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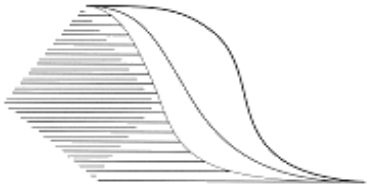

A SYSTEMATIC REVIEW AND CRITICAL APPRAISAL OF THE SCIENTIFIC EVIDENCE ON CRANIOSACRAL THERAPY

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Foreword

The British Columbia Office of Health Technology Assessment (BCOHTA) was established on December 1, 1990 by a grant to the University of British Columbia from the Province, to promote and encourage the use of assessment research in policy, planning and utilization decisions by government, health care executives, and practitioners. It is important to note that the role of the Office is to appraise the scientific evidence only, without involvement in actual policy development for the requesting agency.

Assessments are performed in response to requests from the public sector such as hospitals, physicians, professional associations, health regions, government; private sector groups such as manufacturers; and individuals from the general public. One or more of the following criteria are used to determine the priority of an assessment and the level of analysis: (1) number of users and potential change in quality of life; (2) acquisition and operating costs to the health care system; (3) potential to influence provider and consumer behavior as a result of a review; and (4) availability of accurate information and appropriate research skills.

Electronic bibliographic databases and fugitive literature (that is literature not indexed or distributed publicly) are searched using predefined inclusion and exclusion criteria based on the specific search strategy. The critical appraisal of the retrieved evidence includes the formulation of logical and defensible conclusions about the technology under study.

Health Technology Assessment projects are conducted by faculty and staff (including medical consultants) who are expert in systematic review methodology. Reports are reviewed internally, and then sent to experts from a variety of academic or clinical disciplines for external review. Comments and suggestions are considered before a final document is produced. Distribution of reports is by request from the Office or through inclusion on our mailing list.

The strength of BCOHTA's method of systematic review lies in the process of explicitly detailing the methodology and criteria used to produce recommendations which are based solely on the research evidence. This transparent and reproducible assessment process allows readers to review the evidence objectively for themselves. The ensuing reports are available for public distribution.

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Introduction to the Series

The Joint Heath Technology Assessment Series reports on projects initiated by the British Columbia Office of Health Technology Assessment (BCOHTA) and evidence-based medicine programs in BC. Dedicated to producing unbiased, systematic reviews of clinical efficacy and effectiveness evidence for health care providers, administrators, policy makers, and the general public, these programs currently include:

- Therapeutics Initiative (TI), Department of Pharmacology and Therapeutics, Faculty of Medicine, University of BC, Vancouver
- Technology Assessment Committee, Capital Health Region, Victoria
- Drug Benefit Committee, Pharmacare, and ad hoc Health Technology Assessment Committees, the Ministry of Health and Ministry Responsible for Seniors, Victoria
- Technology Assessment Committee, Workers' Compensation Board of BC, Richmond
- Population Testing Programs, Boundary Health Unit, South Fraser Health Unit, Surrey
- BC Research Institute for Child and Family Health, BC Women's and Children's Hospital, Vancouver
- Centre for Clinical Epidemiology and Evaluation, Vancouver Hospital and Health Sciences Centre, Vancouver
- Public Health Nursing, Boundary Health Unit, South Fraser Health Unit, Surrey
- Cancer Control Research Program, BC Cancer Agency

Topics reflect initiative and institutional needs. Priority is given to topics with significant impact on patient health and health care costs, and with issues in more than one context. The goal of the *Series* is both to demonstrate systematic review and critical appraisal skills, and to co-ordinate research efforts within contexts that are geographically separate and institutionally diverse.

The *Series* addresses two different types of evidence-based medicine issues:

1. Uncertainty regarding new technology;
2. Discrepancy between evidence and practice for established technology.

The *Joint HTA Series* will produce scientifically valid systematic reviews, supported by key individuals in each receptor site. These individuals are able to present and defend the systematic review conclusions during ongoing committee debates. This is an essential step if health policy and funding decisions are to be connected to the available efficacy and effectiveness evidence.

Preface

This systematic review and critical appraisal of craniosacral therapy, conducted in collaboration with the Workers' Compensation Board of British Columbia (WCB), is based on a systematic search of literature until February 2nd 1999. Systematic reviews are scientific investigations which use pre-planned methods to study as their 'subjects' an assembly of original studies. Comprehensive search methods and explicit, reproducible selection criteria are among strategies to limit bias and random error. (Mulrow & Cook 1998)

The Workers' Compensation Board has frequently to consider payment for or endorsement of health technologies, clinical treatments, assessments or diagnostic procedures, and in order to a make a proper evaluation of these elements, a Technology Assessment Committee (TAC) has been established within the WCB Rehabilitation Division. The TAC utilises a formal process of scientific evaluation, applying the established techniques of critical appraisal and evidence based medicine. The British Columbia Office of Health Technology Assessment (BCOHTA) has assisted the TAC in developing a process for systematic review, producing scientific conclusions which are subsequently available to the WCB in its development of policy and practice.

EXECUTIVE SUMMARY

OVERALL CONCLUSIONS

This systematic review and critical appraisal did not find valid scientific evidence that craniosacral therapy provides a benefit to patients. Research methods are available which could conclusively evaluate craniosacral therapy effectiveness. They have not been used to date. The available health outcome research consists of low grade of evidence derived from weak study designs.

Studies conducted in the 1970s reporting acceptable interrater reliability scores for assessment measures used by craniosacral therapy practitioners have not been verified by more recent research using stronger study protocols. This casts doubt on the existence of the underlying phenomenon being measured, or on practitioners' ability to measure it. Adverse events have been reported in head-injured patients following craniosacral therapy.

What is craniosacral therapy?

Craniosacral therapy does not have a standard definition in the literature, nor is a single definition formulated for the purposes of this review. It seems generally accepted by proponents that movement restrictions at the cranial sutures of the skull may negatively affect rhythmic impulses conveyed through the cerebral spinal fluid which surrounds the central nervous system from the cranium to the sacrum. All structures which are in contact with the cerebral spinal fluid, including the brain, the spinal cord, and their protective membranes, are seen as part of the cranio-sacral system and potentially affected by it.

Proponents assert that mobility restrictions or misalignments along the cranial sutures will disturb rhythmic flows of the cerebrospinal fluid, having in turn an adverse effect on health. Manual intervention, it is argued, has the ability to restore normal function within this system.

Craniosacral therapy is said to achieve beneficial health outcomes for a wide range of conditions varying from musculoskeletal problems, sinusitis, trigeminal neuralgia, colic and birth trauma to learning difficulties. A variety of health care practitioners, including chiropractors, physical therapists, physicians, massage therapists, and dentists may provide craniosacral therapy interventions as part of their services. The extent to which this occurs in British Columbia is not precisely known

although craniosacral therapy training programs are available to licensed practitioners such as massage therapists, within and outside regulated training programs.

Objective of review

Third party payers, such as the Workers' Compensation Board of BC (WCB), have recently begun to require assessment of the effectiveness of these techniques. The WCB and the British Columbia Office of Health Technology Assessment consequently undertook a joint systematic review of this regimen. The objective of the review, which forms the subject of this report, was to gather and critically appraise the scientific basis of craniosacral therapy as a therapeutic intervention.

Search strategy

Medline, Embase, Healthstar, Mantis, Allied and Alternative Medicine, Scisearch and Biosis electronic bibliographic databases were searched from their starting date to February 1999. Search terms were 'craniosacral', 'cranial bones,' 'cranial sutures,' 'cerebrospinal pulse' and 'cerebrospinal fluid.' A non-electronic "fugitive" literature search was conducted, and retrieved articles were also scanned for relevant citations. Studies were included if they met the following pre-determined criteria: 1) primary data on any manual manipulation of the cranial sutures of the skull termed by the researchers as craniosacral therapy for the purpose of effecting health benefits; or 2) any primary research on any facet of the craniosacral system put forward in the literature on craniosacral therapy as providing relevant evidence.

FINDINGS

Thirty four studies provided primary data on craniosacral therapy. The studies were categorized and critically appraised within a three-part evaluative framework.

Craniosacral treatment effectiveness

Seven studies of craniosacral therapy effectiveness were identified, retrieved and critically appraised. Study designs were retrospective case control (Phillips & Meyer '95), retrospective case series (Blood '86; Greenman & McPartland '95), before-after (Frymann et al. '92) and case reports (Baker '71; Hollenbery & Dennis '94; Joyce & Clark '96).

Using the Canadian Task Force on Preventive Health Care grades of evidence (Dingle '94), all identified studies can be classified as Level 3 — the lowest grade of evidence. Therefore the benefits of craniosacral therapy on health outcomes have not been demonstrated using research with sufficiently strong study designs and protocols. Not only is there an absence of efficacy evidence, the available research is of methodologically poor quality. Finally, adverse effects were reported when craniosacal therapy was used in brain injured outpatients.

Agreement by practitioners on craniosacral assessment findings

Five studies provided primary data on the assessment of craniosacral dysfunction by craniosacral therapy practitioners (Upledger '77; Upledger & Karni '79; Wirth-Pattullo & Hayes '94; Hanten et al. '98; Rogers et al. '98). These studies have found that assessment of craniosacral dysfunction by this group of practitioners is unreliable; that is, two or more assessors do not agree to the extent required by scientific measures.

Pathophysiology of craniosacral dysfunction

1. The potential association between health and craniosacral mobility restrictions

Three studies (Frymann '66, Upledger '78, White et al. '85) directly examined the association between craniosacral mobility and cerebrospinal fluid flow, and health. The quality of the available research is however poor, and therefore the reliance that can be placed on the reported results is limited. These studies provide very weak evidence of a causal relationship between restrictions or misalignments in the movement of cranial bones, and health.

Other researchers have conducted studies that contribute evidence on the links in the causal chain potentially connecting craniosacral mobility restrictions to health outcomes. They investigated: 1) the existence of movement between cranial bones; and 2) the existence of rhythmic flow patterns in cerebrospinal fluid. Proponents use this literature to support craniosacral system theory. Sceptics meanwhile deny the existence of any significant bone movement or the influx of craniosacral flow.

2. Motion/fusion between cranial bones

Nine studies reported on mobility or fusion at cranial sutures in adults (Greenman ’70; Frymann ’71; Hubbard et al.’71; Kokich ’76; Heifetz & Weiss ’81; Pitlyk et al. ’85; Kostopoulos & Keramidas ’92). Although incomplete, the research evidence reviewed supports the theory that the adult cranium is not always solidly fused, and that minute movements between cranial bones may be possible. However, no research demonstrated that movement at cranial sutures can actually be achieved through manual manipulation.

3. Cerebrospinal fluid rhythmic flow patterns

Eleven studies reported primary data on the motion of cerebrospinal fluid (O’Connell ’43; Du Boulay et al. ’72; Cardoso et al. ’83; Takizawa et al. ’83; Avezaat & van Eijndhoven ’86; Enzmann et al. ’86; Feinberg & Mark ’87; Ursino ’88 1 & 2; Zabolotny et al. ’95; and Li et al. ‘96). None of these studies contributed to the knowledge of craniosacral therapy. This set of studies provides evidence on the pathophysiologic mechanisms pertaining to CSF motion for diagnosis, treatment and monitoring of brain injury and other neurological disorders. The retrieved studies verify that CSF movement and pulsation is a clearly observable phenomenon measurable by encephalogram, mylogram, magnetic resonance imaging and intracranial and intraspinal pressure monitoring. Furthermore, the research evidence supports the contention that there is a cranial “pulse” or “rhythm” distinct from cardiac or respiratory activity. However, changes in CSF due primarily to brain injury are not linked to health outcomes.

1.0 INTRODUCTION

Defining Craniosacral Therapy

Since William Garner Sutherland's [1] first impressions of cranial bone movement in the early 1930s, the literature on craniosacral therapy has expanded significantly. A systematic review of this literature found many definitions, nomenclature and beliefs surrounding the general concept of cranial bone motion. [2-4] Indeed, it is difficult to establish any one specific definition of craniosacral therapy. It is variously defined as:

> "*a systemic approach to evaluating and treating dysfunction occurring within the articulations of the skull*" [5]

and

> "*craniosacral… includes a structured diagnostic process that evaluates the mobility of the osseous cranium, the related mobility of the skull and sacrum and the palpation of the CRI (craniosacral rhythm impulse) throughout the body. Craniosacral osteopathic manipulative techniques attempt to restore motion to restrictions within individual sutures of the skull, the skull as a total entity, and the skull in relation to the sacrum, and apply inherent force to the articulations of the vertebral axis, rib cage and extremity.*" [6]

Upledger JE, a prolific contributor to this literature since the early 1970s, has expanded the initial osteopathic approach of evaluation and treatment of skull articulation dysfunction to one of holistic patient evaluation and treatment. A central concept in the current approach is that of a craniosacral "rhythm", independent of respiration or cardiac activity, that can be detected anywhere in the body, but most accurately in the cranial and sacral regions.

Objective of Review

Recognizing the lack of consensus as to exactly what craniosacral therapy encompasses, the authors of this review elected to adopt as broad a definition as possible. Craniosacral therapy is taken to include any means of assessment, evaluation or alteration of the craniosacral system as defined by the

practitioners and researchers providing primary data. The objective of this review is to gather and critically appraise the scientific basis of craniosacral therapy as a therapeutic intervention.

