

Credibility of Low-Strength Static Magnet Therapy as an Attention Control Intervention for a Randomized Controlled Study of CranioSacral Therapy for Migraine Headaches

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Abstract

Background: Developing valid control groups that generate similar perceptions and expectations to experimental complementary and alternative (CAM) treatments can be challenging. The perceived credibility of treatment and outcome expectancy often contributes to positive clinical responses to CAM therapies, thereby confounding efficacy data. As part of a clinical feasibility study, credibility and expectancy data were obtained from subjects suffering from migraine who received either CranioSacral therapy (CST) or an attention-control, sham, and low-strength magnet (LSSM) intervention.

Objective: The objective of this study was to evaluate whether the LSSM intervention generated similar levels of subject credibility and expectancy compared to CST.

Design: This was a two-arm randomized controlled trial.

Subjects: Sixty-five (65) adults with moderate to severe migraine were the subjects of this study.

Interventions: After an 8-week baseline, subjects were randomized to eight weekly treatments of either CST ($n=36$) or LSSM ($n=29$). The latter involved the use of a magnet-treatment protocol using inactive and low-strength static magnets designed to mimic the CST protocol in terms of setting, visit timing, body positioning, and therapist–subject interaction.

Outcome measures: A four-item, self-administered credibility/expectancy questionnaire, based on a validated instrument, was completed after the first visit.

Results: Using a 0–9 rating scale, the mean score for perceived logicity of treatment was significantly less for LSSM (5.03, standard deviation [SD] 2.34) compared to CST (6.64, SD 2.19). Subject confidence that migraine would improve was greater for CST (5.94, SD 2.01) than for LSSM (4.9, SD 2.21), a difference that was not statistically significant. Significantly more subjects receiving CST (6.08, SD 2.27) would confidently recommend treatment to a friend than those receiving LSSM (4.69, SD 2.49).

Conclusions: Although LSSM did not achieve a comparable level of credibility and expectancy to the CST, several design and implementation factors may have contributed to the disparity. Based on analysis of these factors, the design and implementation of a future study may be improved.

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Introduction

A MAJOR CHALLENGE IN RESEARCH on complementary and alternative medicine (CAM) is the development of a valid control group with which to compare the intervention of interest.¹ In a well-designed study, the ideal control intervention should closely resemble or mimic the intervention in terms of procedure, treatment duration and frequency, and therapist attention.² In this way, researchers can assess and control for placebo effects induced by a range of heterogeneous contextual, personal, and relational factors experienced by the patient during treatment.³

Patient perceptions about treatment credibility and expectancy of treatment outcome can play a large role in persistent clinical improvement.³⁻⁷ For example, in a meta-analysis of four randomized trials of acupuncture for chronic pain, Linde et al. reported that more subjects with high expectations for improvement actually improved, compared with those who had low expectations.⁸ In another systematic review, positive subject expectations were consistently associated with better outcomes in 15 of 16 moderate to high-quality clinical trials.⁴

Treatment credibility in a research context can be defined as the extent to which subjects perceive experimental and control modalities to be rational and believable approaches to their clinical problem.⁹ *Expectancy* is the belief that clinical improvement will occur as a result of the intervention. Both factors must be accounted for in studies of treatment efficacy, usually by using a control intervention that is equally potent in establishing treatment credibility and expectancy of improvement without affecting the biologic mechanism engendered by the intervention under study.^{9,10}

This study reports the credibility and expectation of benefit of a novel attention-control procedure in a feasibility study of CranioSacral therapy (CST) as adjunctive treatment for migraine. The control procedure, involving a sham magnet treatment protocol using inactive and low-strength static magnets (LSSM), was designed to generate similar levels of credibility and expectation of benefit among the subjects in the control group compared to the active intervention group.

