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REVIEW

Therapeutic Effects of Cranial Osteopathic Manipulative Medicine: A Systematic Review

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Context: Cranial osteopathic manipulative medicine (OMM) involves the manipulation of the primary respiratory mechanism to improve structure and function in children and adults.

Objective: To identify and critically evaluate the literature regarding the clinical efficacy of cranial OMM.

Data Sources: The clinical keywords "cranial manipulation" OR "osteopathy in the cranial field" OR "cranial osteopathy" OR "craniosacral technique" were searched in the following electronic databases: EMBASE, MEDLINE In-Process & Other Non-Indexed Citations, The Cochrane Central Register of Controlled Trials, CINAHL (Cumulative Index to Nursing and Allied Health Literature), and AMED (Alternative Medicine). Searches were conducted in April 2011 with no date restriction for when the studies were completed.

Study Selection: Randomized controlled trials and observational studies that measured the effectiveness of cranial OMM on humans were included in the study. Exclusion criteria included non-English language articles, studies not relevant to cranial OMM, animal studies, and studies in which there was no clear indication of the use of cranial OMM. Studies that described the use of cranial OMM with other treatment modalities and that did not perform subgroup analysis were also excluded. The present study did not have criteria regarding type of disease.

Data Extraction: Outcome measures on pain, sleep, quality of life, motor function, and autonomic nervous system function were extracted. The methodological quality of the trials was assessed using the Downs and Black checklist.

Data Synthesis: Of the 8 studies that met the inclusion criteria, 7 were randomized controlled trials and 1 was an observational study. A range of cranial OMM techniques used for the management of a variety of conditions were identified in the included studies. Positive clinical outcomes were reported for pain reduction, change in autonomic nervous system function, and improvement of sleeping patterns. Methodological Downs and Black quality scores ranged from 14 to 23 points out of a maximum of 27 points (overall median score, 16).

Conclusion: The currently available evidence on the clinical efficacy of cranial OMM is heterogeneous and insufficient to draw definitive conclusions. Because of the moderate methodological quality of the studies and scarcity of available data, further research into this area is needed.

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Osteopathic manipulative medicine (OMM) in the cranial field has received widespread and vigorous critical attention compared with other fields of osteopathic medicine.[1-3] It originated in the 1930s by observations of William G. Sutherland, DO, who claimed that the individual bones of the skull reflect mobility.[4] Cranial OMM is primarily concerned with the study of the anatomic and physiologic mechanisms in the cranium and their interrelationship with the body as a whole, including a system of diagnostic and therapeutic modalities with application to prevent and treat disease.[5] Cranial OMM is applied by osteopathic physicians or foreign-trained osteopaths and is used to treat somatic dysfunction of the head and other body parts.

An important component of cranial OMM is the primary respiratory mechanism, which manifests as motion of the cranial bones, sacrum, dural membranes, central nervous system, and cerebrospinal fluid.[5] The primary respiratory mechanism is synchronous with the cranial rhythmic impulse, a 2-phase rhythmic cycle throughout the body that represents a dynamic metabolic interchange with each phase of action. Cranial OMM involves the gentle application of manual force to address somatic dysfunctions of the head and the remainder of the body, subsequently affecting the patient through manipulation of the primary respiratory mechanism.[6,7]

One important cranial OMM technique is compression of the fourth ventricle (CV-4). The CV-4 technique enhances motion of the tissue and fluid and restores flexibility of the

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autonomic response by means of manipulation of the sutures of the skull. To perform this technique, the operator approximates the lateral angles of the occiput of the skull. This action lessens the capacity of the fourth ventricle by approximating its floor and ceiling, which disperses the cerebrospinal fluid through natural channels and regulates the tissue fluids of the body in general.[5] Compression of the fourth ventricle has been shown to have relaxing effects, which can lower the tone of the sympathetic nervous system and enhance fluid exchange.[8]

To the authors' knowledge, OMM research conducted to date has primarily focused on the reliability of palpation, with few good-quality studies focused on the effectiveness of cranial OMM. To provide an overview of the available literature on cranial OMM, the authors conducted a systematic review of randomized controlled trials (RCTs) and observational data to describe the clinical benefit of cranial OMM in patients with a variety of pathologic conditions.

