Preliminary prediction models for autonomic nervous system response to a cranial osteopathic technique

Kim Collard

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Declaration

Name of candidate: Kim Collard

This Research Project entitled ‘Preliminary prediction models for autonomic nervous system response to a cranial osteopathic technique’ is submitted in partial fulfilment for the requirements for the Unitec degree of Master of Osteopathy.

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I confirm that:

- This Thesis/Dissertation/Research Project represents my own work;
- The contribution of supervisors and others to this work was consistent with the Unitec Regulations and Policies.
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Research Ethics Committee Approval Number: 2008-848

Candidate Signature: ....................................................Date: ....................

Student number: 1112467
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Abstract

Preliminary prediction models for autonomic nervous system response to a cranial osteopathic technique

Background and Objectives Osteopathy in the cranial field (OCF) is a contentious area of manual therapy. The literature base has attracted much debate, and consists of theories, anecdotal claims and limited academic research. As such, the potential mechanisms and effects of OCF remain poorly understood. Current research into the physiological effects of OCF is directed toward changes in measures of autonomic nervous system function. One cranial osteopathic technique, the CV4, is commonly claimed to increase parasympathetic activity. The aim of this study was to determine if the CV4 has the potential to increase parasympathetic nervous system activity in some individuals, to examine the notion of ‘responders’ and ‘non-responders’ to the CV4. Further, this study investigated variables from the participants’ history which predicted response to the CV4, with the objective of identifying responder characteristics in order to assist future research into the mechanisms and effects of OCF techniques.

Methods Heart rate variability was measured in thirty participants during an experiment consisting of four phases: baseline, touch control, intervention (CV4) and post-intervention. The CV4 was delivered by one of three registered osteopaths who were experienced in cranial approaches. Response and non-response to the CV4 were operationally defined for the study. Changes in heart rate variability across the phases of the experiment were analysed individually for each participant to determine response or non-response to the CV4. Potential predictor variables for response were collected prior to the experiment. Following allocation of participants into response and non-response categories, logistic regression was used to determine which, if any, variables predicted response to the intervention.

Results 14 participants were classified as responders, 16 participants were classified as non-responders. Logistic regression demonstrated predictive value of the variables relating to the individuals’ history of physical trauma and baseline heart rate variability to predict response. The variable height offered marginal predictive value.

Conclusion Results of this study support claims that the CV4 has the potential to increase parasympathetic activity in some individuals. Short-term parasympathetic response to the CV4, determined by spectral analysis of heart rate variability, may be associated with an individual’s baseline ANS activity, history of physical trauma, and possibly height. Further research is required to refine understanding of response to the CV4, and to establish the relevance of the prediction models developed in this study.

Key words Osteopathy in the cranial field; OCF; cranial osteopathy; CV4; heart rate variability; autonomic nervous system; logistic regression analysis; prediction model
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Preface

This research project is divided into three parts. The first part is a literature review which outlines osteopathy in the cranial field, describes related theories and relevant research, then discusses literature supporting the methodology used in this study. The second part is a manuscript and related appendices which will be submitted for publication to the *International Journal of Osteopathic Medicine*. The manuscript uses the referencing style stipulated by the publisher. Due to the volume of material contained within the manuscript, it will be divided into two separate reports for publication, with the appendices made available on-line. However, for examination purposes is presented here as one report. The third section of this project is an appendix that contains documentation of ethics approval, participant information and guidelines for publication.
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Chapter 1

Introduction

Osteopathy in the Cranial Field (OCF) originated in the early 1900s and has developed into an area of treatment that engenders a great deal of controversy within the osteopathic profession. Anecdotal reports of positive, sometimes profound, treatment outcomes are contrasted by strong criticism of OCF due to the lack of scientific basis behind its principles and techniques. Further research into the mechanisms and effects of OCF may prompt an increase in critical reflection within the osteopathic profession. Such reflection would enable objective review of OCF techniques, as opposed to the polarised and often emotionally laden viewpoints that are frequently expressed.

This literature review begins with a descriptive discussion, outlining the historical background of osteopathy and giving an overview of OCF. The development and principles of OCF are described, followed by an explanation of key theoretical models attempting to explain the purported effects of OCF.

Subsequently, the literature review provides critique of research into the reported mechanisms and effects of OCF, these are considered under three broad categories:

- Research utilising patient-oriented outcome measures
- Investigations into cranial motility and the ‘cranial rhythmic impulse’
- The physiological effects of OCF techniques, particularly the ‘Compression of the fourth ventricle’ technique (CV4)

Researchers investigating the effects of OCF face many challenges, largely because claims about the modality are based on anecdotal findings and presuppositions not recognised by mainstream biomedicine. Challenges include development of research projects that are representative of clinical experience and osteopathic principles, yet are scientifically robust. Commentary on these challenges leads to an explanation of the rationale behind the current study.

The effects of the CV4 technique on the autonomic nervous system have been the subject of a number of investigations (Glonek, 2009; Milnes & Moran, 2007; Richards, McMillin, Mein, & Nelson, 2001), which provide a background for this study. The use of heart rate variability (HRV) as an outcome measure for changes in autonomic function is examined, followed by a review of the methods of data analysis used in this study to develop prediction models for autonomic nervous system response to the CV4 technique.
Chapter 2

A Brief Historical Background to Osteopathic Principles

Osteopathic medicine is a form of manual medicine that draws on a range of theoretical models of health and disease (2006). A variety of treatment approaches are described within the scope of osteopathy, therefore it can be difficult to provide an over-riding definition of osteopathic medicine. The various osteopathic treatment approaches draw on common foundational principles, aiming to facilitate and promote health within a biopsychosocial context, rather than treating only the apparent symptoms of disease (Höppner, 2008). Stone (1999) summarises three main areas of clinical interest to osteopaths; medicine, biomechanics and traumatology.

Osteopathic principles were initially outlined in the late 1800s, by the founder of osteopathy, American physician Andrew Taylor Still. Still’s dissatisfaction with the traditional medicine of his time lead him to develop osteopathy as an alternative approach to medicine, after more than a decade of extensive personal study in anatomy, clinical medicine and philosophy (McKone, 2001). Still’s concept of ‘body unity’ views each person as a unit composed of body, mind and spirit, living in an environment which provides the essentials of life. According to this concept, health can be influenced by any or all of the individual components that make up the body unity, or by the environment which the individual inhabits (Kuchera & Kuchera, 1992). Further, Still viewed the person as a self-sustaining organism, possessing all of the homeostatic mechanisms required for health. This view was in strong contrast to the practices of the orthodox medical establishment of Still’s time, whose therapeutic endeavours involved practices such as purging, blood-letting and the prescription of poisonous substances such as arsenic and mercury (Still, 1908).

Still’s initial teachings had a strong philosophical basis, influenced by his Methodist upbringing and a period in American history where alternative views on spiritualism and technology were emerging. It has been suggested that Still’s philosophies were strongly influenced by the contemporaneous development of the theory of pragmatism by Charles Pierce (Ward, 2003).

Still (1902, p. 18) defines osteopathy as:

“...a scientific knowledge of anatomy and physiology in the hands of a person of intelligence and skill, who can apply that knowledge to the use of man when sick or wounded by strains, shocks, falls or mechanical derangement or injury of any kind to the body.”

In his writings, Still used many mechanical and military analogies to describe his philosophies, he viewed the human body as being created by a ‘master mechanic’ and having the perfect machinery for health. A disruption in the mechanical structure of the body, whether on a gross structural or microscopic level, is what Still believed to be the cause of all ill-health (Still, 1902). Still deliberately sought to keep the principles of osteopathy simple, and intended for these principles to be applied to any type of osteopathic treatment. The original principles were later
simplified for teaching purposes, and to aid understanding of the osteopathic approach to healthcare for those outside the profession (Ward, 2003).

In the 1950s Still’s philosophies were summarised into four basic osteopathic principles (reproduced from Ward, 2003):

1. The body is a unit; the person is a unit of body, mind and spirit.
2. The body is capable of self-regulation, self-healing, and health maintenance.
3. Structure and function are reciprocally integrated.
4. Rational treatment is based upon an understanding of the basic principles of body unity, self-regulation and the interrelationship of structure and function.

As the osteopathic profession has grown over subsequent years, descriptions and explanations for osteopathic treatment have expanded, though the principles remain essentially the same. Stone (1999), osteopath and author of several undergraduate textbooks, states that the application of technique according to osteopathic principles as being the point that makes osteopathy unique amongst the manual therapy professions. While various osteopathic treatment approaches and specialties exist; different branches of osteopathic medicine utilise the described core principles as a basis for viewing and treating each individual patient.
Chapter 3

An Outline of Osteopathy in the Cranial Field

Osteopathy in the Cranial Field (OCF) is one treatment approach that has rapidly gained popularity over recent years (Chaitow, 2005); it originated from William Garner Sutherland, who first taught cranial osteopathy in 1929 (Magoun, 1976).

3.1 Development of Theories about Osteopathy in the Cranial Field

Sutherland was a student of AT Still, and graduated from the American School of Osteopathy in 1899 (Ward, 2003). His fascination with the bevelled sutures of the human skull led Sutherland to thirty years of personal study, resulting in a form of treatment known as osteopathy in the cranial field, or cranial osteopathy. Applying Still’s principle of the relationship between structure and function, Sutherland reasoned that the sutures of the skull were structured to allow movement, and therefore must move, at least to a small degree (Patterson, 2000). Sutherland’s hypothesis was contradictory to the anatomical teaching of the time, which stated that the articulations of the skull ossified and fused after growth had finished. One of Sutherland’s key principles of OCF is what is believed to be the involuntary motion between the bones of the skull, related to rhythmic fluctuations of cerebrospinal fluid. According to Sutherland, this rhythmic motion is driven by what he named the ‘primary respiratory mechanism’ (PRM) (Sutherland, 1939).

The components of the PRM are (reproduced from Sutherland, 1990):

1. inherent motility of the brain and spinal cord
2. fluctuating cerebrospinal fluid (CSF)
3. the ‘reciprocal tension’ of intercranial and spinal membranes (meninges, dura etc.)
4. articular mobility of the cranial bones and involuntary motion of the sacrum between the ilia

The primary respiratory mechanism was so-named by Sutherland because he believed it was related to the ‘internal respiration’ of the central nervous system (CNS), that is the ‘fluidic interchange’ necessary for biochemical and metabolic functions at a cellular level (Magoun, 1976; Sutherland, 1990). Sutherland believed the PRM to be generated by the CNS, transmitted through the fluid and fascia, and palpable anywhere on the body (Ferguson, 2003). The ‘cranio-sacral system’ is a term used to describe the anatomical components of the PRM, being the CNS and its bony and membranous coverings (Upledger & Vredevoogd, 1983).

Osteopathy in the Cranial Field has developed around the concept of the PRM and utilises techniques that are claimed to manually manipulate the components of the PRM in order to
restore what is regarded by proponents of OCF as healthy function of the mechanism. It must be noted that whilst palpation and treatment of the PRM is a phenomenon maintained by cranial practitioners, its existence is contentious and not accepted by many conventional medical practitioners or by a number of osteopaths.

As Sutherland was developing his cranial theories in the early 1900’s, other osteopathic and chiropractic physicians, namely Charlotte Weaver and Nephi Cottman, were developing similar models of cranio-sacral motion (Jordan, 2009). Subsequent to its development, Sutherland’s model has been widely taught in osteopathic education, aided by the Cranial Academy and the Sutherland Cranial Teaching Foundation that Sutherland himself established in 1953 (Jordan, 2009; Sutherland, 1990).

### 3.2 Possible Influences on Development of Sutherland’s Theories

Gintis (2007) cites the influence of mid-twentieth century philosopher Walter Russell, who stated that the universe was founded on a unifying principle of rhythmic balanced interchange, upon the early development of OCF concepts by Sutherland. Recent investigations have highlighted significant similarities between Sutherland’s theories and those of Emanuel Swedenborg, an eighteenth century scientist who reportedly developed original theories on brain physiology (Jordan, 2009). Swedenborg’s writings were translated from German to English in 1882, and Jordan (2009) suggests that Sutherland’s model of the PRM may have been heavily influenced by Swedenborg’s theories. Whilst there appears to be a strong influence of Swedenborg’s theories upon Sutherland’s writings, such speculation is of little use with regards to the treatment outcomes and physiological effects of OCF.

Independent of the Western philosophies contributing to the contemporary concept of cranial therapy, systems of traditional medicine have included the practice of cranial techniques in many cultures. Milne (1995) asserts that whilst Sutherland had a major influence on the development of cranial therapy, he did not ‘invent’ it, as various forms of therapy applied to the head had been practiced centuries before in traditional Chinese, Indian, Egyptian, American Indian and Peruvian medicine. Undoubtedly, Sutherland was the first to develop cranial therapy within the osteopathic profession (Milne, 1995).
3.3 Current Approaches to Cranial Therapy

There is significant overlap in the theories and practices of the different branches of cranial therapeutic treatment. From its beginnings with the hypotheses of William Garner Sutherland, Charlotte Weaver and Nephi Cottam, cranial therapy has developed and diversified. Currently, the area of complementary and alternative medicine (CAM) known as cranial therapy has several branches, one of which is OCF. In turn, OCF is just one branch of osteopathy. Whilst principles and concepts of general osteopathy are applicable to OCF, the principles and concepts specific to OCF are not all applicable to general osteopathy. In New Zealand, the three most practiced forms of cranial therapy are OCF, cranio-sacral therapy (CST) and sacro-occipital technique (SOT) (Evans, B., personal communication, August 30, 2009).

Sacro-occipital Technique has developed from the chiropractic models of Major B. DeJarnette, an acquaintance of Sutherland's who was influenced by his theories (Keating, 2003). Predominantly practiced by chiropractors, SOT utilises muscle testing as a form of diagnosis, and specific guidelines are provided for the following treatment (Pedrick, 2005). During the 1970s and 1980s, American osteopath John Upledger and his colleagues conducted preliminary research on the so-called cranio-sacral system, in an effort to scientifically validate the theories introduced by Sutherland (Upledger, 2004). Upledger's research led to the development of CST, which he went on to teach to a variety of practitioners including those not trained in osteopathy, such as massage therapists and physiotherapists. The theories and principles underlying cranio-sacral therapy are consistent with those of OCF, however their application may differ (Upledger & Vredevoogd, 1983). Two of the major differences between OCF and CST are reported to be the anatomical focus of treatment, and the degree of manual pressure used to treat (Upledger, 2002). According to Upledger, OCF is directed toward movement between sutures whilst CST is directed toward tension within the dural membranes. Upledger (2002) also states that the manual pressure used to treat during CST is far lighter than that used in OCF, and consequently, according to Upledger, CST may be viewed as a more gentle treatment approach. The differences asserted by Upledger may be disputed by OCF practitioners. Initially a ‘mechanistic’ approach developed by Sutherland, OCF has evolved into a style of treatment reportedly utilizing osseous, fluidic and membranous components of the PRM (Chaitow, 2005).

Within OCF itself, there is a spectrum of treatment approaches, ranging from ‘biomechanical’ to ‘biodynamic’ (Parsons & Marcer, 2006). At the biomechanical end of the spectrum, a primarily structural approach is taken to correcting dysfunction or restriction of the bones and membranes, which is said to enhance the flow of CSF, and to assist venous drainage of the skull (Leim, 2004). This structural approach may be viewed from various osteopathic perspectives, and there is some overlap in this area between ‘structural OCF’ and ‘regular’ osteopathy. Reducing bony and articular restrictions within the cranium could be considered at a biomechanical level, and is likely to be accepted by most osteopathic practitioners as a valid treatment approach for certain pathologies, for example a ‘frontal lift’ technique” in cases of headache or sinusitis. However, if the same perceived bony restriction was considered and treated within the context of the PRM,
the treatment approach would be utilising principles specific to OCF. Even though the choice of techniques may be similar, the perceived palpatory phenomena, rationale and theoretical basis for treatment would be quite different. Biomechanical OCF tends to focus on the sphenobasilar synchondrosis\(^b\) as a primary location of cranial motion restrictions, and reportedly utilises mechanical technique to correct perceived dysfunction (Leim, 2004).

Practitioners of OCF may claim to work with gross mechanical lesions, or subtle imbalances in tissues or the electromagnetic fields of the body. McPartland and Skinner (2005) describe how biodynamic OCF employs a more intuitive and instinctual approach than the biomechanical model. The principles of biodynamic OCF have many references to the embryological development of the human. The studies of Erich Blechschmidt, a ‘biodynamic’ embryologist, highlight the crucial role that fluid flow plays in embryogenesis (Blechschmidt & Freeman, 2004). The organized embryonic channels of fluid motion, present from the moment of conception, apparently direct cellular and tissue formation as genes react to hydrostatic pressure and other external forces created by this fluid matrix (Blechschmidt & Freeman, 2004). Biodynamic OCF practitioners base their treatment on the a priori hypothesis that the fluid dynamics involved in embryonic development are early expressions of the PRM, and that the embryologically formed fluid matrix persists throughout life, providing an inherent ‘blueprint’ for health and wellbeing. This theory is integrated with Still’s principle of the person as a self-sustaining and self-regulating organism, with an inherent drive toward and capacity for health. Both philosophical and physiological hypotheses for ‘biodynamic’ OCF theories have been explored and discussed (R. E. Becker & Brooks, 2000; Blacklaw-Jones, 2009; Gintis, 2007; Jealous, 2006; Lee, 2008; McPartland, 2008a; McPartland & Skinner, 2005). However, to date, little substantive data has been presented which supports these hypotheses, and rationale supporting palpation and manipulation of these ‘inherent fluid fluctuations’ and their relationship with health remains primarily within philosophical and anecdotal realms.

Recent ideas in OCF theory (Blacklaw-Jones, 2009; Lee, 2008; McPartland, 2008a; McPartland & Skinner, 2005) consider changes at a cellular and molecular level that are believed to occur during OCF. These models cite the cellular mechanism of mechanotransduction, the ability of cells to ‘translate’ mechanical stimulus into chemical signals, and electromagnetic exchange between patient and practitioner, to explain the therapeutic effects of OCF. Whilst commonly accepted in the field of cell biology, the use of mechanotransduction and electromagnetic exchange concepts to explain the mechanisms of OCF are speculative, and no studies have been found that support these hypotheses. However, the models of mechanotransduction and electromagnetic exchange provide a promising field for research into the mechanisms of OCF.

In a recent survey of 62 New Zealand osteopaths, Wittwer Blaser (2009) found that 27% of respondents used OCF with over 75% of their patients, second only to articulatory technique. Interestingly, in the same report, OCF was also found to be the modality most reported as not being used at all, with 11% of respondents never using OCF in practice, compared to just 2% of respondents never using articulatory technique. The results of Wittwer Blaser’s (2009) survey suggest that of the osteopathic practitioners that use OCF, some incorporate it as part of their treatment approach, while others use OCF as their predominant modality of treatment. Whilst the response rate for this survey represent only 25% of New Zealand osteopaths, the results could reflect: anecdotal reports of a wide spectrum of opinions regarding the use of OCF; evidence that

\(^b\) The sphenobasilar synchondrosis is the articulation in the cranial base where the body of the sphenoid bone articulates with the basilar part of the occiput.
OCF is a clinically utilised modality; and the differing opinions within the osteopathic profession toward OCF.

3.4 Contention around Osteopathy in the Cranial Field

Both historically and currently, OCF is a contentious area within the profession of osteopathy (King, 2002; Moran, 2005) and debate about it’s scientific evidence tends to polarise views within the profession (Leach, 2008). Because of the subtle and subjective nature of this therapy, it is notoriously difficult to obtain valid scientific data that might help researchers and clinicians understand the mechanisms and effects of OCF. Maddick (2007) suggests that while most of the explanatory models for cranial techniques appear to be flawed, this does not mean that the techniques themselves are ineffective.

Even within OCF itself, there is a great deal of debate and contention, as well as a myriad of treatment styles. Difficulties arise when appraising OCF literature, as it is often presented as a mixture of well established fact and anecdotal reports. Some of these anecdotal reports appear far-fetched, and unfortunately are often presented as fact alongside less contentious or well researched information. To a great extent, this dilemma is representative of the field of OCF in general, leading to a situation where many potentially useful techniques are disregarded because of the way they are presented or the information they are presented alongside. Osteopathy is a profession which is based upon principles such as the interrelationship between mind, body and spirit. Research in OCF is faced with the challenge of explaining in objective terms some aspects of treatment which may be inherently subjective and difficult to define, but nevertheless potentially useful and effective. Perhaps this challenge is responsible for the widespread use of metaphor and assumptions based upon random anecdotal claims as an attempt to explain the reported treatment effects of OCF.

Many of the early principles and research supporting them have been heavily criticised (Ferguson, 2003; Green, Martin, Bassett, & Kazanjian, 1999; Hartman, 2005; Patterson, 2000). Within the osteopathic profession, some doubt the efficacy of OCF and challenge its relevance in teaching and practice (Hartman, 2005). Despite these controversies, anecdotal claims of palpable cranial phenomena and successful treatment outcomes warrant further investigation into the effectiveness of OCF (Moran, 2005).
Chapter 4
Principles of Treatment Using Osteopathy in the Cranial Field

4.1 Concepts of Subtle Motion

Central to the principles of OCF is the described interrelationship of motion and stillness within the primary respiratory mechanism (PRM). Rollin Becker used the term ‘dynamic stillness’ to describe the state of stillness perceived to co-exist within the movement of living systems (R. E. Becker & Brooks, 2000). The movement of living systems may be viewed as a collection of cyclic rhythms, which are fundamental to life and exist on many physiological levels. Cycles of activity and rest, cardiac systole and diastole, and neurotransmitter release and reuptake are examples of this rhythmic interchange. Often, the components of biological cycles are functionally inseparable and are responsible for a dynamic physiological balance that is essential for homeostasis, adaptability and health.