Current utilization

Craniosacral practitioners (who include physiotherapists, chiropractors, dentists, and osteopathic, medical or naturopathic physicians, as well as other licensed and unlicensed health care practitioners) suggest that gentle pressure on the craniosacral system may benefit patients with various musculoskeletal problems, as well as learning difficulties, sinusitis, trigeminal neuralgia, colic and birth trauma, to name only some. [7-9]

In British Columbia, relatively few practitioners identify craniosacral therapy as part of their practice. However, because this treatment modality is practised within the confines of what many therapists describe as an "office visit", the actual utilization of this type of therapy in British Columbia is unknown.

As one of a number of therapeutic interventions with the potential to affect WCB patients, cransiosacral therapy was selected as being suitable for priority review under the criteria set out in **Table 1**.

Table 1. Prioritizing criteria as applicable to craniosacral therapy

CRITERIA	EXTENT TO WHICH CRITERIA MET
1. Number of users	Potentially all WCB patients
2. Potential change in health outcomes	A decrease in the morbidity secondary to work related injuries
3. Acquisition and operating costs to the health care system	WCB rehabilitation related reimbursements for the services of physiotherapists, massage therapists and chiropractors
4. Potential to influence provider and consumer behaviour as a result of a review	Potential points of influence are the professional regulatory bodies, reimbursement and provider decisions
5. Availability of accurate information and appropriate research skills	Some scientific evidence is available that is not expected to exceed the resources of the committee

Scope of review

In an effort to retrieve a significant amount of material, the search strategy was designed to be as inclusive as possible without forsaking the scientific process and dependable critical appraisal techniques found in systematic review articles.[10]

The literature was diverse and difficult to classify from a scientific standpoint. An evaluative framework was developed to accommodate it, using the following dimensions:
A) pathophysiological mechanisms of the craniosacral system; B) validity of craniosacral assessment; C) craniosacral interventions and health outcomes.

Since it was clearly essential to establish and review as many "links" as possible in the theoretical model of the craniosacral system, it would be a disservice to the readers of this review to focus on intervention without undertaking critical review of the basic pathophysiology. Research evidence, for and against pathophysiological mechanisms, is put forward in debate on the existence and nature of this physiological or biochemical mechanism.

An essential aim of the present review was to see whether a stepwise sequence of evidence could be established, leading from basic processes to the clinical trial or other therapeutic intervention. To use an analogous example, it would be similarly important to develop an understanding of the renin-angiotensin-angiotensinogen system in order to establish why a particular ACE inhibitor is of benefit to a defined group of hypertensive patients. Without such evidentiary "links", it would be inappropriate in these models to regard any gaps in the evidence as either defensible or indefensible.

2.0 METHODOLOGY

The search was not limited to any specific craniosacral therapeutic technique, research design, health condition, or health outcome.

2.1 CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

i) Participants

Any person with a physical or mental problem of any age group.

ii) Intervention

Any manual manipulation of the cranial sutures of the skull for the purpose of effecting health benefits.

iii) Primary Research

Any primary research on any facet of the craniosacral system.

iv) Outcome measures

Any measurement pertaining to either assessment of cranial bone motion preliminary to craniosacral therapy or to the intervention itself.

v) Types of studies

All research designs involving humans. Systematic reviews of the literature and integrative analysis (for example, cost-effectiveness analysis) will also be considered.

vi) Language

Articles in languages other than English were included.

2.2 SEARCH STRATEGIES FOR IDENTIFICATION AND RETRIEVAL OF INFORMATION

Following outlines by Counsell [11] and Mulrow & Cook [12], several complementary and overlapping search strategies were adopted in this review. Publications were chosen from a DIALOG search of seven databases covering traditional medical literature (Medline 1966-1998, Embase 1976-1998, Healthstar 1975-1997), alternative medical literature (Mantis 1880-1998, Allied and Alternative Medicine 1984-1998), and research-oriented biological literature (Scisearch 1974-1998, Biosis 1969-1998). This selection of databases ensured coverage of European, North American and some Asian journals.

Terminology was discussed by committee members. A subgroup refined these terms. Search terms were selected in order to reflect the diverse terminology used to refer to craniosacral therapy. Keywords such as "craniosacral":, "cranial bones", and "cranial sutures" were combined with "therapy", "therapist", "practitioner", "massage", "mobilization", "manipulation", "motion" and "movement", and were searched throughout the body of the record. Search terms such as "clinical studies", or "randomized trials" were found to be overly restrictive for a non-mainstream therapy, and were therefore not applied. Further searching was done on title keywords for "cerebrospinal pulse" and "cerebrospinal fluid". John E. Upledger, a major contributor in this field, was searched as author and cited source.

References of retrieved articles were reviewed by all three authors to identify further relevant citations.

Limitations of this search strategy include the fact that many electronic databases are by their nature date-restricted. In general, electronic databases do not cover literature prior to the mid 1970s.

The search results were reviewed by committee members. Inclusion criteria **(2.1**) were applied by two reviewers. Disagreements were resolved by discussion. All articles that met the criteria were requested in full text form, and were appraised by two reviewers independently. Following receipt of external reviewers' comments, further articles were obtained. **Appendix A.** provides a record of the online search strategy and fugitive sources. **Appendix B.** lists the articles obtained.

2.3 FUGITIVE LITERATURE SEARCH

A search of the library catalogue of the University of British Columbia and Trace-it, a Canadian union catalogue, was also undertaken. Literature, reports, research papers and information in general were requested from a number of professional associations (College of Physical Therapists of BC, BC Naturopathic Association, Registered Nurses Association of BC, Massage Therapists Association of BC, College of Physicians and Surgeons of BC, BC Medical Association and College of Dental Surgeons of BC, and the Insurance Corporation of BC).

The Cochrane Library CD Rom database was reviewed, as were the Internet Web sites of Bastyr University, British Columbia Office of Health Technology Assessment, the Canadian Coordinating

Office of Health Technology Assessment, the Craniosacral Therapy Association and the Institute for Craniosacral Integration.

2.4 EVALUATIVE FRAMEWORK

An evaluative framework of three dimensions was specifically developed for assessing research evidence on craniosacral therapy. Extending previous work in this area,[13-15] pathophysiology was added as a dimension. This aspect is of particular importance to the evaluation of complementary therapies, since deficiencies in understanding or acceptance of underlying mechanisms continues to fuel debate on the evidence.[16]

Each reviewed article was placed in one of the following three categories by the two main reviewers:

A. Pathophysiological mechanisms of craniosacral dysfunction

B. Craniosacral assessment

C. Craniosacral treatment/interventions

Critical appraisal criteria were applied by each reviewer independently, compared, and disagreements resolved by discussion.

2.4.1 Category A: Evidence relating pathophysiology of craniosacral dysfunction to poor health outcomes

All structures in contact with the cerebral spinal fluid (CSF), including the brain, the spinal cord, and their protective membranes, are seen as part of the cranio-sacral system and potentially affected by it. In theory, movement restrictions at the cranial sutures of the skull negatively affect rhythmic impulses conveyed through the cerebral spinal fluid which surrounds the central nervous system from the cranium to the sacrum. All other structures in the body are potentially affected through innervations arising from or returning to the central nervous system, or mechanically through direct effects on the mobility of the rest of the musculo-skeletal system.

Evidence was sought that might show a causal relationship between restrictions and misalignments in the movement of cranial bones, and health. The basic features of associations that support causation, outlined by Hill [17] (**Table 2**), were applied to the available evidence.

Table 2. Criteria for examining a causal relationship (Hill 1978) [17]

CAUSATION CRITERIA
• Strength of association • Consistency of the observed evidence • Specificity of the relationship • Temporality of the relationship • Biological gradient of the dose-response • Biological plausibility • Coherence of the evidence • Experimental confirmation • Reasoning by analogy

Pathophysiological studies supplying experimental evidence on the relationship between craniosacral system dysfunction and poor health outcomes were critically appraised. Relatively non-specific criteria of research quality as defined in the literature were applied. **Table 3** gives the general principles of the scientific research design considered.

Table 3. Appraisal principles applied to research design

PRINCIPLES APPLIED
• Was the research design appropriate? • Were sampling techniques representative? • Were the outcome measures reliable and valid? • Were the methods of analysis appropriate?

2.4.2 Category B: Evidence evaluating the validity of diagnosing craniosacral system dysfunction

Craniosacral assessments are the means by which dysfunction in the craniosacral system is "diagnosed". Therefore, research methods for comparing the performance of diagnostic tests to a gold

standard test apply. Sackett et al.[18] have described how articles of this nature may be reviewed, and their eight "guides" were adopted.

Following Sackett et al. [18], evidence on the performance characteristics of cranio-sacral assessment methods were appraised where available, including sensitivity, specificity, predictive values, and the consequences of false positive and false negative results.

The most fundamental of all scientific processes is observation, which must, as with all scientific activities, be made in accordance with accepted standards. Such standards strive primarily to ensure *objectiveness*, which in turn comprises two dimensions: (1) protection against bias (such as, ensuring replicability of observations by multiple independent observers); and (2) independence of the theoretical basis of observation from the theory tested by observation. With respect to the former, evidence was appraised following Feinstein's principles for appraising evidence in observer variability. [19] (**Table 4**).

Table 4. Appraisal of evidence on observer variability (Feinstein 1985) (19)

- ***Purpose****:* Was the goal of the research clearly specified? Was it to demonstrate or to remove observer variability?
- ***Input challenge:*** Was the group of specimens or subjects suitably representative of both the customary group and the scope of entities exposed to this procedure?
- ***Procedural components:*** Was the research aimed at the instrumental methods, the performing observers, or both? If the research was aimed at only one of these components, was the other component suitably standardized?
- ***Observations:*** Were they made independently or, if necessary, "blindly"?
- ***Observers:*** Were they appropriately competent and suitably chosen for performing the procedure?
- ***Scale of reporting output:*** Was the scale expressed in a satisfactory manner? Was it chosen and agreed upon before the research began? Should it have been chosen beforehand?
- ***Scale of disagreement:*** Was a suitable scale desirable or necessary for describing the disagreement between any two readings? If so, was such a scale developed and was it satisfactory? If each specimen received more than two readings (i.e., multiple observers), how did the investigators deal with an index of multiple disagreement?
- ***Index of concordance:*** Were the results expressed in a suitable statistical index of concordance? Did it make provision for agreement that might have occurred by chance alone?
- ***Procedural criteria:*** Were criteria stated or developed for the first-phase process of converting observations into raw data?
- ***Interpretation criteria:*** Were criteria stated or developed for the second-phase process of converting the raw data into the output scale of interpretation?
- ***Analysis:*** Was the source (or sources) of variability identified by evaluating disagreements in basic raw data as well as in categories of interpretation?
- ***Improvements:*** Were attempts made to have the observers confront their disagreements and try to determine (or remove) the sources of dissent?
- ***Recommendations:*** Were any suggestions made about how to improve the defects that were noted?

2.4.3 Category C: Evidence pertaining to the effect of craniosacral therapeutic interventions on health outcomes

Evidence on the safety, efficacy and effectiveness of craniosacral therapeutic interventions were appraised using two sets of criteria. First, the study design was graded according to the Canadian Task Force on Preventive Health Care: grades of evidence* [20] (**Table 5**). Second, studies were appraised using standard BC Office of Health Technology Assessment Intervention Study Appraisal Form (**Appendix C.**).

Table 5. Canadian Task Force on Preventive Health Care: Grades of Evidence [20]

GRADE	EVIDENCE
I	Evidence obtained from at least one properly randomized controlled trial.
II-1	Evidence obtained from well-designed controlled trials without randomization.
II-2	Evidence obtained from well-designed cohort or case control analytic studies, preferably from more than one centre or research group.
II-3	Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.
III	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

* Formerly The Canadian Task Force on the Periodic Health Examination. The same grades of evidence have been adopted by the U.S. Preventive Services Task Force.

3.0 RESULTS

Thirty four studies were identified that provided primary data relevant to craniosacral therapy. These were categorized according to the pre-selected evaluation framework (**Table 6**).

In addition, abstracts by Tettambel et al. '78,[21] Norton et al. '92a & '92b,[22] Sibley et al. '92[23] and a letter by Upledger et al. '78[24] were retrieved and examined. However, these latter studies did not subsequently appear in the searched bibliographic databases as complete reports and did not include enough information to permit critical appraisal. They therefore do not appear in the subsequent analysis.

3.1 CATEGORY A: EVIDENCE RELATING PATHOPHYSIOLOGY OF CRANIOSACRAL DYSFUNCTION TO POOR HEALTH OUTCOMES

The survey of research regarding pathophysiology, that is, mechanisms linking craniosacral dysfunction to poor health outcomes, identified 22 studies which reported primary data. This material was divided into three categories. The first category included 3 studies which aimed to provide direct evidence on the effect of craniosacral dysfunction on health; the other studies in this group reported data that provided indirect evidence. The second category included reports on the existence of movement between cranial bones (9 studies). The third category included evidence on the existence of cerebrospinal fluid movement (10 studies).