Methods

Identification of Studies

A comprehensive search strategy was designed to retrieve relevant clinical data from published literature. We completed a search in each of the following databases in April 2011: EMBASE (which also searched the MEDLINE database), MEDLINE In-Process & Other Non-Indexed Citations, The Cochrane Central Register of Controlled Trials, CINAHL (Cumulative Index to Nursing and Allied Health Literature), and AMED (Alternative Medicine). Search terms included the following clinical keywords: "cranial manipulation" OR "osteopathy in the cranial field" OR "cranial osteopathy" OR "craniosacral technique."

Study Selection

To be included in this review, studies had to meet the inclusion criteria, which are defined in *Figure 1*. Studies were excluded if they were not relevant to cranial OMM (eg, spinal manipulation), or if they did not have a clear indication of the use of cranial OMM (eg, if a study's title or author indicated the study might be relevant to cranial OMM, but cranial OMM was not mentioned in the text). Studies that described the use of cranial OMM with other treatment modalities but did not perform subgroup analysis were excluded. For study selection, cranial OMM was defined as any form of manipulation of the primary respiratory mechanism.

The study selection process comprised 2 "passes." During the first pass, we reviewed the studies' abstracts. Those studies that did not meet the eligibility criteria on the basis of the content of their abstracts were excluded during this stage. Duplicate citations due to overlap in the coverage of the databases were also excluded in the first pass. For studies that could not be included or excluded based on the content of their abstracts, we obtained copies of the full-text versions of the studies. We also obtained full-text copies of studies that could potentially meet the eligibility criteria.

Category	Description
Study Design	Randomized controlled trials or observational studies
Population	Human patients (no age restriction)
Disease	No limitations
Intervention	Any form or technique of cranial OMM, as named by the authors
Objective	Investigate the effectiveness of cranial OMM as the only treatment modality performed
Language	English

Figure 1. *Inclusion criteria for systematic review of studies that measured the clinical efficacy of cranial osteopathic manipulative medicine (OMM).*

During the second pass of the selection process, the eligibility criteria were applied to the full-text versions of the studies using the same screening method used for the abstracts. The data in the studies that met the inclusion criteria were extracted.

Data Extraction

The information that was extracted comprised general study information (eg, study size, study design), participant data (eg, conditions reported, treatments given), and outcomes reported (eg, quality of life, pain, sleeping patterns).

Quality Assessment

Studies were assessed for quality by means of the Downs and Black checklist.[6] This scoring system is based on a checklist of 27 questions and has been found to be valid and reliable for critically evaluating experimental and nonexperimental studies.[10,11] The checklist included 4 categories for evaluation: reporting, external validity, internal validity/bias, and internal validity/confounding. Each article was assessed using this scoring system and subsequently was categorized as being of a strong, moderate, limited, or poor quality (*Figure 2*).[12,13]

Quality Index*	Percentage	Methodological Quality Score†
Strong	≥75%	≥21
Moderate	50-74%	14-20
Limited	25-49%	7-13
Poor	<25%	<7

Figure 2. *Categorization of total scores obtained by the Downs and Black Checklist.[9] *Adapted from Hartling[12] and Hignett.[13] †Out of a possible 27 points.*

Table 1.
Database Search Results for Studies on Cranial Osteopathic Manipulative Medicine

Source	Studies, No.
EMBASE (including MEDLINE)	56
MEDLINE In-Process & Other Non-Indexed Citations	1
The Cochrane Central Register of Controlled Trials	18
CINAHL	39
AMED	45
Total	159

Abbreviations: AMED, Alternative Medicine; CINAHL, Cumulative Index to Nursing and Allied Health Literature.

Results

The literature search yielded 159 studies (*Table 1*). Seventy-three of these studies were duplicates and were excluded.

After the first pass, 24 potentially relevant studies were identified. Full-text versions of these studies were obtained for more detailed evaluation. After the second pass, during which we examined the full text versions of the studies, 16 studies were excluded, which left 8 studies (7 randomized controlled trials, 1 observational study) that met the inclusion criteria for the present review (*Figure 3*). The flow of studies through the selection process for the present review is shown in *Figure 4*.