Materials and Methods

Intervention development

A feasibility study was undertaken for developing a randomized, controlled trial to compare the effectiveness of CST as adjunctive treatment for migraine compared to an attention-control intervention using LSSM. The study protocol has been described elsewhere.¹¹ CST was developed by Dr. John Upledger, DO using the concept that abnormal cerebrospinal fluid rhythms may follow birth injury or later traumas and lead to a variety of neurophysiologic disturbances and symptoms.¹¹ CST, which purportedly releases tissue restrictions and eliminates stasis within the hydraulic system of the brain and spinal cord, is increasingly sought by the public for the relief of multiple conditions, including (1) headache, (2) asthma, (3) arthritis, (4) insomnia, (5) cerebral palsy, (6) autism, (7) memory disturbances, (8) whiplash injuries, and (9) fibromyalgia.¹¹

The proposed randomized trial for which this feasibility study was undertaken would compare CST with a control

intervention, as measured by headache frequency and intensity, and quality of life, (using the Headache Impact Test), perception of benefit, migraine-related disability, general health status (SF 36), and health care utilization.¹²⁻¹⁵ This feasibility study was needed to develop, standardize, and clarify treatment and control protocols, recruitment strategies, and measurement and data-collection methods. The development and credibility of treatment and control protocols in the management of moderate to severe migraine headaches are reported here.

Development of treatment protocols. CST and LSSM protocols required development, standardization, and evaluation for their practical and efficient application in the eventual efficacy trial. A CST protocol was based on the clinical evaluation and treatment system developed by the Upledger Institute, comprising the intervention elements shown in Table 1 and described previously.^{11,15} An LSSM protocol was designed as an attention-control condition matching such features of the CST protocol as frequency and duration of visits, therapist-subject interaction, and treatment setting. Table 1 compares the two treatment protocols. The complete CST and LSSM protocols are described in the Appendix.

CST intervention. The CST assessment and intervention was performed by 1 practicing therapist, who is also a

TABLE 1. COMPARISON OF TREATMENT PROTOCOLS: CRANIOSACRAL THERAPY AND MAGNET THERAPY FOR MIGRAINE

All subjects:

- Initial brief review of recent headache and general symptoms
- Assessment of any adverse effects of prior treatment
- Blood pressure and pulse recorded before and after visit
- Headache severity recorded before and after visit
- Visual scan
- Subject remains supine for treatment
- Total clinic visit time = 45 minutes

<i>CranioSacral therapy</i>	<i>Magnet therapy</i>
Evaluation of the CranioSacral rhythm, ^a including amplitude, quality, and rate	Fixed magnets (12) applied around the table Magnet strength assessed at each position
CranioSacral assessment and treatment	Magnet pad application
Pelvis	Pelvis
Lower respiratory	Lower diaphragm
Thoracic inlet	Upper thorax (front and back)
Shoulders	Upper thorax toward shoulders
Neck	Neck
Occiput	Occiput (front and back)
Frontal/parietal bone lifts	Head and feet
Sphenoid and mandible mouth work	

^aThe CranioSacral rhythm is palpated by the practitioner (at the feet) and assessed for rate, quality, and symmetry.

A normal rate is 8-12 cycles per minutes. A normal rhythm shows a balanced vitality.

registered nurse and licensed massage therapist, with extensive training and experience in CST. Only 1 therapist was utilized at this phase of the research because it was believed that a single individual, with training and close supervision in this research setting, was more likely to achieve a standardized approach to each subject than could be achieved by a variety of therapists, especially in a modality where weak clinical reliability between practitioners has been reported.^{16,17}

Control intervention. One important question was whether CST (a manual technique) could be effectively mimicked as a sham procedure, or whether a different but appropriate complementary modality could be used as an effective control procedure. Two options were considered.

Option 1: Sham CST. Sham maneuvers have been widely used as controls in osteopathic medicine and chiropractic research.^{9,18,19} An ideal control method for CST, which consists of assessment and treatment using gentle muscle palpation and mobilization techniques, would be to exactly replicate the CST protocol without producing any treatment effect. Sham CST would have to be given either by an expert CST practitioner or by a specially trained massage therapist. Furthermore, the CST sham procedure would have to last a comparable amount of time (i.e., 45 minutes) as the CST treatment and be standardized and replicable at each visit. Ultimately, it was concluded that it was unlikely a sham manual procedure could be created that would closely mimic CST without producing an unintended biologic effect.

