology

The study was a randomized controlled study with cross-over experimental design. According to power analysis²⁰ with power of 0.8, significance level 0.05 and four responses to the Short-Form Headache Impact Test (HIT-6),^{14,15} 20 participants were required to find the effect of the treatment.

2.1. Participants

A neurologist used guidelines from The International Headache society (IHS)²¹ to select patients from his clinic and invited them to participate in the study. If they accepted, the first author contacted them and introduced the study to each of them. The criteria for the sample were that participants be diagnosed with migraine, and had a history of two or more attacks in a month during the month preceding the study. The age limits were set between 18 and 50 years. The participants were allowed to continue to take any medicine they were using and to follow the same lifestyle as before the study, concerning sleeping habits, exercise, diet and work. They were not allowed to use any alternative form of treatment during the study time.

2.2. Measuring instrument

The Short-Form Headache Impact Test (HIT-6)^{14,15} was used in this study. The HIT-6 Questionnaire was developed to assess the effects of headaches or migraine on the health and well-being of the individual.²² The HIT-6 Questionnaire covers several areas connected with quality of life, namely: pain, social participation, general activity, vitality, intellectual activity and biological suffering. The questions are answered with: “never”; “seldom”; “sometimes”; “very often” or “always”. These responses were given numerical scores of: 6, 8, 10, 11 and 13, respectively. The total score for the questionnaire in each case, could therefore range from 36 to 78. The total score indicates how much influence a headache or a migraine has on an individual's life. A score of 49 or less indicates little or no influence; a score of 50–55 indicates some influence; a score of 56–59 indicates considerable influence; and a score of 60 or more indicates migraines very seriously affect the life of the individual.²²

The HIT-6 Questionnaire is used internationally. Martin et al.¹⁵ assessed the psychometric properties of the HIT-6 Questionnaire and in all 14 translations that were assessed, the reliability coefficient was higher than 0.70. One study showed the HIT-6 Questionnaire more often resulted in a significant correlation with serious migraine rather than with less serious attacks, in comparison to older questionnaires.²² In the current study, the average Cronbach's alpha coefficient for the HIT-6 Questionnaire was 0.86. The age and sex of the participants were also recorded.

2.3. Procedure

Four therapists, three of whom are physiotherapists, and one nurse, who had completed Advanced II in Upledger craniosacral therapy,²³ were the therapists in the research. One of the therapists who did not know the participants ($n = 20$), drew their numbers into equal groups, A and B. The therapists then drew individuals from groups A and B, at random. Each participant arranged six treatment times with the same therapist during a four-week interval between responses to the questionnaire, within the study design (see Table 1, which shows the cross-over experimental design). The study period was 12 weeks for participants and each participant answered the HIT-6 Questionnaire four times at monthly (4 week) intervals between responses. Group A answered the questionnaire at Time 1 before treatment sessions and three times after the treatments (Times 2, 3 and 4). Group B, answered the questionnaire at Time 1 and 2 before the treatment, and then responded at time 3 right after the treatment and four weeks later at Time 4. Neither group received treatment during the last four weeks before the last response (see Table 1). The study period lasted from September 2009 to February 2010.

2.4. Intervention

The craniosacral system (CST) extends from the head down to the sacrum and coccyx. It consists of a compartment formed by the dura mater membrane, the cerebrospinal fluid, the skull bones that attach to the membranes and the joints and sutures that interconnect these bones. Because the brain, spinal cord and all related structures are the contents of the craniosacral system, restrictions or imbalances in it may directly affect any or all aspects of central nervous system performance.¹⁶ Upledger Craniosacral therapy was used as the intervention.¹⁶

During treatment, participants laid on their backs, completely clothed. Therapists recorded the positions of their hands during treatments. The following parts of the body were treated: the pelvic area, diaphragm, inlet of the upper thoracic cavity, muscles around the hyoid and the upper muscles in the back of the neck. In these areas, one hand is placed palm up and flat under the participant's body and the other hand, palm down, on the upper surface of the participant's body, with the hands in approximate vertical alignment, except when the upper muscles in the back of the neck are palpated, at which time all fingers, except the thumbs, are placed on the attachment of the muscles to the bones in the nape of the neck. The therapist then notices and takes account of the release that takes place. Tension over the pelvis is also relieved, as is that in

Table 1
Cross-experimental design.