Study Details

Data were extracted from the 8 studies that met the inclusion criteria. Of the 7 randomized controlled trials, 2 used crossover designs (ie, the patients acted as their own controls). The observational study reported data before and after the intervention. The studied population ranged in size from 9 patients[19] to 142 patients,[18] with patient follow-up (where reported) conducted during periods ranging from 4 weeks[15] to 6 months.[18] In 4 studies,[14,19-21] use of the CV-4 technique was reported; the remaining 4 studies did not define the manual techniques used. Treatment duration ranged from 1 minute[20] to 30 minutes,[15] with treatment sessions of 5 minutes or 10 minutes most frequently reported. The length of treatment period differed, ranging from single treatments to 6 months. Four studies were conducted with healthy adults, whereas the remaining 4 studies used participants of different ages with a variety of conditions, including adults with tension-type headache, infants with colic, children with cerebral palsy, and adults with myopia. *Table 2* provides a summary of each study, including treament sessions and interventions.

Outcomes Reported

Several outcomes were assessed in the identified studies, including change in pain, quality of life, sleeping habits, gross motor function, and autonomic nervous system function. The most common statistically significant results found were improvement in sleeping patterns, compared with placebo or control.[15,18,19] The effect of cranial OMM on pain was investigated in 2 studies, with a positive outcome reported in adults with tension-type headache[14] but not in children with cerebral palsy.[15] Alterations in autonomic nervous system functions after cranial OMM were demonstrated, including a change in blood flow velocity[17,20] and visual function.[16] The autonomic nervous system parameters of heart rate vari-

Study	Design	Objective
Hanten[14]	RCT	To investigate the effect of CV-4 technique on tension-type headache after a single treatment
Hayden[15]	RCT	To investigate the effect of cranial OMM on the pattern of increased crying, irritability, and disturbed sleep associated with infantile colic
Sandhouse[16]	RCT	To determine whether cranial OMM results in an immediate, measurable change in visual function among adults with cranial asymmetry
Sergueef[17]	RCT	To determine the effect of cranial OMM on the Traube-Hering-Mayer oscillation in healthy adults
Wyatt[18]	RCT	To estimate the effect of cranial OMM on general health and well-being, including physical function of children with cerebral palsy
Cutler[19]	RCT with crossover design	To determine effects of CV-4 technique on altered sleep latency and on muscle sympathetic nerve activity
Nelson[20]	RCT with crossover design	To examine the effect of CV-4 technique on blood flow velocity
Milnes[21]	Observational	To investigate the physiologic effects of a single cranial OMM technique (CV-4) on healthy adults

Figure 3. *Overview of studies that measured the clinical efficacy of cranial osteopathic manipulative medicine (OMM).* ***Abbreviations:*** *CV-4, compression of the fourth ventricle; RCT, randomized controlled trial.*

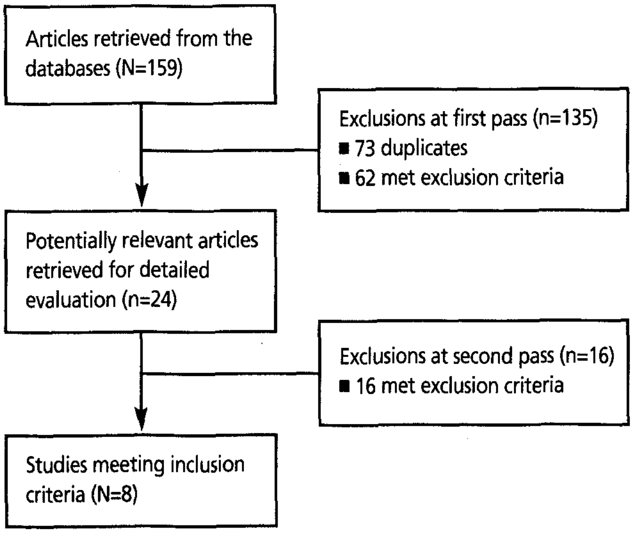

Figure 4. *Flow diagram of study selection.*

ability and respiratory rate variability were investigated in 3 studies[17,19,21] with no change reported; however, it is noteworthy that the study participants were all healthy adults.

