

Craniosacral Therapy for the Treatment of Chronic Neck Pain

A Randomized Sham-controlled Trial

Heidemarie Haller, MSc,* Romy Lauche, PhD,† Holger Cramer, PhD,*
Thomas Rampp, MD,* Felix J. Saha, MD,* Thomas Ostermann, PhD,‡ and
Gustav Dobos, MD*

Objectives: With growing evidence for the effectiveness of craniosacral therapy (CST) for pain management, the efficacy of CST remains unclear. This study therefore aimed at investigating CST in comparison with sham treatment in chronic nonspecific neck pain patients.

Materials and Methods: A total of 54 blinded patients were randomized into either 8 weekly units of CST or light-touch sham treatment. Outcomes were assessed before and after treatment (week 8) and again 3 months later (week 20). The primary outcome was the pain intensity on a visual analog scale at week 8; secondary outcomes included pain on movement, pressure pain sensitivity, functional disability, health-related quality of life, well-being, anxiety, depression, stress perception, pain acceptance, body awareness, patients' global impression of improvement, and safety.

Results: In comparison with sham, CST patients reported significant and clinically relevant effects on pain intensity at week 8 (−21 mm group difference; 95% confidence interval, −32.6 to −9.4; $P = 0.001$; $d = 1.02$) and at week 20 (−16.8 mm group difference; 95% confidence interval, −27.5 to −6.1; $P = 0.003$; $d = 0.88$). Minimal clinically important differences in pain intensity at week 20 were reported by 78% within the CST group, whereas 48% even had substantial clinical benefit. Significant between-group differences at week 20 were also found for pain on movement, functional disability, physical quality of life, anxiety and patients' global improvement. Pressure pain sensitivity and body awareness were significantly improved only at week 8. No serious adverse events were reported.

Discussion: CST was both specifically effective and safe in reducing neck pain intensity and may improve functional disability and the quality of life up to 3 months after intervention.

Key Words: craniosacral therapy, manual therapies, neck pain, sham treatment, randomized controlled trial

(*Clin J Pain* 2016;32:441–449)

Received for publication January 26, 2015; revised September 16, 2015; accepted August 10, 2015.

From the *Department of Internal and Integrative Medicine, Kliniken Essen-Mitte, Faculty of Medicine, University of Duisburg-Essen, Essen; †Department of Psychology, Chair of Research Methodology and Statistics in Psychology, Witten/Herdecke University, Germany; and ‡Australian Research Centre in Complementary and Integrative Medicine (ARCCIM), Faculty of Health, University of Technology Sydney (UTS), Sydney, Australia.

The authors declare no conflict of interest.

Reprints: Heidemarie Haller, MSc, Department of Internal and Integrative Medicine, Kliniken Essen-Mitte, Faculty of Medicine, University of Duisburg-Essen, Am Deimelsberg 34a, Essen 45276, Germany (e-mail: h.haller@kliniken-essen-mitte.de).

Copyright © 2015 Wolters Kluwer Health, Inc. All rights reserved. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially.

DOI: 10.1097/AJP.0000000000000290

Neck pain is a significant public health problem with 1 in 2 people experiencing neck pain at least once in their lifetime.¹ Neck pain is often recurrent, of nonspecific nature, and associated with disability in both social and occupational life.^{2–4} For the treatment of chronic courses, evidence is still limited, as only therapeutic exercises, acupuncture, and manual therapies were recommended in recent clinical practice guidelines.^{5–7} On asking manual therapists about their perception and use of complementary and alternative medicine for the treatment of chronic pain conditions, one repeatedly mentioned treatment was craniosacral therapy (CST).⁸

CST is thought to be a noninvasive, mindfulness-based treatment approach using gentle manual palpation techniques to release fascial restrictions between the cranium and the sacrum.⁹ The craniosacral system anatomically encompasses the structures of the central nervous system including the skull, the cranial sutures, the cerebrospinal fluid, and the membranes of the brain and the spinal cord. It is influenced by and linked to the musculoskeletal system,¹⁰ and presumably to the vascular and endocrine system as well as to the sympathetic and parasympathetic nervous system.¹¹ In the craniosacral theory, fascial restrictions within the craniosacral system lead to abnormal, arrhythmic motion of the cerebrospinal fluid. This craniosacral rhythm is assessable by palpation and quantifiable by encephalogram, myelogram, and magnetic resonance imaging.¹² There is also growing evidence for fascial involvement in pain chronification. Studies have shown increased activity of fascial nociceptors within restricted connective tissue, which can contribute to remodeling processes of inflammation and fibrosis, increased tissue stiffness, muscle tension, and chronic pain.^{13,14} However, research on craniosacral diagnostic and treatment mechanisms revealed very heterogeneous results,^{11,12} with only preliminary evidence supporting inherent processes of peripheral and descending pain inhibition due to gentle fascial palpation techniques.^{11,15,16}

The effectiveness of craniosacral treatment on health outcomes has been shown for a number of chronic pain syndromes, but it is limited to observational designs and randomized controlled trials with low to moderate methodological quality.^{17–19} Efficacy studies and studies on musculoskeletal pain have not been conducted to date,²⁰ although neck and back pain were the most frequent symptoms for which CST was requested.²¹ Therefore, this study aimed at investigating the efficacy of CST in chronic nonspecific neck pain in comparison with a manual sham control intervention.

MATERIALS AND METHODS

Trial Design and Registration

The study was designed as a randomized controlled clinical trial with a parallel-group design and 3 months of follow-up observation. After baseline assessment, patients were randomized into either the CST group or an active attention-control group receiving light-touch sham treatment. Outcome measures were collected at week 8 after randomization (after intervention) and week 20 after randomization (3-month follow-up). The trial was conducted between February 2012 and May 2013 at the Department of Internal and Integrative Medicine, Kliniken Essen-Mitte, University of Duisburg-Essen, Essen, Germany. Before patient recruitment, the trial protocol was approved by the ethics committee of the University of Duisburg-Essen, Germany (11-4850-BO), and registered at ClinicalTrials.gov (NCT01526447).

Randomization

A statistician who was not involved in conducting the study generated a nonstratified allocation sequence with randomly varying block lengths using the random number generator RANUNI from the SAS/STAT software (release 9.2, SAS Inc.). On the basis of these random number tables, he prepared sealed and opaque envelopes sorted in the ascending order of randomization. To reveal patients' group assignment, the envelop with the lowest number was opened directly after each baseline assessment by the trial coordinator who was involved neither in the random sequence generation nor in the assessment of study outcomes.

Sample Criteria

Patients were recruited from specialist care, primary care, and noncare populations through advertisements. To assess eligibility, those who called were screened by a research assistant, whereupon eligible patients obtained written study information and a physical and neurological examination by a study physician. If all eligibility criteria were met, patients had to give written informed consent and were included in the study.