3.1.1 Studies directly relating craniosacral mobility restrictions to health status.

Studies by Frymann '66,[25] Upledger '78,[8] and White et al. '85[26] had the research objective of provided direct evidence of an association between craniosacral dysfunction and poor health outcomes. These studies are described in **Table 7**. Two of the three studies were cross-sectional studies, that is, assessment of the craniosacral system and health outcomes were measured at the same point in time. The third study was observational. However, insufficient description of the methodology in the latter study precluded further classification.

Table 6. The overall results of the systematic review for primary data on craniosacral therapy

A. PATHOPHYSIOLOGY OF CRANIOSACRAL DYSFUNCTION			B. CRANIOSACRAL ASSESSMENT	C. CRANIOSACRAL TREATMENT
Is there an association between health and craniosacral mobility restrictions?	**Is movement between cranial bones possible?**	**Does cerebrospinal fluid move rhythmically?**	**Can practitioners agree on craniosacral evaluation findings?**	**Is craniosacral treatment effective?**
Frymann '66 [25]	Todd & Lyon '24 [27,28]	O'Connell '43 [29]	Upledger '77 [30]	Baker '71 [31]
Upledger '78 [8]	Baker '71 [31]	Du Boulay et al. '72 [32]	Upledger & Karni '79 [33]	Blood '86 [34]
White '85 et al. [26]	Greenman '70 [3]	Cardoso et al.'83 [35]	Wirth-Pattullo & Hayes '94 [36]	Frymann et al.'92 [9]
	Frymann '71 [2]	Takizawa et al. '83 [37]	Hanten et al. '98 [38]	Hollenbery & Dennis '94 [7]
	Hubbard et al. '71 [39]	Avezaat & van Eijndhoven'86 [40]	Rogers et al. '98 [41]	Greenman & McPartland '95 [6]
	Kokich '76 [42]	Enzmann et al. '86 [43]		Phillips & Meyer '95 [44]
	Heifetz & Weiss '81 [45]	Feinberg & Mark '87 [46]		Joyce & Clark '96 [47]
	Pitlyk et al. '85 [48]	Ursino '88 [50] (Parts 1 & 2)		
	Kostopoulos & Keramidas '92 [49]	Zabolotny et al. '95 [51]		
		Li et al. '96 [52]		

Table 7. Research pertaining to the relationship between health and restrictions in the mobility of the "craniosacral system"

Study	Purpose	Design	Population/ sampling technique	Measure of health	Measure of craniosacral mobility restrictions	Analysis
Frymann '66 [25]	To explore the possibility of a relation between symptomatology in newborn infants and anatomic-physiologic disturbances of the craniosacral mechanism.	Cross-sectional	1,250 newborns	Health classifications: asymptomatic, jaundice-mongoloid, nervous, respiratory and circulatory problems	Strain patterns of sphenobasila, temporal, occipital and sacral articulations	Incidence rates
Upledger '78 [8]	To determine if there is a relationship between restricted mobility of the craniosacral system and developmental problems in grade school children.	Cross-sectional	203 children whose parents responded to invitation	Not normal, behavioural problems and learning disabled classes used	Craniosacral motion restriction scores	Correlation coefficients with p values
White et al. '85 [26]	To analyze the systemic effects arising from the relative craniofacial bone positions, specifically the cause and effect relationships between relative mandibular and maxillary positions and the specific dysfunctions that they produce.	Observational	No patient description or sample size reported	None	X-ray, plaster study models and liquid crystal thermography	No statistical analysis

Research Quality

The quality of the available research relating craniosacral dysfunction to health outcomes is poor. The reliance that can be placed on the reported results is therefore limited. A cross-sectional study design may be suitable for obtaining evidence on associations. The study protocols used by these researchers, however, inadequately describes study enrolment and population characteristics. Stronger evidence would be provided by study designs which collect measurements serially and prospectively over time.

Another major appraisal issue pertaining to these studies is the adequacy of both health outcome and craniosacral mobility measurement. The validity and reliability of subjective methods for classifying craniosacral movement restrictions is especially problematic. No validation studies have been conducted to demonstrate that craniosacral assessment "measurements" do in fact measure what they are intended to. Available research on interrater reliability has not been able to demonstrate reliability (see evidence on assessment below, **3.2**). In the studies by Frymann [25] and Upledger, [8] health states were subjectively determined, no explicit classification criteria were used to establish content validity, and categories were arbitrary, lacking face validity.

The Upledger study was particularly questionable since classification was undertaken by parents, educators and a variety of health care providers, but no assessment of agreement amongst them was carried out. A critical appraisal of the Upledger '78 [8] study design conducted by an osteopathic physician found that "no justifiable conclusions can be drawn from the paper." [53]

Summary

A causal relationship between restrictions/misalignments in the movement of cranial bones and health has not been demonstrated. Moreover, although the validity of the available research is important, it is not the only issue. Using Hill's criteria (**Table 2**) for examining a causal relationship, we note specifically that these studies lack any reasonable suggestion of a significant strength of association, experimental confirmation, specificity of relationship, and/or consistency of observed evidence presented in the studies. Moreover, no mention, either explicit or implied, allows the reader of these studies to conclude that Hill's features of biological gradient/dose response or temporality of the relationship have adequately been met.

3.1.2 Studies looking at surrogate measures of motion/fusion of the cranial sutures in adults.

Nine studies reported on mobility or fusion at cranial sutures in adults (**Table 8**). These studies were cited in debate between proponents and sceptics within professional groups. Sceptics argue that the sutures of the skull are fused in adults, and that it is therefore not possible to change alignment. Craniosacral therapy practitioners claim the opposite.

Given that the available literature reviews which informed the discussions were not systematic, and that citations were obtained from articles favouring craniosacral therapy, there may have existed some bias towards presenting evidence in favour of cranial bone mobility. The review was therefore repeated here.

Research Quality

The quality of the available evidence was variable, as were the study designs used. The major appraisal issues include the strength of the research design, the representativeness of study populations, and validity of measurement techniques. Most of the study designs were appropriate only for hypothesis generation and were not aimed at evaluating any causal association. Conclusive evidence of a causal association would require study of human subjects representative of an identifiable population and a valid measurement of suture mobility.

Five of the studies were performed on human cadaverous skulls, although evidence that cadavers are sufficiently similar to the living state to be valid surrogates was not presented. In fact, Pitlyk et al. (1985) [48], in attempting to measure changes in bitemporal skull dimensions in human cadavers, found it was not possible to elevate intracranial pressure, and accordingly abandoned the research. The Kostopoulos & Keramidas (1992) [49] study was the only one that applied craniosacral therapy techniques to a cadaver and then attempted to measure movement. The validity and reproducibility of those measurements were not demonstrated. The study by Hubbard et al. (1971) [39] applied bending as well as failure tests to samples of cranial bone. They concluded that cranial sutures do "move" more than layered cranial bone, but that they show similar strengths when subject to failure testing.

The study that is frequently cited in support of cranial suture fusion in adults was reported in 1924 (Todd & Lyon). [27,28] However, this study suffered from a serious selection bias, in that

Table 8. Research pertaining to the mobility of cranial bones

Study	Purpose	Design	Population/ sampling technique	Outcome measures	Analysis
Todd & Lyon '24 [27,28]	Determination of at least the general features of suture closure	Human cadaver research	Convenience sample of 514 skulls age to 84 classified by sex and race (black/white)	"Broca's arrangement of complication of sutures, degrees of closure and subdivision of particular sutures"	No statistical analysis
Baker '71 [31]	Not stated but study concluded that "head bones moved along their sutures"	Case report (n=1) before/after observational study	1 male with traumatic malocclusion	Serially measured models of maxillary teeth over 6 months	Distance between molars compared with measurement error
Greenman '70 [3]	To develop a method of identifying altered craniosacral mechanics and of correlating the findings with clinical observations	2 case reports	25 human subjects selection criteria not described	x-ray and clinical assessment	Proportion of clinical observations which agreed with x-ray observations
Frymann '71 [2]	To demonstrate a cranial motility slower than and distinguishable from the motility of the vascular pulse and thoracic respiration and that such motion can be recorded instrumentally	Case series	12 tracings from humans Study population not described	An oscillograph and transformers were used to detect minute expansile-contractile motions of the live cranium	Tracings provided
Hubbard et al. '71 [39]	To determine the flexural stiffness and strength of cranial sutures	Human cadaver research Layered beam theory used to compare stiffness of cranial sutures with model	11 embalmed and fourteen unembalmed samples from 3 cadavers	Tension-compression load cell and linear variable differential transformer recorded using oscilloscope and photographs	Compliance (mid-span deflection due to a unit load) compared to model

Table 8. - Continued

Study	Purpose	Design	Population/ sampling technique	Outcome measures	Analysis
Kokich '76 [42]	To describe the age-related changes leading to frontozygomatic sutural fusion in adult human beings	Human cadaver research	61 human specimens ranging in age from 20 to 95 years	Histologic, radiographic and gross techniques	No statistical analysis
Heifetz & Weiss '81 [45]	To see if the expansion of the calvaria with elevated intracranial pressure could be detected in the living state	Intracranial pressure was increased in 19 trials by raising bilateral jugular compression or infusing Ringer's lactate solution into the ventricles	2 comotose patients, a 24-year-old woman and a 48-year-old man with severe brain-stem contusions	Strain gauge transducer as part of a Wheatstone bridge with a Fisher-type intraventricular catheter attached to a transducer and polygraph	Average voltage change
Pitlyk et al. '85 [48]	To reliably measure changes in the bitemporal skull dimension with changes in intracranial hydrostatic pressure	Human cadaver research	Researchers abandoned human cadaver research and finished with dogs	20-40 ml of saline rapidly injected into the cranial vault while data from monitoring instrument collected	Correlation of signals from instrument with volume of saline
Kostopoulos & Keramidas '92 [49]	To determine the degree of relative elongation of the falx cerebri of an embalmed cadavar during the application of craniosacral therapy techniques	Human cadaver research	Embalmed cadaver of 6 month duration	Changes in elongation of falx cerebri	Four observations per technique were averaged

skulls were eliminated in which closure of sutures was 'delayed'. In this respect, this classic study confirms that in some adults, fusion had not occurred. A similar study using contemporary methods applied to one cranial suture reported that fusion did not occur until the ninth decade.

Four studies with live subjects were identified (Baker 1971 [31]; Greenman 1970 [3]; Frymann 1971 [2]; Heifetz & Weiss 1981 [45]) each using a different method of measuring cranial bone movement. Neurosurgeons Heifetz & Weiss (1981) used the most sophisticated and invasive measurement technologies in two comotose patients, in an effort to detect skull expansion associated with increased intracranial pressure. Raising intracranial pressure is not comparable to manual craniosacral therapy techniques; nonetheless this study does provide evidence that minute movements at cranial sutures are detectable.

Using less invasive technologies, Frymann (1971) [2] made electronic tracings of cranial bone motion which were compared to similar tracings of respiratory and pulse rates, and claimed to demonstrate that the rhythmic motions of the cranium were distinct from the others. The study was poorly described, however, and the quality of study design and observations cannot therefore be validated. Greenman (1970) [3] correlated x-ray with clinical observations. The measurement of the clinical observations has not been validated (see **3.2** below). Similarly, the x-ray techniques used to identify altered craniosacral mechanics have not been validated, nor has the concept of a gold standard been reviewed. Greenman notes the poor yield of reports of the x-ray appearance of altered cranial structures. Finally, Baker (1971) [31] presented a case report that resulted from a collaboration between a dentist and an osteopathic physician. In one patient with malocclusion, serial models of maxillary teeth over 6 months showed a difference in the distance between molars, leading the author to conclude that "head bones moved along their sutures".

Summary

The research evidence supports the theory that the adult cranium may not always solidly fuse, and that minute movements between cranial bones are possible. However, the one case report [31] that examined craniosacral therapy technique did not demonstrate that movement at cranial sutures can be achieved manually.

The craniosacral therapy literature does not show that the position of cranial bones can be altered manually in adults, nor does it demonstrate that cranial bones are immobile. As noted above, minute movements appear to be possible. To make the link between these small movements at cranial sutures in some individuals and beneficial health outcomes, however, it is necessary to establish further links in the chain of evidence: this movement must be achievable manually; and that any such movement must affect health. These links have not been established to date, although it is not beyond the capability of scientific methods to provide more definitive proof on this research question.

This set of studies represents citations from the reference list pertaining to craniosacral therapy. It is, therefore, inclusive only of this literature subset. It does not represent all available literature contributing to evidence on the subject of cranial suture mobility. A reasonably exhaustive systematic review specifically designed to retrieve all the available evidence on cranial bone motion/fusion over the lifespan would be required, if a definitive statement is to be made on the state of knowledge on this question. This was beyond the scope of the current report.

3.1.3 Studies looking at motion of cerebrospinal fluid (CSF)

Ten studies were identified and retrieved reporting primary data on the motion of cerebrospinal fluid (CSF) (**Table 9**). None of these studies was undertaken to contribute to the knowledge of craniosacral therapy. Rather, this set of studies represents research carried out to provide neurosurgeons with data on the pathophysiologic mechanisms pertaining to CSF motion for diagnosis, treatment and monitoring of brain injury and other neurological disorders.