Group	Time 1	4 Weeks	Time 2	4 Weeks	Time 3	4 Weeks	Time 4
A	Answer 1	Treatment	Answer 2	Waiting	Answer 3	Waiting	Answer 3
B	Answer 1	No treatment	Answer 2	Treatment	Answer 3	Waiting	Answer 4

The table shows the research cross-experimental design. Times 1, 2, 3 or 4 are the answers to the HIT-6 Questionnaire. The treatment consisted of six craniosacral therapies.

the sutured bones of the skull and the facial bones. As before, the release experienced in the relevant area is followed by the therapist. The spinal sheath and the brain meninges are treated by light-touch handling, aimed at releasing the tension in them, and thus increasing their flexibility.²⁴

2.5. Ethical considerations

The Icelandic National Bioethics Committee (VSNb2009060010/03.7) and Data Protection Authority approved the study. Participants received an introduction letter from the first author and voluntarily, and without pressure, signed an informed consent form.

2.6. Statistics

The SPSS 12.0 for Windows was used for analysis of data with mean, median and standard deviation. Groups were compared using the Mann–Whitney *t*-test and the difference between responses over time was analysed with Wilcoxon's *t*-test. Unanswered questions in the HIT-6 Questionnaire were given an average score based on the scores for other answers by that participant. This is in accordance with the intention-to-treat analysis.²⁵ The significance level was set at $p < 0.05$.

3. Results

All ten participants in Group A completed the study; one participant in Group B ($n = 10$) did not return the last reply to the HIT-6 Questionnaire and one mailing of the HIT-6 Questionnaire from one individual in Group A was lost in post. The participants, comprised of eighteen women and two men, were equally randomized between the groups. The age range was between 20 and 50 years, and the mean age was 37.6, $SD \pm 9.3$ years, with the median age being 38.5 years. The mean age for Group A was 37.4 years and for Group B, 37.9 years, with no significant difference between the groups.

Table 2 presents the mean, median and standard deviation (SD) of the total score for the HIT-6 Questionnaire for each group for each time. It shows the two groups had similar total scores for the HIT-6 Questionnaires at baseline, with no significant difference based on the Mann–Whitney *t*-test. The Table also shows that the total score for Group B during the waiting period before treatment intervention, from Time 1 to Time 2, showed no significant change in HIT-6 scores ($p = 0.86$). A change in the total score of Group A, between Times 1 and 2, when treatment had been completed, showed a trend of significance ($p = 0.05$). The total score of Group B did not change significantly between Times 2 and 3 ($p = 0.14$) after completion of treatment. The total score for the HIT-6 Questionnaire for Group A decreased significantly between Times 1 and 4 ($p = 0.03$), as did the total score for Group B between Times 1 and 4 ($p = 0.04$). Moreover, the standard deviation increased for the third and fourth

Table 2
Mean, median and standard deviation (SD \pm) of the HIT-6 Questionnaire.

Answer	Time 1	Time 2	Time 3	Time 4
Group A				
Mean \pm SD	62 \pm 5.6	59 \pm 6.1	57 \pm 10.1	54 \pm 10.5
Median	62	59	58	58
Group B				
Mean \pm SD	61 \pm 5.7	60 \pm 5.5	55 \pm 8.2	56 \pm 8.4
Median	62	63	54	54

responses (Table 2), indicating that the distribution of the participants' responses had increased.

The mean scoring of HIT-6 Questionnaire for all participants before treatment (I), after treatment (II) and one month after treatment (III) was examined, see Fig. 1. Wilcoxon's *t*-test showed a significant difference in the total HIT-6 scores, before treatment (I) and right after treatment (II) ($t = -2.37$, $p = 0.018$). The effect size (ES) was 0.48. There was also a significant difference in the total HIT-6 scores before treatment (I) and one month after treatment (III) ($t = -2.09$, $p = 0.037$), with effect size 0.43. Wilcoxon's *t*-test was carried out on the mean HIT-6 scores at the beginning of the research (Time 1 = 61) and at the end of the research (Time 4 = 55). The difference between the two measurements was statistically significant ($t = 2.91$, $p = 0.004$). The effect size was 0.55.

4. Discussion

The purpose of this study was to investigate the effects of craniosacral therapy on migraine headaches. In research on CAM, it is a challenge to find a valid comparison group.²⁶ We used a cross-over experimental design in this study, where the two groups functioned as their own comparison group. After six craniosacral therapy treatments, scorings of the HIT-6 Questionnaire had decreased significantly for both groups, at points immediately after craniosacral therapy and one month after the treatment ended. According to the HIT-6 Questionnaire, the effect of migraines on the lives of the individuals in the research had been reduced during the overall study period from being "serious" down to "considerable".^{14,15} It is notable that only a few craniosacral treatments appeared to significantly benefit migraine sufferer, as recorded by the HIT-6 questionnaire response, suggesting this approach could be helpful to this patient group. However, Upledger¹⁶ points out that craniosacral therapy may not be effective for a particular individual if there is no change in the condition after five or six treatments.