Inclusion criteria were an age of 18 to 65 years, chronic nonspecific neck pain for 3 months or more with at least moderate pain intensity of ≥ 45 mm on a 100-mm visual analog scale (VAS),²² and treatment naivety with respect to CST. Participation was not possible in cases of specific neck pain due to degenerative diseases (disk prolapse, scoliosis), inflammatory diseases (spondylitis, arthritis), neurological diseases (neuropathy, multiple sclerosis), physical trauma (whiplash, operation at the cervical spine), or neoplasms of the spine. Severe comorbid somatic and psychiatric disorders such as oncological diseases or major depression and current pregnancy also were exclusion criteria. Patients taking corticosteroids, opiates, muscle relaxants, antidepressants, or those with recently initiated or modified drug therapy or invasive/manipulative treatment were also excluded.

The sample size was calculated on the basis of pain intensity ratings of chronic nonspecific neck pain patients who received osteopathic manipulative treatment²³ using the G*Power software (release 3.1.3, Kiel University, Germany).²⁴ To detect an expected group difference of $1.73 \pm \text{SD of } 2.16$ on a 10-point numeric rating scale (effect size of 0.84) with a power of 80%, a 2-sided *t* test with

$\alpha = 5\%$ significance level required 24 patients per group. Accounting a possible loss of statistical power due to patient withdrawal of 10%, a total sample size of 54 patients was calculated.

Blinding

First, patients were blinded to the group allocation and to the fact that 1 group would receive sham treatment as it was recommended for manual therapy trials²⁵; instead they were told that 2 different CST techniques would be tested. Second, investigators assessing outcomes remained blind to patients' group allocation during the whole study period. Third, the statistician who conducted outcome analyses was blinded to the group allocation by renaming the groups with numbers.

Interventions

Standardized treatment protocols comprised 8 units of CST or sham treatment once a week lasting 45 minutes each. Patients of both groups received initial structural CST examination, which was repeated at the end of each unit, and was treated by 1 of 4 licensed physiotherapists with advanced CST qualification, and on average 6 years of clinical practice. Treatment steps were recorded by therapists using a structured log.

The Treatment Group

The CST protocol was designed to release restrictions of the cranium and the spine up to the pelvis and the sacrum using standardized application of gentle fascial traction, release, and unwinding techniques in accordance with the respective palpated restrictions.^{26,27} The techniques applied included 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 still point induction.^{9,15} If indicated, dialog techniques for increasing body awareness and assisting the process of somato-emotional release were used.²⁸

The Sham Control Group

The sham protocol was designed to be credible but not specifically effective. Therefore, light touch was applied on standardized anatomic areas, equal to those treated with CST, for 2 minutes each time.^{29,30} In addition, body awareness instructions were given to simulate CST dialog techniques.

Outcome Measures

The primary outcome was an average pain intensity during the last 7 days, recorded on a 100-mm VAS at week 8.³¹ Secondary outcomes were pain on movement, pressure pain sensitivity, neck pain-related disability, health-related quality of life, well-being, anxiety and depression, stress perception, pain acceptance, body awareness, patients' global impression of improvement, and safety.

To assess pain on movement, patients obtained the Pain on Movement Questionnaire and were asked to rate the pain intensity on a 100-mm VAS while flexing, extending, laterally flexing, and laterally rotating their head. The average pain on movement score was then

calculated from all movement directions.³² Pressure pain sensitivity was measured at the individual point of maximum pain and bilaterally at anatomically predefined sites (levator scapulae, trapezius, and the semispinalis capitis muscle). For these points, pressure pain thresholds were determined 3 times each using a digital algometer (Somedic AB, Hörby, Sweden) with a 1-cm² cylinder. Pressure was applied in steps of 40 kPa/s until patients stated pain in addition to pressure.^{33,34} Functional disability was assessed using the Neck Disability Index, a 10-item questionnaire that enquired the disability in daily activities induced by neck pain. Scores of <9 indicate no perceived disability, 10 to 29 mild disability, 30 to 49 moderate disability, 50 to 69 severe disability, and 70 to 100 complete disability.³⁵ Health-related quality of life was assessed on 2 subscales, physical and mental quality of life, using the 12-item Short Form Health Survey. Subscales were standardized to a mean of 50 ± SD of 10 and a range of 0 to 100, with 0 indicating the lowest level and 100 the highest level of health.³⁶ Well-being was measured by the sum score of the 16-item Questionnaire for Assessing Subjective Physical Well-being (FEW-16).³⁷ Anxiety and depression were measured using the Hospital Anxiety and Depression Scale. Each subscale is composed of 7 items with a maximum of 21 points. Scores below 8 indicated anxiety and depression levels within normal limits, 8 to 10 points indicated sub-clinical levels, and over 10 points a possible clinical disorder.³⁸ To assess stress perception, patients obtained the Perceived Stress Questionnaire in the 20-item version.³⁹ Pain acceptance was measured by the 8-item Positive Life Construction Scale of the Emotional/Rational Disease Acceptance Questionnaire.⁴⁰ Body awareness was measured by the Scale of Body Connection, which is composed of 2 subscales: Body Awareness and Body Dissociation.⁴¹ Patients' ratings of their Global Impression of Improvement (PGI-I) were assessed on a 7-point scale from 1 (very much improved) to 7 (very much worse).^{42,43} Safety assessment was realized by asking patients at the beginning of each treatment unit about the frequency and the severity of side effects. In addition, patients were requested to document side effects as well as concurrent treatment and medication use in a daily log.

Furthermore, treatment expectancy was assessed as part of the Credibility/Expectancy Questionnaire on a 9-point rating scale from 1 (not at all) to 9 (very much).^{44,45} Treatment credibility and quality of the therapeutic alliance, measured by the Helping Alliance Questionnaire,⁴⁶ were analyzed and reported separately.⁴⁷

Statistical Analysis

All analyses were based on the intention-to-treat population including all patients who were initially randomized, regardless of whether they had missing data or were not fully adhering to the treatment protocol. Missing at random values were imputed 20 times using fully conditional specification iterations, a multiple imputation technique based on multivariate regression models of baseline values and sociodemographic parameters.