Osteopaths claim to utilise palpation of various tissues to identify and treat points of relative non-motion. These points may be anatomical points that provide both stability and a pivot for movement, or areas of dysfunction that demonstrate restricted motion. Such points may be identified in articular or muscular structures, within the viscera, fascia or at a local tissue level. The analogy of a see-saw is often used in biomechanical terms to describe a physiological fulcrum, a non-moving reference point between two moving ends of a lever. Biomechanical fulcnums are frequently used as the therapeutic ‘handle’ to affect change in structural forms of manual therapy. Within the cranial concept a more subtle fulcrum is claimed to exist; the point of inertial stillness within the motion of the PRM (Leim, 2004). This perceived stillness is said to provide a shifting ‘fulcrum’, which acts as a reference point for therapeutic change in dysfunctions of the PRM (R. E. Becker & Brooks, 2000; Gintis, 2007).

Palpation of the PRM is argued to require both refined palpatory skills and the ability of the practitioner to put themselves into a state of relaxed awareness (Chaitow, 2005). It is postulated that such a state enables the practitioner to ‘listen’ to the subtle activity of the PRM (Stone, 1999) and hold an awareness of how this activity operates in the context of the individual’s function.

4.2 A Description of the Cranial Rhythmic Impulse

It is proposed by theorists and practitioners of cranial therapy that ‘primary respiration’ is a cycle consisting of two distinct phases, sometimes named ‘inspiration’ and ‘expiration’ (Leim, 2004). These terms are easily confused with the inspiration and expiration of thoracic respiration, which is regarded by cranial practitioners as ‘secondary respiration’. Within the context of cranial therapy, the ‘inspiration’ phase is also known as ‘flexion’, and the ‘expiration’ phase as ‘extension’. It is proposed that during the flexion phase, midline structures of the body flex, while the paired structures (including the limbs and some of the cranial bones) externally rotate. The opposite is
said to occur during extension, when the midline structures reportedly move into relative extension and the paired structures internally rotate (Sergueef, 2007).

In 1961, osteopaths John and Rachel Woods coined the term ‘Cranial Rhythmic Impulse’ (CRI) to refer to the palpable expression of the PRM (Woods & Woods, 1961). Whilst not used by Sutherland, this term has been widely adopted amongst cranial practitioners. A broad range values have been reported to describe the frequency of the CRI, suggesting that multiple palpable oscillations may be simultaneously present (Leim, 2004). The CRI is generally described as an oscillation of 6-14 cycles per minute (cpm) (Marcer & Parsons, 2006; McPartland & Skinner, 2005). Becker describes two distinct rhythms associated with the PRM, one oscillating at 8-12 cpm which he names the ‘fast tide’ and a slower rate of 0.6 cpm he names the ‘slow tide’ (R. E. Becker & Brooks, 2000). Generally speaking, slower rhythms (0.2 – 3 cpm) are described more often in the biodynamic OCF literature (Jealous, 2006; McPartland & Skinner, 2005).

### 4.3 Cranial Dysfunction

Reportedly, alterations or distortions in the PRM may be a component of various pathological processes, and can be palpated by practitioners trained in OCF as ‘cranial dysfunction’. According to cranial practitioners, this dysfunction then can be treated through facilitatory touch, applying the principles and techniques of OCF, and thereby diminish a patient’s symptoms.

Anatomically, the cranio-sacral system is intimately linked to the CNS. Cranial practitioners argue that any dysfunction or restricted motion within the bony, fluid, membranous or neurological tissues of the system theoretically may lead to dysfunction of the CNS and neuro-endocrine network. Because of it’s reported ability to affect the CNS, OCF is regularly used to treat conditions such as certain types of physical trauma, headache and chronic pain syndromes (Chaitow, 2005).

The cranial nerves are responsible for control of many bodily functions. These nerves originate in the brain and upper spinal cord, exit the skull through small foramina, and travel through various structures on the course to their effector organ (Moore & Dalley, 2006). McPartland (2005) explains that restriction of the cranial nerves can lead to their sub-optimal functioning, which can then subsequently give rise to a wide variety of symptoms within the viscera or sensory organs which the cranial nerves supply. Whilst OCF has an emphasis on optimising the function of cranial nerves, cranial techniques are not limited to the head, and reportedly can be applied to the whole body (Parsons & Marcer, 2006). The term ‘cranial dysfunction’ is used to refer to both dysfunction within the cranium, and supposed alterations of the PRM which may involve any area of the body.
4.4 Aims of Osteopathy in the Cranial Field

Magoun (1976) outlines the specific aims of cranial treatment as:

1. to normalise nerve function
2. to counteract stress producing factors
3. to eliminate circulatory stasis
4. to normalise CSF fluctuation
5. to release membranous tension
6. to correct cranial articular lesions
7. to modify gross structural patterns

Alongside these specific aims, much of the OCF practiced today supposedly takes a more global approach, reportedly working with the ANS to ‘normalise the PRM’ (Sergueef, 2007). Such treatment is aimed at increasing the efficiency of the inherent homeostatic mechanisms of an individual, rather than correction of a specific lesion (Chaitow, 2005). In this way, OCF may be thought of as a therapy that centres on the person receiving the treatment, rather than a therapy that focuses on specific disease processes.
Chapter 5

Theoretical Models Attempting to Explain the Cranial Rhythmic Impulse and Clinically Reported Effects of Osteopathy in the Cranial Field

Some current ideas around the mechanisms of OCF extend well beyond the anatomical boundaries of the cranio-sacral system, and further draw on the concepts of body unity, ‘treating the whole person’ and facilitating health. A potentially confusing aspect of the OCF literature is that theoretical models are often presented alongside research findings which may support aspects of the theory, rather than the complete theory itself. Sometimes these findings are from research specific to OCF, others are adopted from different disciplines and appear at times to be interpreted outside of their intended context. In an attempt to reduce this potential confusion, this chapter presents theoretical models, and the following chapter presents research relating to various aspects of these models.

5.1 The Cranial Rhythmic Impulse

Various models exist which endeavour to explain the source of the CRI. After reviewing much of the literature, Chaitow (2005) summarises these theorised sources of the CRI as; intrinsic motion of the brain and spinal cord; production and fluctuation of the CSF, the neurological activity within muscles; movement of lymphatic fluid; the motion of blood vessels; tissue pressure; autonomic nervous system activity; and entrainment. Several of these sources will be further discussed, as well as recently presented theories involving changes in cellular and extracellular activity.

5.1.1 CSF Fluctuation and Changes in Intracranial Pressure

Upledger and Vredevoogd (1983) proposed a ‘pressure-stat’ model. This model cites the rhythmic production of CSF by the choroid plexus, and its consequent drive of CNS motility to explain the rhythm palpated as the CRI.

Ferguson (2003) refutes the theory that the CRI is driven primarily by CSF production, and states that CSF is not produced in sufficient quantity with sufficient pressure to produce such palpable

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The phrase ‘treating the whole person’ is often used when describing osteopathy, it implies treatment that considers body, mind and spirit. The phrase also implies a therapeutic viewpoint of how the patient’s presenting complaint influences and is influenced by other areas of the body including biomechanical, nervous, metabolic and vascular relationships.
fluctuations. Further, Schleip (2002) points out that if production of CSF was the sole driver of the PRM, it would seem implausible that this fluctuation could be palpated synchronously throughout the body, as a delay in the resulting wave would be expected between the head and the feet.

Chaitow concluded that CSF movement and brain motility is likely to be driven by “variations in intercranial pressure resulting largely from expansion of arterial structures in response to cardiac function” (2005, p. 31). This conclusion is aligned with a theory proposed by Gard (2009), which suggests that there is a vascular mechanism to reduce intercranial pressure which functions in response to cyclical production of CSF, leading to minute increases in intercranial pressure. Gard (2009) further states that the pulsations of vascular compression and release and transmitted through the bones of the cranium and are then palpated as the CRI.

5.1.2 The Potential Role of the Autonomic Nervous System

McPartland and Mein (1997, p. 40) state that “the primary underlying mechanism generating the CRI is the balance between the sympathetic and parasympathetic nervous systems”. Further, McPartland and Mein (1997) postulate that if there is balance in the ANS, then the harmonious entrainment frequency of various biological rhythms (including the Traube-Herring-Mayer (THM) oscillation, fluctuation of CSF and lymphatic fluid, and electrical fields generated by the activity of nerves) will be palpable to the practitioner as a strong and healthy CRI. However, research to test this hypothesis would not be achievable unless a reliable measure of the CRI had been previously developed. The role of the ANS in OCF has been explored in a preliminary manner in the research literature, and will be discussed in the following chapter.

5.2 Proposed Cellular Changes

McPartland (2008a), Lee (2008) and Blacklaw-Jones (2009) propose physiological models for the clinically reported effects of OCF outlined in cellular and molecular terms. McPartland (2008a) speculates that some of the reported therapeutic effects of OCF—such as reduction of pain, anxiety and inflammation—may be mediated through the activation of endocannabinoid production and release. Endocannabinoids have many effects in the body (Marsicano, Pagotto, Cervino, Pasquali, & Larry, 2009; Piomelli, William, & Lane, 2004) and influence the ANS by enhancing parasympathetic activity and decreasing sympathetically-mediated pain by inhibiting release of norepinephrine (McPartland et al., 2005). It has been suggested by McPartland (2008a) that these compounds play a central role in the PRM and treatment with OCF.

Lee (2008) explores the possible function of the PRM within the extracellular matrix (ECM) of the body’s tissues. Lee states that, because of its piezo-electric properties, the ECM is capable of mechanotransduction, whereby mechanical stimulus is converted to an electrical signal. Lee proposes that cell surface receptors transmit the electrical signal into the cell, which may respond to the stimulus by a change in gene expression and intra-cellular function (an example of the

Piezo-electric: The piezoelectric effect is the production of electrical charge in a material by the application of mechanical stress. Many biological materials have been found to be piezoelectric, including tendon, dentin, aorta, trachea, intestine, elastin, and the nucleic acids (R. O. Becker & Marino, 1982).
reverse piezo-electric effect\(^6\)). It is postulated that the described piezo-electric effects may mediate the cellular responses that are believed to occur during OCF (Lee, 2008).

The model presented by Blacklaw-Jones (2009) also cites piezo-electric activity as a possible mediator of responses to OCF, and theorises about the magnetic fields generated by electrical activity within the body. It is stated that the magnetic fields generated by this electrical activity pulsate in synchrony with the electrical waves. Purportedly, this electromagnetic activity causes molecules, and therefore the body’s tissues, to vibrate coherently\(^1\). Blacklaw-Jones (2009) proposes that OCF practitioners, upon entering a meditative or contemplative state during a therapeutic encounter, are able to produce coherent vibration of their own body’s tissues. It is postulated that through physical contact, electromagnetic energy from the practitioner’s coherent body field is transmitted to the patient’s less coherent body field, thereby inducing a therapeutic change in the electromagnetic fields of the patient. Blacklaw-Jones (2009) suggests this increased coherence then stimulates the cellular function of the patients’ tissues, providing a means to enhance self-regulation and homeostasis.

5.3 **The Entrainment Hypothesis**

McPartland and Mein (1997) proposed that the CRI is a rhythm produced by the integration, or entrainment, of multiple biological oscillations of both patient and practitioner. If this hypothesis is correct, it may explain the demonstrated lack of inter-examiner reliability in palpation of the CRI. The idea that motion palpated as the CRI is a summation of changes in both the practitioner and patient was also explored by Norton (2001), who proposed that the CRI is associated with slowly adapting cutaneous mechanoreceptors of both the patient and practitioner. The electromagnetic exchange proposed by Blacklaw-Jones (2009) may provide a biological explanation for the entrainment theory presented by McPartland and Mein (1997). Glonek (2009) also highlights the potential for ‘biomagneto-communication’ as a physical possibility, however alludes to the fact that relatively little is known about this possibility within current scientific understanding.

Electromagnetic exchange and entrainment within the therapeutic encounter are themes emerging in the more recent literature outlined above (Blacklaw-Jones, 2009; Lee, 2008; McPartland & Mein, 1997). The theories underlying these themes are outside the scope of this literature review, however are summarised in Chaitow (2005, pp. 41-45) and Oschman (2000). The therapeutic interaction between patient and practitioner has the potential to influence treatment outcomes. Further investigation may aid current understanding of interactions between patient-practitioner, and help to avoid the potential for misguided or sophisticated explanations for the mechanisms and effects of OCF.

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\(^6\) The reverse piezo-electric effect is where the production of mechanical stress when an electrical field is applied (Bracciano, 2008).

\(^1\) The meaning of ‘coherent’ in this context: “Physics: of, relating to, or having waves with similar direction, amplitude, and phase that are capable of exhibiting interference” (Collins Essential English Dictionary 2nd Edition. 2006).
Chapter 6

Research into the Reported Mechanisms and Effects of Osteopathy in the Cranial Field

Despite a great deal of theorising about the mechanisms of OCF, relatively little scientific research has been conducted. Arguably, OCF is based largely upon anecdotal evidence, conjecture and supposition that the PRM exists. Both a cause and effect relationship between alterations in the PRM and health status, and the clinical relevance of cranial dysfunction have yet to be adequately investigated.

Maddick and Korth (2006, p. 108) emphasize that “evidence-based medicine is the integration of research evidence with clinical expertise, not the rejection of clinical expertise in the absence of evidence”. Moran (2005) highlights that OCF is not the only area of osteopathic practice where conventional explanations require revision of in light of current medical knowledge. A recent systematic review by Ernst and Canter (2006, cited in Maddick & Korth, 2006) brings into question the effectiveness of spinal manipulation, a widely accepted manual therapy technique.

To date, OCF studies have utilised two main types of outcome measure: physiological change; and patient-oriented outcome measures such as pain and disability. Pragmatic clinical trials may provide a more complete picture of an individual’s response to OCF. However, the lack of experimental evidence regarding both the effects of OCF techniques and the physiological basis for the PRM, necessitate further laboratory based research to proceed concurrently with patient-oriented research approaches.
6.1 Research on Osteopathy in the Cranial Field Utilising Patient-Oriented Outcome Measures

Several studies utilise patient-oriented outcome measures to determine the effects of OCF techniques. Tension-type headache has been selected as a target condition in the two studies (Anderson & Seniscal, 2006; Hanten, Olsen, Hodson, Imler, Knab & Magee, 1999). As OCF is often advertised as a particularly gentle form of treatment (Osteopathy in the Cranial Field [Pamphlet], 2009), it is purportedly well suited to the treatment of infants and children. Several studies have been published on OCF treatment outcomes of infants and children, using otitis media and infantile colic as target conditions to examine the effects of OCF (Degenhardt & Kuchera, 2006; Hayden & Mullinger, 2006; Mills, Henley, Barnes, Carreiro, & Degenhardt, 2003).

6.1.1 Tension-type Headache

There are reports that OCF is effective in the treatment of tension-type headaches, both using an isolated OCF technique (Hanten et al., 1999) and as part of a treatment protocol using multiple OCF techniques alongside other non-cranial osteopathic techniques (Anderson & Seniscal, 2006). The non-specific nature of intervention in the study by Anderson and Sensical (2006) makes it impossible to determine the effects of OCF techniques in isolation or to draw conclusions about the effects of OCF in this study.

Hanten et al. conducted a randomized control trial studying the effects of an OCF technique, ‘compression of the fourth ventricle’ (CV4), upon pain in participants suffering from tension-type headache. Sixty participants were randomly allocated to one of three groups, all with intervention periods of ten minutes duration. The treatment group received the CV4 technique, the second group lay supine with their head and neck placed in a comfortable resting position, and the third group received no intervention, lying quietly for ten minutes. The ‘affective component of pain’ and ‘pain intensity’ were both measured using a visual analogue scale before and after the procedure. The researchers found significant (p<0.05) improvement in both the ‘affective component of pain’ and ‘pain intensity’ variables in the treatment group, compared to the resting position and control groups, and concluded that the CV4 technique may be effective in treating tension-type headaches. The effectiveness of multiple treatments and duration of treatment effect have yet to be investigated, and would be necessary before attributing clinical utility to the results of this study. As sub-occipital muscular tension is known to play a role in the presentation of cervicogenic and tension-type headaches (Bogduk, 1995), it is plausible that the CV4 technique had an effect via inhibition and consequent relaxation of these muscles. Future studies could address this possibility by comparing the effect of the CV4 technique with the effect of sub-occipital muscle inhibition in participants with tension-type headaches.

6.1.2 Otitis Media

Otitis media is an infection of the middle ear common in young children, the conventional treatments are antibiotic therapy and surgical insertion of grommets to allow drainage of the middle ear. Research conducted by Degenhardt & Kuchera (2006) and Mills, Henley, Barnes,
Carreiro, & Degenhardt (2003) suggest that OCF treatment alongside allopathic medical treatment may improve outcomes for children with recurrent otitis media. Whilst Degenhart and Kuchera (2006) concluded that OCF may change the progression of recurrent otitis media, the conclusions drawn from reported results are questionable. This study used a small sample size of eight participants, each receiving a total of three OCF treatment sessions, alongside allopathic treatment for otitis media. There is no mention of standardisation of the allopathic treatment in this study, meaning many unexplained variables could confound the results. As the study did not utilise a control group to investigate the progression of the condition without OCF treatment, the effects of OCF alongside allopathic treatment are not able to be compared to the effectiveness of allopathic treatment alone. Five of the eight participants had no recurrence of symptoms as reported by caregivers one year post treatment. Although this improvement may have been partly due to the OCF treatment, the conclusions of the study lack support from the data presented. While the conclusions of this study appear biased, the researchers themselves acknowledge that additional investigation is required before more reliable conclusions can be made regarding the effectiveness of OCF treatment for otitis media.

The earlier study by Mills et al. (2003) also utilised a sample already receiving allopathic care for otitis media. This study used a much larger sample size of 57 participants, with participants divided into control and intervention groups. The osteopath was blind to patient clinical course, and the pediatrician managing allopathic care was blind to study outcomes and patient group allocation, as knowledge of these factors may have prompted bias. Following OCF intervention, fewer episodes of acute otitis media; fewer surgical procedures; and greater improvement in tympanogram measures were reported, compared to the control group.

It can be concluded from both of these studies that osteopathic care alongside allopathic treatment for otitis media may improve patient outcomes.

6.1.3 Infantile Colic

A preliminary study by Hayden and Mullinger (2006) suggests benefits of OCF in the treatment of infantile colic. In this study, 28 infants were randomised into OCF treatment and control groups. The treatment group received a total of four treatments at weekly intervals. Parents recorded time spent crying and time spent sleeping for the infants in a 24 hour diary. Significant improvements were demonstrated for the treatment group over the four week study period, with a mean reduction of 1.5 hours per 24 hours in crying time compared to the control group who demonstrated a mean reduction of 0.5 hours per 24 hours. Sleeping time also improved in the treatment group, showing a mean increase of 1.33 hours per 24 hours, with a smaller mean increase of 0.18 hours in the control group. These studies may be limited because of the subjective nature of the outcome measures and the un-blinded methodology. While the findings are encouraging, more careful study is required before conclusions are drawn.
6.2 Research Investigating Cranial Mobility and the Cranial Rhythmic Impulse

The potential for involuntary motion of the cranio-sacral system has been the subject of much debate. Various sources have been postulated that could plausibly generate the CRI.

In recent years the effects of autonomic nervous system activity have been investigated as a possible source of oscillations that may be palpated by cranial practitioners (Glonek, 2009). After investigating 0.6-15 cpm oscillations in various body tissues, as a possible source of the palpated CRI, Ferguson (2003) noted that arteriolar smooth muscle fluctuates within this range in response to ANS modulation. This fluctuation triggers a baro-receptor reflex which alters heart rate variability at around 6 cpm (0.1 Hz). Breathing influences heart rate variability (HRV) and blood pressure at about 15 cpm (0.25 Hz) in response to changes in venous return associated with alterations in intra thoracic pressure (Ferguson, 2003).

Reliability of CRI palpation has been examined in a number of studies, with mixed conclusions (Hanten et al., 1998; Hartman & Norton, 2002; Moran & Gibbons, 2001; Upledger, 1977). However, oscillations within the reported frequency range of the CRI have been electronically measured with laser-Doppler flowmetry (Sergueef, Nelson, & Glonek, 2002), and shown to be influenced by application of particular OCF techniques.

6.2.1 Studies on Cranial Bone Mobility

Since the theory of cranial bone mobility was proposed by Sutherland, the possibility of movement between sutures was the subject of a number of early OCF studies (Chaitow, 2005). In a review of the literature conducted by Rogers and Witt (1997), it was concluded that while motion is possible at cranial sutures, many of these studies lack scientific rigor.