Option 2: LSSM. Inert and active magnets were provided courtesy of American Health Services Magnets, Palatine, IL. Instead of a sham CST arm, it was decided to develop a control protocol that could generate similar elements of placebo effects. These elements included (1) a similar procedural treatment sequence using gentle physical contact directed at the same anatomical areas; and (2) replication of the CST visit context using the same therapist in the same location (i.e., the therapist's treatment room in an integrative outpatient clinic) as that used for subjects receiving the true CST intervention. It was posited that magnet therapy, widely used by the public for pain syndromes, could generate equivalent therapeutic credibility and outcome expectations if delivered in the same context and by the same therapist as in the CST arm. Static magnet therapy is a popular and near-zero risk modality that, at low to moderate intensities (300–800+ G), has been shown to affect nerve cells and increase local tissue blood flow and oxygenation when magnets are in direct contact with the skin.^{20–22}

The CST therapist was trained in the LSSM protocol for this study. To ensure that the LSSM control protocol had no human biologic effects, the protocol called for the therapist to place six identical inert ceramic magnets (1.6 cm in diameter and 0.4-cm thick) and six weakly active bipolar magnets (300–500 G) at intervals around the perimeter of the examination table on which the control subject was resting. Both the active and inert magnets were placed at distances of 3 to 5 inches from the subject's body, with the active magnets positioned further than the inert magnets. (The inverse square law, as applied to electromagnetism, states that doubling the distance between subject and magnet reduces

field intensity by 75%.) At each session, the therapist used a magnetometer to confirm that for the active magnets the field intensity at the subject's skin was close to zero (no more than 30–80 G) (DC Magnetometer Model 1, with a resolution of 0.1 G, manufactured by AlphaLab, Inc., Salt Lake City, UT). The magnetometer was also used by the therapist to display a positive reading when placed *up against* an active magnet in order to enhance the believability of the magnet intervention for curious subjects.

In order to replicate more exactly the sequence and anatomical location of the CST protocol, three inert magnets (rectangular 2×5 cm by 0.4-cm thick) contained inside a cloth pad were applied by the therapist to several locations on the center of the body (over clothes, from the lower part of the abdomen to the head). This cloth pad was applied to the same locations at the same time intervals as in the CST procedure (Table 2). In contrast to the CST, no soft-tissue pressure or motion was exerted by the pad, and there was no direct touching of the subject by the therapist (other than assistance in getting on and off the table). The therapist remained attentive and in the room with the subject during the entire procedure, either sitting or moving about the room to apply the magnets and monitor their strength. In both the CST and LSSM protocols, conversation between subject and therapist was driven by subjects' preferences.

In the process of informed consent, the study volunteers were given a description of CST and magnet therapy and their potential usefulness for improving migraine headaches. At the beginning of the first treatment, the therapist described, per scripted protocol, how CST and magnets might produce a biologic effect, referring to available articles and pamphlets describing the benefits of CST and magnet

TABLE 2. CHARACTERISTICS OF THE STUDY SAMPLE: CRANIOSACRAL THERAPY FOR MIGRAINE, 2006–2008

Characteristic	CranioSacral therapy group (N=36) ^a	Magnet therapy group (N=33)
	Mean (range)	Mean (range)
Age (years)	42.9 (12–71)	41.2 (19–72)
Education (years of school)	16.7 (7–28)	16.9 (12–20)
Average number of monthly headache days, pretreatment ^b	13.4 (5–28)	13.6 (6–27)
	N (%)	N (%)
Female	33 (91.7)	32 (97.0)
White	28 (77.8)	29 (87.9)
Living with partner	24 (66.7)	23 (69.7)
Employed	24 (66.7)	29 (87.9)
Household income		
< \$20,000	6 (16.7)	1 (3.03)
\$20,000–59,999	12 (33.3)	8 (24.2)
\$60,000–99,999	4 (11.1)	8 (24.2)
> \$100,000	13 (36.1)	10 (30.3)
Missing	1	6

^aReported N reflects the 69 randomized subjects.

^bThe mean number of headache days was calculated from the mean number of headaches in the 2 months prior to the intervention and the mean number of days reported in the diaries.

therapy, available in her treatment room (see the Appendix for therapist's script for CST and LSSM conditions).

Reliability of the therapist

The therapist was a key participant in the initial development of both CST and magnet protocols (subject communication, technique, and sequencing) and was subsequently trained in the procedures over several weeks. Particular emphasis was given to standardizing communication, movement, and contact with the subject to eliminate bias; the first, third, fifth, and seventh treatment sessions with each subject were videotaped and evaluated by research staff for communication or physical bias toward one or other of the protocols.