Dropout analyses and baseline comparability were analyzed using independent-samples *t* tests for continuous data and χ^2 tests for categorical data. Concurrent medication use was converted into defined daily doses (DDD)⁴⁸ and analyzed using repeated measures analysis of covariance with the treatment group as the classified factor and patients' expectations as the linear covariate. The primary

outcome was analyzed as a function of the treatment group (classified factor), patients' expectations, and respective baseline values (linear covariates) using univariate analysis of covariance. Between-group differences (Δ) and 95% confidence intervals (CI) were estimated using 2-sided *t* tests, and an alpha level of 5%. Equal models were applied for secondary outcomes, which were analyzed were exploratory. This way, no alpha-level adjustment for multiple testing was necessary.⁴⁹ For each outcome, standardized effect sizes (Cohen's *d*) were calculated by dividing estimated group differences by the pooled SD at baseline. In addition, responder analyses were calculated for patients who improved by at least 20% of their respective baseline values (minimal clinically important difference) and for patients with at least 50% improvement (substantial clinical benefit).^{50,51} Between-group differences for treatment response analyses were tested with χ^2 tests. All analyses were performed using the SPSS software (release 22.0, IBM).

RESULTS

Patient Recruitment and Flow

Figure 1 displays the Consort flow chart of patient recruitment and loss during the study period. Out of 150 initially interested patients, 96 had to be excluded because of not fulfilling the eligibility criteria or for reporting scheduling problems. In total, 54 patients were randomized and allocated to 1 of the 2 treatment groups. Whereas 4 patients from the CST group and 8 patients from the sham group did not attend all treatment units provided, only 3 patients were lost to assessment at week 8. Reasons for dropout were scheduling problems and loss of interest. At week 20, dropout of 7 patients was recorded due to scheduling problems, whereas 2 others made no further reply. Comparisons of patients who completed the study with those who were lost to week 8 and week 20 revealed no significant differences concerning their social demographics, neck pain characteristics, and treatment expectancy ($P \geq 0.05$) (Table 1).

Sample Characteristics at Baseline

Patients' baseline characteristics are shown in Table 2. Their ages ranged from 19 to 65 years, with a mean of 44.6 ± 10.0 years. All were whites. Most were female (81.5%), employed, and of normal body mass index. The sample included patients from all educational levels, which were equally distributed. Patients reported 9.6 ± 8.9 years of neck pain duration, and most of them had received several pharmacological and nonpharmacological treatments during that time. No significant differences in patients' social demographics and neck pain characteristics were found between study groups ($P \geq 0.05$). Patient's expectations that CST would be successful in reducing their neck pain symptoms were also comparable between groups ($P \geq 0.05$).

Concurrent Treatments

Patients' use of concurrent pain medication is illustrated in Figure 2. During the 8 weeks of treatment, the average intake of analgesics was 0.1 ± 0.1 DDD in the CST group and 0.5 ± 0.3 DDD in the sham group. Analysis revealed no significant main effect of time ($P = 0.716$) and group ($P = 0.099$), and no significant time-group interaction ($P = 0.069$). Other concurrent treatments were reported by 5 patients in the sham group who used massage 4 times and acupuncture 2 times.

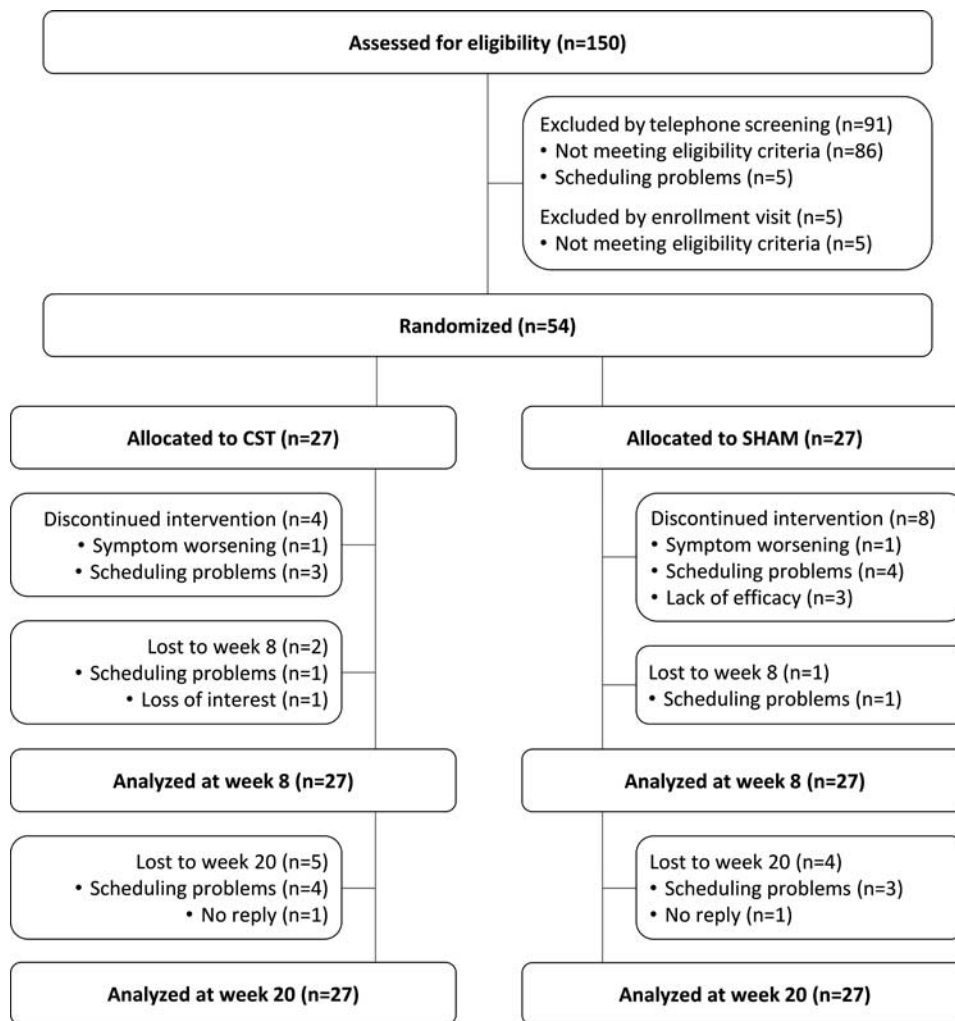


FIGURE 1. A consort flow chart of patient recruitment and loss. CST indicates craniosacral therapy.