Studies on the effects of osteopathic techniques on cranial bone motion show variable results. For example, Downey, Barbano, Kapur-Wadhwa, Sciote, Siegel & Mooney (2006) performed the OCF ‘frontal lift’ technique (as previously described in Footnote 1) on anesthetized rabbits, and found no significant sutural movement. In contrast, Kostopoulos and Keramidas (1992) demonstrated significant movement in the falx cerebri of an embalmed cadaver using the same ‘frontal lift’ technique as well as several other similar OCF techniques. These two studies could be used to support opposing sides of the argument for cranial articular mobility. However, both appear to be based on the premise that findings regarding sutural mobility in rabbits or cadavers could provide an experimental substitute for the physiological behaviour of living human tissue.

Expansion of the skull in the frontal and sagittal planes has been demonstrated in 18 healthy adults, by measurement of consecutive nucleo-paramagnetic resonance tomogram scans (Moskalenko, Kravchenko, Gaidar, Vainshtein, Semernya & Maiorova, 1999). Periodic changes in
cranial dimensions were shown to occur at a frequency of 6-14 cpm with mean amplitude of 0.38 millimetres. Further, this study showed that injection of 20 millilitres of radio-opaque solution into the carotid artery resulted in immediate expansion of the skull. The researchers suggest that restrictions in the demonstrated cranial movement may have a negative effect on the compensatory blood filling of the cranial cavity in response to normal physiological stressors (Moskalenko et al., 1999). Whilst the described compromise could possibly play a role in some clinical presentations, it would be difficult to objectively demonstrate such a restriction given the small amplitude of expansion and the difficulty of relating a particular restriction to common clinically presenting symptoms.

In a later study, Moskalenko, Frymann, Weinstein, Semernya, Kravchenko & Markovets (2001) researched slow rhythmic oscillations (5-12 cpm) in the human cranium, using a bioimpedence method which calculated fluctuating cranial fluid (blood and CSF) ratios, and trans-cranial Doppler ultrasound to measure cerebral blood flow. Intercranial hypertension syndrome was chosen as a target disorder to examine the effects of cranial osteopathic manipulation on the parameters specified above, compared to the effects of the same treatment in healthy individuals. Thirty-six individuals participated in the study, although it was not specified how many participants were assigned to the symptomatic or asymptomatic groups. Participants with intercranial hypertension syndrome were observed to have rhythmic cranial oscillations recorded at amplitudes 2-3 times less than the healthy participants. After treatment with OCF, the oscillatory amplitude changed to approximate those of the healthy participants. Moskalenko et al. (2001) concluded that slow rhythmic oscillations in the cranium are related to changes in the ratio of blood to CSF within the cranium, which is regulated by cellular respiratory mechanisms and influenced by the functional demands of nervous tissue.

6.2.2 Palpation of the Cranial Rhythmic Impulse

In a systematic review of the literature conducted by Green et al. (1999), it was noted that while there has been quantifiable evidence of the CRI, reliable palpation⁹ by an examiner has not been demonstrated. After Upledger’s (1977) original study in which data support reliability and reproducibility of examination findings, multiple studies demonstrate poor inter-examiner reliability in palpation of the CRI (Hanten et al., 1998; Hartman & Norton, 2002; Moran & Gibbons, 2001; Rogers, Witt, Gross, Hacke, & Genova, 1998; Sommerfeld, Kaidel, & Klein, 2004; Wilk & Vivian, 2000; Wirth-Pattullo & Hayes, 1994). Higher intra-examiner reliability (not to be confused the with inter-examiner reliability discussed above), with a variation in the rates palpated, suggests that individual examiners may be perceiving different oscillatory phenomena (Hartman & Norton, 2002).

Whilst intra-examiner reliability has been demonstrated in some studies (Hanten et al., 1998; Moran & Gibbons, 2001), the poor diagnostic reliability of CRI palpation demonstrated to date has brought into question the relevance of OCF in osteopathic education and treatment (Hartman, 2005, 2006; Hartman & Norton, 2002). Such suggestions prompt debate within the osteopathic profession and highlight the difficulties of designing studies that are methodologically robust and at the same time provide useful information that may be clinically applicable.

⁹ For a discussion on palpation of the CRI, refer to Leim (2004) pg. 7
Hanten et al. (1998) and Wirth-Patullo & Hayes (1994) have investigated the notion that movement perceived to be the patient’s CRI, may instead be related to the examiner’s own cardiac or respiratory rates. In sample sizes of 40 and 12 participants, respectively, neither study showed a strong relationship between the reported CRI and the heart or respiratory rate of the examiner. Therefore, both studies concluded that the CRI palpated by the examiner was not related to the examiner’s own heart or respiratory rates. These results support claims from OCF practitioners, who have maintained that the oscillation palpated as the CRI is independent of cardiac and respiratory rates.

6.2.3 Palpable Oscillations Controlled by the Autonomic Nervous System

Current theories surrounding the CRI tend towards suggesting links between the CRI and the dynamic control of blood flow by the autonomic nervous system (Glonek, 2009). Nelson (2001) noted that there is a relationship between palpable aspects of the CRI and subtle fluctuations in pulse pressure known as Traube-Hering-Mayer (THM) oscillations. These oscillations reflect small, regular changes in pulse pressure, under the influence of the sympathetic and parasympathetic divisions of the ANS. The THM oscillation has been demonstrated to be palpated at a 2:1 ratio with the CRI (Nelson, 2006), though the relevance of this ratio is unclear. Schleip (2002) describes the THM oscillation and heart rate variability as expressions of the same phenomenon – the motion of blood vessels, known as vasomotion and venomotion.

6.3 Research Investigating the Physiological Effects of Cranial Osteopathic Techniques

With little evidence supporting the original theories of the mechanisms of OCF, recent studies have focused on measurable physiological effects in an attempt to explain the positive clinical outcomes reported anecdotally by OCF patients and practitioners.

Compression of the fourth ventricle (CV4) has been the OCF technique chosen in a number of studies (Cutler, Holland, Stupski, Gamber, & Smith, 2005; Grill, 2006; Milnes & Moran, 2007; Nelson, Sergueef, & Glonek, 2006). The performance and effects of the CV4 technique are widely described in the literature (Chaitow, 2005; Leim, 2004; Magoun, 1976; Sutherland, 1990), and the technique is relatively easy to standardise, both factors that contribute to the suitability of the technique for experimental research. In delivery of the CV4 technique, light manual pressure is applied to the lateral angles of the occiput in a medial direction, in order to gently compress the fourth ventricle of the brain. It is argued that this technique stimulates the nerve centres of the fourth ventricle (including the respiratory centres and the vagal nuclei), thus enhancing parasympathetic function, the flow of CSF and the quality of the CRI. Glonek (2009 p.13) describes the action of the CV4 technique as “therapeutic control of a biological oscillation”. The therapeutic end point of the technique is known as the ‘stillpoint’. Reportedly, the CRI slowly decreases in rate and amplitude whilst the technique is being administered until it pauses briefly. This ‘stillpoint’ in the CRI is said to act as a ‘fulcrum’ around which homeostatic mechanisms may engage and reset themselves (Gintis, 2007). The concept of the ‘stillpoint’ is clearly open to a great deal of subjective interpretation regarding its palpation and mechanism of effect.
6.3.1 Popularity of the CV4 Technique

The CV4 technique has been described as the “osteopathic aspirin” (Parsons & Marcer, 2006, p. 215), and is a key part of the algorithm for craniosacral diagnosis and treatment presented by Greenman et al. (1996). The CV4 technique has also been described by Chaitow (2005) as one of a group of cranial techniques that appears to be safe and effective, yet its mode of operation has yet to be scientifically explained. The clinically reported therapeutic effects of the technique are wide, ranging from positive effects on stress symptoms and anxiety, to stimulating fluid flow throughout the body (Leim, 2004). Upledger and Vredevoogd (1983) describe the CV4 as an excellent ‘shotgun’ technique suitable for addressing a multitude of symptoms, and Magoun (1976, p. 110) advocates the CV4 technique as the “most comprehensive and effective therapeutic procedure in the whole cranial concept”. It should be noted that whilst this is the clinical experience of many cranial practitioners, it is sweeping statements such as these that tend to prompt scepticism about the scientific validity of OCF.

6.3.2 Theoretical Models Attempting to Explain the Effects of the CV4 Technique

Gard (2009) proposes a mechanical model for the effects of the CV4 technique, whereby suboccipital muscles are compressed during the technique, as opposed to compression of the fourth ventricle occurring as commonly believed. It is maintained that the reflex relaxation of the suboccipital muscles enables the occipitoatlantal joints to extend more easily, thereby “allowing the cranial base to flatten into expansion” (Gard, 2009, p. 252). Further, it is suggested that the ‘stillpoint’ perceived as an indication of treatment effect may in fact be merely a mechanical blockage due to the movement of the occiput being limited by the sphenoid and frontal bones (Gard, 2009).

Changes in sub-occipital muscular tension had been previously suggested as a mechanism for the effects of the CV4 by Ferguson (2003), who cites the connection between the rectus capitis posterior major (RCPM) muscle and the upper cervical spinal dura. Ferguson considers it possible that CSF is pumped in and out of the RCPM during cardiac systole and diastole, and that relaxation of the muscle in response to the CV4 aids healthy CSF motion. This is said to enhance proprioceptive function of the muscle, thereby contributing to the treatment effects ascribed to compression of the fourth ventricle (Ferguson, 2003). The suggestion that CSF is pumped in and out of a muscle that is external to the spinal dura appears to lack biological plausibility, and this description has not been found elsewhere in the OCF literature.

McPartland and Skinner (2005) hypothesize that the therapeutic changes induced by the CV4 technique may be mediated by the periaqueductal grey tissue surrounding the fourth ventricle, which responds to stimulation by activating neuroreceptors and releasing neurotransmitters that inhibit pain signals. McPartland (2008b) suggests that the CV4 may induce therapeutic benefits by using hydrostatic pressure to activate the endocannabinoid and endorphin systems related to the periaqueductal grey. Such activation is proposed to explain many of the reported effects of the CV4 technique, such as increased relaxation and decreased sympathetic nerve activity.
6.3.3 Research into the Autonomic Effects of the CV4 Technique

After concluding that cranial manipulation affects the autonomic nervous system (Sergueef, Nelson & Glonek, 2002), the same group of researchers showed that application of the CV4 technique can induce changes in Traube-Herring (TH) component of Traube-Herring-Mayer (THM) oscillations, and concurrent amplitude of the CRI (Glonek, 2009). Further, neuronal circuits that coordinate the THM oscillation are related to the tractus solitarius, which is the vasomotor centre (responsible for regulating blood pressure and cardiac function through the ANS), found in the fourth ventricle.

In a study by Nelson, Sergueef & Glonek (2006), twenty-eight practitioners were each paired with one of twenty-eight participants, and twenty of the resulting data sets were suitable and used for analysis. Results showed an increase in the TH wave during the treatment period of the experiment, compared to the pre-treatment control period and the post-treatment ‘response’ period. Whilst these results appear promising, lack of sham procedure and absence of a control group of participants are weaknesses highlighted by the researchers (Nelson et al., 2006). An additional weakness of the study is the lack of standardisation of the CV4 technique, as individual practitioners were allowed their own variations, and it was not stated to what extent these variations occurred. Whilst this lack of technique standardisation may be viewed as a methodological weakness, it is also more reflective of clinical practice and in this respect could be viewed as strengthening the results in a clinical context.

Cutler, Holland, Stupski, Gamber, & Smith (2005) examined the effects of CV4 on sleep latency in twenty healthy participants, and muscle sympathetic nerve activity (MSNA) in nine healthy participants. The rationale behind this study being that the autonomic nervous system plays a crucial role with both sleep latency and MSNA, and that this may have a relationship with cranial manipulation. The study showed that CV4 technique decreased sleep latency (mean 5.9 minutes SD 1.4), compared with sham (mean 12.6 minutes SD 3.3) and control (mean 17.2 minutes SD 3.3) procedures. Muscle sympathetic nerve activity was measured before and during CV4 induced ‘stillpoint’ or time-matched recordings, and was found to decrease significantly with the technique (p< 0.01), compared to the sham (p=0.25) and control (p= 0.41). The mechanisms behind these changes remain open to clarification, and whilst sleep latency may be reflective of a systemic ANS response, MSNA is regarded by some as a localised response, not able to be generalised to a systemic ANS response (Esler & Rumantir, 2003). Despite the small sample size (n=9) and the inability to generalise MSNA to a systematic ANS response, the results of this study are interesting and may provide the basis for further research utilising these outcome measures, perhaps comparing them to changes in broader measures of ANS activity.

More recently, the physiological effects of the CV4 technique on ANS function have been investigated (Milnes & Moran, 2007). The experimental protocol involved five consecutive phases; baseline (no physical contact between patient and practitioner), simple touch, intervention with the CV4 technique, a second period of simple touch, and a second period of no physical contact between practitioner and participant. Once data from the ten subjects was pooled, only statistically trivial changes in the recorded autonomic variables (heart rate variability, galvanic skin resistance, skin temperature and respiration rate) were observed during the application of the CV4
technique. However, other studies (Cutler et al., 2005; Grill, 2006; Nelson et al., 2006; Sergueef et al., 2002) have concluded that the CV4 technique does have the ability to influence the autonomic nervous system. Indeed, Milnes & Moran (2007) noted that upon examination of individual subject’s heart rate variability data, there was a non-trivial change in autonomic nervous system activity for three of the ten subjects.

Milnes & Moran (2007) raised the suggestion that there may be ‘responders’ and ‘non-responders’ to the CV4 technique. This idea was also alluded to by Grill (2006) who stated in an unpublished Masters thesis, that the CV4 technique had ‘person specific effects’ upon measures of heart and respiratory rate, skin conductance and temperature. Richards, McMillin, Mein and Nelson (2001) used the same outcome measures as Grill investigate responses to the OCF technique “holding the vasomotor centre\textsuperscript{h}. Eighteen healthy participants also showed variable individual responses, reinforcing the notion of ‘responders’ and ‘non-responders’ or ‘person-specific effects’ with OCF.

Maddick (2007), argues that osteopathic research must be directed toward testing the reality of clinical practice, rather than the validity of Sutherland’s seemingly outdated models. In OCF practice, the CV4 is generally regarded as a useful technique that is effective for a number of patients. Further research into the mechanisms of action may support the emerging understanding of the reported clinical effectiveness of this OCF technique.

\textsuperscript{h} ‘Holding the Vasomotor Centre’: the researchers define this technique as “inhibitory pressure in the cervical area, intended to affect sympathetic nervous system control of circulation” (Richards et al., 2001).
Chapter 7

Challenges Faced by Research Development in Osteopathy in the Cranial Field

There appears to be a general theme within the literature regarding the requirement for more rigorous and clinically relevant research in the field of OCF. Poor diagnostic reliability of the CRI has been clearly demonstrated, and as discussed may be related to the complex interaction between biological oscillations of both the patient and practitioner, and the presence of more than one palpable oscillation. Fowles (2004) suggests that the single case study examples which have been presented should be substantiated by larger clinical research studies, on specific patient groups and using validated outcome measures. Both Moran (2005) and Fowles (2004) highlight the need for research investigating the link between cranial dysfunction and health status, and also the need for research investigating the association between cranial treatment and positive health outcomes.

Fenwick (2001) describes how many of the current investigations into treatment effects within the allopathic medical profession take the viewpoint of upward causation – that is how microscopic changes in cellular biology give rise to more complex processes, which in turn have effects upon the total organism. The alternative viewpoint of downward causation, that macroscopic events may direct cellular processes, may provide a more useful perspective for investigations into the effects of manual therapy. Downward causation could provide a theoretical viewpoint and a research approach that is well suited to osteopathic medicine, as it may incorporate the multidimensional nature of structure and function, which is one of the key philosophical bases for osteopathic treatment.

Whilst OCF has generally been considered safe, there have been reported instances of iatrogenic effects in patients with traumatic brain injury (McPartland, 1996). This report highlights the need for caution and minimisation of risk to participants when researching OCF techniques. However, the fact that the ethical constraints of many research projects require healthy, asymptomatic participants may confound the results of a number of investigations. In studies utilising an asymptomatic population to investigate the effects of OCF techniques, the sample profile is likely to be distorted by floor effect bias, limiting the interpretability and validity of the results (Hagino, 2003). It may be unreasonable to assume that a subtle OCF technique, aimed at restoring the inherent homeostatic mechanisms of the body, would have a measurable effect upon an asymptomatic participant for whom the technique may not be indicated. Further, anecdotal reports of positive treatment outcomes are generally from observations occurring within a clinical setting.

With any form of treatment, be it osteopathic or allopathic, the clinical setting and context with which the patient seeks treatment are factors which combine with physiological effects of the chosen techniques. This combination constitutes a treatment experience which has both specific and non-specific effects (Ernst, 2001; Helman, 2001). Desirable non-specific treatment effects have previously been shunned as placebo effects which mask the ‘true’ effects of an intervention. As contemporary understanding of the complex aspects of mind-body interactions develops, the
complete treatment experience, which includes both specific and non-specific effects is being valued for its pragmatic relevance (Ernst, 2001). This complete treatment experience cannot easily be reproduced in a laboratory setting.

Patterson (1992) describes research undertaken by a practicing physician in a clinical setting as having practical and logistic difficulties, but being the most applicable setting to test osteopathic ideas and theories. Whilst this may clearly be the ideal, the relative immaturity of the body of OCF research results in a lack of established physiological treatment effects. Measuring changes in physiological parameters such as ANS function requires laboratory equipment, and as such these outcome measures do not lend themselves to recreation of a regular clinical treatment experience. Leach (2008) challenges the usefulness of the randomised control trial in osteopathic research, and suggests that pragmatic trials are more reflective of the complex nature of osteopathic intervention. As previously stated, there is a need for both laboratory based experiments and pragmatic clinical trials in the field of OCF.

Because individual responses to OCF tend to be variable, when assessed by the outcome measures used to date (Grill, 2006; Milnes & Moran, 2007; Richards, McMillan, Mein & Nelson, 2001), difficulties arise when determining suitable methods of data analysis. As seen in the study by Milnes and Moran (2007), individual responses may be masked when data from a group of participants are pooled for analysis. Berntson (Berntson et al., 1997) emphasises the importance of caution in interpreting between-subject comparisons of ANS components when using HRV as an outcome measure, due to the complexity of interactions between the various functions of the ANS. A single-systems approach may provide a more suitable platform for investigations into the physiological effects of OCF, particularly when utilising HRV as an outcome measure. However single-systems research design can be time consuming and limit the number of subjects that are able to participate in the study.

7.1 Rationale for Development of the Current Study

The current research was designed to develop the CV4 technique study previously conducted at Unitec NZ (Milnes & Moran, 2007), investigating the notion of ‘responders’ and ‘non-responders’ to the CV4 technique.

This study is divided into two parts, the first is designed to investigate individual ANS responses to the CV4 technique using the experimental protocol developed by Milnes and Moran (2007). One premise of the study is the relationship between the effects of OCF techniques on the ANS. As previously discussed, literature is emerging which supports this relationship. The CV4 is a widely utilised technique, which is generally considered to be very safe. Because the CV4 technique is often reported to affect the ANS, the use of ANS-based outcome measures is well suited to investigation into the effects of the CV4 technique. As highlighted, the potential for floor effect bias has confounded the results of studies of asymptomatic populations. This problem prompted development of the second part of the current study, which explores possible predictors for ‘response’ to the CV4 technique using regression methods similar to those used to develop clinical prediction rules. The following section of this literature review explores supporting literature for the chosen outcome measure and methods of analysis.
Chapter 8

Determining a Response to the CV4 Technique

This chapter examines the use of heart rate variability (HRV) as an outcome measure for the autonomic effects of the CV4 technique. The physiological basis for HRV is explained, and the experimental uses of this outcome measure are briefly outlined.

8.1 The Autonomic Nervous System

The ANS is the portion of the peripheral nervous system which facilitates homeostasis by rapidly adapting to changes in the internal and external environment. As well as providing involuntary motor control of the smooth muscle, cardiac muscle and glands, the ANS also controls divisions of the central nervous system involved in regulation of survival mechanisms, immune function and emotional behaviour (Willis, 2004). The role of the ANS has been described as the ability “to handle information in order to guarantee adaptation of the organism to the flow of time-dependent stimuli and tasks arising from the environment, be it internal or external” (Pagani & Lucini, 2003, p. 324). Components of the ANS are the sympathetic (SNS), parasympathetic (PNS) and enteric (ENS) divisions.

Cell bodies of the sympathetic neurons lie in the thoracic and upper lumbar sections of the spinal cord, and synapse with effector neurons at the paravertebral chain ganglia adjacent to the vertebrae. There is a great deal of communication between the various spinal ganglia, as well as the sympathetic abdominal ganglia and the adrenal medullae (Bray, Cragg, Macknight, & Mills, 1999).

Parasympathetic preganglionic neurons leave the brainstem via cranial nerves III, VII, IX and X, and also emerge from cell bodies within the sacral spinal cord (Willis, 2004). Approximately 70% of all parasympathetic neurons leave the CNS via cranial nerve X, the vagus nerve, which innervates all thoracic viscera and the majority of abdominal viscera (Bray et al., 1999). Most of the remaining 30% of parasympathetic neurons leave the CNS via the sacral spinal cord to supply the lower abdominal and pelvic viscera. All parasympathetic ganglia are located within or adjacent to their effector organ.