Assessment of treatment credibility and expectancy

The credibility of the protocols and the expectancy of improvement for each subject were assessed by their completion of a commonly used and adapted self-report instrument that had been originally developed by Borkovec and Nau.^{23,24} Borkovec and Nau used a 0- to 9-point scale for five questions to which the subject could mark his/her degree of confidence in treatment rationale and expected outcome, regarding psychologic interventions for a specific psychologic problem: anxiety in public speaking. Others have successfully modified this scale, adapting it for use with other illnesses and interventions.^{25,26} The first three of the original five items in Borkovec and Nau's instrument were adapted: (1) How logical does this type of treatment seem to you? (2) How confident would you be that this treatment would be successful? and (3) How confident would you be in recommending this treatment to a friend? An attempt was made to adapt the final two questions of Borkovec and Nau's original questionnaire, which deal with hypothetical situations involving anxiety²³ (i.e., "If you were extremely anxious in speech situations, would you be willing to undergo such treatment?" and "How successful do you feel this treatment would be in decreasing a different fear, for example, strong anxiety about taking tests?"). Instead, a question was added regarding the subject's confidence in the therapist's competence—a factor closely linked to treatment credibility. The resulting four-item questionnaire was completed by each subject at the beginning of the second treatment visit and was placed in an envelope for retrieval by the research staff. The four questions were worded as follows:

1. How logical does this type of therapy seem to you for helping people treat or prevent their headache? (*Not logical [0]—very logical [9]*)
2. How confident are you that this treatment will be successful in reducing your headache symptoms if you were to have approximately eight such treatments over the course of 2 months? (*Not at all confident [0]—very confident [9]*)
3. How confident would you be in recommending this treatment to a friend who has a problem with headaches? (*Not at all confident [0]—very confident [9]*)
4. How competent do you consider the therapist who gave you treatment to be? (*Not at all competent [0]—very competent [9]*)

Results

Sixty-five (65) of 69 randomized subjects completed the credibility/expectancy instrument. Subjects were predominantly white, female, and college educated. The mean age in the CST group was 42.9 and that in the LSSM group was 41; ages ranged from 12 to 71 years in the CST group (Table 2).

Using a 0–9 rating scale, the mean score for perceived logicity of treatment (question 1) was significantly less for LSSM (5.03, SD 2.34) compared to the CST group (6.64, SD 2.19), $p=0.005$. Although subjects' confidence that migraine would improve (question 2) was greater for CST (5.94, SD 2.01) than for LSSM (4.9, SD 2.21), this difference was not statistically significant ($p=0.06$). In response to question 3, significantly more subjects receiving CST (6.08, SD 2.27) would confidently recommend treatment to a friend than those receiving LSSM (4.69, SD 2.49), $p=0.03$ (Table 3). On the other hand, subjects from both groups were equally and strongly positive about the competence of the therapist (question 4), with no between-group differences (8.41, SD 0.95 versus 8.31, SD 1.09), $p=0.815$ on the Wilcoxon sum rank test. The withdrawal/dropout rate was very similar between the groups (11.1% for CST and 15.2% for LSSM [$p=0.62$]).

Upon examining individual responses, it was noted that scores for some subjects—1 in the CST group and 4 in the magnet group—differed dramatically from the norm. These individuals had responded with a 0 or 1 for every item, except confidence in the therapist, indicating a complete lack of confidence in the proposed treatment. When the data from these five outliers were removed, the only significant difference remaining between LSSM and CST on any of the items was in logicalness of therapy (Table 4).

Discussion

Study participants in the CST and LSSM groups responded significantly differently in terms of treatment credibility and expectancy of benefit. Removal from the analysis of outlier data from those subjects in either group who perceived that their treatment had no credibility and expressed no confidence in it (1 in the CST group and 4 in the LSSM group) revealed that the only remaining significant difference between LSSM and CST was in the logicity of the procedure.