TABLE 1. Dropout Analysis

	Completed Week 8 (n = 51)	Lost to Week 8 (n = 3)	P	Completed Week 20 (n = 45)	Lost to Week 20 (n = 9)	P
Age (y) (mean ± SD)	44.8 ± 10.1	40.3 ± 8.3	0.455	44.7 ± 10.4	44.3 ± 8.7	0.920
Sex (female/male) (%)	80.4/19.6	100/0	0.390	79.5/20.5	90.0/10.0	0.442
Education (< high school/high school/university) (%)	34.0/34.0/32.0	33.3/66.7/0	0.553	29.5/34.1/36.4	55.6/44.4/0	0.143
Employment (unemployed/employed/pensioned) (%)	3.9/92.2/3.9	0/100/0	0.881	4.5/93.2/2.3	0/90.0/10.0	0.411
Duration of pain (y) (mean ± SD)	9.9 ± 9.1	4.6 ± 4.6	0.328	9.5 ± 9.0	10.0 ± 9.3	0.889
Pain intensity at baseline (VAS) (mean ± SD)	64.5 ± 13.2	60.0 ± 0.66	0.560	64.4 ± 13.5	63.8 ± 10.6	0.898
Functional disability at baseline (NDI) (mean ± SD)	31.0 ± 8.0	29.0 ± 2.6	0.672	31.3 ± 7.6	28.8 ± 8.6	0.356
Treatment expectancy (CEQ) (mean ± SD)	6.8 ± 1.3	6.7 ± 1.2	0.878	6.8 ± 1.3	6.7 ± 1.4	0.833

CEQ indicates Credibility/Expectancy Questionnaire; NDI, Neck Disability Index; VAS, Visual Analog Scale.

TABLE 2. Sample Characteristics at Baseline

	Total (n = 54)	Craniosacral Therapy (n = 27)	Sham (n = 27)	P
Social demographics				
Age (y) (mean ± SD)	44.6 ± 10.0	44.2 ± 9.7	45.0 ± 10.5	0.769
Sex (female/male) (%)	81.5/18.5	70.4/29.6	92.6/7.4	0.076
BMI (kg/m ²) (mean ± SD)	25.0 ± 4.6	24.5 ± 4.3	25.5 ± 5.0	0.461
Education (< high school/high school/university) (%)	34.0/35.8/30.2	33.3/29.6/37.1	34.6/42.3/23.1	0.153
Employment (unemployed/employed/pensioned) (%)	3.7/92.6/3.7	7.4/88.9/3.7	0/96.3/3.7	0.388
Neck pain characteristics				
Duration of pain (y) (mean ± SD)	9.6 ± 8.9	9.9 ± 9.2	9.3 ± 8.8	0.809
Pain intensity (VAS) (mean ± SD)	64.3 ± 12.9	64.1 ± 12.8	64.4 ± 13.3	0.942
Functional disability (NDI) (mean ± SD)	30.9 ± 7.8	32.4 ± 7.2	29.3 ± 8.2	0.140
Current pain medication (regularly/when needed) (%)	1.9/39.6	0/25.9	3.9/53.9	0.052
Treatment history (%)				
Pain medication	59.3	48.2	70.4	0.166
Injections	42.6	44.4	40.7	0.783
Physical therapy	61.1	55.6	66.7	0.577
Massage	75.9	74.1	77.8	0.750
Acupuncture	31.5	29.6	33.3	0.770
Chiropractic	33.3	29.6	37.0	0.773
Relaxation techniques	27.8	29.6	25.9	0.761
Psychotherapy	9.3	7.4	11.1	0.639
Treatment expectancy (CEQ) (mean ± SD)	6.8 ± 1.3	7.0 ± 1.1	6.5 ± 1.4	0.136

BMI indicates body mass index; CEQ, Credibility/Expectancy Questionnaire; NDI, Neck Disability Index; VAS, Visual Analog Scale.

Primary Outcome

Effects on the primary outcome are shown in Table 3. In comparison with sham, patients in the CST group reported a significantly lesser pain intensity of Δ = -21.0 mm at week 8 (95% CI, -32.6 to -9.4; P = 0.001; d = 1.02) and Δ = -16.8 mm at week 20 (95% CI, -27.5 to -6.1; P = 0.003; d = 0.88).

A minimal clinically important pain reduction of at least 20% was reported by 74.1% of the CST patients against 40.7% of the sham patients at week 8 (P = 0.013), and 77.8% of the CST patients against 51.9% of the sham patients at week 20 (P = 0.046). A substantial clinical benefit of at least 50% pain relief at week 8 was reported by 44.4% of the CST patients against 14.8% of the sham patients (P = 0.017). At week 20, a comparison of 50% response rates did not reach the level of significance (P = 0.091) (Table 4).

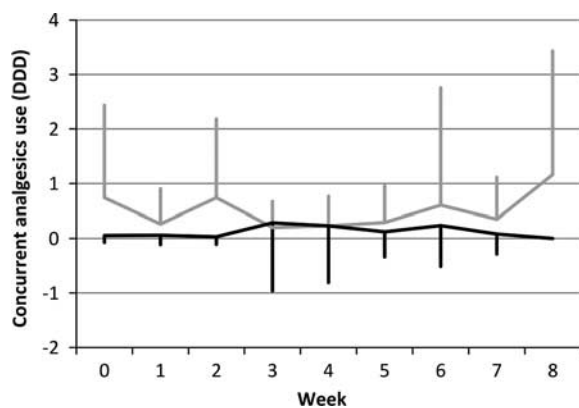


FIGURE 2. Concurrent analgesics use (mean ± SD) of craniosacral therapy (black) and sham patients (gray) during the active study period.

Secondary Outcomes

Analyses of secondary outcomes are also shown in Table 3. At week 8, significant between-group differences were detected for pain on movement (P = 0.001; d = 0.92), pressure pain thresholds at the point of maximum pain (P = 0.038; d = 0.52), and bilaterally at the trapezius muscle (P = 0.042; d = 0.43), functional disability (P = 0.010; d = 0.73), physical quality of life (P = 0.013; d = 0.64), body awareness (P = 0.001; d = 0.59), and global improvement (P = 0.000; d = 1.01). At week 20, significant effects could be detected for pain on movement (P = 0.020; d = 0.66), functional disability (P = 0.006; d = 0.80), physical quality of life (P = 0.000; d = 1.07), and global improvement (P = 0.029; d = 0.62). Although anxiety and depression levels were reduced in the CST group and increased in the sham group, between-group comparisons were significant only for anxiety and only at week 20 (P = 0.020; d = 0.58). No significant group differences were found for stress perception, well-being, mental quality of life, pain acceptance, and body dissociation (P ≥ 0.05).

Safety

No serious adverse events were reported. Minor adverse events during or subsequent to the treatment were reported by 6 patients in the CST group and included increased neck pain in 2 patients and pain in the jaw area, shivering, tiredness, strong emotional reactions, and weeping in 1 patient, respectively. Within the sham group, 8 patients reported minor side effects, which included transient headache or migraine in 7 patients, worsened neck pain in 3 patients, tingling sensations in 2 patients, and dizziness in 1 patient. In all reported cases, symptom worsening subsided shortly after the respective treatment unit. Another 2 patients, 1 from each group, discontinued study participation in consequence of recurrent headache during treatment, but were free of headaches at both follow-up assessments.