The enteric nervous system relates to control of the gastro-intestinal tract, and is divided into the myenteric and submucosal plexi. The activity of the enteric division is modulated by both sympathetic and parasympathetic activity (Willis, 2004), and as such, the SNS and PNS are usually considered to be the two primary branches of the ANS.

In very simplistic terms, the SNS is said to control stress responses, causing changes in blood flow that allow for increased cardiac, respiratory, musculoskeletal and cognitive function. The PNS is said to cause opposing changes in blood flow, allowing digestion, assimilation and rest. Enhanced sympathetic activity can be seen during physical and mental exercise, while enhanced vagal
(parasympathetic) activity is seen in states of sleep, relaxation and gastric fullness (Pagani & Lucini, 2003). Chronic sympathetic nervous activation is associated with depression, obesity, hepatic cirrhosis, hypertension and heart failure (Esler & Rumantir, 2003).

In contrast to the often described concept of the SNS and PNS acting in a global and antagonistic manner, it is now recognized that the two systems work in a coordinated way, at times synergistically, at other times reciprocally (Willis, 2004). Regional differentiation and patterning are an integral part of ANS responses. Homeostasis is maintained by fine, moment-to moment visceral control exerted by both sympathetic and parasympathetic mechanisms. An example of this control has been demonstrated in a study where subjects attempted a difficult mental arithmetic problem: a relative increase in plasma norepinephrine occurred (indicating increased sympathetic activity), however, muscle sympathetic nerve activity decreased (Esler & Rumantir, 2003). Many examples of similar sympathetic regionalisation exist, and this differentiation is reflected in the neuro-anatomical organisation of functional sympathetic responses (Esler & Rumantir, 2003).

In both the SNS and PNS, the main pre-ganglionic neurotransmitter is acetylcholine. Acetylcholine is also the main post-ganglionic neurotransmitter in the PNS, whilst norepinephrine is the predominant post-ganglionic neurotransmitter in the SNS. The adrenal medullae release epinephrine and norepinephrine directly into the bloodstream in response to sympathetic stimulation. Acetylcholine and norepinephrine may both have either excitatory or inhibitory effects, depending upon the type of receptor activated in the cells of effector organs (Willis, 2004).

### 8.2 The Autonomic Control of Cardiac Activity

The ANS controls cardiovascular function in a variety of ways, including control of heart rate and blood pressure, as well as vasoconstriction to direct blood flow (Pumprla, Howorka, Groves, Chester, & Nolan, 2002). Sympathetic stimulation increases heart rate, conduction velocity and cardiac muscle contractility, whilst parasympathetic stimulation tends to cause opposite effects in cardiac muscle (Willis, 2004).

Control of heart rate is via the sino-atrial (SA) node of the heart. Known as the cardiac pacemaker, the SA node initiates the electrical impulse that leads to contraction of the cardiac muscle. The conduction of this cardiac impulse can be measured by electrodes placed on the surface of the body, and recorded using an electrocardiogram (ECG). The SA node is richly innervated with both sympathetic and vagal fibres, reflecting the high degree of control exerted by the ANS. Without autonomic control, the intrinsic rate of the heart is approximately 100-120 beats per minute (bpm) (M. N. Levy, 2004). However, a normal resting heart rate in healthy adults is around 70 bpm due to the relative parasympathetic dominance of cardiac control in the resting state (M. N. Levy, 2004).

Parasympathetic activity decreases heart rate, mediated by the action of the neurotransmitter acetylcholine on the cardiac pacemaker cells of the SA node. Acetylcholine is a fast-acting neurotransmitter, quickly activating cardiac cells, with a very short latency period of only 50-100 ms (M. N. Levy, 2004). Cholinesterase, the enzyme that breaks down acetylcholine, is abundant in the SA node of the heart, therefore the effects of vagal stimulation on the SA node rapidly
decrease when vagal stimulation ceases. Because of this short latency and rapid decrease in parasympathetic responses, the vagal nerves are able to exert beat-to-beat control of the heart rate.

The sympathetic nervous system exerts slower control over the rate of SA firing, due to the relatively slow release, metabolism and removal of the sympathetic neurotransmitter norepinephrine in the cardiac neuromuscular synapses (M. N. Levy, 2004). Because of the difference in speed of the actions of the sympathetic and parasympathetic nervous systems, the two divisions tend to operate at different frequencies. Variation in heart rate can be related to varying degrees of sympathetic or parasympathetic activity (Pumpila et al., 2002).

The ANS is the primary regulator of heart rate. However, other influences contribute to heart rate regulation, including baroreceptor, chemoreceptor and ventilatory reflexes. Various hormonal and intrinsic myocardial mechanisms also play a role in heart rate regulation (M. N. Levy, 2004).
8.3 Heart Rate Variability

The variation in time between consecutive heart beats is known as heart rate variability (HRV) (Rajendra Acharya, Paul Joseph, Kannathal, Lim, & Suri, 2006). From the QRS complex of standard electrocardiograms (ECGs), intervals between consecutive R waves are measured; these are known as the R-R intervals. Heart rate fluctuates dynamically in response to sympathetic and vagal activity, under control of the ANS. Therefore R-R intervals differ in length according to changes in activity of the sympathetic and parasympathetic divisions.

Heart rate variability is a recognised indicator of the health of an individual’s ANS (Stein, Bosner, Kleiger, & Conger, 1994). Generally speaking, high HRV may be viewed as a sign of a healthy and adaptive ANS, which adjusts heart rate easily in response to changes in the internal or external environment. Low HRV is demonstrated in a variety of pathological conditions, including cardiovascular disease and diabetic neuropathy, and indicates a decrease in the ability of the ANS to respond to environmental changes (Pumprla et al., 2002).

HRV analysis is a non-invasive, objective measure that may be used in experimental settings to measure the ANS modulation of the heart, thereby providing information about levels of sympathetic and parasympathetic activity. Other methods of quantifying ANS responses currently used in health research include clinical microneurography (involving insertion of fine electrodes into nerves); measurement of plasma norepinephrine; pharmacological autonomic blockade; and radio-imaging techniques (Esler & Rumantir, 2003). Because HRV is less influenced by regionalisation of sympathetic responses than the other ANS measures available, as it is controlled by the CNS modulation of autonomic outflow (Esler & Rumantir, 2003), giving HRV further advantages as an experimental outcome measure.

8.4 Methods of Analysis for Heart Rate Variability

Heart rate variability may be analysed in either the time domain or the frequency domain. Time domain measures are obtained from ECG recordings of at least 18 hours (Kleiger, Stein, & Bigger, 2005) and mathematical analysis quantifies the total HRV over a 24 hour period (Pumprla et al., 2002). The obtained time domain HRV data can be used to assess overall autonomic balance, but does not quantify specific changes in either sympathetic or parasympathetic activity. However, frequency domain analysis of HRV can be used to investigate relative differences in sympathetic and parasympathetic activity over short periods of time, so is useful to assess the short-term autonomic effects of specific interventions. Generally, spectral analysis of HRV in the frequency domain involves analysis of ECG segments of at least five minutes duration (Kleiger, Stein & Bigger, 2005). Time domain methods are considered a simpler method of analysis, as frequency domain methods require fulfillment of strict mathematical criteria, and ECG recordings require extensive checking and editing before use. However, Pumprla et al. (2002, p. 6) state that “frequency domain techniques facilitate a more precise evaluation of the direction and magnitude of changes in sympathovagal changes than is possible with time domain analysis”.

8.5 Spectral Analysis of Heart Rate Variability in the Frequency Domain

From a standard ECG recording, the R-R intervals are separated into different frequency bands, which reflect different components of ANS activity. The frequency bands are conventionally set as follows: low frequency between 0.04 and 0.15 Hz and high frequency between 0.15 and 0.40 Hz. There are also ‘very low frequency’ (VLF) and ‘ultra low frequency’ (ULF) bands, operating at frequencies below 0.04 Hz.

The low frequency band (LF) is influenced by both sympathetic and parasympathetic activity, whilst the high frequency band (HF) is usually influenced only by parasympathetic activity (Berntson et al., 1997). The ratio between the two (LF/HF) can be used as an index of changes in sympathetic and parasympathetic balance (Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology, 1996), however changes in the ratio must be interpreted cautiously as an increase in sympathetic activity is not necessarily accompanied by a decrease in parasympathetic activity, and vice versa (Kleiger, Stein & Bigger, 2005).

The slower VLF and ULF frequencies are less well understood, and are subject to influences such as circadian rhythms and the rennin-angiotensin mechanism (Berntson et al., 1997). The VLF and ULF bands are not applicable to the short term measures of HRV used in this study, as they require a continuous 24 hour ECG recording for accurate analysis (Kleiger, Stein & Bigger, 2005). The various frequency bands are measured in absolute units (ms²), and LF and HF may also be reported in normalised units (nu) which are calculated by multiplying absolute units by 100, then dividing this figure by (total power minus VLF power) (Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology, 1996).

The LF band of HRV is modulated by a combination of sympathetic and parasympathetic efferent impulses to the SA node of the heart. The way in which both ANS divisions contribute to LF HRV is complex and poorly understood (Berntson et al., 1997). Initially, it was believed that the LF spectral band was modulated entirely by sympathetic activity, however it has been demonstrated that vagal blockade, as well as sympathetic blockade, affects LF oscillations (Pumprla et al., 2002). Alterations in posture, blood pressure and baroreflexes affect LF measures, reflecting the role of the SNS in modulating HRV at low frequencies (Berntson et al., 1997).

The HF band of HRV is modulated by vagal activity at the SA node, and is heavily influenced by the frequency of ventilation. The ventilatory modulation of R-R intervals is known as respiratory sinus arrhythmia (RSA) and at normal respiratory rates this fluctuation is contained entirely within the HF band of HRV (Kleiger, Stein & Bigger, 2005). Respiratory sinus arrhythmia (RSA) has an active homeostatic role, increasing the efficiency of respiratory gas exchange (Yasuma & Hayano, 2004). The oscillatory ventilation patterns entrain the cardiovascular system into fluctuations of heart rate, blood pressure, stroke volume and cardiac output (Davies et al., 2000), a further indication of the homeostatic control of the ANS. Pharmacological vagal blockade eliminates HF heart rate oscillations (Berntson et al., 1997), and when the frequency of breathing changes, the centre point of HF HRV changes in accord with the rate of ventilation (Kleiger, Stein & Bigger, 2005). Berntson et al. (1997) summarise the parasympathetic parameters associated with HF HRV fluctuations, or RSA, as: central vagal outflow to the heart; baro-reflex activity; cardiac vagal tone; and the phasic respiratory modulation of vagal activity.
8.6 Factors that Influence Heart Rate Variability

Heart rate variability parameters may be influenced by age and gender (Koskinen, Kahonen, Jula, Laitinen, Keltikangas-Jarvinen, Viikari, et al., 2009), body mass index (Antelmi, De Paula, Shinzato, Peres, Mansur & Grupi, 2004), fitness (W. C. Levy et al., 1998), posture (Rajendra Acharya, Kannathal, Mei Hua, & Mei Yi, 2005) and breathing frequency (Berntson et al., 1997). Various pathologies, such as hypertension, myocardial infarction, brain damage, diabetic neuropathy and renal failure have been shown to alter HRV (Rajendra Acharya et al., 2006), therefore it is recommended that studies utilising HRV as an outcome measure exclude participants with these pathologies.

It has been suggested that control of respiratory rate in experimental conditions is used to ensure that RSA is contained within the HF spectrum of HRV, and does not influence LF oscillations (Badra, Cooke, Hoag, Crossman, Kuusela, Tahvanainen, et al., 2001; Eckberg & Nerhed, 1985). Metronome regulated breathing at a rate of 15 breaths per minute (br.m⁻¹) has been used in previous studies (Budgell & Igarashi, 2001; Piepoli, Sleight, Leuzzi, Valle, Spadacini, Passino, et al., 1997) which allows the RSA to be contained entirely within the HF spectrum of HRV. Metronome regulated breathing has been criticised as an experimental control, as the mental effort required to regulate breathing may in itself affect HRV (Berntson et al., 1997). This mental effort has been demonstrated both to affect experimental findings (Driscoll & Dicicco, 2000) and not to affect them (Patwardhan, Evans, Bruce, & Knapp, 2001). In a recent study by Milnes and Moran (2007), respiratory rate was not controlled, however it was recorded to ensure it remained within the 9 – 20 br.m⁻¹ frequency as outlined in commonly accepted guidelines (Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology, 1996).

Myllyia, Korpelainen, Haapaniemi, Tolonen, Makkallio, Sotaniemi, et al. (2003) emphasise the importance of standardising experimental conditions when measuring HRV, and recommend that participants avoid food and caffeine for 3 hours prior to the experiment, and alcohol for 12-14 hours. These researchers also recommend that the laboratory is warm, quiet and comfortable and that subjects are not taking any drugs that affect the ANS (Myllyia et al., 2003).

8.7 The Use of Heart Rate Variability as an Outcome Measure in Health Research

The use of HRV in health research has grown exponentially since it’s introduction in the 1960’s and 1970’s (Pagani, 2003). Heart rate variability has been used extensively to study the risk and autonomic effects of cardiovascular disease (Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology, 1996), as well as non-cardiac diseases such as diabetes mellitus, neonatal distress, stroke, multiple sclerosis and renal disease (Kleiger et al., 2005). The introduction of spectral analysis of HRV in the early 1980’s has enabled quantification of short-term changes in autonomic output, useful for assessing the immediate response of the ANS to a given stimulus or change in condition (Akselrod et al., 1981).
Within the field of complementary and alternative medicine (CAM), HRV has more recently been utilised to study the treatment effects of certain interventions. Examples of such interventions include cervical manipulation (Giles, 2006), acupuncture (Li, Wang, Mak, & Chow, 2005) and osteopathy in the cranial field (Milnes & Moran, 2007).

Li et al. (2005) investigated the effects of acupuncture on HRV under fatigue and non-fatigue states. Twenty-nine healthy individuals were divided into 4 groups, two groups receiving acupuncture (the acupuncture points used were different for each group) and two control groups. In fatigue states, subjects in one acupuncture group demonstrated changes in HRV consistent with a decrease in sympathetic and an increase in parasympathetic modulation of the heart, compared with non-intervention controls and non-fatigue states (Li et al., 2005).

Heart rate variability has been used to investigate the effects of chiropractic techniques. One clinical study demonstrated that chiropractic care over a 4 week period decreased the LF component and total power of HRV (Zhang, Dean, Nosco, Strathopulos, & Floros, 2006). In a controlled cross-over trial involving 28 healthy subjects, Budgell and Polus (2006) found that the LF component of HRV increased after a high-velocity, low-amplitude thrust was applied to restricted thoracic spinal segments, compared to the application of a sham procedure. An earlier study by Budgell and Hirano (2001) had demonstrated a similar increase in LF HRV after a high-velocity, low-amplitude thrust was applied to the cervical spine. The clinical relevance of these immediate changes has yet to be explored.

Giles (2006) demonstrated changes in the time domain and LF/HF ratio of the frequency domain of HRV with an osteopathic technique applied to the upper cervical spine. In 24 healthy subjects using a cross-over design, Giles compared the OCF technique ‘sub-occipital decompression’ with a sham procedure. The technique was hypothesised to increase HRV measures of vagal control. This hypothesis is consistent with the changes in LF/HF HRV demonstrated in the study, however no significant changes were demonstrated in the LF or HF parameters individually.

8.8 Changes in Heart Rate Variability Associated with Psychological and Emotional Regulation

Because of the well-documented effects of various psychological and emotional states on the autonomic nervous system, HRV has been utilised within behavioural science and psychology (Appelhans & Luecken, 2006; Brosschot, Van Dijk, & Thayer, 2007; Dishman, Nakamura, Garcia, Thompson, Dunn & Blair, 2000; Montano, Porta, Cogilati, Constantino, Tobaldini, Casali, et al., 2009). Low heart rate variability has been associated with both depression and anxiety (Brosschot, Van Dijk & Thayer, 2007; Carney, Freedland, Stein, Skala, Hoffman & Jaffe, 2000). Chronic autonomic hyper activation, with a decreased autonomic response to acute stressful

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1 In this technique, traction in a superior direction is applied to the base of the occiput, and minor manual adjustments are made by the practitioner in various planes of motion until a point of ‘balanced ligamentous tension’ is achieved (Giles, 2006).
stimulus has been demonstrated in patients with post-traumatic stress disorder (Cohen, Kotler, Matar, Kaplan, Loewenthal, Miodownik, et al., 1998). The chronic autonomic changes occurring in post-traumatic stress disorder are demonstrated by a decrease in both RSA and Traube-Herring waves (Schleip, 2002).

Tiller, McCrory and Atkinson (1995, 1996) have conducted several published experiments relating certain emotional and mental states to changes in HRV. In one study, these researchers found that emotions such as anger cause sympathetically dominated changes in HRV, with an increase in LF measures. Conversely, emotions such as love and appreciation caused a shift in HRV toward more parasympathetically mediated autonomic output (McCraty, Atkinson, Tiller, Rein, & Watkins, 1995). In a subsequent study, the same researchers found that subjects could intentionally shift their attention to invoke feelings of love and appreciation, resulting in several quantifiable changes in HRV associated with healthy autonomic function (McCraty & Atkinson, 1995). Using an emotional self-management technique in which they had been trained, participants demonstrated the ability to generate two discrete states of HRV at will. The first is a state where both the HF and LF components of the HRV frequency spectrum entrain to a frequency of 0.1 Hz, followed by entrainment of other physiological oscillations, specifically respiration and pulse transit time. The second state generated by participants is named by the researchers the ‘internal coherence’ state, where HRV dropped almost to zero, meaning the heart was beating with almost perfect regularity. Whilst low HRV is usually associated with poor autonomic health, this ‘internal coherence’ state was completely reversible. This state was considered by the researchers to be an indication of exceptional emotional self-management and was reportedly associated with feelings of deep peace and inner harmony (McCraty & Atkinson, 1995). In a further study, the ‘entrainment’ and ‘internal coherence’ states were compared in two different environments and found to be reproducible in both laboratory and real-life stressful situations (Tiller, McCraty, & Atkinson, 1996). The researchers highlight the relevance of emotional experiences in autonomic balance, and suggest that emotional self-management techniques may be of benefit in pathologies associated with autonomic imbalance, such as hypertension and coronary artery disease (Tiller et al., 1996).

Links between ANS function and emotional regulation have led to the development of theories to explain the association of mental and emotional processes with health and well-being. Thayer and Brosschot (2005, p. 1050) propose a theory of neuro-visceral integration and suggest that autonomic imbalance, in particular decreased parasympathetic tone, may be the “final common pathway linking negative affective states to ill health”. Further, Thayer and Larry (2009) describe HRV as an index of the relationship between the central nervous system and cardiac activity, effected by cognitive, emotional and somatic regulation.

Respiratory sinus arrhythmia (RSA) is the variability in heart rate associated with breathing and influenced by the parasympathetic nervous system and vagal activity. After researching RSA for several decades, Stephen Porges developed his ‘poly-vagal theory’ (Porges, 2001). Porges states that the HRV associated with parasympathetic regulation – that is, RSA - is an expression of the uniquely mammalian ventral vagus complex. Porges describes three phases of autonomic regulation in his poly-vagal theory. The first phase relates to the dorsal vagus, which Porges describes as the primitive, unmyelinated visceral vagus which suppresses visceral activity in response to threat. During the second phase, the where the visceral vagus is inhibited by the sympathetic nervous system, in order to mobilise sympathetic responses and respond to threat. In the third phase, the myelinated ventral vagus provides rapid control of cardiac output in
response to environmental stimulus. This ventral vagus has anatomical and functional relationships to the immune system, the stress response mediated by the hypothalamic-pituitary-adrenal axis, and to the neuro-hormones oxytocin and vasopressin associated with love and social bonding (Porges, 2001).

8.9 A Potential Role of the Autonomic Nervous System during Treatment with Osteopathy in the Cranial Field

Theories such as neuro-visceral integration and the poly-vagal theory could provide some biological context for the early theories of Still and Sutherland, such as body unity, the self-regulating nature of the human organism, and the relationship of health with optimal biological oscillations. Heart rate variability may provide a means to further explore the integration of body and mind in various states of health and disease, which is relevant to osteopathic concepts.

Schleip (2002) suggests that the effectiveness of OCF treatment may lie more with the interpersonal skills of the practitioner, and their ability to understand and observe changes in ANS activity, than with the practitioners biomechanical understanding of the PRM. McFarlane, Standen, Roy, & McPartland (2006) report that patients’ perception of OCF treatment experiences is influenced by the presence or absence of the therapeutic intention of the practitioner during treatment. Many OCF practitioners use ‘centering’ or relaxation techniques actively during treatment, which should theoretically alter ANS balance, decreasing sympathetic and increasing parasympathetic activity. It is speculated that though such ‘centering’ techniques, the practitioner is able to bring their own ANS to a homeostatic balance between sympathetic and parasympathetic activity. This ANS ‘balance’ is believed to produce a dominant oscillation is ANS activity, able to entrain the patient’s ANS activity to oscillate at a similar frequency, closer to that of a homeostatic ‘ideal’ (McPartland & Mein, 1997). This entrainment may occur via the electromagnetic transference described by Blacklaw-Jones (2009) and Oschman (2000). The notion is further supported by the experimental findings of McCraty, Atkinson, Tomansino and Tiller (1998). In a series of experiments an exchange in the electromagnetic energy produced by the heart was demonstrated using signal averaging techniques, to show the registering of an individual’s ECG signal in the electroencephalogram of another individual during physical contact or when subjects were in close proximity (McCraty et al., 1998).