Quality of life and global health were addressed in 1 study, which focused on cranial OMM for children with cerebral palsy.[18] Compared with caregivers of children in the control group, more caregivers of children in the intervention group reported an improvement on global health. In addition, children in the intervention group showed statistically significant improvement in 1 of the 4 subscales of the Child Health Questionnaire at 10-week follow-up. The same study explored motor function after cranial OMM, with no statistically significant effect being demonstrated.[18] This study was also the only study that reported on the safety of cranial OMM, with no worsening effect of cranial OMM in children mentioned.[18]

Another study demonstrated how cranial OMM was associated with a reduction of crying and required parental attention in infants with colic.[15] A summary of outcomes in patients who received cranial OMM compared with control patients are presented in *Table 3*.

Critical Appraisal

All studies were analyzed using the Downs and Black checklist, which is structured to assess both comparative and noncomparative studies (*Table 4*). Overall, the results of this systematic review illustrate a moderate methodological quality among the included studies (median score, 16 of 27), resulting in a variation of data in relation to the particular study design. The highest median critical appraisal score was achieved by randomized controlled trials (median score, 18 of 27), followed by randomized controlled trials with crossover designs (median score, 15 of 27). Most studies included in the present review earned higher scores in the Downs and Black checklist categories on reporting and internal validity/bias (median, 7 of 10 and 5 of 7, respectively), whereas the categories on external validity and internal validity/confounding were insufficiently covered (median 1 of 4 and 2 of 6, respectively.

One RCT[18] was of strong methodological quality, resulting in a score of 23 out of 27 and showing relative consistency in all 4 Downs and Black checklist categories. This trial was also the only trial that reported a power calculation for sample size determination.

Comment

The present systematic review identified a range of studies evaluating the effectiveness of cranial OMM in patients with various conditions. The results of this review highlight that the available evidence is heterogeneous and insufficient to draw definitive conclusions. In general, the effectiveness of cranial OMM as a manual therapy approach, as analyzed, is well reported. In addition, the majority of the reviewed studies showed positive outcomes, implying that the clinical benefit of this treatment approach in certain clinical outcomes is therefore confirmed. These findings support the use of cranial OMM as an effective and clinically beneficial treatment modality for patients of all ages with a variety of conditions. However, it is noteworthy that the majority of trials used very small sample sizes and were therefore lacking necessary power. For this reason, the available evidence must be interpreted with care.

The methodology of the included studies was of overall moderate quality, with only 1 RCT earning a strong methodological score.[18] The methodological quality of future research needs to be more robust to improve the evidence base. The general reporting quality of studies can be improved with the documentation of adverse events, dropouts, confounding variables, and methods of recruitment. Internal validity of studies can be strengthened with the use of RCT design, with optimal designs including double blinding and placebo groups. To enhance external validity, study sample sizes should be increased, which would improve the statistical power of the sample population because it would be easier to detect statistically significant changes between groups. Further, the reporting and usage of appropriate statistical methods need to be improved to generate reliable and valid results.

For the present review, the use of relevant search terms and databases ensured that all possible studies concerning the benefit of cranial OMM were included for analysis. A valid and reliable critical appraisal tool was employed to assess the methodological quality of the included studies. However, the present systematic review consists of some limitations. For example, only English-language articles were included, which may have lead to the exclusion of other relevant studies. Further, a statistical analysis was not performed for the present review, which may weaken the interpretation of the results.