TABLE 3. COMPARISON OF MEAN CREDIBILITY SCORES BY TREATMENT TYPE: CRANIOSACRAL THERAPY FOR MIGRAINE

Survey items	Magnet therapy	CranioSacral therapy	p-Value ^a
	(N=29)	(N=36)	
	Mean (SD)	Mean (SD)	
1. Therapy is logical	5.03 (2.34)	6.64 (2.19)	0.005
2. Confident in success	4.90 (2.21)	5.94 (2.01)	0.062
3. Willing to recommend to a friend	4.69 (2.49)	6.08 (2.27)	0.029
4. Therapist is competent	8.41 (0.95)	8.31 (1.09)	0.815

^aBased on Wilcoxon two-sample, two-sided test. SD, standard deviation.

TABLE 4. COMPARISON OF MEAN CREDIBILITY SCORES BY TREATMENT TYPE: CRANIOSACRAL AND MAGNET THERAPY FOR MIGRAINE WITH REMOVAL OF OUTLIERS (>1 SD)

Survey items	Magnet therapy (N=25) Mean (SD)	CranioSacral therapy (N=35) Mean (SD)	p-Value ^a
1. Therapy is logical	5.54 (1.88)	7.03 (1.51)	0.004
2. Confident in success	5.56 (1.53)	6.11 (1.76)	0.200
3. Willing to recommend to a friend	5.36 (1.96)	6.25 (2.05)	0.095
4. Therapist is competent	8.44 (0.96)	8.40 (0.95)	0.815

^aBased on Wilcoxon two-sample, two-sided test. SD, standard deviation.

Since the credibility/expectancy scores diverged significantly between the CST and LSSM groups, and since beliefs about logicity and expectation of benefit have been known to influence outcomes, it was important to explore and identify possible factors in the management and implementation of this feasibility study that may have contributed to differences in credibility scores between the CST and LSSM treatments, as follows: (1) Was there any bias in recruiting subjects and explaining the protocols? (2) Was the design or execution of the LSSM protocol less than optimal? (3) Was the assessment of credibility flawed in terms of validity or timing?^{23,27} (4) How credible were either of the interventions?

These questions are addressed below.

1. *Possible bias in recruiting subjects and explaining the protocols.* At recruitment, and on the first treatment visit, subjects may have received inadequate information or may not have clearly understood the rationale of one or both interventions. The degree of understanding was assessed verbally by the therapist at the recruitment and first treatment visit but not measured quantitatively. Horvath reported that treatment expectancy was closely linked to the amount and quality of information presented to subjects as part of explaining therapeutic rationales.²⁸ A communication disparity between CST and LSSM groups might have adversely affected the credibility score of LSSM. In a future study, this possible disparity could be remedied by applying a survey instrument to test understanding and knowledge.

In retrospect, there were subtle biases toward promoting CST in the recruitment and consent materials, such as describing the therapist as highly experienced in CST but not giving an equivalent statement for her skills with LSSM; and placing CST description text first in the consent and informational materials, possibly emphasizing its relative importance. Also, all subjects were treated in the CST therapist's office, which was located in a holistic health treatment facility that offered CST. Flyers available in the waiting area regarding CST, while not related to the study, may have introduced bias in the participants, since information about LSSM was available only in the treatment room.²⁹

2. *LSSM protocol: Possible flaws and solutions.* Several factors may have limited the credibility of the LSSM

protocol and could be improved in a subsequent study: (1) The magnets were located in Velcro pockets, created by a local seamstress, and may not have had the same cachet as the use of commercially marketed magnet products. (2) The therapist, an expert in CST, had no prior experience with magnet therapy and may have been subconsciously biased against giving this form of treatment. Thus, hiring a separate therapist who used magnets regularly in a CAM practice might have added to the credibility of the intervention. (3) Also, blinding the therapist to the relative activity of the magnets might have increased her own belief in magnet capability, and her belief could have been passed on to subjects. (4) Moreover, the therapist reported that some subjects mentioned to her that they had been especially attracted to the study by the opportunity to receive CST and were disappointed when they found that they were assigned to the LSSM group.

3. *Possible flaws in use of credibility instrument.* The use or timing of the credibility instrument may not have been optimal. (1) The credibility instrument was modified, as was done in previous studies, but was not revalidated. It is unclear whether the modified instrument remains entirely valid. It has become common practice to administer the credibility instrument after the first exposure to the treatment. Would other timing be more useful? Or should the expectancy question have been asked immediately after randomization? (2) Should the credibility questionnaire have been re-administered at the end of the treatment period? (3) From the data and careful review of the study design and trajectory, several problems were identified that probably influenced the credibility and expectancy scores.