Research Quality

The research quality was variable. The methodological strength of a number of the studies is that they used measurement tools capable of producing valid and reproducible observations, for example: intracranial pressure monitoring (O'Connell [29]; Cardoso et al.[35]; Takizawa et al.[37]; Li et al.[52]); magnetic resonance imaging (Enzmann et al.[43]; Feinberg & Mark [46]); and encephalograms/myelography (Du Boulay et al.[32]). The consistency of the observed phenomena, and the fact that these studies arise from a discipline not linked to the practice of craniosacral therapy, tends to strengthen the confidence that can be placed on the observations.

Table 9. Research pertaining to motion of cerebrospinal fluid

Study	Purpose	Design	Population/ sampling technique	Outcome measures	Analysis
O'Connell '43 [29]	To review the development of modern knowledge of the vascular factor in intracranial pressure and the maintenance of cerebrospinal fluid circulation	Observational	Living subjects and cadavers	Lumbar, cisternal and ventricular puncture with pressure variations measured using a manometer	No statistical analysis
Du Boulay et al.'72 [32]	To investigate pulsatile movements in the cerebrospinal fluid pathways	Case reports	9 human subjects	Encephalograms and myelography	Reported observations
Cardoso et al. '83 [35]	To determine the modifications in the CSF pulse wave configuration induced by acute changes in the dynamics of the intracranial compartment.	Experimental	10 hydrocephalic, 3 benign intracranial hypertension, 2 head injury	ICP monitoring with changes in head elevation, voluntary hyperventilation and CSF withdrawal	Tracings Mean changes.
Takizawa et al. '83 [37]	To determine the change of auto power spectrum of CSF pulse when CSF pressure was increased by the slow infusion of lactate linger solution	Experimental	English abstract doesn't state. Full article not translated	Intracranial pressure monitoring	English abstract doesn't state. Full article not translated
Avezaat & Eijndhoven'86 [40]	To establish the relationship between cerebrospinal fluid pulse pressure and intracranial pressure… and to compare this relationship with the volume-pressure relationship	Analysis of CSF and ICP parameters	Patients with various neurological conditions	Ventricular catheter attached to an external pressure transducer	Tracings Mathematical modelling Correlation coefficients

Table 9. - Continued

Study	Purpose	Design	Population/ sampling technique	Outcome measures	Analysis
Enzmann et al. '86 [43]	To describe selected clinical situations that illustrate how cerebrospinal fluid flow effects can alter diagnosis	Case study	Selected patients	Quantitative magnetic resonance imaging	No statistical analysis
Feinberg & Mark '87 [46]	To show reproducible magnitudes and directions of CSF flow	Observational	25 healthy volunteers and 5 patients	Quantitative magnetic resonance imaging	Reported observations
Ursino '88 [50] a & b	To elucidate the role of different factors in determining the morphology and time pattern of the CSF pulse pressure	Mathematical model using physiological and anatomical data	Not applicable	Not applicable	Not applicable
Zabolotny et al. '95 [51]	To investigate the relationship between high-frequency centroid [a cerebrospinal fluid pulse pressure waveform] and selected compensatory parameters measured via a computerized lumbar infusion test	Analysis of observed cerebrospinal fluid parameters	Hydrocephalic children	Amplitude, resistance to outflow, elasticity	Linear correlation coefficients
Li et al.'96 [52]	To use a simple method to assess cerebral compliance, i.e. to observe the changes of the CSF pulse waveforms during ICP monitoring	Observational	30 head injury or stroke patients in a neurological ICU	Intracranial pressure monitoring (ICP)	Mean volume-pressure test and amplitude analysis

The limitations of the research include the use of study designs which were weak for the purpose of linking CSF movement to health outcomes, since this was not its intention. For example, Enzmann et al.[43] aimed to illustrate how CSF flow effects could alter diagnosis. Avezaat & Eijndhoven'86 [40] aimed to related CSF pulse pressure and intracranial pressure. In these surveys, the existence of CSF movement was itself not a question for the researchers. Most of the studies were undertaken in subjects with neurological disorders, or in small populations that are poorly described. The flow patterns observed, therefore, may not be representative of individuals undergoing craniosacral therapy.

Summary

The retrieved studies verify that CSF movement and pulsation are phenomena measurable by encephalogram, myelogram, magnetic resonance imaging and intracranial and intraspinal pressure monitoring - thereby meeting a number of Hill's criteria for establishing causation (**Table 2**). Furthermore, the evidence supports the contention that there is a cranial "pulse" or "rhythm" distinct from cardiac or respiratory activity.

This set of studies represents citations identified through a search to find primary data on craniosacral therapy. Therefore, it is inclusive only of the citations given in the CSF literature or identified by the search terms used in this review. The retrieved set does not represent all available literature contributing evidence on the subject. A systematic review specifically designed to retrieve all the available evidence on cerebrospinal flow would require a different strategy. This was beyond the scope of the present report.

3.1.4 Interpreting the evidence relating craniosacral dysfunction to health outcomes

Direct Evidence

Three studies (Frymann '66 [25]; Upledger '78 [8]; White et al. '85 [26]) were identified that provided direct evidence on the question: Is there an association between health and craniosacral dysfunction? Each was retrieved and critically appraised. They were of such poor methodological quality, however, that they did not advance knowledge in this area. Methodologically rigorous

research may be feasible, although this must depend on the development of a valid measure of craniosacral dysfunction. Many valid measures of health outcome already exist.

Indirect Evidence: links in the causal chain

Two sets of research provide indirect evidence on the association between health and craniosacral dysfunction. This research suggests that:

- minute movement between cranial bones is possible;
- cerebrospinal fluid flows in a pulse-like rhythmic manner.

However, support for these two claims is not adequate support for the theory that craniosacral dysfunction is associated with health outcomes. In fact, the relationship between these discrete physiological phenomena has not been studied. Allowing that cranial bone movement and cerebrospinal fluid pulsations may occur, there is no evidence that either of these phenomena is linked in a causal way to health outcomes. Missing from the causal chain are evidential links to show that:

- different cranial bones positions produce different CSF flow patterns;
- such different CSF flow patterns produce different health outcomes.

These significant gaps in the scientific chain of evidence, coupled with a noticeable lack of discussion of the leaps or assumptions made, undermine the validity of any conclusions drawn. At the same time, it may be noted that there is considerable opportunity for research in this field.

3.2 CATEGORY B: EVIDENCE ON THE ASSESSMENT OF CRANIOSACRAL DYSFUNCTION BY PRACTITIONERS OF CRANIOSACRAL THERAPY

Five studies examined assessment of craniosacral dysfunction by practitioners of craniosacral therapy. These studies are described in the text and **Table 10**. Two bodies of research are separated in time by about 20 years. The first two studies were undertaken in the late 1970s by JE Upledger, an osteopathic physician who founded a craniosacral therapy teaching institute. The three more recent studies were undertaken by physical therapists.

Table 10. Research pertaining to the assessment of craniosacral dysfunction by practitioners of craniosacral therapy

Study	Purpose	Population/ sampling technique	Exam description	Observer description	Analysis
Upledger '77 [30]	To test the reproducibility of the author's craniosacral examination findings	25 preschool children age 3-5 from a day care centre	19 cranio-sacral parameters rated on a 5-point scale from no to severe/absolute restriction	The author's observations were compared with those of one of three other osteopathic physicians	Reliability coefficient, percent of agreement, total percentage of agreement allowing up to 0.5 rating variance
Upledger & Karni '79 [33]	To determine whether there were correlations between selected mechano-electric parameters and physician's impression of the changes in craniosacral motion	No description of study participants	Mechano-electrical patterns were measured by placing electrocardiogram and electromyogram electrodes on the lower chest and thighs. Second observer recorded verbal descriptions	The author rated CS rhythm as normal, still point, end of still point, release, shifting, pulsating, wobbling and torsion	Select ECG and EMG tracings were visually correlated with subjective examiner impressions
Wirth-Pattullo & Hayes '94 [36]	To examine the interexaminer reliability of craniosacral rate and the relationships among craniosacral rate and subjects' and examiners' heart and respiratory rates	12 children and adults with histories of physical trauma, surgery, or learning disabilities	Examiner rated cranial motion as flexion or extension. Research assistants recorded verbalizations and respiration rate/pulse of both patient and examiner	3 physical therapists trained in craniosacral techniques blinded as to ratings of other examiners	Correlation coefficients with p values

Table 10. - Continued

Study	Purpose	Population/ sampling technique	Exam description	Observer description	Analysis
Hanten et al. '98 [38]	To determine the intra- and inter-examiner reliability of the palpation of the rate of the craniosacral rhythm (CSR) and to examine whether a relationship exists between the rate of the CSR of the subjects and the subjects' and/or examiners' heart and/or respiratory rates.	10 male and 30 female volunteers age 22-54 with no diagnosed cranial or spinal pathology and no surgery affecting the skull, spine, and/or spinal column	Heart rate monitor Flexion and extension indicated by foot signals and recorded by observer Respiratory rate and CSR cycles over a 3 minute cycle recorded by observer	2 physical therapists with 11 months of experience in palpating the CSR	Intraclass correlation coefficients Multiple regression analysis
Rogers et al. '98 [41]	To determine the interrater and intrarater reliability of measurements obtained during palpation of the craniosacral rate at the head and feet.	10 men and 18 women over age 18, able to understand instruction and able to lie supine for 45 minutes	A foot switch was used to signal the craniosacral rate which was converted through a analog-to-digital data acquisition system and plotted as a function of time	One nurse and one physical therapist simultaneously (head and foot) observed in blinded fashion	Intraclass correlation coefficients Analysis of variance

Upledger (1977)

Description

The Upledger 1977 study,[30] was conducted to support the larger project reported in Upledger 1978.[8] Its aim was "to test the reproducibility of the author's craniosacral examination findings."[30] Twenty-five children age 3 to 5 were tested by Upledger and one of three other examiners blinded to the responses of the others. A technician recorded the verbal responses on ease/restriction to examiner-induced passive motion for each of 19 parameters of craniosacral motion of the following bones restricted in the named directions: occiput (right or left), temporal bones (right or left), sphenobasilar joint (flexion /extension, sidebending rotation to right or left, torsion to right or left, compression-decompression, lateral strain right or left, vertical strain towards superior or inferior motion), sacrum (flexion/extension/torsion to right or left). In response to induced passive motion, movements were rated as: 1) easy or 'normal' response; 2) moderate or transient restriction; 3) severe or complete restriction with half rankings allowed converting the scale from 3 to 5 points.

Upledger's ratings were compared with those of each of the other three examiners, individually and aggregately for percentage of agreement and the reliability coefficients. Upledger reports an overall percentage of agreement of 71% with reliability coefficients varying from 0.16 to 0.91. The raw data was presented which allowed a recalculation of Kappa statistics with ranks of 1-1.5 as 'normal', and 2 and higher 'abnormal'. The recalculated Kappa statistics, presented in **Table 11**, range from 0.20 to 1.0 over 18 parameters.

Upledger & Karni (1979)

Description

The aim of this study[33] was to determine whether a physician's impression of the changes in craniosacral motion correlated with selected mechano-electric parameters. No description of the study participants or sample size was provided. Mechano-electrical patterns were measured by placing electrocardiogram and electromyogram electrodes on the lower chest and thighs. These were categorized as: rapid oscillations, transient waveforms, rapid waveforms, and baseline

Table 11. Calculation of Kappa statistic from Upledger '77 [30] data
Subject children age 3-5, N=25

Craniosacral parameter	Observed agreement (%)	Agreement expected by chance(%)	Kappa index
1	84	52	0.67
2	88	56	0.73
3	72	44	0.36
4	84	52	0.67
5	92	60	0.80
6	96	64	0.89
7	84	52	0.67
8	88	56	0.73
9	80	48	0.57
10	80	64	0.44
11	100	52	1.0
12	100	52	1.0
13	72	48	0.46
14	56	52	0.50
15	76	48	0.62
16	68	60	0.20
17	76	68	0.25
18	76	60	0.40
19	76	52	0.50

changes. A second observer recorded Upledger's verbal descriptions. Craniosacral rhythm was rated as normal, still point, end of still point, release, shifting, pulsating, wobbling and torsion.

Select ECG and EMG tracings were visually correlated with subjective examiner impressions. No statistical analysis was undertaken. The authors reported that this study "shows that distinct strain gauge, electrocardiography, electromyography, and integrated-electromyography patterns correspond with each one of the palpatory sensations. This correlation far exceeds random probability."

Wirth-Pattullo & Hayes (1994)

Description

The objective of this study [36] was to examine the interexaminer reliability of craniosacral rate and the relationships among craniosacral rate and subjects' and examiners' heart and respiratory rates. Subjects were 12 children and adults with histories of physical trauma, surgery, or learning disabilities. Three physical therapists trained in craniosacral techniques rated cranial motion as flexion or extension. Each was blinded as to ratings of other examiners. Research assistants recorded verbalizations and respiration rate/pulse of both patient and examiner.

There was a lack of agreement among observers with a negative correlation of - 0.2 reported. A scatter plot demonstrated this lack of agreement. Correlations between subject craniosacral rate and heart rate and subject and examiner heart and respiratory rates were low and not statistically significant. Wirth-Pattullo & Hayes also recalculated correlation coefficients for the 1977 Upledger [30] study using the raw data provided in the report (**Table 12**).