Table 2.
Patient Cohorts and Types of Intervention in Studies Measuring the Efficacy of Cranial Osteopathic Manipulative Medicine

Study	Patient Population	Follow-up	Groups	n	Frequency and Duration of Treatment Sessions	Intervention
Hanten[14]	Adults with tension-type headaches	Single treatment	Experimental	20	10 min	CV-4 (occiput)
			Sham	20	10 min	Protraction or retraction of head, with subsequent flexion or extension of the head, then rest in this position
			Control	20	10 min	No manual therapy, laid quietly
Hayden[15]	Infants with colic	4 weeks	Experimental	14	Once per wk for 30 min	Individualized treatments, involving standard cranial osteopathic techniques until a palpable release of tensions and dysfunction was achieved
			Control	12	Once per wk for 30 min	No physical intervention
Sandhouse[16]	Healthy adults with myopia or hyperopia	Single treatment	Experimental	15	5 min	Specific OMT technique (balanced membranous tension)
			Control	14	5 min	Single session of sham therapy (light pressure applied to the cranium without OMT)
Sergueef[17]	Healthy adults	Single treatment	Experimental	10	10-20 min	Cranial manipulation (not defined)
			Control	13	10-20 min	Cranial palpation (counting CRI without intervention)
Wyatt[18]	Children with cerebral palsy	6 months	Experimental	71	Average 21 min, 3 sessions in the first 10 wk, remaining 3 sessions within 6 mo	Cranial osteopathy according to children's needs (not further defined)
			Control	71	NA	6 mo waiting list
Cutler[19]	Healthy adults	Single treatment	Sleep latency	11	5-7 min for each intervention	Randomly ordered treatments (1-h recovery period between treatments): CV-4 (occiput); CV-4 sham (light touch without cradling); control (no treatment)
			MSNA	9	5-7 min for each intervention	Randomly ordered treatments (30-min recovery period between treatments): CV-4 (occiput); CV-4 sham (light touch without cradling); control (no treatment)
Nelson[20]	Healthy adults	Single treatment	Experimental	20	1-10 min	CV-4 (occiput)
Milnes[21]*	Healthy adults	Single treatment	Experimental	10	5 phases: no touch, 10 min; touch only, 5 min; CV-4, length dictated by practitioner; touch only, 5 min; no touch time given	CV-4 (occiput), touch-only phase involved same handhold but practitioner was instructed not to consciously "engage" with the patient or to provide any therapeutic intent or treatment

* Observational study. All other studies were randomized controlled trials.

Abbreviations: CRI, cranial rhythmic impulse; CV-4; compression of the fourth ventricle; MSNA, muscle sympathetic nerve activity; NA, not applicable; OMT, osteopathic manipulative treatment.

Table 3.
Outcomes Reported in Studies on Efficacy of Cranial Osteopathic Manipulative Medicine

Outcome and Methods	Condition	Findings Compared With Control or Baseline	Study
■ **Pain**			
□ VAS (100 mm)	Tension-type headache	Statistically significant improvement in pain intensity	Hanten[14]
□ Paediatric Pain Profile (recorded by parents or care givers)	Children with cerebral palsy	No statistically significant differences on parental assessment of child's pain	Wyatt[18]
■ **QoL of Patients or Caregivers and General Health**			
□ CHQ (recorded by parents/caregivers)	Children with cerebral palsy	Statistically significant differences in 1 out of 4 subscales at 10 wk, no statistically significant differences at 6 mo	Wyatt[18]
□ SF-36 (assessment of main care giver's QoL)	Children with cerebral palsy	Statistically significant differences in the mental component score at 10 wk, no statistically significant differences at 6 mo	Wyatt[18]
□ Global health (recorded by parents/care givers)	Children with cerebral palsy	Greater proportion of parents with children in intervention group rated their child as having better general health at 10-wk and 6-mo follow-up	Wyatt[18]
■ **Sleep**			
□ EEG, EOG, EMG	Healthy adults	Sleep latency significantly decreased	Cutler[19]
□ Number of hours spent sleeping per 24 h (recorded by parents)	Infants with colic	Statistically significant improvement in time spent sleeping	Hayden[15]
□ Sleep diary (recorded by parents/care givers)	Children with cerebral palsy	Statistically significant differences in mean time to sleep at 10 wk, no statistically significant differences on time to sleep and time spent asleep at 6 mo	Wyatt[18]
□ Global sleeping (recorded by parents or care givers)	Children with cerebral palsy	Greater proportion of parents with children in intervention group rated their child as having better sleeping at 10-wk and 6-mo follow-up	Wyatt[18]
■ **Gross Motor Function**			
□ GMFM-66 (recorded by physiotherapists)	Children with cerebral palsy	No statistically significant difference at 6 mo	Wyatt[18]
■ **Crying, Parental Attention**			
□ Amount of inconsolable crying and time the infant was being held or rocked	Infants with colic	Less parental attention was required Statistically significant reduction in crying per 24 h (recorded by parents)	Hayden[15]

(continued)

* Visual, cardiovascular, respiratory, skin temperature, and blood flow velocity.