The time point during the study at which these beliefs are measured may be important. Martin et al. reported that although valid expectancies of treatment can often be derived from patient perceptions before therapy begins, these beliefs can sometimes change quickly after the first treatment experience.^{28,30} In the current study, the credibility data were obtained just before the second treatment, in keeping with current thinking about appropriate timing of expectancy measures; but timing can affect response validity. For example, although question 3 in the credibility instrument asks the subject to score his/her confidence in recommending the modality to a friend, in this study the question was asked after only one treatment session. Hence, subject response would have been more likely the result of guesswork than derived from a thorough experience with the intervention. Currently, there is no general agreement in the literature on when and how often credibility and expectancy measures should be undertaken.

Although data from the credibility surveys showed that LSSM therapy was less credible than CST with diminished expectancy of improved outcome, there are some concerns that the instrument may not be measuring what has been claimed for it.^{23,28} Although labeled a "credibility" instrument, the second and third questions in this assessment tool deal with treatment expectancy. Given the fact that, over time, Borkovec and Nau's instrument has been modified and adapted in terms of questions and type of scale with little further validation, it would be useful to re-assess the constructs

of the instrument with particular reference to complementary therapies.

It is interesting that the dropout rate during treatment was not significantly different between the groups. A high subject dropout rate would have been expected for a CAM therapy that lacked credibility and generated low expectations of success. Second, some validation of the LSSM control in terms of producing similar expectancy and placebo effects to CST comes from the high ratings of the procedural competence of the therapist by both study groups. Rating the therapist highly would not fit easily with the perception that they were receiving illogical treatment and had low expectations of improvement.

4. *Credibility of either intervention.* Apart from the high positive scores regarding the competence of the therapist, overall expectancy scores in this study were only in the moderate range of the scale. Goossens et al. reported similar findings of moderate expectancy scores in their study of behavioral interventions in chronic pain,²⁸ suggesting that patients suffering from a chronic problem might well have low expectations and credibility because of previous disappointments. It is possible that many migraine subjects in this study fell into this chronic symptom category. However, this result may have been influenced by the fact that the questionnaire was given to the subject by the therapist just before the second intervention session.

Second, the often lackluster medical experience of migraine sufferers might produce a degree of skepticism and reticence toward the claims of benefit for either CST or LSSM made during recruitment. Thus, it might be useful in the future to probe responses to such credibility surveys in more detail to explore why subjects do, or do not, believe in the potential efficacy of any therapies they are receiving.

Conclusions

While several design and implementation factors may have contributed to the observed differences, LSSM did not achieve comparable levels of credibility and expectancy to CST. Valuable information has been gained that will assist with interpretation of outcomes, for which analysis is under way, and that will improve the design and execution of a future clinical trial. First, the authors have developed and tested a popular CAM therapeutic modality, CST, with a population of patients with migraine headache and found that it is at least moderately credible as an intervention. Second, the authors have developed and tested the feasibility of using a novel attention-control intervention, LSSM, gaining important information about possible improvements in design and implementation of future studies. Finally, an improved attention-control strategy could offer a viable attention-control methodology for research on CAM interventions in which establishing a rigorously mimicked control group is required but problematic.

Future Directions

Future research will focus on incorporating changes in design of the LSSM intervention, based on the above findings. If credibility/expectancy equivalence is established, the

authors will proceed to test the effectiveness of CST in migraine using a larger study population. In addition, it is planned to revisit the construct and validity of measuring credibility as it applies to CAM interventions.

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Disclosure Statement

There were competing financial interests.

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APPENDIX: PROTOCOL FOR CRANIOSACRAL THERAPY

[Therapist script is in italics]

1. Explain the rationale for CranioSacral therapy, and then help the subject settle comfortably on the massage table.

Let me tell you how the CranioSacral treatment will be organized today. First of all, I want you to know that CranioSacral therapy has few adverse effects; you may feel a bit sleepy after your treatment and some people notice vivid dreams. As you may know, CranioSacral therapy is already widely used for treatment, although there hasn't been much research in conventional medicine. That's why we are doing this study. It is thought that CranioSacral therapy helps people with headaches by normalizing the rhythm of fluid in the nervous system.