8.10 Hypothesised Effects of the CV4 Technique on Heart Rate Variability

In the current study, HRV has been selected as the outcome measure to investigate the effects of delivery of a cranial osteopathic technique, Compression of the Fourth Ventricle (CV4), on the ANS activity of the participant. This technique is theorised to decrease sympathetic and increase parasympathetic activity (Chaitow, 2005), producing a relaxation response. Such a change should be reflected as a change in HRV, with an increase in HF, and a decrease in the LF and LF/HF ratio measures of HRV.
Chapter 9

Identification of Predictors for Response to the CV4 Technique

Individual osteopathic practitioners may utilise predominantly musculoskeletal, visceral or cranial techniques, whilst some practitioners prefer to use a combination of these modalities. However, the best techniques and treatments for each patient should ideally be selected based upon the predicted benefit to the patients rather than the preferences of the practitioner (Gard, 2009), a concept known as differential indication (Wittmann & Walach, 2002). In certain treatment situations a particular treatment model or specific technique may be clearly indicated, but often the practitioner must determine what they believe will be the most effective approach for the patient. Such decisions may be based largely on what the practitioner has learnt during their training (Chaitow, 2005), and their clinical experience. Currently, no data is known to exist which supports clinical technique choices for particular patients or conditions.

9.1 Clinical Prediction Rules

Clinical prediction rules (CPRs) are used in health care to assist in making clinical decisions. These ‘rules’ contain variables from the patients history, physical examination findings, and responses to simple diagnostic tests (Laupacis, Sekar, & Stiell, 1997). Certain combinations of variables are used to predict a diagnosis, prognosis or response to treatment. Beattie and Nelson (2006) caution against indiscriminate use of CPRs, emphasising that they should not be used to replace clinical judgment, but to be used adjunctively to clinical opinion and intuition.

Because CPRs pertain to patient care, it is essential they are thoroughly developed and validated before clinical use (Laupacis, Sekar & Stiell, 1997; Wasson & Sox, 1996; Wasson, Sox, Neff, & Goldman, 1985). The development of CPRs is a lengthy process; Childs and Cleland (2006) identify three main steps in the process before CPRs are suitable for use in a clinical setting:

1- Creating the clinical prediction rule – deriving factors with predictive value.
2- Validating the clinical prediction rule – replicating results in a different population.
3- Conducting an impact analysis – assessing the clinical usefulness of the rule in improving clinical decision making and patient outcomes.

As cited by Childs and Cleland (2006), within the field of physical therapy, CPRs have been developed to improve diagnosis of ankle and knee fractures, neck trauma, cervical radiculopathy and carpal tunnel syndrome, as well as the predicted prognosis for whiplash injuries. Regarding treatment, preliminary development has been initiated for the use of cervical manipulation to treat neck pain (Tseng, Wang, Chen, W., Hou, Chen, T. C. & Leiu, 2006) and the use of stabilisation exercises to treat low back pain (Hicks, Fritz, Delitto, & McGill, 2005).
9.2 Investigating Differential Indication for the CV4 Technique

Clinical prediction rules provide a useful format to understand the use of regression analyses to predict outcomes. Wittmann and Walach (2002) discuss the importance of predictor research in the field of CAM, stating that differential indication is an important factor to consider in research, as there are few types of treatment that work well for all patients. Because the presenting complaints of osteopathic patients are heterogeneous in nature, the most effective treatments are also likely to be heterogeneous. Often there are groups of patients who will benefit more, and groups who will benefit less, or even experience adverse reactions to any given treatment. These factors are an important consideration in clinical decision making. However, in the context of the current study, the objective of exploring differential indication for the CV4 technique is to identify populations for further research into OCF.

Childs and Cleland (2006) emphasise the contribution clinical prediction rules may make to research, by identifying homogenous groups of participants for researchers to study. Whilst the current study does not aim to produce a clinical prediction rule, the first stage of this process – deriving factors with predictive value (Childs & Cleland, 2006), can be used to describe the purposes of the study. Logistic regression analysis is used in situations where it is anticipated that independent variables can be used to predict a binary dependant variable (Hagino, 2003), such as ‘response’ or ‘non-response’ to a technique or treatment.

9.3 The Rationale Underlying Selection of Potential Predictor Variables

In the current study, potential predictors were selected based on theoretical concepts of OCF, and general factors anticipated to potentially influence treatment outcomes. Of particular interest were variables which may, based on OCF theories, be a clinical indication for the use of the CV4 technique, for example history of physical trauma and conditions increasing sympathetic activity. Psychological factors potentially influencing autonomic responses were also considered, such as attitudes toward CAM and naivety to OCF. Indications given in the literature include trauma, chronic illness, and conditions causing increased sympathetic activity. The PRM is described as being very sensitive to trauma, in particular injuries to the head and neck (Greenman et al., 1996). Because pain and stress tend to affect the ANS, they are believed to be amenable to treatment with OCF (McPartland, 2008a). Chronic diseases are also believed to have a detrimental effect on the PRM, and indeed OCF is often utilised in the treatment of chronic pain and dysfunction (Marcer & Parsons, 2006). Both cranial dysfunction and therapeutic changes are purportedly palpable to OCF practitioners (Chaitow, 2005). Despite poor inter-examiner reliability of palpation of the rate of the CRI, as previously discussed, some studies have demonstrated practitioner palpation of a ‘stillpoint’ during OCF to correspond with measured physiological changes in autonomic variables (Cutler, et al., 2005; Nelson, 2006).

It is commonly believed amongst the scientific community that the effects or outcomes of CAM are mediated by the placebo effect (Kirsch, 2002). Wittmann and Walach (2002) state that patients’ response to treatment may be influenced by whether they believe or disbelieve in the

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\(^1\) The specific measures of these potential predictors will be discussed in the Methods section of the following manuscript.
efficacy of the treatment. Trust is a central component to treatment outcomes, and it has been shown that patients trust or mistrust of OCF is based initially on reports and credibility attributed by a patient’s social network, and after this upon the meaning the patient finds from their own treatment experiences. This personal interpretation appears to play more of a role in trust than the practitioner and their therapy (Lee-Treweek, 2002).
Chapter 10

Future Directions

A willingness to rethink previously accepted models, and establish a scientifically robust explanation for treatment effects is required to advance contemporary understanding of OCF. Recent studies into the physiological effects of OCF are attempting to fulfill this task (Glonek, 2009; Milnes & Moran, 2007; Richards et al., 2001). However, these studies represent only the beginning of the research required to establish the therapeutic value and physiological effects of OCF (Glonek, 2009).

One of the difficulties with research in OCF is that a number of theoretical models, with sometimes very bizarre and differing explanations, exist to explain the clinically observed treatment effects. It often appears to be neglected that these models were created to explain clinical observations; they are not necessarily representative of reality in terms of scientific understanding. Rather than reviewing the currently proposed models or developing further models, research-based evidence is required to “quantify the contribution that cranial osteopathy brings to osteopathic medicine” (Glonek, 2009 p.14). Research into OCF should prioritise the documentation of evidence, and assess the effectiveness of OCF techniques and treatment approaches (Moran, 2005). Only then can the theoretical models be tested for their ability to accurately predict effect.

The basis of treatment with OCF is predicated on the assumed existence and clinical relevance of the cranial concepts. Whilst this assumption may be considered to weaken rationale for OCF, it is supported by clinical experience (R. E. Becker & Brooks, 2000; Chaitow, 2005; Milne, 1995; Sergueef, 2007) and therefore is worthy of investigation.
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Note: This manuscript has been prepared in accordance with the instructions for authors given by the International Journal of Osteopathic Medicine (Appendix E)
Preliminary prediction models for autonomic nervous system response to a cranial osteopathic technique
Abstract

Preliminary prediction models for autonomic nervous system response to a cranial osteopathic technique

Background and Objectives Osteopathy in the cranial field (OCF) is a contentious area of manual therapy. The literature base has attracted much debate, and consists of theories, anecdotal claims and limited academic research. As such, the mechanisms and effects of OCF remain poorly understood. Current research into the physiological effects of OCF is directed toward changes in measures of autonomic nervous system function. One cranial osteopathic technique, the CV4, is commonly claimed to increase parasympathetic activity. The aim of this study was to determine if the CV4 technique has the potential to increase parasympathetic nervous system activity in some individuals, and to examine the notion of ‘responders’ and ‘non-responders’ to the CV4 technique. Further, this study investigated variables from the participants’ history which predicted response to the CV4 technique, with the objective of identifying responder characteristics in order to assist future research into the mechanisms and effects of OCF techniques.

Methods Heart rate variability was measured in thirty participants during an experiment consisting of four phases: baseline, touch control, intervention (CV4) and post-intervention. The CV4 technique was delivered by one of three registered osteopaths who were experienced in cranial approaches. Response and non-response to the CV4 were operationally defined for the study. Changes in heart rate variability across the phases of the experiment were analysed individually for each participant to determine response or non-response to the CV4 technique. Potential predictor variables for response were collected prior to the experiment. Following allocation of participants into response and non-response categories, logistic regression was used to determine which, if any, variables predicted response to the intervention.

Results 14 participants were classified as responders, 16 participants were classified as non-responders. Logistic regression demonstrated the predictive value of variables relating to the individuals’ history of physical trauma and baseline heart rate variability to predict response. The variable height offered marginal predictive value.

Conclusion Results of this study support claims that the CV4 technique has the potential to increase parasympathetic activity in some individuals. Short-term parasympathetic response to the CV4 technique, determined by spectral analysis of heart rate variability, may be associated with an individual’s baseline ANS activity, history of physical trauma, and possibly height. Further research is required to refine understanding of response to the CV4 technique, and to establish the relevance of the prediction models developed in this study.

Key words Osteopathy in the cranial field; OCF; cranial osteopathy; CV4; heart rate variability; autonomic nervous system; logistic regression analysis; prediction model
Introduction

Osteopathy in the Cranial Field (OCF) originated in the early 1900s and has developed into a treatment modality that engenders considerable controversy within the osteopathic profession. The OCF treatment approach is routinely described as being subtle in nature, targeted at normalising the body’s natural rhythms in order to improve health and wellbeing.\(^1\) Osteopathy in the Cranial Field is based upon the putative existence of a subtle rhythmic motion known as the “primary respiratory mechanism” (PRM).\(^2\) The existence of the PRM is contentious; therefore the effectiveness of OCF techniques is subject to scepticism from critics of OCF. Anecdotal accounts of positive treatment outcomes are harshly scrutinised due to the lack of scientific basis for many aspects of OCF. Despite the controversy described, OCF continues to be taught and practiced in New Zealand. The lack of scientifically robust research into OCF has the potential to cause “both misuse and marginalisation” of OCF techniques\(^3\) and it is clear that further understanding of the mechanisms of OCF techniques is required.

Previous OCF research has centred around three main areas: the inter-examiner reliability of palpation specific to OCF; patient-oriented OCF outcomes; and a small number of studies have investigated the physiological effects of OCF techniques. Compression of the Fourth Ventricle (CV4) is an OCF technique claimed to have two main effects: enhancing the flow of cerebrospinal fluid; and balancing the activity of the autonomic nuclei that are located in the floor of the fourth ventricle, leading to an increase in parasympathetic and decrease in sympathetic nervous system activity.\(^4\)

The CV4 technique has widespread clinical use, and has been used in previous research to investigate the physiological effects of OCF.\(^5\)\(^-\)\(^8\) In a recent study,\(^8\) the physiological effects of the CV4 technique on autonomic nervous system function were explored. Once data from the ten participants was pooled, minimal physiological changes in the recorded autonomic variables were observed during the application of the CV4 technique, however, upon examination of individual subjects’ heart rate variability data, there was a change in ANS activity for three of the ten subjects. Several other studies\(^5\)\(^,\)\(^7\)\(^,\)\(^9\)\(^,\)\(^10\) conclude that the CV4 technique does have the ability to influence the autonomic nervous system. The
notion of ‘responders’ and ‘non-responders’ to the CV4 technique has been alluded to in at least two studies using outcome measures related to the ANS. 8, 10 There are a broad range of claimed clinical indications for the CV4 technique listed in the theoretical literature, 4, 11 however, there is a distinct lack of research to substantiate these claims.

This study investigated participants’ ANS responses to the CV4 technique, using heart rate variability as an outcome measure. Heart rate variability (HRV) has been widely used in experimental settings to measure the effects of various interventions on the ANS modulation of the heart, 12-14 providing information about sympathetic and parasympathetic activity. Further, this study investigated variables from the participants’ history, using regression analysis to develop a prediction model for response to the CV4 technique. This study is divided into two distinct sections, and methods are presented separately for Sections A and B. Results of each section are shown, and the discussion that follows integrates findings of both sections before conclusions are presented.

The aim of this study was to determine if the CV4 technique has the potential to increase parasympathetic nervous system activity in some individuals, to examine the notion of ‘responders’ and ‘non-responders’ to the CV4 technique. A further aim of this study was to identify preliminary responder characteristics in order to assist future research into the mechanisms and effects of OCF techniques.
Methods

Operational Definitions

In the absence of previous literature, operational definitions for response and non-response to the CV4 technique were devised. For the purposes of this study, response is defined as a minimum of 10% change in all measured HRV frequency parameters during delivery of the CV4 technique, or in the five minute period immediately following delivery. Specifically, the HRV parameter changes required for response were a decrease in low frequency (LF), an increase in high frequency (HF), and a decrease in the low frequency: high frequency ratio (LF/HF), all indicating an increase in parasympathetic and decrease in sympathetic nervous system modulation of the heart. Non-Response is defined as any changes in HRV parameters not meeting the minimum requirement for response described above.

Outline of the Study Design

Section A describes investigations into individual participant’s immediate physiological responses to the CV4 technique, using change in HRV as the outcome measure. Section A utilised a novel quasi-experimental approach, based on the principles of single-systems design. Visual analysis, combined with a quantitative analytical method developed specifically for this study, was used to group participants into response and non-response categories.

Section B used multivariate regression analysis to identify predictors for response as defined in Section A. Prior to the laboratory-based experimental protocol, variables considered to potentially predict an individual’s response to the CV4 technique were collected from participants, through an interview and a cluster of questionnaires. These predictor variables were used in a stepwise multiple logistic regression analysis to develop preliminary prediction models for response.
Participants

The study was approved by the Unitec Research Ethics Committee, and written informed consent was given by all participants prior to their involvement. Thirty-six participants were recruited using convenience sampling. Participants were normo-tensive, non-smokers and not taking any medication effecting their ANS or cardiovascular system (CVS). All participants were free of any absolute or relative contraindication to OCF as outlined by Leim, specifically: acute fractures; acute traumatic head injury; acute cerebral bleeding; risk of cerebral bleeding; and epilepsy.

Practitioners

Registered osteopathic practitioners were selected by convenience sampling according to the following criteria: a minimum of eight years experience practicing osteopathy; postgraduate training in OCF; use of OCF as the main treatment modality in practice; familiarity and confidence with the use of the CV4 technique. Due to constraints in recruiting one practitioner for all data collection, three osteopathic practitioners participated in delivery of the CV4 technique; each was randomly assigned 12 of the 36 participants.
Response to the CV4 Technique - Section A

The objective of Section A is to identify a group of participants showing response to the CV4 technique as operationally defined for this study.

Data Collection and Experimental Procedure – Section A

Closely following the conventionally accepted recommendations, prior to the experiment participants were required to avoid the consumption of: alcohol for 12 hours; caffeine for four hours; and food for two hours. This requirement reduced confounding factors that could influence ANS activity.

Upon arrival at the laboratory, the participants’ height and weight were recorded. Figure 1 outlines the experimental protocol, consisting of a rest period and four consecutive phases, modified from the protocol outlined by Milnes and Moran. Participants’ cardiac electrical activity and respiratory rate were recorded throughout phases 1-4. The practitioners’ cardiac electrical activity was also recorded during the experiment, however will not be discussed as part of the current study.

The osteopathic practitioner was seated at the head of the table for the duration of the experiment. The procedure was outlined in basic terms to the participant; however the touch control and intervention phases (Figure 1) were not distinguished in the explanation. No verbal contact was made between the practitioner, researcher and participant throughout the duration of Phases 1-4, and the participant was asked to refrain from moving or speaking for the duration of recording.
Figure 1: Experimental Protocol

Rest Period – The participant sat quietly for a 20 minute rest period, allowing cardiac and respiratory activity to settle. Blood pressure was measured, and then the participant lay supine on a standard osteopathic treatment table for approximately five minutes, whilst ECG electrodes and the respiratory transducer were fitted and their recordings tested.

Phase 1 – Baseline: recording with no physical or verbal contact between practitioner and participant for ten minutes.

Phase 2 – Touch Control: the practitioner initiated contact with the participant using the vault hold (described in the independent variables section). The practitioner refrained from palpation or delivery of any therapeutic technique, and was asked to consciously disengage from the participant for the six minute duration of this phase. At the end of Phase 2, there was a two minute period during which the practitioner made a palpatory assessment of perceived ‘cranial dysfunction’. This was recorded on a linear visual analogue scale (VAS).

Phase 3 – Intervention: the practitioner began delivery of the CV4 technique (described in the independent variables section). The practitioner indicated with a footswitch the beginning of any perceived stillpoint (refer to Appendix 1 for a description of the stillpoint), after which recording continued for a minimum of six minutes. At the end of Phase 3, the practitioner ceased physical contact with the participant and recorded on a linear VAS their palpatory assessment of the participant’s ‘receptivity’ to the technique.

Phase 4 – Post Intervention: recordings continued for ten minutes with no contact between practitioner and participant. After Phase 4, recording was ceased and the transducer and electrodes disconnected from the participant.

\(^{k}\) Perceived ‘cranial dysfunction’ – the perception of sub-optimal rhythm, rate, symmetry, quality or function of the primary respiratory mechanism maintained to be palpated by cranial practitioners. For further discussion of cranial dysfunction, refer to Leim (2004) or Chaitow (2005).

\(^{l}\) ‘Receptivity’ to the technique – the perceived change in function of the ‘primary respiratory mechanism’ reported by cranial practitioners.
Variables – Section A

*Independent Variables*

The specific requirements for practitioner contact and therapeutic technique during the experiment were discussed with the three involved practitioners prior to data collection. Consensus was reached regarding the technical details of Touch Control and Intervention phases to minimise inter-practitioner discrepancies.

**Touch Control**

During Phase 2 of the experimental protocol, the participant was lying supine with the practitioner seated at the head of the treatment table. The practitioner’s hands were placed gently on the participant’s head using the *vault hold*, as described by Chaitow (Figure 2).4 During this phase the practitioner was asked to consciously disengage from the participant and refrain from any palpation or delivery of any therapeutic technique. This touch control phase allowed discrimination between each participant’s response to the intervention and their response to touch alone. The participant was not informed of when the practitioner was using non-specific touch and when the intervention was being delivered.

*Figure 2: Vault Hold*
The practitioner’s fingertips lightly contact over the frontal, sphenoid and temporal bones.

Intervention

Phase 3 of the experiment involved delivery of the CV4 technique in accordance with the method described by Chaitow, and refined by discussion with practitioners prior to the experiment. Figure 3 illustrates and describes the hand hold used for delivery of the CV4 technique. Once the practitioner palpated the participant’s CRI (see Appendix 1 for an operational definition), the technique began. During the reported ‘flexion phase of the CRI’, perceived cranial movement was very slightly resisted by the practitioner through contraction of the deep flexors of the forearm. Resistance during the ‘flexion phase’ was maintained until a pause in the CRI was perceived by the practitioner, a phenomenon known as the ‘stillpoint’ (see Appendix 1 for an operational definition). Once the practitioner perceived the resumed fluctuation of the CRI, the pressure on the occiput was gently released.

Figure 3: Practitioner’s Hand Position for Delivery of the CV4

With fingers interlocked, the practitioner’s thenar eminences contacted the participant’s occiput, medial to the lateral angles of the occipital squama and lateral to the external occipital protuberance. The participant’s head and neck were relaxed and resting in the bowl shape formed by the practitioner’s hand-hold.

The description of the CV4 technique is in accordance with the reports of cranial practitioners. The technique is based on the assumption of the existence and palpability of the CRI and its phases, as well as the assumption of the existence of the stillpoint. For definitions of the CRI and the stillpoint, see Appendix 1.
Dependant Variables

Experimental environment
The laboratory was monitored to maintain consistently low levels of noise and light. Ambient temperature and humidity were maintained at constant, comfortable levels during each experimental procedure.

Participant’s Heart Rate
A three lead electrocardiogram (ECG) was used to record cardiac electric activity (ML132, AD Instruments Pty Ltd, Victoria, Australia). Electrodes were adhered to the participant’s right medial malleolus, and to the anterior surface of the left and right wrists.

Participant’s Respiration Rate
To monitor expansion of the thoracic cage, an elasticised Respiratory Belt Transducer (MLT1132, AD Instruments Pty Ltd, Victoria, Australia), was fastened over the participant’s clothes at the level of the xiphi-sternum.