TABLE 3. Effects (Mean \pm SD) of Craniosacral Therapy in Comparison With Sham

	Craniosacral Therapy (n = 27)			Sham (n = 27)		
	Baseline	Week 8	Week 20	Baseline	Week 8	Week 20
Pain						
Pain intensity (VAS)	64.1 \pm 12.8	31.7 \pm 20.7	31.6 \pm 19.0	64.4 \pm 13.3	53.5 \pm 20.3	47.8 \pm 19.3
Pain on movement (POM)	54.6 \pm 19.8	25.8 \pm 19.5	23.4 \pm 15.7	58.0 \pm 17.7	46.8 \pm 21.0	36.9 \pm 18.9
Point of max. pain (PPT)	234.4 \pm 120.1	255.4 \pm 122.9	226.5 \pm 62.6	238.5 \pm 137.1	206.7 \pm 77.1	204.9 \pm 63.4
M. levator scapulae (PPT)	271.4 \pm 109.4	290.9 \pm 87.0	254.6 \pm 62.8	250.5 \pm 115.4	246.2 \pm 85.5	241.2 \pm 70.0
M. trapezius (PPT)	241.7 \pm 101.7	238.9 \pm 77.6	230.4 \pm 59.3	220.6 \pm 108.1	200.8 \pm 69.2	222.0 \pm 74.3
M. semispinalis capitis (PPT)	156.4 \pm 60.1	164.2 \pm 48.8	167.2 \pm 58.2	162.6 \pm 78.7	160.9 \pm 76.5	155.6 \pm 50.8
Physical health						
Functional disability (NDI)	32.4 \pm 7.2	17.6 \pm 11.6	18.5 \pm 7.5	29.3 \pm 8.1	24.8 \pm 10.8	23.9 \pm 8.7
Physical quality of life (SF-12)	38.0 \pm 8.3	47.2 \pm 9.0	48.5 \pm 5.1	41.2 \pm 6.0	43.3 \pm 9.3	43.2 \pm 5.9
Physical well-being (FEW)	2.9 \pm 0.6	3.1 \pm 0.8	3.1 \pm 0.6	2.7 \pm 0.8	2.7 \pm 0.8	2.8 \pm 0.8
Mental health						
Mental quality of life (SF-12)	48.5 \pm 10.6	51.2 \pm 9.7	48.4 \pm 10.0	48.8 \pm 11.4	47.7 \pm 12.5	46.2 \pm 12.4
Anxiety (HADS)	7.0 \pm 3.7	5.4 \pm 4.3	5.1 \pm 3.4	6.0 \pm 3.4	5.9 \pm 3.6	6.7 \pm 3.8
Depression (HADS)	4.8 \pm 3.5	4.1 \pm 4.0	5.0 \pm 3.5	4.4 \pm 3.5	4.7 \pm 3.7	6.8 \pm 3.8
Stress perception (PSQ)	44.9 \pm 14.6	40.8 \pm 18.0	38.7 \pm 15.5	47.6 \pm 18.5	45.2 \pm 20.3	47.2 \pm 19.9
Pain acceptance (ERDA)	2.8 \pm 0.5	3.0 \pm 0.7	3.2 \pm 0.6	3.0 \pm 0.5	3.0 \pm 0.4	3.0 \pm 0.5
Body awareness						
Body awareness (SBC)	2.9 \pm 0.5	3.1 \pm 0.5	3.1 \pm 0.5	2.8 \pm 0.6	2.7 \pm 0.6	3.0 \pm 0.5
Body dissociation (SBC)	0.8 \pm 0.4	0.8 \pm 0.7	0.9 \pm 0.4	0.7 \pm 0.6	0.7 \pm 0.5	0.8 \pm 0.8
Global improvement						
Global improvement (PGI-I)	—	2.2 \pm 1.0	2.3 \pm 1.1	—	3.3 \pm 1.0	3.1 \pm 1.1

CI indicates confidence interval; ERDA, Emotional/Rational Disease Acceptance Questionnaire; FEW, Questionnaire for Assessing Subjective Physical Well-being; HADS, Hospital Anxiety and Depression Scale; NDI, Neck Disability Index; PGI-I, Patients' Global Impression of Improvement; POM, Pain on Movement Questionnaire; PPT, pressure pain thresholds; PSQ, Perceived Stress Questionnaire; SBC, Scale of Body Connection; SF-12, 12-item Short Form Health Survey; VAS, Visual Analog Scale.

*Significant between-group difference ($P \leq 0.05$).

DISCUSSION

Summary of Evidence

The present study is the first randomized controlled trial that revealed efficacy for CST in comparison with manual sham treatment. In a patient sample with a mean duration of 9.6 years of nonspecific neck pain, significant and clinically relevant effects on the pain intensity were found directly after the active treatment period and at week 20, a further 3 months later. Minimal clinically important differences in pain intensity at week 20 were reported by almost 78% within the CST group, whereas 48% even had substantial clinical benefit. An exploratory analysis also revealed significant between-group differences at weeks 8 and 20 for pain on movement, functional disability, physical quality of life, and patients' global impression of improvement. Pressure pain sensitivity and body awareness were significantly improved only directly after 8 weeks of treatment, and anxiety only at week 20. No serious adverse events were reported.

Results are in line with previous pain research in CST and recommended neck pain treatments. Although CST was shown to be effective in improving pain intensity, functional disability, and health-related quality of life in comparison with waiting list,⁵² relaxation,^{53,54} off-state physical devices,^{55,56} or standard medical care,⁵⁷ this study found comparable effects in blinded patients with respect to sham. The effect sizes are comparable to those of neck pain guideline treatments⁵⁸⁻⁶¹ and more than likely cannot be explained exclusively by nonspecific treatment effects, which were found to be only of small to medium effect sizes.⁶² Specific effects of the used CST techniques seem to

be probable, given the broad nociceptive and low-threshold mechanosensory innervations of the fasciae.^{16,63} Treating fasciae has been shown to induce a decreased tone of intrafascial muscle cells, decreased muscles tension, and increased parasympathetic nervous system response and vagal tone, *in vitro*⁶³ and *in vivo*.⁶⁴ Pain relief, decreasing muscles tension, and the experience of deep relaxation and release were also reported by the interviewed patients treated with CST.^{65,66} Further described results of CST included the reduction of state and trait anxiety, whereas depression levels were often not influenced significantly.^{29,56} Adverse events have been reported only by 1 randomized controlled trial in detail, with temporarily increased symptoms and tiredness occurring most often.⁵⁷ In the CST theory, such transient symptom aggravation, tiredness, and the described emotional release reactions are usually understood as positive vegetative responses to treatment,²⁸ which were also reported in studies of osteopathy, massage therapy, and acupuncture.⁶⁷⁻⁶⁹

Strengths and Weaknesses

The strengths of the study design included the random and concealed allocation procedure, the intention-to-treat analysis, the active attention-control and touch-control condition, comparable concurrent treatments, and the successful blinding of patients⁴⁷ and outcome assessors.