Are you ready to go ahead now?

Visit	Tasks
1	Explain protocol; VIDEOTAPE; treat; document.
2	Give patient credibility questionnaire; treat; document.
3	VIDEOTAPE; treat; document.
4	Treat; document.
5	VIDEOTAPE; treat; document.
6	Treat; document.
7	VIDEOTAPE; treat; document.
8	Ask subject to continue diary; treat; document.

Headache history:

Duration of headaches: _____ years
 History of physical trauma: _____
 Location of headaches: _____
 Type of headache: _____

If you feel like talking during the therapy, you may do so; it does not interfere with the therapy. It is also fine if you do not talk or even if you fall sleep.

CranioSacral session 1 Date: _____ Subject ID: _____

Headache intensity prior to therapy:
 0 None 1 Mild 2 Moderate 3 Severe

➡ BP: _____ / _____ P: _____

Action	Results
Visual scan	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal:
CS rhythm, rate, and symmetry	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal:
Feet/ankles/knees	
Assessment	<input type="checkbox"/> Assessed <input type="checkbox"/> NA
RTM	<input type="checkbox"/> Not treated <input type="checkbox"/> Simple <input type="checkbox"/> Complex:
Sacrum	
Assessment	<input type="checkbox"/> Assessed <input type="checkbox"/> NA
RTM	<input type="checkbox"/> Abdomen <input type="checkbox"/> L ₅ -S ₁ decompression <input type="checkbox"/> Dural tube <input type="checkbox"/> Traction
Lower thoracic	
RTM	<input type="checkbox"/> Not treated <input type="checkbox"/> Simple <input type="checkbox"/> Complex:
Upper thoracic	
Assessment	<input type="checkbox"/> Assessed <input type="checkbox"/> NA
RTM	<input type="checkbox"/> Not treated <input type="checkbox"/> Simple <input type="checkbox"/> Complex:
Shoulders	
Assessment	<input type="checkbox"/> Assessed <input type="checkbox"/> NA
RTM	<input type="checkbox"/> Not treated <input type="checkbox"/> Simple <input type="checkbox"/> Complex:
Neck	
Assessment	<input type="checkbox"/> Assessed <input type="checkbox"/> NA
ROM	<input type="checkbox"/> Normal <input type="checkbox"/> Restricted:
RTM	<input type="checkbox"/> Not treated <input type="checkbox"/> Simple <input type="checkbox"/> Complex:

Hyoid

Treated NA

Occiput

Assessment Assessed NA
 ROM Normal Abnormal:
 Treatment None Simple Complex:

Parietal

Parietal lift Not treated Simple Complex:

Frontal

Frontal lift Not treated Simple Complex:

Sphenoid

Not treated
 Flexion
 Extension
 Torsion Left Right
 Side bend Left Right
 Lateral strain Left Right
 Vertical strain Superior Inferior
 Compression Treated

Temporal

Not treated
 Temporal wobble
 Ear circumduction
 Decompression

Mandible

Assessment Assessed NA
 Compression–decompression

Mouth work

1. Maxilla Assessed NA
 Flexion–extension with sphenoid
 Torsion Left Right
 Shear Left Right
 Impaction–compression
 2. Vomer Not treated Torsion: Shear:
 3. Nasal bone Not treated
 4. Palatines Not treated
 5. Teeth Not treated Quadrant:
 6. Zygoma Not treated

Rocking the falx Not treated Simple Complex:

Dural tube Rock Glide

CV4

Summary assessment

Restrictions Mild Moderate Severe

Percent improvement _____ %

Comments:

Headache intensity at end of therapy:

₀ None ₁ Mild ₂ Moderate ₃ Severe

➡ BP: _____ / _____ P: _____

PROTOCOL FOR MAGNET THERAPY

[Therapist script is in italics]