† Donder push-ups involve a movable target and a ruler with metrics and dioptric markings placed on the patient's forehead. The patient has distance correction in place and the movable target is slowly moved towards the patient along the ruler until blurring is reported and the dioptric result is recorded.

Abbreviations: ANS, autonomic nervous system; CHQ, Child Health Questionnaire; ECG, electrocardiography; EEG, electroencephalography; EMG, electromyography; EOG, electro-oculography; GMFM, gross motor function measure; MSNA, muscle sympathetic nerve activity; QoL, quality of life; VAS, visual analog scale.

Conclusion

The present systematic review provides an overview of studies in the medical literature that evaluate the clinical benefit of cranial OMM. The currently available evidence on the topic is heterogeneous. Because of the moderate methodological quality of the studies and scarcity of available data, further research into this area is needed.

References

1. Moran R. Osteopathy in the cranial field – moving towards evidence for causality and effectiveness. *Int J Osteopath Med.* 2005:8(3):79-80.

2. Hartman SE. Cranial osteopathy: its fate seems clear. *Chiropr Osteopath.* 2006;14:10. doi:10.1186/1746-1340-14-10.

3. Ferguson A. A review of the physiology of cranial osteopathy. *J Osteopath Med.* 2003;6(2):74-88.

4. Sutherland WG. *The Cranial Bowl.* Mankato, MN: Free Press Company; 1939.

5. Magoun HI, ed. *Osteopathy in the Cranial Field.* 3rd ed. Kirksville, MO: The Journal Printing Company; 1976.

6. King HH, Lay E. Osteopathy in the cranial field. In: Ward RC, ed. *Foundations for Osteopathic Medicine.* 2nd ed. Baltimore, MD: Lippincott Williams and Wilkins; 2003:985-1001.

Table 3 (continued).
Outcomes Reported in Studies on Efficacy of Cranial Osteopathic Manipulative Medicine

Outcome and Methods	Condition	Findings Compared With Control or Baseline	Study
■ ANS Function*			
□ Distance visual acuity; accommodative system testing (Donder push-ups†); □ Local stereoacuity; pupil size; vergence	Myopia or hyperopia	Statistically significant effect in pupil size measured under bright illumination	Sandhouse[16]
□ Postganglionic MSNA (microneurography), ECG (heart rate), arterial blood pressure (photoplethysmography)	Healthy adults	Heart rate and BP were not significantly different at any time points during all 3 trials; MSNA during the CV-4 stillpoint was decreased when compared to pre-stillpoint MSNA (no difference during sham or control procedure)	Cutler[19]
□ Galvanic skin resistance, skin temperature, heart rate (ECG), respiration rate	Healthy adults	No statistically significant differences in any variable across the 5 phases	Milnes[21]
□ Flowmetry time-course records, measurement of Traube-Hering oscillations	Healthy adults	Statistically significant differences were seen for the baro (Traube-Hering) signal; No significant differences were determined for the thermo (Mayer) signal	Nelson[20]
□ Laser Doppler flowmetry (Traube-Hering-Mayer oscillations)	Healthy adults	Decrease of thermal signal power and increase of baro signal; no change of respiratory and cardiac signal seen	Sergueef[17]
■ Safety			
□ Side effects of procedure	Children with cerebral palsy	No serious adverse events reported and no child withdrew from the study because of side effects of the treatment	Wyatt[18]

* Visual, cardiovascular, respiratory, skin temperature, and blood flow velocity.
† Donder push-ups involve a movable target and a ruler with metrics and dioptric markings placed on the patient's forehead. The patient has distance correction in place and the movable target is slowly moved towards the patient along the ruler until blurring is reported and the dioptric result is recorded.