However, there are certain limitations. First of all, the sample size was relatively small and consisted of 81.5% of female patients, which may reduce the representativity and the generalizability of the results. Even so, the analyses conducted had adequate statistical power, suggesting comparable results even in bigger samples. Epidemiological

TABLE 3. (continued)

Between-group Difference (95% CI)		P		Effect Size (95% CI)	
Week 8	Week 20	Week 8	Week 20	Week 8	Week 20
Pain					
-21.0 (-32.6 to -9.4)	-16.8 (-27.5 to -6.1)	0.001*	0.003*	1.02 (0.46 to 1.59)	0.88 (0.32 to 1.44)
-18.6 (-29.2 to -8.0)	-11.4 (-20.9 to -1.9)	0.001*	0.020*	0.92 (0.36 to 1.48)	0.66 (0.11 to 1.21)
50.3 (2.8 to 97.7)	23.9 (-9.9 to 57.3)	0.038*	0.163	0.52 (-0.02 to 1.06)	0.38 (-0.16 to 0.91)
34.2 (-2.9 to 71.3)	10.4 (-25.1 to 45.8)	0.070	0.560	0.40 (-0.14 to 0.94)	0.16 (-0.38 to 0.69)
31.8 (1.2 to 62.4)	4.4 (-28.9 to 37.7)	0.042*	0.788	0.43 (-0.11 to 0.97)	0.07 (-0.47 to 0.60)
5.8 (-19.2 to 30.8)	15.1 (-12.4 to 42.5)	0.644	0.276	0.09 (-0.44 to 0.62)	0.28 (-0.26 to 0.81)
Physical health					
-8.2 (-14.4 to -2.1)	-6.5 (-11.1 to -2.0)	0.010*	0.006*	0.73 (0.18 to 1.28)	0.80 (0.25 to 1.36)
5.8 (1.3 to 10.4)	5.9 (2.8 to 9.1)	0.013*	0.000*	0.64 (0.09 to 1.18)	1.07 (0.05 to 1.64)
0.2 (-0.2 to 0.5)	0.2 (-0.1 to 0.7)	0.384	0.155	0.19 (-0.34 to 0.72)	0.38 (-0.16 to 0.92)
Mental health					
3.5 (-1.6 to 8.5)	2.7 (-3.2 to 8.6)	0.178	0.363	0.31 (-0.23 to 0.85)	0.24 (-0.30 to 0.77)
-1.0 (-2.8 to 0.9)	-2.1 (-3.8 to -0.3)	0.299	0.020*	0.24 (-0.30 to 0.78)	0.58 (0.03 to 1.12)
-0.7 (-2.2 to 0.8)	-1.9 (-3.9 to 0.2)	0.329	0.079	0.19 (-0.35 to 0.72)	0.50 (-0.04 to 1.05)
-0.4 (-2.2 to 0.4)	-6.4 (-15.5 to 2.8)	0.912	0.171	0.02 (-0.51 to 0.56)	0.36 (-0.18 to 0.89)
0.1 (-0.2 to 0.4)	0.2 (-0.1 to 0.4)	0.392	0.146	0.21 (-0.33 to 0.74)	0.37 (-0.17 to 0.91)
Body awareness					
0.3 (0.1 to 0.5)	0.1 (-0.1 to 0.4)	0.001*	0.330	0.59 (0.04 to 1.13)	0.26 (-0.27 to 0.80)
0.9 (-0.1 to 0.4)	0 (-0.3 to 0.3)	0.183	0.935	0.30 (-0.23 to 0.84)	0.02 (-0.51 to 0.55)
Global improvement					
-1.0 (-1.5 to -0.5)	-0.7 (-1.3 to -0.1)	0.000*	0.029*	1.01 (0.45 to 1.58)	0.62 (0.07 to 1.17)

surveys otherwise show a generally higher neck pain prevalence in women,^{1,3} which in turn would explain the greater percentage of included women compared with men. Second, the comparability of the CST and the sham groups may be limited due to the allocation to the therapists. Whereas 3 therapists performed CST, only 1 therapist performed the sham treatment. However, secondary analyses have shown that the alliance to the assigned therapists did not systematically affect study outcomes.⁴⁷ Nonetheless, the treatment protocols used only allow for conclusions about the effect of CST on subjective clinical outcomes. It remains unclear whether CST techniques actually affect the indicated fascial structures and joints, and if so, whether these changes in turn would result in quantifiable physiological responses. The design therefore would have to include further objective physiological measures and an even more standardized application of fascial palpation techniques.

CONCLUSIONS

CST was shown to be specifically effective and safe in reducing neck pain intensity and may improve the functional disability and the quality of life up to 3 months after the intervention. Particularly in chronic and recurrent neck pain, CST may be a worthwhile treatment option in addition to standard medical care. Further studies with rigorous methodological designs and long-term follow ups are needed to confirm CST efficacy in neck pain treatment.

ACKNOWLEDGMENTS

The authors thank Rainer Lütke, MSc, Karl and Veronica Carstens Foundation, Essen, Germany, for his statistical support; Arndt Büssing, Prof MD, Institute of Integrative Medicine, Department of Health, Witten/Herdecke University, Herdecke, Germany, for his methodological support;

TABLE 4. Responder Analysis

	Craniosacral Therapy (N = 27)		Sham (N = 27)		P
	Nonresponder	Responder	Nonresponder	Responder	
20% VAS reduction at week 8	7 (25.9%)	20 (74.1%)	16 (59.3%)	11 (40.7%)	0.013*
20% VAS reduction at week 20	6 (22.2%)	21 (77.8%)	13 (48.1%)	14 (51.9%)	0.046*
50% VAS reduction at week 8	15 (55.6%)	12 (44.4%)	23 (85.2%)	4 (14.8%)	0.017*
50% VAS reduction at week 20	14 (51.9%)	13 (48.1%)	20 (74.1%)	7 (25.9%)	0.091

% indicates within-group percentages; VAS, Visual Analog Scale.
*Significant between-group difference (P ≤ 0.05).

Florian Gass, MD, Department of Internal and Integrative Medicine, Kliniken Essen-Mitte, Faculty of Medicine, University of Duisburg-Essen, Essen, Germany for his assistance in patient assessment; Petra Klose, PhD, Department of Internal and Integrative Medicine, Kliniken Essen-Mitte, Faculty of Medicine, University of Duisburg-Essen, Essen, Germany, for her assistance in literature search. Special thanks to Christiane Schulze, PT, Essen, Germany; Yin-Ping Haas, PT, Essen, Germany; Heike Frenzel, PT, Dortmund, Germany; and Heribert Georg, PT, Havixbeck, Germany, for their assistance in developing the treatment protocols and treating study patients. The authors also thank the Craniosacral Association Germany and the Upledger Association Germany for their contribution to the open access fee.