Minimal attrition levels were recorded during this study (1:80), as one participant in Group B did not return the last HIT-6 Questionnaire. According to the intention-to-treat analyses,²⁵ this participant's average HIT-6 scorings were used for Time 4. This may have affected results, as can be seen in increased mean scoring of the HIT-6 Questionnaire at Time 4 for Group B. Standard deviation increased for the third and fourth responses, indicating the migraine improved more for some participants than others. The reason is

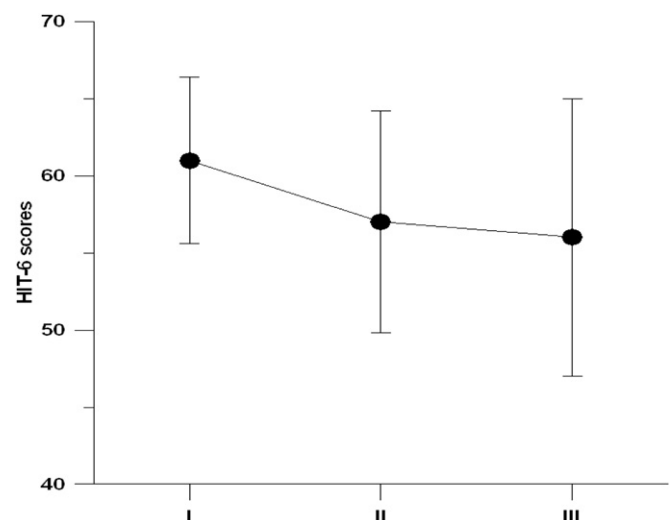


Fig. 1. Mean and standard deviation of the total score for the HIT-6 Questionnaire, before treatment (I), after treatment (II) and one month after treatment (III).

unclear, but weak clinical reliability between therapists to assess the craniosacral rhythm has been reported.^{27,28} Four therapists gave the treatment which may have affected the results and this factor should, therefore, be considered as a limitation of the study.

This study provides new information on the effects of craniosacral therapy for the management of migraine. This is important as migraine is a common disorder^{1,2} severely affecting individuals' lives.¹ Because, no similar study was retrieved upon literature search, it is not possible to compare our results directly to other research. Green et al.¹⁷ found seven studies investigating the effectiveness of craniosacral therapy. Most were low-quality retrospective studies, preventing comparison, but one showed adverse effects in people with brain injury.

The design of this study included individuals who had, or were receiving, treatment from a neurologist. This may incorporate a bias towards people with more severe migraines and affect the results. As Martin et al.¹⁵ demonstrated, the HIT-6 Questionnaire showed more correlation with more severe migraine than less severe.

The study's limitations are the low number of participants and the potential differences in skills and technique between therapists and lack of control groups. More comparative research with valid control groups as a placebo group is needed. But it is difficult to find a valid control group²⁶ and evidence suggests that placebo effects may release endorphins in the brain, which may affect the biochemistry of migraines.²⁹

The HIT-6 Questionnaire measures the subjective disability and impact of migraine on the participants' lives. The benefits from the CST are also assessed by the participants according to the HIT-6 Questionnaire. That may be a limitation, as well as the lack of knowledge on exactly how craniosacral therapy affects migraine. Upledger¹⁶ believes that sutural immobility of the cranial bones is a contributing factor in migraine. Some therapists in this research found sutural immobility of the cranial bones among their patients, and these patients experienced migraine pain when the technique for the sutures was performed. However debate continues regarding suture movement.¹⁹

There is a need for further research on the effect of CST on migraine to demonstrate whether or not CST affects migraine. It would be interesting to repeat this study using additional measurement tools, a larger study cohort and a comparison group. As this study was based on only 20 participants and had no direct comparison group. It is important that future research include a comparison group such as a placebo group and preferably even include comparison with other types of therapies used to treat migraine. A longer follow-up time to ascertain the immediate and long-term effects of the craniosacral therapy is also recommended.

5. Conclusion

More knowledge is needed to determine if, and how, craniosacral therapy affects migraine. However, our results indicate that craniosacral therapy could be considered as a potential therapy for migraine sufferers with the aim of improving quality of life.

Conflict of interest

None declared.

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