Heart and respiratory rate data were captured using a Powerlab Data Acquisition system (Model 4/SP, AD Instruments Pty Ltd, Victoria, Australia). All data were saved for off-line analysis.
Data Extraction – Section A

Participants Respiration Rate

The average respiration rate for each phase of each individual experiment was extracted using Chart 5.0.1 (AD Instruments Pty Ltd, Victoria, Australia). A rate within the range of 9-20 br.min\(^{-1}\) was required to control for the influence of respiratory modulation of HRV. Any mean rate falling outside the specified range necessitated removal of the associated participant’s data from further analysis.

Participants Heart Rate Variability

A minimum of five minutes of continuous ECG recording for each phase is required to obtain sufficient data for HRV extraction. The last five minutes of Phases 1, 2 and 4 were selected for analysis. The period selected for Phase 3 was a minimum of 5 minutes duration, which began upon palpation of ‘stillpoint’ by the practitioner, and continued until the end of the phase.

Using the HRV extension package (Chart v 5.0.1 with HRV extension v 1.0), R-R intervals were detected for each cardiac cycle from the raw ECG tracings. Data were extracted from the ECG tracings according to commonly accepted recommendations. Participants’ complete data records were excluded from analysis if the level of ectopy exceeded 5%. When the level of ectopy was less than 5%, the ectopic beats were removed, and interpolated with a new beat derived from the average of the normal beat immediately previous and the normal beat immediately subsequent to the ectopic beat. Power spectral density of the HRV was then calculated with Fast Fourier Transforms and displayed in the conventional frequency bands. The high frequency (HF, 0.15-0.5 Hz) and low frequency (LF, 0.04-0.15 Hz) bands, as well as the low frequency to high frequency ratio (LF/HF) were calculated for each experimental phase, and reported in normalised units (nu). Raw HRV data are shown in Appendix 2.

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\( ^{16} \) R-R Intervals – the intervals between consecutive R waves on a recorded ECG, measured in milliseconds.
Data Analysis – Section A

An analytical method was developed specifically for this study, which enables analysis of individual participants’ HRV responses during the experimental procedure. Refer to Appendix 3 for a worked example of the following process of data analysis, used individually on each participant’s data. Analysis was conducted using Microsoft Excel 2007 (Microsoft Corp., Seattle, WA).

Initial Assessment of Changes in Heart Rate Variability

Graphs were generated from raw HRV data (Appendix 3.1) in order to visually assess changes in the following three HRV parameters: LF; HF; and the LF/HF ratio. These graphs provide an initial reference to indicate HRV changes for the participant. As there is a wide range in baseline HRV, it was necessary to convert the obtained measures into a form that enables comparison between individuals, to avoid potentially masking or exaggerating changes which may constitute a response. This conversion was also considered necessary to determine a threshold of change which can be defined as a response to the CV4 technique (as operationally defined in the Outline of the Study Design).

In order to compare changes in HRV measurements between individual participants, the HRV measurements for Phases 2 – 4 were converted into a percentage of the baseline (Phase 1) measurement (Appendix 3.2). This step enables visualisation of a percentage change for each phase, in relation to each individual’s baseline HRV, thereby indexing change between phases for individual participants.

The resulting figures for each phase were then used to generate line graphs to demonstrate the percentage change in each of the HRV parameters across the 4 phases of the experiment (Appendix 3.3). Each line graph has a baseline starting at zero and uses the same scale, providing a simple visual reference to assess patterns of HRV change and reinforce interpretation of the HRV patterns outlined below.
The percent change figures for each phase are colour-coded according to the direction of change, at the selected cut-off threshold of 10% for each of the three HRV frequency parameters (LF, HF and LF/HF) (Appendix 3.4). The data were then transferred to HRV grids in order for each phase to be compared to baseline as well as to the previous phase. Each of the HRV frequency parameters (LF, HF and LF/HF) is represented in a separate HRV grid (Appendix 3.5). The grids were then used to establish HRV patterns for each participant for each of the three HRV frequency parameters.

Response Analysis

The participants’ HRV patterns for LF, HF, and LF/HF were analysed to determine if the participant showed response or non-response to the intervention. Comparisons were made between consecutive phases as well as between the baseline phase and each subsequent phase to ensure changes in the intervention phase did not represent a return to baseline (Appendix 3.5). Heart rate variability measures, converted percentages, colour-coding and HRV grids for all participants are shown in Appendix 4.

Each participant was then categorised into response or non-response group according to their HRV patterns across all three parameters. As previously specified in the operational definitions, demonstrated response across all three HRV frequency parameters was required for a participant to be categorised into the response group; response in only one or two of the parameters meant the participant was categorised into the non-response group. All possible HRV patterns had been previously classified as response or non-response, according to the operationally defined study criteria. The response category was further subdivided into immediate response and delayed response groups, depending upon the HRV changes being demonstrated in the intervention phase or post-intervention phase, respectively. The non-response category contained the sub-group touch-only response to classify participants that met the HRV change criteria during the touch control phase of the experiment, but not during the intervention phase. In order to obtain additional information for use in Section B of the study, participants HRV patterns were analysed for response to touch during the touch control phase of the experiment.
Predictors for Response – Section B

Following identification of a group of participants showing response in Section A of this study, the objective of Section B was to identify variables that may have predictive value for response in this population. Predictor research may be particularly useful in the field of complementary and alternative medicine (CAM). As there are few types of treatment that work well for all patients, differential indication for the CV4 technique may be an important factor to consider in order to identify possible subgroups for further research and practice.

Data Collection – Section B

Prior to the experiment, data were collected from each of the participants by structured interview, questionnaire, and visual analogue scales (VAS) for use as predictor variables in a logistic regression analysis using response as the outcome variable. Data collection tools comprised a collection of both previously validated measures and measures devised particularly for the current study. Wherever possible, previously validated measures were utilised. However, devising novel question items for some of the predictor variables was necessary due to the lack of previous research into factors anecdotally reported to influence the outcomes of OCF (see Appendix 5 for copies of the questionnaires, interview sheets and VAS utilised in Section B).

\[\text{\textsuperscript{\textcircled{o}}}\text{Differential indication: various valid reasons for use of a particular intervention.}\]
Variables – Section B

Predictor Variables

Predictor variables were selected based on theoretical concepts of OCF, and general factors considered by the author to potentially influence intervention outcomes. Of particular interest were variables which may, based on OCF theories, be a clinical indication for the use of the CV4 technique. The selected variables were intended to provide a preliminary indication of possible predictors for response to the CV4 technique.

Basic Characteristics

Standard measures of age and gender, height, weight and blood pressure were used as predictor variables (Appendix 5.1 and 5.3).

Current Health and Wellbeing

To broadly assess current levels of physical and mental health and wellbeing, the Short Form 36 (SF-36) questionnaire was completed by each participant within the 24 hours prior to the experiment (Appendix 5.2).

Perceived Stress Levels

To indicate participants’ perception of their current stress levels, the Perceived Stress Scale was completed by the participant within the 24 hours preceding the experiment (Appendix 5.2).
Attitude toward Complementary and Alternative Medicine
The Holistic Complementary and Alternative Medicine Questionnaire (HCAMQ)\textsuperscript{20} was completed by participants within the 24 hours preceding the experiment (Appendix 5.2).

History of Chronic Illness
Information relating to history of chronic illness, the number and length of any identified chronic illnesses, and the effect of the illness on activities of daily living was collected during a structured interview between the researcher and the participant (Appendix 5.1).

History of Physical Trauma or Injury
Information relating to previous physical trauma was collected during a structured interview between the researcher and the participant. The location, severity, effect on activities of daily living and recovery time of any injuries or procedures, including surgery, were recorded (Appendix 5.1).

Naivety to OCF
To assess the participant’s previous experiences and knowledge of osteopathy and OCF, a questionnaire devised by the researchers was completed by the participant within the 24 hours prior to the experiment (Appendix 5.1).

Current Levels of Physical Pain or Discomfort
A VAS was marked by the participant, just prior to the experiment. The scale was composed of a 100mm horizontal line, anchored on the left with ‘zero physical pain or discomfort’, and on the right with ‘maximal physical pain or discomfort’ (Appendix 5.3).
Perceived Cranial Dysfunction

The participants’ level of ‘cranial dysfunction’ was assessed by the practitioner, using commonly accepted osteopathic methods of palpation. This was recorded manually by the practitioner on a VAS, after a two minute period of palpation between the touch control and intervention phases of the experiment. The scale was composed of a 100mm horizontal line, anchored on the left with ‘zero dysfunction’ and on the right with ‘maximal dysfunction’ (Appendix 5.4).

Perceived Receptivity to the CV4 Technique

The practitioner’s perception of the participant’s ‘receptivity’ to the technique was assessed, using commonly accepted clinical methods of palpation. ‘Receptivity’ was recorded manually by the practitioner on a VAS, composed of a 100mm horizontal line anchored on the left ‘zero receptivity’, and on the right with ‘maximal receptivity’ (Appendix 5.4).

Baseline Ratio of LF/HF HRV

The ratio of low frequency to high frequency heart rate variability during the baseline phase of the experiment in Section A (baseline LF/HF HRV) was used as a predictor variable (Appendix 3).

Response to Touch

As described in Section A, HRV changes during Phase 2 of the experiment led to allocation of each participant into either response to touch or non-response to touch categories. These categories were used as a predictor variable (Appendix 4).

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For a discussion on the diagnosis of cranial dysfunction by palpation, refer to Leim (2004) pg. 7

Palpation of ‘receptivity to the CV4 - the sense of change in the function of the PRM perceived by the cranial practitioner following delivery of the CV4.'
**Practitioner**

The individual practitioner (of the three practitioners participating in the study) delivering the intervention was used as a predictor variable (Appendix 7).

**Outcome Variable**

The participant’s physiological ANS response or non-response to the applied CV4 technique, as shown in Section A of the study, was used as the outcome variable in Section B (Appendix 4).
Data Extraction – Section B

Methods of data extraction were dependent upon the collection method used for each variable. Extraction methods are outlined below and raw data is given in Appendix 7.

‘Current Health and Wellbeing’, ‘Perceived Stress Levels’ and ‘Attitude toward Complementary and Alternative Medicine’

Wherever previously validated instruments were used to collect data, scales and subscales were scored in accordance with the developer’s instructions. Scales and subscales were converted to a common scale of 0 – 100, however only the total scores were used as predictor variables.  

‘History of Physical Trauma or Injury’ and ‘History of Chronic Illness’

Information collected by interview was subject to discussion between the principal researcher and two advisors. A consensus was reached about the objective effects each condition or event were likely to have had upon the participant’s usual daily activities and ability to work, and each chronic illness or physical trauma was graded on a scale of 0-3 (0=absent, 1=mild, 2=moderate, 3=severe). Scoring criteria are described in Appendix 7.

Following this grading, Physical Trauma was divided into three anatomical groups; 1) Head/Neck/Face, 2) Support Structures (Back, Chest, Abdomen, Pelvis, Hips), 3) Extremities (Shoulder, Arm, Hand, Leg, Foot). Scores from individual trauma to each anatomical group were added together, to give a score for the following variables: total mild trauma; total moderate trauma; total severe trauma; mild head/neck/face trauma; moderate head/neck/face trauma; severe head/neck/face trauma; mild axial trauma; moderate axial trauma; and severe axial trauma. The variables: mild extremity trauma;
moderate extremity trauma; and severe extremity trauma were scored, however not used as predictor variables.\(^5\)

Scores from each chronic illness were added to give an overall rating of total mild, moderate and severe chronic illness scores for each participant.

‘Naivety to OCF’
A scale was devised by the principal researcher in conjunction with two advisors to rate the participants’ prior knowledge of OCF and their previous history of treatment with OCF (Appendix 6). Scores were added to give a total Naivety to OCF’ score. Participants’ previous experience of OCF treatment was also used in the analysis as a separate predictor variable.

‘Current Levels of Physical Pain or Discomfort’, ‘Dysfunction’ and ‘Receptivity’
Visual analogue scales were measured in millimetres and used as a predictor variable.

‘Baseline LF/HF HRV’ and ‘Response to Touch’
Predictor variables relating to HRV were extracted from HRV measurements during Section A of the study.

\(^5\) Because of the large number of predictor variables, it was required that certain variables be excluded or grouped for the univariate analysis. Subscales of the SF-36 and HCAMQ were not used for this reason; however this data was contained within the total scores which were used in the univariate analysis. The three extremity trauma variables (mild extremity trauma, moderate extremity trauma and severe extremity trauma) were excluded from the univariate analysis as they were believed to have less predictive potential compared to the other trauma variables. However, the data from these variables were contained within the total trauma variables, which were included in the univariate analysis. This exclusion will be further addressed in the discussion section.
Data Analysis – Section B

The purpose of this analysis was to identify predictors for response according to the specified criteria, and to construct a model to predict response in the obtained data set. Potential predictors were selected for inclusion in the model, using stepwise regression techniques on variables deemed significant by univariate analysis. The stepwise regression was performed twice; first using response as the outcome variable (which included immediate response and delayed response) and secondly using immediate response (without the delayed response group) as the outcome variable. Statistical analysis was conducted using SPSS 12.0.1 for Windows (SPSS Inc., Chicago, IL). Throughout the manuscript descriptive statistics are reported as mean ± standard deviation (SD).

Univariate Analyses

To reduce the number of predictor variables for the logistic regression analysis, a correlation analysis\(^1\) was conducted to determine which predictor variables demonstrated a univariate correlation with response. A liberal significance value \((p\leq0.15)\) was used at this stage of analysis, to avoid eliminating any predictor variables with possible clinical significance.

In order to meet the assumptions of logistic regression analysis, predictor variables showing a significant univariate correlation with response were tested for multicollinearity and interaction by scanning of a correlation matrix. Any predictor variables demonstrating multicollinearity or interaction were adjusted to meet assumptions, either through

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\(^1\) Pearson’s correlation was used. Although some of the variables were non-parametric, due to the fact they were discrete a parametric regression was still selected because there is no non-parametric alternative for multiple regression.
combination by principal components analysis\textsuperscript{4} to identify the linear components of the two variables, or through selection of the most clinically applicable variable.

Once univariate associations for response had been identified, an additional correlation analysis was performed, to determine which predictor variables correlated with touch-only response. The purpose of this step was to determine if predictor variables demonstrating a univariate association with response also demonstrated an association with touch-only response. Such an association may invalidate the use of predictor variables as predictors for response, as it could indicate the participants classified as showing response to the technique were part of the group just responding to touch.

Regression Analyses

The α-level for the inclusion of predictors in the regression was set at $p \leq 0.10$. Suitable predictor variables were visually assessed for outliers before inclusion in further analyses. Initially, a pre-predictor mean model was developed for the data to use a basis for comparison of subsequent prediction models. A multiple logistic regression using the enter method was conducted to obtain an order for predictor variables to be entered into the subsequent stepwise regression. Based on this order, a stepwise multiple logistic regression was conducted using the forward method, with response as the outcome variable. Because of the preliminary nature of this study, speculation exists as to the most clinically significant outcome variable, therefore a second stepwise multiple logistic regression using the forward method was conducted, using immediate response as the outcome variable.

The goodness-of-fit of each model was assessed by evaluation of both the Cox & Snell’s $R^2$ and Nagelkerke $R^2$ statistics. Accuracy of the final prediction models was compared to the accuracy of the mean pre-predictor model to further assess goodness-of-fit of the models to the collected data.

\textsuperscript{4}Principal Components Analysis: defined by Field\textsuperscript{21} as a multivariate technique for identifying the linear components of a set of variables. For further information refer to Field\textsuperscript{21} or Chatterjee and Hadl.\textsuperscript{22}
The statistics from each prediction model were interpreted to determine the fit of the model to the collected data and the strength of the predictors within each model. The qualifying descriptions for the predictor odds ratios were based upon the scale of magnitudes outlined by Hopkins.\textsuperscript{23}
Results

Section A

Environment – Section A

The ambient temperature was maintained at 24 to 26 °C; mean 24.95 ± 0.47 °C throughout all sessions. The mean humidity was 45 ± 4.72 %. The maximum variation for any single experiment was 0.8 °C and 2% humidity, the maximum variation across all sessions was 1.9 °C and 17% humidity.

Respiration Rate – Section A

The participants’ respiration rates were maintained within the range required to control for RSA (9 to 20 br.min\(^{-1}\)). The mean breathing rate across all participants was 13 ± 2 br.min\(^{-1}\), and the range was 9 to 17 br.min\(^{-1}\).

Heart Rate Variability – Section A

Data from 36 participants were collected. Five participants were excluded from analysis due to combined rates of ectopic beats and artefact exceeding 5%. One participant was excluded because they commenced a course of medication affecting the ANS several days prior to the experimental procedure. Data from 30 participants were analysed.

Baseline HRV measures varied greatly between participants. The range for LF was 12.84 to 90.56 nu; mean 49.31 ± 21.93 nu, the range for HF was 8.40 to 74.34 nu; mean 46.01 ± 20.96 nu, and the range for the LF/HF ratio was 0.20 to 5.14; mean 2.06 ± 2. Raw HRV data is contained in Appendix 2.
Response Analysis – Section A

The raw HRV data were converted into percentages of baseline measures for each individual participant, and converted HRV measures for all participants are shown with corresponding HRV grids in Appendix 4.

Examples of percentage change in HRV across the experimental phases and the corresponding HRV grids are shown below in Figure 4 for the two subgroups of response: immediate response (Panel 1); and delayed response (Panel 2). Further examples are shown for non-response (Panel 3) and touch-only response (Panel 4).
Figure 4: Examples of Various Heart Rate Variability Responses

* refer to legend on the following page
Legend for Figure 4

1  = phase 1 of the experiment, baseline
2  = phase 2 of the experiment, touch control
3  = phase 3 of the experiment, intervention
4  = phase 4 of the experiment, post-intervention

% change in HRV parameters = the percentage change in heart rate variability parameters compared to the baseline measure

HRV  = heart rate variability
LF/HF = low frequency/ high frequency HRV ratio
LF   = low frequency HRV
HF   = high frequency HRV

Cf 1  = phase on the Y axis compared to phase 1
Cf 2  = phase on the Y axis compared to phase 2
Cf 3  = phase on the Y axis compared to phase 3

= minimum 10% change indicating increased parasympathetic activity and decreased sympathetic activity
= no change, or change below the 10% threshold
= minimum 10% change indicating decreased parasympathetic activity and increased sympathetic activity
From the HRV grids, a total of 27 possible HRV patterns were identified. Of these possible HRV patterns, 15 met the criteria defined for response to the technique, the remaining 12 patterns constituted non-response. Upon analysis of HRV grids for all phases, 14 participants demonstrated response to the CV4 technique and 16 participants demonstrated non-response. The response group was further subdivided according to the type of response shown, 8 participants showed immediate response and 6 showed delayed response.

During the touch control phase of the experiment, 13 participants showed response to touch, the remaining 17 participants showed non-response to touch. This classification was used in Section B, independent of response or non-response to the CV4 technique, and is not relevant to the objective of Section A.

Six of the 13 participants showing response to touch showed touch-only response, meaning they showed an increase in parasympathetic activity during the touch control phase. This parasympathetic activity either remained unchanged, or was reversed toward increased sympathetic activity during the intervention phase. Therefore, the touch-only response group represents a subgroup of non-response. Results of the response analysis are summarised in Table 1.
Table 1: Responses to the touch control and CV4 Technique

<table>
<thead>
<tr>
<th>Touch Response</th>
<th>CV4 Response</th>
<th>Yes</th>
<th>No</th>
<th>n=</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Immediate</td>
<td>2</td>
<td>6</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Delayed</td>
<td>5</td>
<td>10</td>
<td>17</td>
</tr>
<tr>
<td>n=</td>
<td></td>
<td>8</td>
<td>6</td>
<td>16</td>
</tr>
</tbody>
</table>

Cut-off for response is a minimum 10% change towards increased parasympathetic activity in all three of the HRV parameters: LF; HF; and LF/HF. Total n=30. CV4=compression of the fourth ventricle technique (the intervention).
Results – Section B

Baseline characteristics of the 30 participants are given in Appendix 6. According to the specified criteria of determining response to the CV4 technique, 14 participants were allocated to the response group, and of these participants, eight showed immediate response.

Univariate Associations

Univariate analyses indicate that four predictor variables correlate with response: height (Pearson’s correlation; r= 0.297, p= 0.112 ), baseline LF/HF HRV (Pearson’s correlation; r= 0.037 , p= 0.099), total severe trauma (Pearson’s correlation; r=0.302 , p=0.105), and severe axial trauma (Pearson’s correlation; r= 0.0393, p= 0.032). Two predictor variables negatively correlated with response: total mild trauma (Pearson’s correlation; r= -0.284, p=0.129), moderate head neck and face trauma (Pearson’s correlation; r= -0.311, p= 0.094).

When testing these predictor variables for multi-collinearity, total severe trauma and severe axial trauma were found to correlate with each other (Pearson’s correlation; r= 0.623, p≤ 0.001). Therefore, severe axial trauma was eliminated from further analysis, as this data was contained within the total severe trauma variable. Total mild trauma and moderate head, neck and face trauma also demonstrated multi-collinearity (Pearson’s correlation; r= 0.439, p= 0.015). As both variables were considered to be potentially important predictors, a principal components analysis was run, and a new predictor variable – combined trauma was constructed using the linear components of total mild trauma and moderate head, neck and face trauma. The values for the new combined trauma predictor variable are given in Appendix 8.
Predictor variables that were considered, but do not show significant univariate association with response are reported in Appendix 9. Two predictor variables negatively correlate with touch-only response, these were height (Pearson’s correlation; r=-0.363, p=0.048) and weight (Pearson’s correlation; r=-0.325, p=0.080). The lack of correlation between touch-only response and the variables positively correlating with response support the assumption that touch-only response is a subgroup of non-response rather than a subgroup of response.