REFERENCES

- Fejer R, Kyvik KO, Hartvigsen J. The prevalence of neck pain in the world population: a systematic critical review of the literature. *Eur Spine J*. 2006;15:834–848.
- Cote P, van der Velde G, Cassidy JD, et al. The burden and determinants of neck pain in workers: results of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. *Spine (Phila Pa 1976)*. 2008;33:S60–S74.
- Hogg-Johnson S, van der Velde G, Carroll LJ, et al. The burden and determinants of neck pain in the general population: results of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. *Spine (Phila Pa 1976)*. 2008;33:S39–S51.
- Hoy D, March L, Woolf A, et al. The global burden of neck pain: estimates from the global burden of disease 2010 study. *Ann Rheum Dis*. 2014;73:1309–1315.
- Childs JD, Cleland JA, Elliott JM, et al. Neck pain: clinical practice guidelines linked to the International Classification of Functioning, Disability, and Health from the Orthopedic Section of the American Physical Therapy Association. *J Orthop Sports Phys Ther*. 2008;38:A1–A34.
- Hurwitz EL, Carragee EJ, van der Velde G, et al. Treatment of neck pain: noninvasive interventions: results of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. *Spine (Phila Pa 1976)*. 2008;33:S123–S152.
- Scherer M, Plat E. *Neck Pain—DEGAM Clinical Practice Guideline*. Düsseldorf: Omikron; 2009.
- Hughes CM, Quinn F, Baxter GD. Complementary and alternative medicine: perception and use by physiotherapists in the management of low back pain. *Complement Ther Med*. 2011;19:149–154.
- Upledger JE, Vredevoogt J. *Craniosacral Therapy*. Seattle, WA: Eastland Press; 1983.
- Kahkeshani K, Ward PJ. Connection between the spinal dura mater and suboccipital musculature: evidence for the myodural bridge and a route for its dissection—a review. *Clin Anat*. 2012;25:415–422.
- Ferguson A. A review of the physiology of cranial osteopathy. *J Osteopath Med*. 2003;6:74–84.
- Green C, Martin CW, Bassett K, et al. *A Systematic Review and Critical Appraisal of the Scientific Evidence on Craniosacral Therapy*. Vancouver: British Columbia Office of Health Technology Assessment; 1999.
- Langevin HM, Sherman KJ. Pathophysiological model for chronic low back pain integrating connective tissue and nervous system mechanisms. *Med Hypotheses*. 2007;68:74–80.
- Stecco A, Meneghini A, Stern R, et al. Ultrasonography in myofascial neck pain: randomized clinical trial for diagnosis and follow-up. *Surg Radiol Anat*. 2014;36:243–253.
- Minasny B. Understanding the process of fascial unwinding. *Int J Ther Massage Bodywork*. 2009;2:10–17.
- Vrontou S, Wong AM, Rau KK, et al. Genetic identification of C fibres that detect massage-like stroking of hairy skin in vivo. *Nature*. 2013;493:669–673.
- Jäkel A, von Hauenschild P. A systematic review to evaluate the clinical benefits of craniosacral therapy. *Complement Ther Med*. 2012;20:456–465.
- Ernst E. Craniosacral therapy: a systematic review of the clinical evidence. *Focus Altern Complement Ther*. 2012;17:197–201.
- Tan G, Craine MH, Bair MJ, et al. Efficacy of selected complementary and alternative medicine interventions for chronic pain. *J Rehabil Res Dev*. 2007;44:195–222.
- Ferreira ML, Ferreira PH, Latimer J, et al. Does spinal manipulative therapy help people with chronic low back pain? *Aust J Physiother*. 2002;48:277–284.
- Harrison RE, Page JS. Multipractitioner Upledger CranioSacral Therapy: descriptive outcome study 2007-2008. *J Altern Complement Med*. 2011;17:13–17.
- Jensen MP, Chen C, Brugger AM. Interpretation of visual analog scale ratings and change scores: a reanalysis of two clinical trials of postoperative pain. *J Pain*. 2003;4:407–414.
- Schwerla F, Bischoff A, Nurnberger A, et al. Osteopathic treatment of patients with chronic non-specific neck pain: a randomised controlled trial of efficacy. *Forsch Komplettmed*. 2008;15:138–145.
- Faul F, Erdfelder E, Lang AG, et al. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods*. 2007;39:175–191.
- Bialosky JE, Bishop MD, George SZ, et al. Placebo response to manual therapy: something out of nothing? *J Man Manip Ther*. 2011;19:11–19.
- Mann JD, Faurot KR, Wilkinson L, et al. Craniosacral therapy for migraine: protocol development for an exploratory controlled clinical trial. *BMC Complement Altern Med*. 2008;8:28.
- Koes BW. How to evaluate manual therapy: value and pitfalls of randomized clinical trials. *Man Ther*. 2004;9:183–184.
- Upledger JE. *SomatoEmotional Release*. Berkeley: North Atlantic Books; 2002.
- Mehl-Madrona L, Kligler B, Silverman S, et al. The impact of acupuncture and craniosacral therapy interventions on clinical outcomes in adults with asthma. *Explore (NY)*. 2007;3:28–36.
- Noll DR, Degenhardt BF, Stuart M, et al. Effectiveness of a sham protocol and adverse effects in a clinical trial of osteopathic manipulative treatment in nursing home patients. *J Am Osteopath Assoc*. 2004;104:107–113.
- Hjermstad MJ, Fayers PM, Haugen DF, et al. Studies comparing numerical rating scales, verbal rating scales, and visual analogue scales for assessment of pain intensity in adults: a systematic literature review. *J Pain Symptom Manage*. 2011;41:1073–1093.
- Lauche R, Cramer H, Langhorst J, et al. Reliability and validity of the pain on movement questionnaire (POM) in chronic neck pain. *Pain Med*. 2014;15:1850–1856.
- Cramer H, Lauche R, Hohmann C, et al. Randomized-controlled trial comparing yoga and home-based exercise for chronic neck pain. *Clin J Pain*. 2013;29:216–223.
- Johnston V, Jimmieson NL, Jull G, et al. Quantitative sensory measures distinguish office workers with varying levels of neck pain and disability. *Pain*. 2008;137:257–265.
- Cramer H, Lauche R, Langhorst J, et al. Validation of the German version of the Neck Disability Index (NDI). *BMC Musculoskelet Disord*. 2014;15:91.
- Jenkinson C, Layte R, Jenkinson D, et al. A shorter form health survey: can the SF-12 replicate results from the SF-36 in longitudinal studies? *J Public Health Med*. 1997;19:179–186.
- Albani C, Blaser G, Geyer M, et al. Validation and standardization of the “Questionnaire for Assessing Subjective Physical Well-Being” by Kolip and Schmidt in a representative German sample. *Psychother Psychosom Med Psychol*. 2006;56:172–181.