Hanten et al. (1998)

Description

The objective of this study [38] was to determine the intra- and inter-examiner reliability of the palpation of the rate of the craniosacral rhythm (CSR) and to examine whether a relationship exists between the rate of the CSR of the subjects and the subjects' and/or examiners' heart and/or respiratory rates. Study subjects were 10 male and 30 female volunteers age 22-54 with no diagnosed cranial or spinal pathology and no surgery affecting the skull, spine, and/or spinal

Table 12. Correlation coefficients from inter-rater reliability research

Study	Correlation coefficients (cc)
Upledger '78 [8] (from Wirth-Pattullo & Hayes reanalysis of Upledger '77 [30] raw data from the trial)	0.57 – Intraclass CC comparing author with 3 other examiners 0.007 to 0.164 for Pearson Product-Moment CC comparing craniosacral rate with heart and respiratory rates of children and examiner
Wirth-Pattullo & Hayes '94 [36]	-0.02 – Intraclass CC among 3 examiners using ANOVA Low and not significant Pearson Product-Moment CC comparing craniosacral rate with heart and respiratory rates of children and examiner
Hanten et al. '98 [38]	0.22 – interexaminer reliability coefficient 0.78 and 0.83 – intraexaminer reliability coefficient
Rogers et al. '98 [41]	Interexaminer reliability coefficient 0.08 – measured at the head 0.19 – measured at the feet Intraexaminer reliability coefficient 0.08 and 0.12 – measured at the head 0.19 and 0.23 – measured at the feet

column. CSR was observed by 2 physical therapists with 11 months of combined palpation experience. Flexion and extension was indicated by foot signals and recorded by observer. A heart rate monitor was used. Respiratory rate and CSR cycles over a 3-minute cycle were recorded by an observer. Each subject was examined by two examiners and each examiner repeated the examination.

Intraclass correlation coefficients were conducted "to determine if significant differences in the group means of the CSR occurred between the two sessions of each examiner and between the first session of both examiners. Two multiple regression analyses were conducted, one for each examiner, to determine whether significant relationships existed between the CSR of the subjects and the subjects' and examiners' heart and respiratory rates." [38] The reported interexaminer reliability coefficient was 0.22. Intraexaminer ratings were 0.78, 0.83.

Rogers et al. (1998)

Description

The objective of this study [41] was to determine the interrater and intrarater reliability of measurements obtained during palpation of the craniosacral rate at the head and feet. Study subjects, recruited by researchers and through posted notices, were 10 men and 18 women who were over age 18, able to understand instruction and able to lie supine for 45 minutes. They had a variety of current and past medical conditions that could have contributed to changes in the craniosacral rate.

The craniosacral rate was observed by two trained craniosacral practitioners: a nurse with 17 years' experience, and a physical therapist with 5 years' experience using craniosacral therapy in patient care. A foot switch was used to signal the rate, which was converted through an analogue-to-digital data acquisition system and plotted as a function of time. Each subject was simultaneously examined by two examiners for 2 minutes, four times. Examiners switched positions between the head and feet, were blinded to the other's recordings, and were out of visual contact.

Intraclass correlation coefficients were conducted using the method described by Shrout & Fleiss. [54] Contributions to variance were analysed with a factorial analysis of variance.

Research Quality

Many of Feinstein's [19] criteria for appraising evidence of observer variability (**Table 4**) were met by Upledger & Karni '79, [33] Wirth-Pattulo & Hayes, [36] Hanten et al. [38] and Rogers et al. [41]. Criteria reported to be met were: specified study purpose, blinded observations, competent observers, and procedural protocol for converting observations into raw data.

Some Feinstein criteria were not well met. The studies are small and their subjects do not constitute a representative sample of patients who might be offered craniosacral therapy. For example, Upledger & Karni '79 [33] studied 25 young children, an age group where the issue of suture fusion is not prominent. The Wirth-Pattullo & Hayes study [36] also included children over 10, although how many is not stated, and all 12 subjects had a history of trauma. In the Hanten et

al. study,[38] the 40 subjects were described as normal. Population characteristics were not clearly described.

Most serious are issues surrounding the index of concordance used. The kappa index of inter- and intra-observer agreement has gained supremacy in clinical medicine because it corrects for the expected agreement by chance.[18] None of the studies analysed the data using the kappa index, although if craniosacral movement or rhythm was coded as restricted/ abnormal, as opposed to normal, the subject would lend itself to this type of analysis. The Upledger & Karni[33] study itself used a reliability coefficient of unspecified methodology and percentage of agreement between observers, methods which do not take into account agreement by chance. Upledger & Karni also created a 5-point ranking system with 4 shades of movement restriction in each of 19 craniosacral movements. They found a high degree of agreement beyond chance for many of the parameters. However, when the Kappa values were recalculated from the raw data provided in the study report, three aspects are noteworthy:
1) none of the subjects was judged to be normal on all parameters by any of the observers;
2) the detailed ranking scale and number of parameters studied are based on extremely minute phenomena; 3) this study has not been replicated in the 20 years since it was published.

Both Wirth-Pattulo & Hayes[36] and Hanten et al.[38] measured concordance in observations of craniosacral rhythms. The intraclass correlation coefficients used to evaluate inter-rater reliability represent an acceptable index of concordance (Feinstein 1985).[19] It would be more useful, however, to see how assessment of craniosacral movement or rhythm fared as a diagnostic test; that is, to categorize subjects as normal or otherwise.

The Upledger & Karni[33] '79 study combined strain gauge, electrocardiography and electromyography tracings with subjective impressions. The authors claim that the tracings correlate with palpatory sensations and that this correlation exceeds chance probability. There was, however, no method of statistical analysis described to support this claim. The experiment has not been repeated or confirmed by other researchers.

Summary

The study by Upledger 77[30] reported high inter-rater reliability for some parameters comprising the assessment of craniosacral movement. This study has a number of limitations however. Of

concern is that all of the subjects studied (25 children between the ages of 3 and 5) were judged to have movement restrictions on multiple parameters; that is, none were identified as normal. In order to demonstrate the ability of a test to distinguish adequately between affected subjects, however, a study of this type should also include a sufficient number of subjects classified as normal.

Furthermore, the study has not been replicated in the intervening 20 years. More recent research successfully refutes Upledger's findings. Intraclass correlation coefficients were minus 0.02 in the Wirth-Pattullo & Hayes [36] study, 0.20 in the Hanten et al.[38] study, 0.08 and 0.19 in the Rogers et al.[41] study, and 0.57 in the Upledger [30] study (recalculation). The trend of the more recent and better designed studies is that they did not find assessment of craniosacral rhythm reliable. Because the reliability of the observation among multiple observers is a basic requirement of a scientific measurement tool, a high correlation would have validated craniosacral rhythm as an observable phenomenon. In this respect, the correlations seen were not high enough. Therefore, the highest quality inter-observer agreement studies have found that assessment of craniosacral dysfunction by practitioners of craniosacral therapy is unreliable. It may be noted that research methods are available which can adequately address this question, if proponents of craniosacral therapy submit their techniques to further evaluation.

3.3 CATEGORY C: EVIDENCE ON THE EFFECTIVENESS OF CRANIOSACRAL THERAPY IN ALTERING HEALTH OUTCOMES

Seven studies reported on the effectiveness of craniosacral therapy in altering health outcomes. Using the Canadian Task Force on Preventive Health Care grades of evidence, all would be classified as Level III, the lowest grade of evidence (see **2.4.3**). Study designs used were retrospective case control (Phillips & Meyer '95 [44]), retrospective case series (Blood '86 [34]; Greenman & McPartland '95 [6]), before-after (Frymann et al. '92 [9]) and case reports (Baker '71 [31]; Hollenbery & Denis '94 [7]; Joyce & Clark '96 [47]). Due to the heterogeneous nature of these seven studies and their varied level of detail, the study reviews were not amenable to tabulation form. Hence, the studies and their critical appraisal are described separately.

Phillips & Meyer (1995)

Description

This was a retrospective case control study.[44] The purpose was to determine whether the addition of chiropractic care including craniosacral therapy to a regimen of standard obstetrical care during pregnancy results in fewer obstetric interventions during labour and delivery. From a consecutive series of 63 pregnant women receiving chiropractic care at an out-patient clinic, 35 were matched with controls. Rates of obstetrical interventions were obtained for both groups from Vital Statistics Minnesota. Selection criteria were: 1) specified county and time period; 2) non-Hispanic Caucasian; 3) ≥ 36 weeks gestation; 4) number of previous births; 5) method of delivery recorded; 6) no record of fetal alcohol syndrome; 7) no repeat C-section. Matching criteria were: 1) age; 2) birth attendant title; 3) patient education level; 4) number of births; 5) plurality of current birth; 6) prior C-section; 7) tobacco use; 8) alcohol use; 9) delivery facility name; 10) complications of labour and/or delivery; 11) risk factors: diabetes, hydramnios/oligohydramnios, hypertension, eclampsia. Twenty-eight subjects were excluded: birth certificate data were unavailable in 17, scheduled repeat c-section in 3, no matching control in 8.

The chiropractic program "consisted of spinal adjustments using various techniques, such as diversified, Thompson, Logan, and/or Webster adjustment techniques. General prenatal health education included nutritional advice, exercise recommendations and birth education. In addition to conservative chiropractice care, these patients also received (Upledger) craniosacral therapy. Bradley Birth Classes were recommended to those patients who expressed an interest in an advanced course of study in childbirth education, although the number of women choosing this option was not recorded."[44]

Research Quality

No significant differences were found. The study did not however have the power to detect a true difference had there been one. The large confidence intervals confirm that the sample size was inadequate. The authors interpret the findings to be suggestive that chiropractic care and craniosacral therapy may be safely employed for pregnancy-associated disorders without complications on labour and delivery. This interpretation of the study findings is unwarranted. The intervention rates (induction, stimulation, forceps/vacuum/C-section) were 46% for the cases and 48% for controls. Over 1000 patients would be needed in order to detect a 5% difference in

intervention rates between groups (alpha of 0.05 two sided, beta of 0.20 one sided). An even larger sample size would be needed to detect a difference in less frequent complications.

Other aspects of the trial limit its validity. The interventions were not adequately described; craniosacral therapy cannot be distinguished from other chiropractic modalities. The actual care received and setting of the comparison group is unknown, and it is therefore difficult to determine whether the groups were comparable in all aspects but chiropractic care. The accuracy and reliability of source of outcome data were not ascertained.

Frymann et al. (1992)

Description

This before-after study [9] reports on a total of 186 children, 18 months to 12 years of age, with neurological, structural or medical problems, over a three-year period at an osteopathic outpatient service. The high withdrawal rate was 46%, with 88 of 186 children seen only once. Up to four assessments were done on the remaining sample, but it appears that only 83 completed the immediate post-treatment test, and only 43 a later follow-up assessment. Examination included "the structure and inherent motion of the cranial mechanism." Treatment techniques were not described but included "measures to influence … cerebrospinal fluid motility." Six to 12 treatments were given at 1 week intervals. Neurological development was measured using the Houle Profile of Development, [55] which rates development as slow, average and exceptional within 3 sensory and 3 motor performance categories.

Research Quality

The before-after method is not appropriate for children who are developing rapidly, regardless of intervention. Although the authors report that they age-standardised scores, not enough information is given on the methodology to be confident that this was done correctly. The age distribution of the subjects was not reported, and accordingly age standardisation may be irrelevant.

Invalid comparisons were used. Comparisons were made between "waiting list" and "start first" groups, though no explanation was given as to how children were assigned to these groups. In addition, children who did not complete any assessment post treatment were arbitrarily assigned to

a comparison group. There is no evidence presented to suggest that groups were comparable at their outset.

The accuracy and reliability of the Houle Profile of Development score was not reported. The scale used does not appear to be appropriate for testing children over 8 years old.

Greenman & McPartland (1995)

Description

The purpose of this retrospective case series study [6] was not stated. Data from craniosacral examination and history were recorded for 55 consecutive patients with traumatic brain injury seen at an outpatient rehabilitation program during a five-year period. The following craniosacral findings of cases were described: the cranial rhythmic impulse rate and amplitude, presence or absence of strain patterns of either cranium or sacrum, motion restrictions of cranial bones, cranial suture and synchondrosis compressions, restrictions, or tenderness, and sacral restrictions.

Iatrogenesis was defined as "very unfavourable response to therapy." The case histories of three patients who were deemed to have iatrogenic reactions to craniosacral therapy were given. Six hours following a two-person decompression technique, Case 1 experienced an increase in headache with associated nausea, vomiting, diarrhoea, cardiac palpitation, and anxious respiration rate. These symptoms cleared the next day. Case 2 was found to have hypertension in addition to other symptoms related to traumatic brain injury. Following craniosacral therapy, the patient experienced an acute intensification of head pain, requiring analgesia. At follow-up, Case 2 developed increasingly angry thoughts and difficulty in controlling his emotions, and craniosacral therapy was discontinued. In Case 3, following what was described as a "two-person sphenobasilar decompression", the patient developed opisthotonos, tonic spasms of the four extremities and Cheyne-Stokes respiration requiring emergency hospitalization. No new lesion was identified to account for the signs and symptoms despite extensive testing, including MRI and EEG studies.