**Stepwise Multiple Logistic Regression Analysis**

Four predictor variables identified through the univariate analyses were entered into the logistic regression analyses. The order of significance of the variable obtained from the initial multiple regression analysis using the enter method was: baseline LF/HF HRV, total severe trauma, combined trauma and height.

Results of the stepwise multiple logistic regression analyses using the forward method are given in the following three tables. Table 2 shows results of the three predictor model produced at the third step of the stepwise regression using response as the outcome variable (which included both immediate response and delayed response). Table 3 shows results of the four predictor model produced at the fourth step of the stepwise regression using response as the outcome variable. Table 4 shows results of the analysis using immediate response as the outcome variable.
### Table 2

**Prediction model for response to the CV4 Technique (Three-predictor model)**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coefficient (SE)</th>
<th>Wald $X^2$</th>
<th>$P$ value</th>
<th>95% CI for OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combined Trauma</td>
<td>-3.303 (1.756)</td>
<td>3.539</td>
<td>0.060</td>
<td>0.001 - 0.037</td>
</tr>
<tr>
<td>Baseline LF/HF HRV</td>
<td>1.222 (0.642)</td>
<td>3.616</td>
<td>0.057</td>
<td>0.963 - 3.392</td>
</tr>
<tr>
<td>Total Severe Trauma</td>
<td>1.631 (0.856)</td>
<td>3.634</td>
<td>0.057</td>
<td>0.955 - 5.111</td>
</tr>
<tr>
<td>Constant</td>
<td>-3.851 (1.913)</td>
<td>4.051</td>
<td>0.044</td>
<td>- - 0.000</td>
</tr>
</tbody>
</table>

**Model goodness-of-fit:** $R^2 = 0.417$ (Cox & Snell), $0.557$ (Nagelkerke).

Accuracy of the model in classifying response and non-response in the collected data = 86.7% (compared to accuracy of the mean pre-predictor model of 53.3%).

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**Legend for Tables 2-4**

- **Variable** = potential predictor variable
- **Constant** = a mathematical constant, no clinical interpretation
- **Coefficient** = the mathematical weighting of the explanatory variable in the equation
- **SE** = standard error: the estimated error of the mathematical weighting
- **Wald $X^2$** = the Wald test statistic calculated from the data to be compared with the chi-square distribution with 1 degree of freedom
- **$P$ value** = the probability value of the Wald test statistic indicating that the variables are statistically significant associated with the outcome variable
- **OR** = odds ratio: an indicator of change in odds resulting from a unit change in predictor, when other variables in the model are controlled, for every unit increase in the predictor. Values >1 indicate that as the predictor increases, the odds of the outcome occurring also increase. Values <1 indicate that as a predictor increases, the odds of the outcome occurring decrease.
- **95% CI** = the 95% confidence interval for the OR
- **CT** = combined trauma variable constructed using the linear components of total mild trauma and moderate head, neck and face trauma

Baseline LF/HF HRV = baseline low frequency to high frequency heart rate variability ratio

$R^2$ = coefficient of determination; how much variability in the outcome is accounted for by the model. Cox and Snell’s $R^2$ and Nagelkerke’s $R^2$ are both versions of the coefficient of determination for logistic regression.
Table 3

Prediction model for response to the CV4 Technique (Four-predictor model)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coefficient (SE)</th>
<th>Wald X²</th>
<th>P value</th>
<th>95% CI for OR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lower</td>
</tr>
<tr>
<td>Combined Trauma</td>
<td>-2.920 (1.662)</td>
<td>3.086</td>
<td>0.079</td>
<td>0.002</td>
</tr>
<tr>
<td>Height</td>
<td>0.165 (0.102)</td>
<td>2.623</td>
<td>0.105</td>
<td>0.966</td>
</tr>
<tr>
<td>Baseline LF/HF HRV</td>
<td>1.131 (0.617)</td>
<td>3.354</td>
<td>0.067</td>
<td>0.924</td>
</tr>
<tr>
<td>Total Severe Trauma</td>
<td>1.654 (0.939)</td>
<td>3.099</td>
<td>0.078</td>
<td>0.829</td>
</tr>
<tr>
<td>Constant</td>
<td>-32.041 (18.022)</td>
<td>3.161</td>
<td>0.075</td>
<td>-</td>
</tr>
</tbody>
</table>

Model goodness-of-fit: $R^2 = .484$ (Cox & Snell), .646 (Nagelkerke).

Accuracy of the model in classifying response and non-response in the collected data = 83.3% (compared to accuracy of the mean pre-predictor model of 53.3%).

*for Legend refer to Table 2
Table 4
Prediction model for *Immediate Response* to the CV4 Technique

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coefficient (SE)</th>
<th>Wald X²</th>
<th>P value</th>
<th>95% CI for OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline LF/HF HRV</td>
<td>0.427 (0.292)</td>
<td>2.140</td>
<td>0.143</td>
<td>0.865 - 1.533</td>
</tr>
<tr>
<td>Total Severe Trauma</td>
<td>0.826 (0.514)</td>
<td>2.581</td>
<td>0.108</td>
<td>0.834 - 2.285</td>
</tr>
<tr>
<td>Constant</td>
<td>-2.338 (-2.338)</td>
<td>8.015</td>
<td>0.005</td>
<td>-0.096 - 0.096</td>
</tr>
</tbody>
</table>

*Model goodness-of-fit:* $R^2 = .196$ (Cox & Snell) .286 (Nagelkerke).

Accuracy of the model in classifying response and non-response in the collected data = 83.3% (compared to accuracy of the mean pre-predictor model of 73.3%).

*For Legend refer to Table 2

The models constructed from the above results may be expressed as the logistic regression equations given in **Table 5**, which can be used to predict *response* (or *immediate response*) to the CV4 technique in the sample population of the current study.

**Table 5**

**Logistic Regression Equations for the Prediction Models**

*Response* (Three predictor model)

\[ \ln(p/1-p) = -3.851 + 3.303(CT) + 0.222(LF/HF HRV) + 1.631 \text{ (total severe trauma)} \]

*Response* (Four predictor model)

\[ \ln(p/1-p) = -32.041 + 2.920(CT) + 1.131(LF/HF HRV) + 1.654 \text{ (total severe trauma)} + 0.165 \text{ (height)} \]

*Immediate Response*

\[ \ln(p/1-p) = -2.338 + 0.427(LF/HF HRV) + 0.826 \text{ (total severe trauma)} \]

Where: \(\ln\) = natural log; \(p\) = probability of specified response; \(CT\) = combined trauma; \(LF/HF \text{ HRV}\) = baseline low frequency: high frequency heart rate variability ratio.
Interpretation of Results – Section B

Results of the logistic regression analyses were interpreted to provide meaningful findings in relation to the study objective of identifying variables that may be important in predicting response to the CV4 technique.

Three-predictor model for response to the CV4 technique (Table 2)
This model explains a substantial proportion of variance within the collected data (41-56%). When used to predict response within the collected data, the model accuracy is 86.7% (compared to the mean pre-predictor model accuracy of 53.3%). Based on the width of the confidence intervals: combined trauma offers a trivial to small contribution to the model (95% CI 0.001 – 1.148); baseline LF/HF HRV offers a trivial to large contribution to the model (95% CI 0.963 – 11.947); total severe trauma offers a trivial to very large contribution to the model (95% CI 0.955 – 27.354).

Four-predictor model for response to the CV4 technique (Table 3)
This model explains a substantial proportion of variance within the collected data (48-55%). When used to predict response within the collected data, the model accuracy is 83.3% (compared to the mean pre-predictor model accuracy of 53.3%). Based on the width of the confidence intervals: combined trauma offers a trivial to small contribution to the model (95% CI 0.002 – 1.402); height offers a trivial to small contribution to the model (95% CI 0.966 – 1.439); baseline LF/HF HRV offers a trivial to large contribution to the model (95% CI 0.924 – 10.393); total severe trauma offers a trivial to very large contribution to the model (95% CI 0.829 – 32.944).
Model for Immediate Response to the CV4 technique (Table 4)

This model explains a moderate proportion of variance within the data (20-29%). When used to predict response within the collected data, the model accuracy is 83.3% (compared to the mean pre-predictor model accuracy of 73.3%). Based on the width of the confidence intervals: baseline LF/HF HRV offers a trivial to moderate contribution to the model (95% CI 0.865 – 2.715); total severe trauma offers a trivial to moderately large contribution to the model (95% CI 0.834 – 6.261)

One objective of this study was to provide a preliminary indication of the types of variables that may be predictive of response to the CV4 technique. Therefore exact figures within the models are of secondary importance with relevance to the stated objective, and one model is not favoured over another. However, comparisons between the models may be drawn. The three-predictor and four-predictor models for response are different steps of the same stepwise logistic regression. Both steps are presented, because on comparison the three-predictor model predicts response for the data more accurately, while the four-predictor model explains more of the variance within the collected data. There is no difference between models in the performance of the first three predictor variables (total severe trauma, baseline LF/HF HRV and combined trauma). The model for immediate response explained less of the variance within the collected data, and the low proportion of participants classified into the immediate response group is reflected in the relatively high mean pre-predictor model accuracy (73.3%). The total severe trauma and baseline LF/HF HRV variables are shown to have the strongest association with response and immediate response, however the wide confidence intervals indicate that the sample size was underpowered for the prediction models.
Discussion

The aim of this study was to investigate ideas presented in osteopathic theory, specifically the effects of the CV4 technique on the autonomic nervous system, to determine if some individuals respond to the technique with an increase in parasympathetic nervous system activity as indicated by changes in HRV. A further aim was to identify potential predictors of response to the CV4 technique. This study found that around half the participants showed changes in heart rate variability consistent with increased parasympathetic activity during, or immediately after, delivery of the CV4 technique. Within the study participants, baseline HRV and aspects of physical trauma history are predictors of response, with height offering marginal predictive value.

Findings of the current study support the anecdotal claim that OCF may influence the ANS. A number of studies have demonstrated that the CV4 technique can affect low-frequency oscillations controlled either directly or indirectly by the ANS. These oscillations are within the same low-frequency range as reported rates of the CRI, and Glonek suggests that while it would be premature to conclude that these low-frequency oscillations are the same phenomenon as the PRM or the CRI, the use of these ANS oscillations as experimental outcome measures for OCF provide a promising starting point for further research. Milnes and Moran raised the notion that there may be ‘responders’ and ‘non-responders’ to cranial techniques and suggest that anecdotal claims of successful treatment outcomes are probably based upon clinical observations of ‘responders’. The issue of individual responses has been further discussed in the relevant research literature, highlighting the need for recognition of individual variation when researching treatment effects.

The preliminary prediction models developed in this study for response (including immediate and delayed response) and immediate response (a subgroup of the response category) contained four variables: baseline LF/HF HRV; total severe trauma; combined trauma; and height. With the exception of height, these variables seem plausible based on the limited theoretical literature available. The CV4 technique is widely claimed to decrease the tone of the SNS, and enhance parasympathetic activity. A number of
predictor variables with the potential to influence ANS activity were investigated, including measures of perceived stress, general health and well-being, current pain levels, blood pressure and baseline LF/HF HRV. It is reasonable to assume that individuals with a clinical indication for the technique would be more likely to show a response. Consistent with anecdotal claims that the CV4 technique is indicated for the reduction of SNS tone, baseline LF/HF HRV was found to be one of the two strongest predictor variables present in all of the three final prediction models, with a higher ratio (indicating relatively higher SNS and lower PNS activity) correlating with response. However, whilst the relationship between baseline LF/HF HRV and response may potentially be clinically useful, it would be difficult to clinically apply, as baseline LF/HF HRV did not correlate with the self-reported measures relating to SNS activity and it would obviously not be practical to measure HRV before selecting a technique in clinical practice. As such, the predictive value of baseline LF/HF HRV has experimental, rather than pragmatic, utility at this stage.

It is widely claimed that trauma is a major cause of PRM dysfunction and strain of the cranial articulations. Literature states that head trauma, birth trauma and extensive dental work can contribute to cranial membranous and sutural strains. Further, it is believed that trauma to any part of the body has the potential to affect the PRM. In the initial stages of analysis of this study, variables relating to trauma of the extremities were excluded from the univariate correlation analysis. Although this data was contained within the total trauma scores which were included, inclusion of the individual extremity scores may have provided more specific information. Results of this study presented an apparent contradiction: an increase in the total severe trauma variable was one of the two strongest predictors of response, however, a decrease in the combined trauma variable – which included moderate head neck and face trauma as well as total mild trauma - was also a predictor. While these apparent discrepancies may be due to the rudimentary nature of the trauma questionnaire used, another possibility is that various types of trauma influence an individual’s response to the CV4 technique in ways that are not yet understood. Given the current findings it may be wise to further refine and
validate the trauma questionnaire developed for this study to formally establish its utility. Regardless of the apparent contradiction, findings suggest that an individual’s history of physical trauma may contribute, at least to some extent, to how they respond to the CV4 technique.

The value of *height* as a variable in the prediction model is marginal, and may be a false positive result (Type I error). The $\alpha$-level for inclusion of variables in the stepwise logistic regression was 0.100, and the p value for *height* was 0.105. Indeed, the only model including *height* is the four-predictor model for response, with *height* being added at the last step and providing ambiguous contribution to the model. A limited amount of literature has been found regarding anecdotal claims that an individual’s ‘biotype’ may indicate a preferred treatment approach.$^{1,31}$ Whilst emphasising that many factors besides biotype dictate the most suitable treatment approach for an individual, Dummer$^{31}$ has claimed that individuals of an ectomorphic body type are generally more responsive to OCF than individuals of endomorphic or mesomorphic body type. Whilst it is possible that body morphology may be a contributing factor to an individuals’ response to OCF, it may be more productive to focus OCF research upon areas that have a greater level of support in the literature and anecdotal clinical experience.

Although the individual predictor variables did not perform particularly well within the final prediction models, this pilot study highlights the types of variables that may be important in predicting response to the CV4 technique. Research to identify potential clinical prediction rules is an important, yet often neglected area of research within CAM.$^{17}$, and this study represents the preliminary stages of formulation of a clinical prediction rule to identify an OCF research population. Validation of the model is outside the scope of the current study and was not performed. The mechanisms and clinical importance of the identified predictors require further research before formulation of a usable clinical prediction rule.

Prediction of success or failure of particular interventions is valuable for clinicians when selecting techniques. As data about the effects of an intervention in individuals may be
masked by the group mean in statistical analysis of group designs, an understanding of the likelihood of success or failure for a particular intervention is also valuable for researchers. It is reasonable to assume that certain interventions may be more effective for some individuals than for others. As such, single-system research designs have been advocated as an effective method to measure the effect of an intervention on an individual, and therefore are particularly applicable to the individualised treatment approach of osteopathy. The role of case studies, single-systems research and small pilot studies in providing the background for osteopathic clinical trials has recently been emphasised. Whilst the current study does not meet the conventionally accepted criteria of multiple baseline measures for single-systems research design, the principles of analysing individual response are appropriate given recent findings in OCF research.

Immediate physiological responses to OCF techniques remain poorly understood. While HRV represents a promising outcome measure, there is still debate as to the interpretation of the LF frequency band and the LF/HF ratio. Therefore, changes in all three HRV parameters were deemed necessary to meet the criteria for the operational definition of response in this study. A spectrum of responses was shown from the participants in this study, which were dichotomised for the regression analysis. In the absence of an established minimum clinically important difference (MCID) for HRV changes, the cut-off 10% change was defined as the threshold for response. This cut-off was reasoned to be a substantial change in ANS activity, given that other than the outcome variable, environmental variables remained unchanged during the intervention phase of the experiment. When the 10% cut-off was increased to 15%, 12 of the 14 participants in the response group still met the operational definition of response. The utility of this cut-off could be strengthened in future studies by construction of a receiver-operator curve (ROC) to determine the optimal cut-off point for response.

The categorisation of response into the subgroups of touch response, immediate response and delayed response is based on the assumption that HRV changes in the post-
intervention phase of the experiment are a result of the intervention in the previous phase. One of the limitations of the study is, that following this reasoning, that HRV changes in the intervention phase could be a delayed result of the touch control rather than being a result of the intervention itself. The difficulty highlighted here is that the duration of effect of the CV4 technique and the clinical relevance of lasting changes resulting from OCF techniques is entirely unexplored in the research. However, establishing the clinical relevance of the CV4 technique was not the objective of this study, and immediate effects require further understanding before speculation as to duration of these possible effects.

Within manual therapy research, finding an appropriate control or sham treatment is a well-recognised difficulty. Simple touch is not an inert placebo, and in itself has the potential to influence HRV. The common understanding of placebo effects in manual therapy appears to be changing, with some contemporary authors suggesting that the non-specific effects of a therapeutic encounter are a valid and potentially useful component of treatment that should be embraced alongside the specific effects, rather than excluded from the evaluation of an intervention. Conversely, some non-specific effects may also be undesirable and further understanding of these non-specific elements would maximise their therapeutic use. Some studies control for the effects of non-specific touch with a randomised cross-over design, however this randomisation is not possible when analysing individual responses. Quantifying the wash-out period for the effects of non-specific touch on HRV could be addressed in future studies, in order to improve the interpretation of a touch control phase in experimental OCF research.

Given the potential value of desirable non-specific effects alongside specific effects in a therapeutic encounter, HRV appears to be a particularly suitable outcome measure to investigate responses to OCF. As the specific and non-specific components of OCF are still poorly understood, HRV provides a measure of global change, as it could be expected that any substantial physiological changes resulting from the technique would detectably alter
ANS activity. Heart rate variability provides an indication of how an individual is responding during experimental research, and encompasses physiological as well as psychological responses. Spectral analysis of HRV provides an insight into alterations of each component of the ANS. Despite providing a useful window to view changes in the ANS related to OCF intervention, the sensitivity of the ANS to both external environmental changes and internal physiological and psychological processes mean that many uncontrollable variables have the potential to influence HRV during the experiment. The use of a laboratory environment may in itself influence results, and whilst every effort was made to ensure the laboratory was comfortable and closely replicated a clinic room, the ECG and respiratory recording represented an unfamiliar situation for the participants. As participants became more familiar with the environment and continued to adapt to the supine position and the physical contact from the practitioner during progression of the experiment, initial changes in HRV may have regressed to levels similar to those at baseline in a familiar environment. Physical contact from the practitioner could potentially provoke anxiety and affect cardiac activity in some individuals, as seen in the effects of white-coat hypertension. However, while some studies have shown changes in short-term recordings of HRV associated with changes in emotion, other studies have reported incongruent findings between self-reported anxiety to touch and associated physiological measures of ANS function.

Due to logistical constraints, it was necessary to recruit three practitioners for the study rather than one. While this may improve external validity of the results, the potential still existed for inter-practitioner discrepancies to bias the effects of the CV4 technique measured in Section A despite measures to standardise delivery of the intervention. However, analysis showed that each of the three practitioners had around the same number of response and non-response outcomes. Using the individual practitioner delivering the technique as a predictor variable in Section B, the potential effects of this assignment bias were controlled to some degree, and showed that in this population, the individual practitioner delivering technique was not a predictor of response.
Previous reports suggest that 10-15 participants are needed per predictor variable when using multivariate analyses to predict risk. In preliminary work of this nature, sufficient sample size can only be evaluated retrospectively. Following the suggested estimation, the sample size of the current study (n=30) was of borderline sufficiency given that the final prediction models contained between two and four predictor variables each. The broad confidence intervals of the calculated odds ratios indicate that the study was underpowered for the final prediction models.

The prediction models developed in this study have limited external validity, however may assist in population selection for future pragmatic trials with broader clinical applicability. Pragmatic, quasi-experimental research approaches are recommended to provide externally valid research on treatment effects. It has been suggested that clinical outcome studies are imperative to justify the place of osteopathy as a conventionally accepted allied health profession. However, public funding issues and legislative demands do not negate the need to understand the physiological effects of OCF. While pragmatic trials more accurately represent the practical application of a complete treatment approach, fastidious trial designs provide more information about the specific effects of treatment. Therefore, it would stand to reason that both pragmatic and fastidious trials proceed concurrently in the area of OCF research. Such an approach would suit the model of ‘evidence-informed osteopathy’ that integrates clinical experience and empirical evidence.