Abbreviations: ANS, autonomic nervous system; CHQ, Child Health Questionnaire; ECG, electrocardiography; EEG, electroencephalography; EMG, electromyography; EOG, electro-oculography; GMFM, gross motor function measure; MSNA, muscle sympathetic nerve activity; QoL, quality of life; VAS, visual analog scale.

7. Magoun HI. The primary respiratory mechanism. In: Magoun HI, ed. *Osteopathy in the Cranial Field*. 3rd ed. Kirksville, MO: The Cranial Academy; 1976:23-42.

8. Chaitow L. *Osseous and Soft Tissue Approaches. Cranial Manipulation Theory and Practice*. London, England: Churchill Livingstone; 1999:116.

9. Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. *J Epidemiol Community Health*. 1998;52(6):377-384.

10. Altman DG, Burton MJ. The Cochrane Collaboration. *Langenbecks Arch Surg*. 1999;384(5):432-436.

11. Saunders LD, Soomro GM, Buckingham J, Jamtvedt G, Raina P. Assessing the methodological quality of nonrandomized intervention studies. *West J Nurs Res*. 2003;25(2):223-237.

12. Hartling L, Brison RJ, Crumley ET, Klassen TP, Pickett W. A systematic review of interventions to prevent childhood farm injuries. *Pediatrics*. 2004;114(4):e483-e496.

13. Hignett S. Systematic review of patient handling activities starting in lying, sitting and standing positions. *J Adv Nurs*. 2003;41(6):545-552.

14. 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 and Manipulative Ther*. 1999;7(2):64-70.

15. Hayden C, Mullinger B. A preliminary assessment of the impact of cranial osteopathy for the relief of infantile colic. *Complement Ther Clin Pract*. 2006;12(2):83-90.

16. Sandhouse ME, Shechtman D, Sorkin R, et al. Effect of osteopathy in the cranial field on visual function—a pilot study. *J Am Osteopath Assoc*. 2010;110(4):239-243.

17. Sergueef N, Nelson KE, Glonek T. The effect of cranial manipulation on the Traube-Hering-Mayer oscillation as measured by laser-Doppler flowmetry. *Altern Ther Health Med*. 2002;8(6):74-76.

18. Wyatt K, Edwards V, Franck L, et al. Cranial osteopathy for children with cerebral palsy: a randomised controlled trial [published online ahead of print February 24, 2011]. *Arch Dis Child*. 2011;96(6):505-512.

19. Cutler MJ, Holland BS, Stupski BA, Gamber RG, Smith ML. Cranial manipulation can alter sleep latency and sympathetic nerve activity in humans: a pilot study. *J Altern Complement Med*. 2005;11(1):103-108.

20. Nelson KE, Sergueef N, Glonek T. The effect of an alternative medical procedure upon low-frequency oscillations in cutaneous blood flow velocity. *J Manipulative Physiol Ther*. 2006;29(8):626-636.

21. Milnes K, Moran RW. Physiological effects of a CV4 cranial osteopathic technique on autonomic nervous system function: a preliminary investigation. *Int J Osteopath Med*. 2007;10:8-17.

(continued)

Table 4.
Summary of Critical Appraisal Score* of the Included Studies According to the Downs and Black Checklist[9]