Research Quality

Case series reports cannot definitively establish a causal relationship between craniosacral therapy or the adverse reactions described. However, these documented harmful reactions call into question the safety of craniosacral therapy in this group of patients.

Blood (1986)

Description

In this retrospective case series,[34] the recorded history and cranial evaluations of 130 patients with temporomandibular joint syndrome were reviewed. These represent all patients with this condition seen during a nine-year period in the private practice of one osteopathic physician. Compression/strain/restriction was found in relation to the occiput (35), sphenobasilar symphysis (23), frontosphenoid (15), and sphenobasilar symphysis (14). Cranial strain pattern was reported in 17 and a locked cranial mechanism in 2.

Research Quality

The scientific validity of the measures used in this study has not been established (see **3.2** above). Health outcome benefits (such as pain reduction etc.) were claimed but were not systematically measured or reported.

Case Reports

Three studies presenting case reports are given in **Table 13**.

3.4 SUMMARY OF RESULTS

The benefit of craniosacral therapy has not been demonstrated using well-designed research. The available studies are of low grade evidence as rated by the Canadian Task Force on Preventive Health Care[20] ranking system, and are of poor quality when judged using standard critical appraisal criteria. Inadequacies in the studies cited above preclude any statement attesting to craniosacral therapy effectiveness.

Adverse effects were reported when craniosacral therapy was used in some brain injured outpatients Although research methods are feasible for the evaluation of craniosacral therapy, they have not been used. High quality research is required to demonstrate effectiveness. The observation by two researchers (Phillips & Meyer '95)[44] that the addition of craniosacral

Table 13. Case reports of the effectiveness of craniosacral therapy intervention on health outcomes

Study	Patient Type	Intervention	Outcome measure	Finding
Baker '71 [31]	Male with traumatic malocclusion	Treatment by occlusal equilibration and osteopathic adjustment over 6 months	Serially measured models of maxillary teeth	Relief of pain and established centric jaw relation
Hollenbery & Dennis '94 [7]	1. Scalp and jaw 'tightness' with history of motor vehicle accident 4 years prior	Craniosacral therapy of sphenobasilar base	Not reported	Reduction in cranial symptoms
	2. Buttock pain, confusion, inability to concentrate and pressure behind the eyes	Craniosacral therapy with particular attention to occipital and frontal areas of the skull and sacrum	Not reported	Symptoms eliminated
Joyce & Clark '96 [47]	Infant with gastroesophageal reflux	10 step protocol from Upledger Institute's curriculum	Reflux as reported by mother	Reflux did not return after fourth CST session

therapy to other modalities in obstetrical care did not appear to do harm and could therefore be "safely employed" in prenatal care (in those patients with associated neuromuscular conditions) is without merit.

The report by Greenman & McPartland (1995) [6] of adverse effects in out-patients with traumatic brain injury raises concern over claims that craniosacral therapy is without negative side effects. In the absence of demonstrable benefits and in the face of reports of harm, the benefit/risk ratio is negative for this group of patients.

4.0 DISCUSSION & CONCLUSIONS

This systematic review found there is insufficient scientific evidence to recommend craniosacral therapy to patients, practitioners or third party payers for any clinical condition.

The literature suggests that the adult cranium does not obliterate, fuse or ossify its sutures until well into late life. There is also some evidence (albeit of variable research quality) that there is potential movement at these suture sites in earlier life. Questions remain as to whether such "movement" is detectable by human palpation or whether mobility has any influence on health or disease.

The authors of this review also note that, in accord with a basic tenet of craniosacral therapy, there is evidence for a craniosacral rhythm, impulse or "primary respiration" independent of other measurable body rhythms (heart rate, or respiration). Avezaat & Eijndhoven '86 [40] and Feinberg & Mark '87 [46] used sophisticated technology to gain an understanding of the phenomenon. However, these and other studies do not provide any valid evidence that such a craniosacral "rhythm" or "pulse" can be reliably perceived by an examiner. Our review does not suggest any reasonable data that would allow such a conclusion. The influence of this craniosacral rhythm on health or disease states is completely unknown.

Clinicians require a reliable means of assessment for decision making. Craniosacral assessment has not been shown to be reliable.

The literature on craniosacral therapy does not include any high grade evidence, such as random controlled trials, of its effects on health outcomes. [20] The evidence that is available is of poor methodological quality, is highly variable, lacks consistency and does not allow any logical "positive" conclusions regarding craniosacral therapy.

Upledger ('95), osteopath and founder of the Institute of Craniosacral Integration, argues that:

> *"[P]ositive patient outcomes as a result of CranioSacral Therapy should weigh greater than data from designed research protocols involving human subjects, as it is not possible to control all of the variables of such studies.* [56]

This point of view has successfully been countered by groups such as the Quantitative Methods Working Group of the U.S. National Institutes of Health Office of Alternative Medicine,[57] as well as the Cochrane Collaboration on Complementary and Alternative Medicine.[58] Many validated measures of a variety of health outcomes exist to measure 'positive patient outcomes'. Complex complementary medical systems can be studied as 'gestalts' (integrated wholes) for the purpose of evaluation from within an intervention/trials framework. Claims that the scientific methods currently available are not suitable for evaluating the therapies variously categorized as 'non-traditional', 'alternative', or 'complementary' are not valid.

The issue is not that craniosacral therapy is a "non mainstream" entity.[59] Rigorous and scientifically defensible studies are clearly possible on all its aspects. If undertaken, such research would be of great value in providing the necessary direction for administrators, practitioners and patients alike.

References

[1] Sutherland WG. The cranial bowl. Maukato (MN): WG Sutherland; 1939.

[2] Frymann VM. A study of the rhythmic motions of the living cranium. J Am Osteopath Assoc 1971 May;70(9):928-45.

[3] Greenman PE. Roentgen findings in the craniosacral mechanism. J Am Osteopath Assoc 1970 Sep;70(1):60-71.

[4] Upledger JE. Research and observations that support the existence of a craniosacral system. 1995 [cited 1998 Apr 15]. Available from: URL: http://www.cranio.org/JEU_Article_en.htm.

[5] Rogers JS, Witt PL. The controversy of cranial bone motion. J Orthop Sports Phys Ther 1997 Aug;26(2):95-103.

[6] Greenman PE, McPartland JM. Cranial findings and iatrogenesis from craniosacral manipulation in patients with traumatic brain syndrome. J Am Osteopath Assoc 1995 Mar;95(3):182-88.

[7] Hollenbery S, Dennis M. An introduction to craniosacral therapy. Physiotherapy 1994 Aug;80(8):528-32.

[8] Upledger JE. The relationship of craniosacral examination findings in grade school children with developmental problems. J Am Osteopath Assoc 1978 Jun;77(10):760-76.

[9] Frymann VM, Carney RE, Springall P. Effect of osteopathic medical management on neurologic development in children. J Am Osteopath Assoc 1992 Jun;92(6):729-44.

[10] Greenhalgh T. How to read a paper. London: BMJ Publishing Group; 1997.

[11] Counsell C. Formulating questions and locating primary studies for inclusion in systematic reviews. Ann Intern Med 1997 Sep 1;127(5):380-7.Danoff J. Evaluating scientific merit. Phys Ther 1996 Jul;76(7):786-87.

[12] Mulrow C, Cook D. Systematic Reviews: synthesis of best evidence for health care decisions. Philadelphia (PA): American College of Physicians; 1998.

[13] Kazanjian A, Cardiff K, Pagliccia N. Design and development of a conceptual and quantitative framework for health technology decisions: a multi-project compendium of research underway. Vancouver, BC: University of BC, 1995. BC Office of Health Technology Assessment Report 95:2D.

[14] Kazanjian A. Doing the right thing, not just doing things right. In: Gender Working Group, United Nations Commission on Science and Technology for Development. Missing links: gender equity in science and technology for development. New York: International Development Research Centre in association with Intermediate Technology Publications and UNIFEM, 1995, p. 159-80.

[15] Green CJ, Bassett K, Kazanjian A. Bone mineral density testing: Does the evidence support its selective use in well women? Vancouver, BC: University of BC, 1997. BC Office of Health Technology Assessment Report 97:2R.

[16] Lewith G, Kenyon J, Lewis P. Complementary medical research: tactics strategies, and problems. In: Complementary Medicine: An integrated approach. Oxford: Oxford University Press; 1996. p 14-20.

[17] Hill AB. Principles of medical statistics. New York: Oxford University Press; 1971.

[18] Sackett DL, Haynes RB, Tugwell P. Clinical Epidemiology: a basic science for clinical medicine.

Boston (MA): Little, Brown; 1991.

[19] Feinstein AR. Clinical epidemiology: the structure of clinical research. Philadelphia (PA): WB Saunders; 1985. p.648

[20] Dingle JL. Methodology. In: The Canadian Task Force on the Periodic Health Examination. The Canadian guide to clinical preventive health care. Ottawa: Minister of Supply and Services; 1994.

[21] Tettambel M, Cicora RA, Lay EM. Recording of the cranial rhythmic impulse [abstract]. J Am Osteopath Assoc 1978;78:149.

[22] Norton JM, Sibley G, Broder-Oldach RE. Quantification of the cranial rhythmic impulse in human subjects [abstract]. J Am Osteopath Assoc 1992;92:1285.(b)

[23] Sibley G, Broder-Oldach E, Norton JM. Interexaminer agreement in the characterization of the cranial rhythmic impulse [abstract]. J Am Osteopath Assoc 1992;92:1285.

[24] Upledger JE, Karni Z, Retzlaff E. Mechanoelectrically recorded physiological patterns which relate to subjectively reported craniosacral mechanism phenomena [letter]. J Am Osteopath Assoc 1978;78(4):297.

[25] Frymann V. Relation of disturbances of craniosacral mechanisms to symptomatology of the newborn: study of 1,250 infants. J Am Osteopath Assoc 1966 Jun;65(10):1059-75.

[26] White WK,White JE, Baldt G. The relation of the craniofacial bones to specific somatic dysfunctions: a clinical study of the effects of manipulation. J Am Osteopath Assoc. 1985 Sept;85(9) 603-4

[27] Todd TW, Lyon DW Jr. Endocranial suture closure: its progress and age relationship. Part I: adult males of white stock. Am J Phys Anthrop 1924;VII(3):325-84.

[28] Todd TW, Lyon DW Jr. Cranial suture closure: its progress and age relationship. Part II: ectocranial closure in adult males of white stock. Am J. Phys Anthrop 1925;VIII(1)23-45.

[29] O'Connell JE. The vascular factor in intracranial pressure and the maintenance of the cerebrospinal fluid circulation. Brain 1943;66:204-28.

[30] Upledger JE. The reproducibility of craniosacral examination findings: a statistical analysis. J Am Osteopath Assoc 1977 Aug; 76(12):890-9.

[31] Baker EG. Alteration in width of maxillary arch and its relation to sutural movement of cranial bones. J Am Osteopath Assoc 1971;70:559-64.

[32] Du Boulay G, O'Connell J, Currie J, Bostick T, Verity P. Further investigations on pulsatile movements in the cerebrospinal fluid pathways. Acta Radiol [diagn] (Stockh) 1972;13:496-523.

[33] Upledger JE, Karni Z. Mechano-electric patterns during craniosacral osteopathic diagnosis and treatment. J Am Osteopath Assoc 1979 Jul;78(11):782-91.

[34] Blood SD. The craniosacral mechanism and the temporomandibular joint. J Am Osteopath Assoc 1986 Aug;86(8):512-19.

[35] Cardoso ER, Rowan JO, Galbraith S. Analysis of the cerebrospinal fluid pulse wave in intracranial pressure. J Neurosurg 1983 Nov;59(5):817-21.

[36] Wirth-Pattullo V, Hayes KW. Interrater reliability of craniosacral rate measurements and their relationship with subjects' and examiners' heart and respiratory rate measurements. Phys Ther 1994 Oct;74(10):908-20.

[37] Takizawa H, Sugiura K, Baba M, Tachizawa T, Kamatsuka E, Hayama N. Spectral analysis of cerebrospinal fluid pulse wave [Engl abstract]. No To Khinkwi 1983 Dec;35(12):1227.

[38] Hanten WP, Dawson DD, Iwata M, Seiden M, Whitten FG, Zink T. Craniosacral rhythm: reliability and relationships with cardiac and respiratory rates. J Orthop Sports Phys Ther 1998 Mar;27(3):213-18.

[39] Hubbard RP, Melvin JW, Barodawala IT. Flexure of cranial sutures. J Biomech 1971 Dec;4(6):491-96.

[40] Avezaat CJ, van Eijndhoven JH. Clinical observations on the relationship between cerebrospinal fluid pulse pressure and intracranial pressure. Acta Neurochir (Wien) 1986;79(1):13-29.

[41] Rogers JS, Witt PL, Gross MT, Hacke JD, Genova PA. Simultaneous palpation of the craniosacral rate at the head and feet: intrarater and interrater reliability and rate comparisons. Phys Ther 1998;78(11):1175-85.

[42] Kokich VG. Age changes in the human frontozygomatic suture from 20 to 95 years. Am J Orthod 1976 Apr;69(4):411-30.

[43] Enzmann DR, Rubin JB, DeLaPaz R, Wright A. Cerebrospinal fluid pulsation: benefits and pitfalls in MR imaging. Radiology 1986 Dec;161(3):773-78.