1. Explain the rationale for CranioSacral therapy, and then help the subject settle comfortably on the massage table.
2. Explain how the magnets are set up on the table, and that pads containing magnets will be applied for 5–10-minute periods to different parts of the body and the head.
3. Show subject the small pads containing the magnets and explain how they will be used. Let subject know that you will check the magnetic fields twice during the session.
4. Ask subject to lie down comfortably on the table. If they need to get up and stretch from time to time, they can do this.
5. Attach magnets according to the diagram, using Velcro to the sides of the sheet lying on the table while patient watches.
6. Apply the stretch wraps with magnetic pads over washable flannel covers to the patient's body in sequence as follows:
 - (a) Around both ankles (5 minutes)
 - (b) Around both knees or thighs (5 minutes)
 - (c) Under sacrum and over pelvis (5 minutes)
 - (d) Over anterior lower rib cage and over upper rib cage (5 minutes)
 - (e) Around both shoulders (5 minutes)
 - (f) Neck and occiput (5 minutes)
 - (g) Forehead and feet (5 minutes)

Let me tell you how the magnet treatment will be organized today. First of all, I want you to know that magnet therapy produces no adverse effects and the magnets are of low strength (300–800 G). As you may know, magnets are already widely used for treatment, although there hasn't been much research in conventional medicine. That's why we are doing this study.

Their health benefits come from the fact that magnets have been shown to affect local blood vessels and improve local blood flow and they increase oxygenation and cell metabolism. That's what we are hoping will help the migraine headache.

Would you like to look at a magnet? This is what they look like before we sew them into the material. (Show participant an active loose magnet and let him or her handle). *I will be placing magnets around you on the table to create a magnetic field. This Gaussmeter lets me check the field.*

In addition to the magnets I place around the table, I will be using these pads that contain several small magnets on different parts of your body, starting at your ankles, going up the body and ending with your head. I will change the positions about every 5 minutes.

If you feel like talking during the therapy, you may do so; it does not interfere with the therapy. It is also fine if you do not talk or even if you fall sleep.

Are you ready to go ahead now?

Reminders:

1. Treatment duration: 45 minutes
2. Background magnets should be attached to sheet with Velcro
3. Move magnet pads around body every 5 minutes
4. No adverse effects
5. *Do you have any questions about the magnets?*
6. Show magnets if asked. 3, 4, 7, 8, 11, 12 are active

<input type="radio"/> 8	Above head	7 <input type="radio"/>
<input type="radio"/> 9	Shoulder level	6 <input type="radio"/>
<input type="radio"/> 10	Hip level	5 <input type="radio"/>
<input type="radio"/> 11	Knee level	4 <input type="radio"/>
<input type="radio"/> 12	Ankle level	3 <input type="radio"/>
	<input type="radio"/> 1	<input type="radio"/> 2

Visit Tasks

- 1 Explain protocol; videotape, treat; document.
 - 2 Give patient credibility questionnaire; treat; document.
 - 3 Videotape; treat; document.
 - 4 Treat; document.
 - 5 Videotape; treat; document.
 - 6 Treat; document.
 - 7 Videotape; treat; document.
 - 8 Ask subject to continue diary; treat; document.
-

Headache history:

Duration of headaches: _____ years

History of physical trauma:

Location of headaches:

Type of headache:

Magnet session 1 Date: _____

Subject ID: _____

Headache intensity prior to therapy:

₀ None ₁ Mild ₂ Moderate ₃ Severe

➡ BP: _____/_____ P: _____

Action

Results

Visual scan

Normal Abnormal:

Magnets attached to sheet

1 2 3 4 5 6

7 8 9 10 11 12

CS rhythm: feet

Assessment

Rate Normal <8 >12

Magnet applications

Around both ankles 5 minutes Other:

Intensity of magnets at ankles None <300 300-500 >500

Around both knees or thighs 5 minutes Other:

Intensity of magnets at knees None <300 300-500 >500

Under sacrum and over pelvis 5 minutes Other:

Intensity of magnets at hips None <300 300-500 >500

Lower and upper rib cage 5 minutes Other:

Around both shoulders 5 minutes Other:

Intensity of magnets at shoulders None <300 300-500 >500

Neck and occiput 5 minutes Other:

Intensity of magnets above head None <300 300-500 >500

Forehead and feet 5 minutes Other:

Intensity of magnets at feet None <300 300-500 >500

Summary assessment

Comments:

Headache intensity at end of therapy:

₀ None ₁ Mild ₂ Moderate ₃ Severe

➡ BP: _____/_____ P: _____

BP, blood pressure; P, pulse; CS, CranioSacral; NA, not applicable; RTM, rhythm; ROM, range of motion.

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