Checklist Criteria	Study							
	Hanten[14]	Hayden[15]	Sandhouse[16]	Sergueef[17]	Wyatt[18]	Cutler[19]	Nelson[20]	Milnes[21]
■ **Reporting**								
□ 1. Is the hypothesis/aim/objective of the study clearly described?	Y	Y	Y	Y	Y	Y	Y	Y
□ 2. Are the main outcomes to be measured clearly described in the introduction or methods section?	Y	Y	Y	Y	Y	Y	Y	Y
□ 3. Are the characteristics of the patients included in the study clearly described?	Y	Y	Y	N/U	Y	N/U	Y	Y
□ 4. Are the interventions of interest clearly described?	Y	Y	Y	Y	N/U	Y	Y	Y
□ 5. Are the distributions of principal confounders in each group of subjects to be compared clearly described?	N/U	Y	N/U	N/U	Y	N/U	P	P
□ 6. Are the main findings of the study clearly described?	Y	Y	Y	Y	Y	Y	Y	Y
□ 7. Does the study provide estimates of the random variability in the data for the main outcomes?	Y	Y	Y	Y	Y	Y	Y	Y
□ 8. Have all important adverse events that may be a consequence of the intervention been reported?	N/U	N/U	N/U	N/U	Y	N/U	N/U	N/U
□ 9. Have the characteristics of patients lost to follow-up been described?	N/U	N/U	N/U	N/U	Y	Y	N/U	N/U
□ 10. Have the actual probability values been reported?	N/U	Y	Y	Y	N/U	N/U	Y	Y
■ **External Validity**								
□ 11. Were the subjects asked to participate in the study representative of the entire population from which they were recruited?	N/U	Y	N/U	N/U	Y	N/U	N/U	N/U
□ 12. Were those subjects who were prepared to participate representative of the entire population from which they were recruited?	N/U	Y	N/U	N/U	Y	N/U	N/U	N/U
□ 13. Were the staff, places, and facilities where the patients were treated representative of the treatment the majority of patients received?	Y	Y	Y	Y	Y	Y	Y	Y
□ 14. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance was less than 5%?	N/U	N/U	N/U	N/U	Y	N/U	N/U	N/U

(continued)

* Y=1 point, N/U=0 points; P=0 points.
† Data dredging is the analysis of large volumes of data to find any possible relationship. In contrast, traditional scientific methods begin with a hypothesis and follow with an examination of the data.

Abbreviations: N/U, no/unable to determine; P, partially; Y, yes

Table 4 (continued).
Summary of Critical Appraisal Score* of the Included Studies According to the Downs and Black Checklist[9]

Checklist Criteria	Hanten[14]	Hayden[15]	Sandhouse[16]	Sergueef[17]	Wyatt[18]	Cutler[19]	Nelson[20]	Milnes[21]
■ **Internal Validity/Bias**								
□ 15. Was an attempt made to blind study subjects to the intervention they have received?	N/U	N/U	Y	Y	N/U	Y	N/U	N/U
□ 16. Was an attempt made to blind those measuring the main outcomes of the intervention?	N/U	N/U	Y	Y	Y	N/U	N/U	N/U
□ 17. If any of the results of the study were based on "data dredging,"† was this made clear?	Y	Y	Y	Y	Y	Y	Y	Y
□ 18. In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?	Y	Y	Y	Y	Y	Y	Y	Y
□ 19. Were the statistical tests used to assess the main outcomes appropriate?	Y	Y	Y	Y	N/U	Y	Y	Y
□ 20. Was compliance with the intervention(s) reliable?	Y	Y	Y	Y	Y	Y	Y	Y
□ 21. Were the main outcome measures used accurate (valid and reliable)?	Y	Y	Y	Y	Y	Y	Y	Y
■ **Internal Validity/Confounding**								
□ 22. Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?	N/U	Y	N/U	Y	Y	N/U	N/U	N/U
□ 23. Were the study subjects in different intervention groups (trial and cohort studies) or were the cases and controls (case-control studies) recruited over the same time period?	Y	N/U	Y	Y	Y	Y	Y	Y
□ 24. Were the study subjects randomized to intervention groups?	Y	Y	N/U	Y	Y	Y	N/U	N/U
□ 25. Was the randomized intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?	N/U	N/U	N/U	N/U	Y	N/U	N/U	N/U
□ 26. Was there adequate adjustment for confounding in the analysis from which the main findings were drawn?	N/U	Y	Y	Y	Y	N/U	N/U	N/U
□ 27. Were losses of patients to follow-up taken into account?	N/U	N/U	N/U	N/U	Y	N/U	Y	N/U
■ ***Total Score***	**14**	**19**	**17**	**18**	**23**	**15**	**15**	**14**

* Y=1 point, N/U=0 points; P=0 points.
† Data dredging is the analysis of large volumes of data to find any possible relationship. In contrast, traditional scientific methods begin with a hypothesis and follow with an examination of the data.

Abbreviations: N/U, no/unable to determine; P, partially; Y, yes