[44] Phillips CJ, Meyer JJ. Chiropractic care, including craniosacral therapy, during pregnancy: a static-group comparison of obstetric interventions during labor and delivery. J Manipulative Physiol Ther 1995 Oct;18(8):525-29.

[45] Heifetz MD, Weiss M. Detection of skull expansion with increased intracranial pressure. J Neurosurg 1981 Nov;55(5):811-12.

[46] Feinberg DA, Mark AS. Human brain motion and cerebrospinal fluid circulation demonstrated with MR velocity imaging. Radiology 1987 Jun;163(3):793-99.

[47] Joyce P, Clark C. The use of craniosacral therapy to treat gastroesophageal reflux in infants. Inf Young Children 1996;9(2):51-58.

[48] Pitlyk PJ, Piantanida TP, Ploeger DW. Noninvasive intracranial pressure monitoring. Neurosurgery 1985 Oct;17(4):581-84.

[49] Kostopoulos DC, Keramidas G. Changes in elongation of falx cerebri during craniosacral therapy techniques applied on the skull of an embalmed cadaver. Cranio 1992 Jan;10(1):9-12.

[50] Ursino M. A mathematical study of human intracranial hydrodynamics, part 1: the cerebrospinal fluid pulse pressure. Ann Biomed Eng 1988;16(4):379-401.(part 1)

Ursino M. A mathematical study of human intracranial hydrodynamics, part 2: simulation of clinical tests. Ann Biomed Eng 1988;16(4):403-16.(part 2)

[51] Zabolotny W, Czosnyka M, Walencik A. Cerebrospinal fluid pulse pressure waveform analysis in hydrocephalic children. Childs Nerv Syst 1995 Jul;11(7):397-399.

[52] Li J, He W, Yao J, Wen H. Possibility of observing the changes of cerebrospinal fluid pulse waves as a substitute for volume pressure test. Clin Med J (Engl) 1996 May;109(5):411-13.

[53] Steiner C. Subjectivity: unsound basis for craniosacral research [letter]. J Am Osteopath Assoc 1979;78(6):386.

[54] Shrout PE, Fleiss JL. Intraclass correlations: uses in assessing rater reliability. Psychol Bull 1970;S6:420-428.

[55] Houle N: Profile of Development. 2nd ed. Piqua Ohio: American Academy for Human Development;1980. Appendix 1.

[56] Upledger JE. Research and observations that support the existence of a craniosacral system. 1995 [cited 1998 Apr 15]. Available from: URL: http://www.cranio.org/JEU_Article_en.htm.

[57] Levin JS, Glass TA, Kushi LH, Schuck JR, Steele L, Jonas WB. Quantitative methods in research on complementary and alternative medicine. A methodological manifesto. NIH Office of Alternative Medicine. Med Care 1997 Nov;35(11):1079-94

[58] Cochrane Collaboration. Cochrane complementary medicine field. In: The Cochrane Library [database on CDROM]. Oxford: Update Software; 1998. Issue 3.

[59] Vickers A, Cassileth B, Ernst E, Fisher P, Goldman P, Jonas W, et al. How should we research unconventional therapies? A panel report from the Conference on Complementary and Alternative Medicine Research Methodology, National Institutes of Health. Int J Technol Assess Health Care 1997;13(1):111-21.

Appendix A. Online search strategy

1. DIALOG Databases searched
Updated to February 2, 1999

File 155: Medline 1966-1998
File 73: Embase 1974-1998
File 91: Mantis 1880-1998
File 164: Allied & Alternative Medicine 1984-1998
File 434: Scisearch 1974-1998
File 5: Biosis 1969-1998
File 151: HealthStar 1975-1997

2. DIALOG Search Strategy

? = *Dialog prompt*	rd = *remove duplicates command*
s = *search command*	au = *author field*
t = *type command*	ca = *cited author*

?s ((craniosacral or cranio(w)sacral or cranial(w)(bone? or suture? or sacral))(2n)(therapy or therapist? or practitioner? or massage or mobili? or manipulat? or motion or movement?))
?rd s1
?t s2/7/all
?s ((cerebrospinal(w)(pulse or fluid))(2n)(circulation or fluctuation? or pulse or pulsation))
?s s3/ti
?rd s4
?t s5/ti/all
?s au=upledger j?
?s s6 not s2
?s (craniosacral or cranio(w)sacral or cranial(w)(bone? or suture? or sacral))
?s s7 and s8
?t s9/7/all
?s ca=upledger j?
?s s10 not (s2 or s9)
?t s11/7/all

3. CD-ROM Databases

Cochrane Library

4. Websites

University of British Columbia Library catalogue

AG-Canada (a union catalogue of Canadian libraries)

Bastyr University

BC Office of Health Technology Assessment

Canadian Coordinating Office of Health Technology Assessment

Craniosacral Therapy Association

Institute for Craniosacral Integration (ICI) homepage

ICI - Articles; Research and observations that support the existence of a craniosacral system, by John E. Upledger

OAM Clearinghouse (Office of Alternative Medicine, U.S. National Institutes of Health)

Rehma Osteopathy and American Whole Health

Craniosacral Therapy Resources

5. Organizations Contacted

BC Medical Association

BC Naturopathic Association

College of Dental Surgeons of BC

College of Physical Therapists of BC

College of Physicians and Surgeons of BC

Insurance Corporation of BC

Massage Therapists Association of BC

Registered Nurses Association of BC

Appendix B. Articles obtained from online and fugitive search

WEBSITES

D'Astolfo C. Cranio-Sacral Therapy. [1998 Jan 14]. Available from: URL: http://www.cwinds.com/topages/cranio.htm – size3K – 16-Jul-97

Beil-Kautz K. Occupational Therapist Kellie Beil-Kautz specializing in Professional Massage Therapy, including Myofascial Release, Craniosacral Therapy, Therapeutic. [1998 Jan 14]. Available from: URL: http://www.cqnet.com/kbk-massage/cranio.html – size 3K – 5-Sep-97 – English –Translate

Deavin A. Healing by Touch Polarity and Cranio-Sacral Therapy. [1998 Jan 14]. Available from: URL: http://www.ursasoft.com/paths/Deavin/Jul96.htm – Size 4K – 10-Aug-94 – English-Translate

Mayborn L. Craniosacral Therapy. 1998 [1998 Apr 15]. Available from: URL: http://www.cadenza.org/cst.

Upledger JE. Research and observations that support the existence of a craniosacral system. 1995 [cited 1998 Apr 15]. Available from: URL: http://www.cranio.org/JEU_Article_en.htm.

JOURNAL ARTICLES & BOOKS

Avezaat CJ, van Eijndhoven JH. Clinical observations on the relationship between cerebrospinal fluid pulse pressure and intracranial pressure. Acta Neurochir (Wien) 1986;79(1):13-29.

Avezaat CJ, van Eijndhoven JH, Wyper DJ. Effects of hypercapnia and arterial hypotension and hypertension on cerebrospinal fluid pulse pressure and intracranial volume-pressure relationships. J Neurol Neurosurg Psychiatry 1980 Mar;43(3):222-34.

Baker EG. Alteration in width of maxillary arch and its relation to sutural movement of cranial bones. J Am Osteopath Assoc 1971;70:559-64.

Becker RF. Cranial therapy revisited. Osteopath Ann 1977 Jul;5(7):316-34.

Berger D, Davis CM. What constitutes evidence? [letter]. Phys Ther 1996 Sep;76(9):1011-4.

Blood SD. The craniosacral mechanism and the temporomandibular joint. J Am Osteopath Assoc 1986 Aug; 86(8):512-19.

Blum CL. Biodynamics of the cranium: a survey. Cranio 1985 Mar;3(2):165-71.

Bollen KA. Structural equations with latent variables. New York: John Wiley & Sons; 1989.

Cardoso ER, Rowan JO, Galbraith S. Analysis of the cerebrospinal fluid pulse wave in intracranial pressure. J Neurosurg 1983 Nov;59(5):817-21.

Christ F, Raithel P, Gartside IB, Gamble J, Peter K, Messmer K. Investigating the origin of cyclic changes in limb volume using mercury-in-silastic strain gauge plethysmography in man. J Physiol (Lond) 1995 Aug 15;487(Pt 1):259-72.

Cohen D. An introduction to craniosacral therapy: anatomy, function and treatment. Berkeley (CA): North Atlantic Books; 1995.

Cohen D. Palpation of craniosacral motion. Am Chiropractor 1989 May:40-43.

Counsell C. Formulating questions and locating primary studies for inclusion in systematic reviews.

Ann Intern Med 1997 Sep 1;127(5):380-7.

Danoff J. Evaluating scientific merit. Phys Ther 1996 Jul;76(7):786-87.

Dingle JL. Methodology. In: The Canadian Task Force on the Periodic Health Examination. The Canadian guide to clinical preventive health care. Ottawa: Minister of Supply and Services; 1994.

Dove CI. The origin and development of cranio-sacral osteopathy. Holistic Med 1988;3:35-45.

Du Boulay G, O'Connell J, Currie J, Bostick T, Verity P. Further investigations on pulsatile movements in the cerebrospinal fluid pathways. Acta Radiol [diagn] (Stockh) 1972;13:496-523.

Dunbar HS, Guthrie TC, Karpell B. A study of the cerebrospinal fluid pulse wave. Arch Neurol 1966 Jun;14(6):624-30.

Edelman RR, Wedeen VJ, Davis KR, Widder D, Hahn P, Shoukimas G, et al. Multiphasic MR imaging: a new method for direct imaging of pulsatile CSF flow. Radiology 1986 Dec;161(3):779-82.

Enzmann DR, Rubin JB, DeLaPaz R, Wright A. Cerebrospinal fluid pulsation: benefits and pitfalls in MR imaging. Radiology 1986 Dec;161(3):773-78.

Feinberg DA, Mark AS. Human brain motion and cerebrospinal fluid circulation demonstrated with MR velocity imaging. Radiology 1987 Jun;163(3):793-99.

Feinstein AR. Clinical epidemiology: the structure of clinical research. Philadelphia (PA): WB Saunders; 1985.

Ferguson A. Cranial osteopathy: a new perspective. AAO Journal 1991 Win:12-16.

Frymann V. Relation of disturbances of craniosacral mechanisms to symptomatology of the newborn: study of 1,250 infants. J Am Osteopath Assoc 1966 Jun;65(10):1059-75.

Frymann VM. A study of the rhythmic motions of the living cranium. J Am Osteopath Assoc 1971 May;70(9):928-45.

Frymann VM, Carney RE, Springall P. Effect of osteopathic medical management on neurologic development in children. J Am Osteopath Assoc 1992 Jun;92(6):729-44.

Greenhalgh T. How to read a paper. London: BMJ Publishing Group; 1997.

Greenman PE. Roentgen findings in the craniosacral mechanism. J Am Osteopath Assoc 1970 Sep;70(1):60-71.

Greenman PE, McPartland JM. Cranial findings and iatrogenesis from craniosacral manipulation in patients with traumatic brain syndrome. J Am Osteopath Assoc 1995 Mar;95(3):182-88.

Greenman PE, Mein EA, Andary M. Craniosacral manipulation. Phys Med Rehabil Clinics N Am 1996 Nov;7(4):877-96.

Guyatt GH, Sackett DL, Sinclair JC, Hayward R, Cook DJ, Cook CJ. Users Guide to the Medical Literature. IX. A method for grading health care recommendations. JAMA1995 Dec 13;274,22:1800-1805.

Hanten WP, Dawson DD, Iwata M, Seiden M, Whitten FG, Zink T. Craniosacral rhythm: reliability and relationships with cardiac and respiratory rates. J Orthop Sports Phys Ther 1998 Mar;27(3):213-18.

Harris SR. How should treatments be critiqued for scientific merit? Phys Ther 1996 Feb;76(2):175-81.

Harris SR. How should treatments be critiqued for scientific merit: response [letter]. Phys Ther 1996 Jun;76(6):668.

Harris SR. What constitutes evidence: response [letter]. Phys Ther 1996 Sep;76(9):1014-5.

Heifetz MD, Weiss M. Detection of skull expansion with increased intracranial pressure. J Neurosurg 1981 Nov;55(5):811-12.

Heisey SR, Adams T. Role of cranial bone mobility in cranial compliance. Neurosurgery 1993 Nov;33(5):869-76.

Hill AB. Principles of medical statistics. New York: Oxford University Press; 1971.

Hollenbery S, Dennis M. An introduction to craniosacral therapy. Physiotherapy 1994 Aug;80(8):528-32.

Hornstein S. Craniosacral therapy: a report on the evidence. Vancouver (BC): British Columbia College of Physical Therapists; 1998.

Hubbard RP, Melvin JW, Barodawala IT. Flexure of cranial sutures. J Biomech 1971 Dec;4(6):491-96.

Jaslow CR. Mechanical properties of cranial sutures. J Biomech 1990;23(4):313-21.

Joyce P, Clark C. The use of craniosacral therapy to treat gastroesophageal reflux in infants. Inf Young Children 1996;9(2):51-58.

Kokich VG. Age changes in the human frontozygomatic suture from 20 to 95 years. Am J Orthod 1976 Apr;69(4):411-30.