38. Herrmann C. International experiences with the Hospital Anxiety and Depression Scale—a review of validation data and clinical results. *J Psychosom Res.* 1997;42:17–41.
39. Fliege H, Rose M, Arck P, et al. The Perceived Stress Questionnaire (PSQ) reconsidered: validation and reference values from different clinical and healthy adult samples. *Psychosom Med.* 2005;67:78–88.
40. Büssing A, Matthiessen PF, Mundle G. Emotional and rational disease acceptance in patients with depression and alcohol addiction. *Health Qual Life Outcomes.* 2008;6:4.
41. Price CJ, Thompson EA. Measuring dimensions of body connection: body awareness and bodily dissociation. *J Altern Complement Med.* 2007;13:945–953.
42. Guy W. Clinical Global Impressions. In: Guy W, ed. *ECDEU Assessment Manual for Psychopharmacology, revised.* Rockville, MD: US Department of Health, Education, and Welfare. Public Health Service. Alcohol, Drug Abuse, and Mental Health Administration; 1976:217–222.
43. Hudson JI, Arnold LM, Bradley LA, et al. What makes patients with fibromyalgia feel better? Correlations between Patient Global Impression of Improvement and changes in clinical symptoms and function: a pooled analysis of 4 randomized placebo-controlled trials of duloxetine. *J Rheumatol.* 2009;36:2517–2522.
44. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. *J Behav Ther Exp Psychiatry.* 2000;31:73–86.
45. Smeets RJ, Beelen S, Goossens ME, et al. Treatment expectancy and credibility are associated with the outcome of both physical and cognitive-behavioral treatment in chronic low back pain. *Clin J Pain.* 2008;24:305–315.
46. Luborsky L, Barber JP, Siqueland L, et al. The Revised Helping Alliance Questionnaire (HAQ-II): Psychometric Properties. *J Psychother Pract Res.* 1996;5:260–271.
47. Haller H, Ostermann T, Lauche R, et al. Credibility of a comparative sham control intervention for craniosacral therapy in patients with chronic neck pain. *Complement Ther Med.* 2014;22:1053–1059.
48. WHO. *Collaborating Centre for Drug Statistics Methodology Guidelines for ATC classification and DDD assignment 2014.* Oslo, Norway: Norwegian Institute of Public Health; 2013.
49. Feise RJ. Do multiple outcome measures require p-value adjustment? *BMC Med Res Methodol.* 2002;2:8.
50. Dworkin RH, Turk DC, Wyrwich KW, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. *J Pain.* 2008;9:105–121.
51. Kovacs FM, Abaira V, Royuela A, et al. Minimum detectable and minimal clinically important changes for pain in patients with nonspecific neck pain. *BMC Musculoskelet Disord.* 2008;9:43.
52. Arnadottir TS, Sigurdardottir AK. Is craniosacral therapy effective for migraine? Tested with HIT-6 Questionnaire. *Complement Ther Clin Pract.* 2013;19:11–14.
53. Anderson RE, Seniscal C. A comparison of selected osteopathic treatment and relaxation for tension-type headaches. *Headache.* 2006;46:1273–1280.
54. Hanten WP, Olson SL, Hodson JL, et al. The effectiveness of CV-4 and resting position techniques on subjects with tension-type headaches. *J Man Manip Ther.* 1999;7:64–70.
55. Castro-Sanchez AM, Mataran-Penarrocha GA, Sanchez-Labraca N, et al. A randomized controlled trial investigating the effects of craniosacral therapy on pain and heart rate variability in fibromyalgia patients. *Clin Rehabil.* 2011;25:25–35.
56. Mataran-Penarrocha GA, Castro-Sanchez AM, Garcia GC, et al. Influence of craniosacral therapy on anxiety, depression and quality of life in patients with fibromyalgia. *Evid Based Complement Alternat Med.* 2011;2011:178769.
57. Elden H, Ostgaard HC, Glantz A, et al. Effects of craniosacral therapy as adjunct to standard treatment for pelvic girdle pain in pregnant women: a multicenter, single blind, randomized controlled trial. *Acta Obstet Gynecol Scand.* 2013;92:775–782.
58. Bertozzi L, Gardenghi I, Turoni F, et al. Effect of therapeutic exercise on pain and disability in the management of chronic nonspecific neck pain: systematic review and meta-analysis of randomized trials. *Phys Ther.* 2013;93:1026–1036.
59. Gross AR, Hoving JL, Haines TA, et al. A Cochrane review of manipulation and mobilization for mechanical neck disorders. *Spine (Phila Pa 1976).* 2004;29:1541–1548.
60. Kay TM, Gross A, Goldsmith C, et al. Exercises for mechanical neck disorders. *Cochrane Database Syst Rev.* 2005: CD004250.
61. Trinh K, Graham N, Gross A, et al. Acupuncture for neck disorders. *Spine (Phila Pa 1976).* 2007;32:236–243.
62. Vernon H, Humphreys BK, Hagino C. The outcome of control groups in clinical trials of conservative treatments for chronic mechanical neck pain: a systematic review. *BMC Musculoskelet Disord.* 2006;7:58.
63. Schleip R. Fascial plasticity – a new neurobiological explanation. Part 2. *J Bodyw Mov Ther.* 2003;7:104–116.
64. Moyer CA, Rounds J, Hannum JW. A meta-analysis of massage therapy research. *Psychol Bull.* 2004;130:3–18.
65. Elden H, Lundgren I, Robertson E. Effects of craniosacral therapy as experienced by pregnant women with severe pelvic girdle pain: an interview study. *Clin Nursing Stud.* 2014;2:140–151.
66. Brough N, Lindenmeyer A, Thistlethwaite J, et al. Perspectives on the effects and mechanisms of craniosacral therapy: a qualitative study of users' views. *Eur J Integr Med.* 2015;7:172–183.
67. Campbell A. The limbic system and emotion in relation to acupuncture. *Acupunct Med.* 1999;17:124–130.
68. Mazzeo CA. *Nurturing the Mind/body Connection: A Phenomenological Analysis of Emotional Release in Massage Therapy.* Ann Arbor, MI: ProQuest, UMI Dissertations Publishing; 2008.
69. Rajendran D, Bright P, Bettles S, et al. What puts the adverse in 'adverse events'? Patients' perceptions of post-treatment experiences in osteopathy—a qualitative study using focus groups. *Man Ther.* 2012;17:305–311.