Kostopoulos DC, Keramidas G. Changes in elongation of falx cerebri during craniosacral therapy techniques applied on the skull of an embalmed cadaver. Cranio 1992 Jan;10(1):9-12.

Kotzsch R. Craniosacral therapy. Natural Health 1993 Jul/Aug:42-44.

Lay EM. Teaching cranial therapy to undergraduates. Osteopath Ann 1976 May:226-30.

Lee RP. Primary and secondary respiration, part II. AAO Journal 1993 Spr:17-27.

Lee RP. A report to the statutory advisory committee on medical care: craniosacral manipulation. AAO Journal 1991;1:13-14.

Levin JS, Glass TA, Kushi LH, Schuck JR, Steele L, Jonas WB. Quantitative methods in research on complementary and alternative medicine: a methodological manifesto: NIH Office of Alternative Medicine. Med Care 1997 Nov;35(11):1079-94.

Lewith G, Kenyon J, Lewis P. Complementary medical research: tactics strategies, and problems. In: Complementary Medicine: An integrated approach. Oxford: Oxford University Press; 1996. p 14-20.Literature. IX. A method for grading health care recommendations. JAMA1995 Dec 13;274(22):1800-1805.

Li J, He W, Yao J, Wen H. Possibility of observing the changes of cerebrospinal fluid pulse waves as a substitute for volume pressure test. Clin Med J (Engl) 1996 May;109(5):411-13.

Lin JH. Evaluating the alternatives. JAMA 1998 Mar 4;279(9):706.

Manheim C.J. and Lowett, D.K. Craniosacral Therapy and Somato-emotional Release. Thorofare, N.J: Slack Inc; 1989.

Marshall E. The politics of alternative medicine. Science 1994 Sep 30;265(5181):2000-2.

Michels E. How should treatments be critiqued for scientific merit? [letter]. Phys Ther 1996 Jun:76(6):667-8.

Mulrow C, Cook D. Systematic Reviews: synthesis of best evidence for health care decisions. Philadelphia (PA): American College of Physicians; 1998.

Norton JM. Failure of a tissue pressure model to predict cranial rhythmic impulse frequency [abstract]. J Am Osteopath Assoc 1992;92:1285.(a)

Norton JM, Sibley G, Broder-Oldach RE. Quantification of the cranial rhythmic impulse in human subjects [abstract]. J Am Osteopath Assoc 1992;92:1285.(b)

Nunnally JC. Psychometric theroy. 2nd ed. New York: McGraw-Hill; 1978.

O'Connell JE. The vascular factor in intracranial pressure and the maintenance of the cerebrospinal fluid circulation. Brain 1943;66:204-28.

Patterson MM. Study demonstrates cranial bone mobility [editorial]. J Am Osteopath Assoc 1992;92(5):589.

Pederick FO. For debate: cranial adjusting, an overview. Chiropractic J Australia 1993 Sep;23(3):106-12.

Pederick FO. A Kaminski-type evaluation of cranial adjusting. Chiropractic Technique 1997 Feb;9(1):1-15.

Phillips CJ, Meyer JJ. Chiropractic care, including craniosacral therapy, during pregnancy: a static-group comparison of obstetric interventions during labor and delivery. J Manipulative Physiol Ther 1995 Oct;18(8):525-29.

Pitlyk PJ, Piantanida TP, Ploeger DW. Noninvasive intracranial pressure monitoring. Neurosurgery 1985 Oct;17(4):581-84.

Portnoy HD, Chopp M. Cerebrospinal fluid pulse wave form analysis during hypercapnia and hypoxia. Neurosurgery 1981 Jul;9(1):14-27.

Portnoy HD, Chopp M, Branch C, Shannon MB. Cerebrospinal fluid pulse waveform as an indicator of cerebral autoregulation. J Neurosurg 1982 May;56(5):666-78.

Quaid A. Craniosacral controversy [letter]. Phys Ther 1995 Mar;75(3):240.

Retzlaff E, Roppel R, Becker RF, Mitchell F, Upledger J. Craniosacral mechanisms [abstract]. J Am Osteopath Assoc 1976;76:288-9

Retzlaff EW, Michael DK, Roppel RM. Cranial bone mobility. J Am Osteopath Assoc 1975 May;74(9):869-73.

Retzlaff EW, Michael D, Roppel R, Mitchell F. The structures of cranial bone sutures [abstract]. J Am Osteopath Assoc 1976;75:607-8.

Retzlaff EW, Mitchell FL, Upledger JE, Biggert T. Nerve fibers and endings in cranial sutures [abstract]. J Am Osteopath Assoc 1978;77:474-5.

Rogers JS, Witt PL. The controversy of cranial bone motion. J Orthop Sports Phys Ther 1997 Aug;26(2):95-103.

Rogers JS, Witt PL, Gross MT, Hacke JD, Genova PA. Simultaneous palpation of the craniosacral rate at the head and feet: intrarater and interrater reliability and rate comparisons. Phys Ther 1998;78(11):1175-85.

Rosenberg W, Donald A. Evidence based medicine: an approach to clinical problem-solving. BMJ 1995;310:1122-5.

Rothstein JM. Craniosacral controversy: response [letter]. Phys Ther 1995 Mar;75(3):240.

Sackett DL, Haynes RB, Tugwell P. Clinical Epidemiology: a basic science for clinical medicine. Boston (MA): Little, Brown; 1991.

Sibley G, Broder-Oldach E, Norton JM. Interexaminer agreement in the characterization of the cranial rhythmic impulse [abstract]. J Am Osteopath Assoc 1992;92:1285.

St. Pierre N, Roppel R, Retzlaff E. The detection of relative movements of cranial bones [letter]. J Am Osteopath Assoc 1976 Dec;76(4):289.

Steiner C. Subjectivity: unsound basis for craniosacral research [letter]. J Am Osteopath Assoc 1979;78(6):386.

Sutherland WG. The cranial bowl. Maukato (MN): WG Sutherland; 1939.

Takizawa H, Gabra-Sanders T, Miller JD. Changes in the cerebrospinal fluid pulse wave spectrum associated with raised intracranial pressure. Neurosurgery 1987 Mar;20(3):355-61.

Takizawa H, Sugiura K, Baba M, Tachizawa T, Kamatsuka E, Hayama N. Spectral analysis of cerebrospinal fluid pulse wave [Engl abstract]. No To Khinkwi 1983 Dec;35(12):1227.

Tettambel M, Cicora RA, Lay EM. Recording of the cranial rhythmic impulse [abstract]. J Am Osteopath Assoc 1978;78:149.

Todd TW, Lyon DW Jr. Endocranial suture closure: its progress and age relationship. Part I: adult males of white stock. Am J Phys Anthrop 1924;VII(3):325-84.

Todd TW, Lyon DW Jr. Cranial suture closure: its progress and age relationship. Part II: ectocranial closure in adult males of white stock. Am J. Phys Anthrop 1925;VIII(1)23-45.

Upledger JE. A brain is born: exploring the birth and development of the central nervous system. Berkeley (CA); North Atlantic Books; 1996.

Upledger JE. Craniosacral therapy [letter]. Phys Ther 1995 Apr;75(4):328-29.

Upledger JE. Craniosacral therapy II: beyond the dura. Seattle: Eastland Press; 1987.

Upledger JE. An overview of craniosacral therapy: its origin and its applications for newborns and infants [letter]. Inf Young Children 1996;9(2):59-68.

Upledger JE. The relationship between craniosacral examination findings and the problems of special education students. J Am Osteopath Assoc 1979;78(5):379.

Upledger JE. The relationship of craniosacral examination findings in grade school children with developmental problems. J Am Osteopath Assoc 1978 Jun;77(10):760-76.

Upledger JE. The reproducibility of craniosacral examination findings: a statistical analysis. J Am Osteopath Assoc 1977 Aug; 76(12):890-9.

Upledger JE. Subjectivity: unsound basis for craniosacral research: author's reply [letter]. J Am Osteopath Assoc 1979;78(6):386-88.

Upledger JE, Karni S. Bioelectric and strain measurements during cranial manipulation. J Am Osteopath Assoc 1978;77:476.

Upledger JE, Karni Z. Mechano-electric patterns during craniosacral osteopathic diagnosis and treatment. J Am Osteopath Assoc 1979 Jul;78(11):782-91.

Upledger JE, Karni Z, Retzlaff E. Mechanoelectrically recorded physiological patterns which relate to subjectively reported craniosacral mechanism phenomena [letter]. J Am Osteopath Assoc 1978;78(4):297.

Upledger JE, Vredevoogd JD. Craniosacral therapy. Seattle(WA): Eastland Press; 1983.

Urayama K. Origin of lumbar cerebrospinal fluid pulse wave. Spine 1994 Feb 15;19(4):441-5.

Ursino M. A mathematical study of human intracranial hydrodynamics, part 1: the cerebrospinal fluid pulse pressure. Ann Biomed Eng 1988;16(4):379-401.(part 1)

Ursino M. A mathematical study of human intracranial hydrodynamics, part 2: simulation of clinical tests. Ann Biomed Eng 1988;16(4):403-16.(part 2)

Vickers A, Cassileth B, Ernst E, Fisher P, Goldman P, Jonas W, et al. How should we research unconventional therapies? A panel report from the Conference on Complementary and Alternative Medicine Research Methodology, National Institutes of Health. Int J Technol Assess Health Care 1997;13(1):111-21.

Weed DL, Hursting SD. Biologic plausibility in causal inference: current method and practice. Am J Epidemiol 1998 Mar 1;147(5):415-25.

White WK,White JE, Baldt G. The relation of the craniofacial bones to specific somatic dysfunctions: a clinical study of the effects of manipulation. J Am Osteopath Assoc 1985;85(9):603-4.

Wirth-Pattullo V, Hayes KW. Craniosacral controversy: response [letter]. Phys Ther 1995 Mar;75(3):240.

Wirth-Patullo V, Hayes KW. Craniosacral therapy: response [letter]. Phys Ther 1995 Apr;75(4):329-30.

Wirth-Pattullo V, Hayes KW. Interrater reliability of craniosacral rate measurements and their relationship with subjects' and examiners' heart and respiratory rate measurements. Phys Ther 1994 Oct;74(10):908-20.

Zabolotny W, Czosnyka M, Walencik A. Cerebrospinal fluid pulse pressure waveform analysis in hydrocephalic children. Childs Nerv Syst 1995 Jul;11(7):397-399.

Appendix C. BCOHTA Intervention Study Appraisal Form

BC OFFICE OF HEALTH TECHNOLOGY ASSESSMENT
Centre for Health Services and Policy Research
University of British Columbia
S184 Koerner Pavilion - 2211 Wesbrook Mall
Vancouver BC (Canada) V6T 1Z3

INTERVENTION STUDY APPRAISAL FORM

Reference	Assessment ÿ Excellent ÿ Good ÿ Fair ÿ Poor	
WHY	**HOW**	**WHO**
ÿ Is sufficient evidence presented to justify the study?	**STUDY DESIGN** ÿ controlled trial ÿ prospective analytic study ÿ retrospective analytic study ÿ before-after study ÿ cross-sectional study ÿ case series	ÿ Is the population from which the sample is drawn CLEARLY described?
ÿ Is there a CLEAR statement of the purpose of the study		ÿ Are inclusion and exclusion criteria specified and replicable?
ÿ Is there a CLEAR statement of the study hypothesis?		ÿ Do the inclusion and exclusion criteria match the goals of the study?
ÿ Is it clearly outlined whether the study is considering: EFFICACY or EFFECTIVENESS?		ÿ Do the authors account for every patient who is eligible for the study but does NOT enter it?
COMMENTS	ÿ If it is a controlled trial, is the allocation of subjects TRULY randomized?	ÿ Is the baseline comparability of the treatment and control groups documented?
	BLINDNESS ÿ Unblinded ÿ double-blind ÿ single-blind ÿ triple-blind	**COMMENTS**
	ÿ Was prognostic stratification used?	
	COMMENTS	

Appendix C. - Continued

2.

WHAT	HOW MANY	SO WHAT
ÿ What is the intervention? Is it clearly defined and replicable?	ÿ Was statistical significance considered?	ÿ If differences were detected, were they clinically significant?
ÿ Was compliance with intervention(s) measured and were non-compliers analyzed correctly?	ÿ Were statistical tests applied appropriately?	ÿ Were the patients entered and analyzed in the study sufficiently representative that the results can be generalized to other patients?
ÿ Were CONTAMINATION and CO-INTERVENTION considered?	ÿ How many tests of hypothesis (p-value) appear in the article?	ÿ Was the intervention as performed by those in the study sufficiently representative that the results may be generalized to other settings?
ÿ Were all patients who entered the study accounted for?	ÿ Did the authors consider sample size requirements prior to the study?	ÿ Were the outcomes assessed in the study sufficient to guarantee which of the therapies under study does the greatest good?
ÿ Were withdrawals, drop-outs, cross-overs, and poor compliers analyzed in accordance with the aims of the study?	ÿ When no differences were found, was there any consideration of possible β-error?	**COMMENTS**
ÿ What outcome measures were utilized? Were all the relevant outcomes reported?	ÿ Was the study large enough to detect important differences?	
COMMENTS	**COMMENTS**	