Future studies could further develop the methods devised for this study, establishing optimal cut-off points for response by constructing ROC curves for response. Use of an ambulatory heart rate monitor would enable measurement of HRV in a standard clinical environment, and reduce the potential for the laboratory environment to affect ANS activity. Various cranial techniques, orl more complex cranial treatment sessions
reflective of clinical practice, could be tested for their influence on the ANS utilising the methods developed in this study. Refinement and validation of the trauma questionnaire would contribute to testing the anecdotal claims that physical trauma is an indication for OCF treatment. Investigation into other potential predictors of response, and testing the prediction models in a larger population would assist in understanding the influence of predictors on ANS response to the CV4 technique. Further research into the mechanisms and effects of OCF may prompt an increase in critical reflection within the osteopathic profession, enabling objective review of OCF techniques, as opposed to the polarised and often emotionally laden viewpoints that are frequently expressed.
Conclusion

The findings of this study support claims that the CV4 technique has the potential to increase parasympathetic activity in some individuals. Short-term parasympathetic response to the CV4 technique, determined by spectral analysis of heart rate variability, may be associated with an individual’s baseline ANS activity, history of physical trauma, and possibly height. Further research is required to refine understanding of response to the CV4 technique, and to establish the clinical relevance of the prediction models developed in this study.
<table>
<thead>
<tr>
<th>References</th>
<th>Author(s)</th>
<th>Title</th>
<th>Details</th>
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<tbody>
<tr>
<td>2</td>
<td>Sutherland WG.</td>
<td>Teachings in the science of osteopathy.</td>
<td>Fort Worth, TX: Sutherland Cranial Teaching Foundation; 1990.</td>
</tr>
<tr>
<td>12</td>
<td>Giles PD.</td>
<td>Effects of cervical manipulation on cardiac autonomic control.</td>
<td>Science Center Unpublished Masters Thesis: University of North Texas Fort Worth; 2006</td>
</tr>
</tbody>
</table>


Appendix 1
Operational Definitions for Concepts Specific to OCF

‘Primary Respiratory Mechanism’ (PRM)
The name given by William Garner Sutherland to describe his ‘cranial concept’; a concept of physiologic action. The integrated structure and function of the following five components:

1. fluctuating cerebrospinal fluid (CSF)
2. mobility of intercranial and spinal membranes (meninges, dura etc.)
3. inherent motility of the brain and spinal cord
4. mobility of the bones of the skull
5. involuntary motion of the sacrum between the ilia

‘Cranial Rhythmic Impulse’ (CRI)
A phrase coined by John and Rachel Woods to describe the rhythmic oscillation of the body’s structures believed by cranial practitioners to be an expression the ‘primary respiratory mechanism’ first described by William Garner Sutherland.

Palpation of the ‘CRI’
Palpation is a technique used in physical examination where touching or feeling is used to examine the physical characteristics of the tissue or organ concerned. Cranial practitioners maintain to palpate the CRI using light hand touch most often on, but not limited to, the cranium or sacrum.

‘Stillpoint’
A palpable, brief pause of the CRI when a ‘point of balance’ indicating treatment effect is reached during cranial treatment. The stillpoint, like the PRM and the CRI, is a concept...
unique to cranial therapy and is not commonly accepted or utilized by conventional medical practitioners.

Appendix 2

Heart Rate Variability Measurements – Raw Data

Table 6  HRV Measures from Spectral Analysis  * refer to legend on pg 129

<table>
<thead>
<tr>
<th>Participant</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Phase 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LF(nu)</td>
<td>HF(nu)</td>
<td>LF/HF</td>
<td>LF(nu)</td>
</tr>
<tr>
<td>A</td>
<td>70.85</td>
<td>65.56</td>
<td>2.67</td>
<td>56.42</td>
</tr>
<tr>
<td>B</td>
<td>78.97</td>
<td>20.39</td>
<td>3.87</td>
<td>43.23</td>
</tr>
<tr>
<td>C</td>
<td>67.20</td>
<td>31.94</td>
<td>2.10</td>
<td>54.76</td>
</tr>
<tr>
<td>D</td>
<td>60.96</td>
<td>39.04</td>
<td>1.56</td>
<td>65.04</td>
</tr>
<tr>
<td>E</td>
<td>25.06</td>
<td>70.48</td>
<td>0.36</td>
<td>17.33</td>
</tr>
<tr>
<td>F</td>
<td>73.46</td>
<td>23.55</td>
<td>3.12</td>
<td>81.33</td>
</tr>
<tr>
<td>G</td>
<td>34.33</td>
<td>64.08</td>
<td>0.54</td>
<td>50.43</td>
</tr>
<tr>
<td>H</td>
<td>43.29</td>
<td>30.38</td>
<td>1.42</td>
<td>55.90</td>
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<tr>
<td>I</td>
<td>82.37</td>
<td>16.03</td>
<td>5.14</td>
<td>88.85</td>
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<tr>
<td>J</td>
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<td>48.21</td>
<td>1.02</td>
<td>28.11</td>
</tr>
<tr>
<td>K</td>
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<td>30.93</td>
<td>2.21</td>
<td>64.74</td>
</tr>
<tr>
<td>L</td>
<td>49.14</td>
<td>49.94</td>
<td>0.98</td>
<td>37.16</td>
</tr>
<tr>
<td>M</td>
<td>64.51</td>
<td>34.26</td>
<td>1.88</td>
<td>55.76</td>
</tr>
<tr>
<td>O</td>
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<td>39.67</td>
<td>1.43</td>
<td>66.81</td>
</tr>
<tr>
<td>P</td>
<td>22.55</td>
<td>72.95</td>
<td>0.31</td>
<td>25.44</td>
</tr>
<tr>
<td>Q</td>
<td>58.15</td>
<td>36.69</td>
<td>1.58</td>
<td>54.07</td>
</tr>
<tr>
<td>R</td>
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<td>8.40</td>
<td>10.78</td>
<td>91.07</td>
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<td>S</td>
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<td>51.56</td>
<td>0.37</td>
<td>12.26</td>
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<tr>
<td>T</td>
<td>16.50</td>
<td>81.89</td>
<td>0.20</td>
<td>7.25</td>
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<tr>
<td>U</td>
<td>26.59</td>
<td>72.81</td>
<td>0.37</td>
<td>15.80</td>
</tr>
<tr>
<td>V</td>
<td>53.51</td>
<td>42.56</td>
<td>1.26</td>
<td>48.54</td>
</tr>
<tr>
<td>W</td>
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<td>43.98</td>
<td>1.20</td>
<td>52.72</td>
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<tr>
<td>X</td>
<td>40.72</td>
<td>41.58</td>
<td>0.98</td>
<td>51.46</td>
</tr>
<tr>
<td>Z</td>
<td>79.01</td>
<td>20.04</td>
<td>3.94</td>
<td>73.11</td>
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<tr>
<td>aa</td>
<td>47.97</td>
<td>37.37</td>
<td>1.28</td>
<td>50.19</td>
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<tr>
<td>bb</td>
<td>45.92</td>
<td>54.08</td>
<td>0.85</td>
<td>49.27</td>
</tr>
<tr>
<td>cc</td>
<td>22.41</td>
<td>69.92</td>
<td>0.32</td>
<td>37.80</td>
</tr>
<tr>
<td>dd</td>
<td>24.13</td>
<td>74.11</td>
<td>0.33</td>
<td>29.57</td>
</tr>
<tr>
<td>ee</td>
<td>23.74</td>
<td>74.34</td>
<td>0.32</td>
<td>47.20</td>
</tr>
</tbody>
</table>
### Legend for Table 11

- **Participant** = the individual participant in question
- **Phase 1** = the first phase of the experiment, baseline with no contact between practitioner and participant
- **Phase 2** = the second phase of the experiment, touch control with no technique delivery or therapeutic intent
- **Phase 3** = the third phase of the experiment, delivery of the CV4 technique
- **Phase 4** = the fourth phase of the experiment, post-intervention with no contact between practitioner and participant
- **LF (nu)** = the mean heart rate variability within the low frequency domain, for the phase. Shown in normalised units.
- **HF (nu)** = the mean heart rate variability, within the high frequency domain, for the phase. Shown in normalised units.
- **LF/HF** = the ratio between low frequency and high frequency components of heart rate variability, for the phase.

<table>
<thead>
<tr>
<th></th>
<th>12.84</th>
<th>86.27</th>
<th>0.15</th>
<th>19.32</th>
<th>80.66</th>
<th>0.24</th>
<th>21.90</th>
<th>78.10</th>
<th>0.28</th>
<th>26.17</th>
<th>68.95</th>
<th>0.41</th>
</tr>
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<tr>
<td>ff</td>
<td>73.14</td>
<td>26.03</td>
<td>2.81</td>
<td>28.47</td>
<td>68.94</td>
<td>0.41</td>
<td>51.84</td>
<td>46.13</td>
<td>1.12</td>
<td>62.21</td>
<td>35.41</td>
<td>1.76</td>
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<td>gg</td>
<td>44.18</td>
<td>52.17</td>
<td>0.85</td>
<td>52.92</td>
<td>38.09</td>
<td>1.39</td>
<td>27.85</td>
<td>70.47</td>
<td>0.39</td>
<td>45.38</td>
<td>46.47</td>
<td>0.98</td>
</tr>
</tbody>
</table>
Appendix 3

A Worked Example of the Data Analysis Method Used in Section A

Participant ‘W’

Legend of all of Appendix 3

1 = phase 1 of the experiment, baseline
2 = phase 2 of the experiment, touch control
3 = phase 3 of the experiment, intervention
4 = phase 4 of the experiment, post-intervention

Cf 1 = phase on the Y axis compared to phase 1
Cf 2 = phase on the Y axis compared to phase 2
Cf 3 = phase on the Y axis compared to phase 3

HRV = heart rate variability
nu = normalised units of heart rate variability
LF/HF = low frequency/ high frequency HRV ratio
LF = low frequency HRV
HF = high frequency HRV
SNS = sympathetic nervous system
PNS = parasympathetic nervous system

% = the percentage change in heart rate variability parameters
Diff b/w = numerical difference between the phases in question
Diff b/w...as a % of 1 = the percentage change in heart rate variability parameters compared to the baseline measure

= minimum 10% change indicating increased parasympathetic activity and decreased sympathetic activity
= no change, or change below the 10% threshold
= minimum 10% change indicating decreased parasympathetic activity and increased sympathetic activity
3.1 **HRV Measures Across the Four Phases of the Experiment.**

*refer to legend on pg 130

<table>
<thead>
<tr>
<th>Phase</th>
<th>Phase</th>
<th>Phase</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>LF1</td>
<td>HF1</td>
<td>LF/HF1</td>
<td>LF2</td>
</tr>
<tr>
<td>52.7</td>
<td>44.0</td>
<td>1.2</td>
<td>52.7</td>
</tr>
</tbody>
</table>

**Table 7**  
Mean HRV Measures Across the Four Phases of the Experiment

![Histogram and Line Graph Demonstrating HRV Changes across the Four Phases of the Experiment for Participant W](image)

**Figure 4**  
Histogram and Line Graph Demonstrating HRV Changes across the Four Phases of the Experiment for Participant W
3.3 Conversion of HRV Measurements

Measurements from Phases 2 – 4 of the experiment were converted into a percentage of the Baseline (Phase 1) measurement. * refer to legend on pg 130

Table 8  Original and Converted HRV Measures

<table>
<thead>
<tr>
<th>W (participant)</th>
<th>LF/HF</th>
<th>Diff</th>
<th>%</th>
<th>LF</th>
<th>Diff</th>
<th>%</th>
<th>HF</th>
<th>Diff</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>1.20</td>
<td></td>
<td></td>
<td>52.70</td>
<td></td>
<td></td>
<td>43.98</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 2</td>
<td>1.15</td>
<td>0.05</td>
<td>3.78%</td>
<td>52.72</td>
<td>-0.01</td>
<td>-0.02%</td>
<td>45.72</td>
<td>-1.74</td>
<td>-3.95%</td>
</tr>
<tr>
<td>Diff b/w 1 &amp; 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 3</td>
<td>0.58</td>
<td></td>
<td></td>
<td>36.28</td>
<td></td>
<td></td>
<td>62.10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff b/w 1 &amp; 3</td>
<td>0.61</td>
<td>51.25%</td>
<td>16.42</td>
<td>31.16%</td>
<td>18.12</td>
<td>41.21%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff b/w 2 &amp; 3</td>
<td>0.57</td>
<td>49.34%</td>
<td>16.44</td>
<td>31.18%</td>
<td>16.39</td>
<td>35.85%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff b/w 2 &amp; 3 as % of 1</td>
<td>47.48%</td>
<td>31.19%</td>
<td>37.26%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 4</td>
<td>1.12</td>
<td></td>
<td></td>
<td>51.41</td>
<td></td>
<td></td>
<td>45.70</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff b/w 1 &amp; 4</td>
<td>0.07</td>
<td>6.13%</td>
<td>1.30</td>
<td>2.46%</td>
<td></td>
<td>-1.72</td>
<td>-3.91%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff b/w 2 &amp; 4</td>
<td>0.03</td>
<td>2.45%</td>
<td>1.31</td>
<td>2.48%</td>
<td></td>
<td>0.02</td>
<td>0.04%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff b/w 2 &amp; 4 as % of 1</td>
<td>2.35%</td>
<td>2.48%</td>
<td>0.04%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3.3 Comparisons of Changes in the HRV Components (LF/HF, HF and LF) of the Participant across the Four Phases of the Experiment.

In this instance, the graph demonstrates an increase in parasympathetic activity and a decrease in sympathetic activity during Phase 3 – the intervention phase – of the experiment. The figures have been adjusted to aid the interpretability of the graph in terms of autonomic nervous system activity. In reality there is a decrease in the LF component and LF/HF ratio, and an increase in the HF component during phase 3, all consistent with the increased parasympathetic and decreased sympathetic activity outlined on the Y axis of the graph.

Figure 5  HRV Changes in LF, HF and LF/HF Parameters (Converted Values)
* refer to legend on pg 130
3.4 Coding for HRV Changes

The table demonstrates how the percentage change for each Phase was colour coded. There was a ten percent threshold for change (i.e., changes of less than +/- 10% were classified as ‘no change’).

Table 9 Colour Coding for HRV Changes

<table>
<thead>
<tr>
<th>W</th>
<th>LF/HF</th>
<th>% 10%</th>
<th>LF</th>
<th>% 10%</th>
<th>HF</th>
<th>% 10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>1.20</td>
<td>52.70</td>
<td>43.98</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 2</td>
<td>1.15</td>
<td>52.72</td>
<td>45.72</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff b/w 1 &amp; 2</td>
<td>3.78%</td>
<td>(0.02%)</td>
<td>(3.95%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 3</td>
<td>0.58</td>
<td>36.28</td>
<td>62.10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff b/w 1 &amp; 3</td>
<td>51.25%</td>
<td>31.16%</td>
<td>(41.21%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff b/w 2 &amp; 3</td>
<td>49.34%</td>
<td>31.18%</td>
<td>(35.85%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff b/w 2 &amp; 3 as % of 1</td>
<td>47.48%</td>
<td>31.19%</td>
<td>(37.26%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 4</td>
<td>1.12</td>
<td>51.41</td>
<td>45.70</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Diff b/w 1 &amp; 4</td>
<td>6.13%</td>
<td>2.46%</td>
<td>(3.91%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff b/w 2 &amp; 4</td>
<td>2.45%</td>
<td>2.48%</td>
<td>0.04%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff b/w 2 &amp; 4 as % of 1</td>
<td>2.35%</td>
<td>2.48%</td>
<td>0.04%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff b/w 3 &amp; 4</td>
<td>(92.57%)</td>
<td>(41.70%)</td>
<td>26.42%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diff b/w 3 &amp; 4 as % of 1</td>
<td>(45.12%)</td>
<td>(28.71%)</td>
<td>37.30%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3.5 Analysing Participant HRV Patterns

These grids show response patterns for the LF/HF, LF and HF components of HRV across the phases of the experiment.

Table 10: HRV Grids

<table>
<thead>
<tr>
<th>W (participant)</th>
<th>LF/HF</th>
<th>LF</th>
<th>HF</th>
</tr>
</thead>
<tbody>
<tr>
<td>* refer to legend on pg 130</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>phase 2</td>
<td>cf 1</td>
<td>cf 2</td>
<td>cf 3</td>
</tr>
<tr>
<td>phase 3</td>
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<td></td>
</tr>
<tr>
<td>phase 4</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

The diagonal pattern of each grid shows the change in each phase, when compared to the phase before (cf 1= 'compared to phase 1, etc). The vertical pattern in the left column of each grid shows the change in each phase, when compared to the baseline phase. These grids were then translated into ‘response patterns’ By checking both the vertical and diagonal patterns, it can be confirmed that changes between phases are also relevant with regards to the baseline HRV measurements. For example, in the LF/HF component below, it can be seen that Phase 4 shows a decrease in parasympathetic activity when compared to Phase 3. When comparing Phase 4 to Phase 1 (baseline) it can be seen that there is no change. This indicates that whilst there was a decrease in parasympathetic activity in Phase 4, it was a return to baseline levels only. This is represented schematically in the Figure 6.
### Table 11: HRV Patterns

<table>
<thead>
<tr>
<th>W (LF/HF)</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Phase 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Pattern when each phase is compared to the previous phase (from the diagonal line of the response grid)

Pattern when each phase is compared to the baseline phase (from the vertical line of the response grid)

<table>
<thead>
<tr>
<th>W (LF)</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Phase 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

Pattern when each phase is compared to the previous phase (from the diagonal line of the response grid)

Pattern when each phase is compared to the baseline phase (from the vertical line of the response grid)

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Pattern when each phase is compared to the previous phase (from the diagonal line of the response grid)

Pattern when each phase is compared to the baseline phase (from the vertical line of the response grid)

### Figure 6: Schematic Changes in HRV

* refer to legend on pg 130

Schematic Representation of Participant HRV Measurements

- W

![Schematic Representation of Participant HRV Measurements](image)
Appendix 4

Converted HRV Measures and Corresponding HRV Grids

Table 12  Converted HRV Measures and Corresponding HRV Grids

* refer to legend on pg 138
Legend for Table 12

LF/HF: the ratio between low frequency and high frequency components of heart rate variability, for the phase.

Diff: the numerical difference between the phases in question

%: the percentage difference between the phases in question

Phase 1: first phase of the experiment, baseline with no contact between practitioner and participant

Phase 2: the second phase of the experiment, touch control with no technique delivery or therapeutic intent

Phase 3: the third phase of the experiment, delivery of the CV4 technique

Phase 4: the fourth phase of the experiment, post-intervention with no contact between practitioner and participant

Cf 1: the phase in question compared to phase one of the experiment

Cf 2: the phase in question compared to phase two of the experiment

Cf 3: the phase in question compared to phase three of the experiment
Appendix 5

Questionnaire, Interview Sheet and VAS for Predictor Variables

5.2 Screening and Medical History Interview (insert Appendix 5.2 here)
5.3 Participant Questionnaire (insert Appendix 5.3 here)
5.3 Pre-experiment Checklist

Participant: Practitioner: Date:

**Are you experiencing any physical pain or discomfort at the moment?**
Please indicate your level of physical pain or discomfort by marking the line below

<table>
<thead>
<tr>
<th>0%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>No physical pain or discomfort at all</td>
<td>The worst physical pain or discomfort you have experienced</td>
</tr>
</tbody>
</table>

**Checklist:**
Have you eaten any food in the past 2 – 3 hours?
Have you had any stimulants, such as caffeine (tea, coffee, chocolate, soft drinks, energy drinks) in the past 4 hours?
Have you had any alcohol in the past 12 hours?
Have you taken any medicines (other than your usual medication) in the past 48 hours?
Have you had any recent injuries or surgery (in the past month)? If so, please state the location (site) of the injury, its severity and how long it took before you were able to use the injured body part in a normal way.

**Consent:**

**Blood Pressure:**
Height:
Weight:
5.4 Practitioner’s Dysfunction and Receptivity Visual Analogue Scales

Participant: 

Practitioner: 

Date: 

**Dysfunction Burden:**

0% 
No dysfunction

100% 
Worst dysfunction possible

Please mark on the line above your perception of the participant’s dysfunction burden as palpated during Phase 2 (touch control) of the experiment. 

**Dysfunction burden** is defined as the total amount of dysfunction present within the participant’s system that is detectable by palpation of the participant’s head using the vault hold i.e. a general impression of “How dysfunctional does this person’s system feel?”

**Receptivity to the CV4**

0% 
No receptivity

100% 
Maximum receptivity possible

Please mark on the line above your perception of the participant’s receptivity to the CV4 as palpated at the end of Phase 3 (technique delivery) of the experiment. 

**Receptivity** is defined as the change palpated in the participant’s system as a result of receiving the CV4 technique. Examples of this include tissue change and a decrease in sympathetic nervous system activity. The opposite of receptivity may be thought of as resistance to the technique form the participant’s system.
Appendix 6

Predictor Variables for Section B

6.1 Potential Predictor Variables – Raw Data

Table 13 a Raw Data for Potential Predictor Variables *refer to legend on pg 154

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Table 13c  Raw Data for Potential Predictor Variables  * refer to legend on pg 154

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</table>
Legend for tables 13 a, b & c

- **Pt**: participant
- **Response**: Y=yes, N=no
- **Touch**: 1=negative response, 2=no change, 3=positive response
- **LF/HF**: the low frequency/high frequency ratio of heart rate variability at baseline
- **Age**: participant’s age in years
- **Gender**: 1=Female, 2=Male
- **Height**: participant’s height in centimetres
- **BMI**: body mass index: weight in kilograms divided by height in centimetres squared
- **Prac**: practitioner delivering the CV4: 1=practitioner 1, 2=practitioner 2, 3=practitioner 3
- **SF36**: overall score (%) for SF36 health and wellbeing questionnaire
- **PSS**: perceived stress scale (%) 0=least stressed, 100=most stressed
- **HCAMQ**: overall score (%) for attitudes and beliefs to complementary alternative medicine and holistic health - higher score = more positive attitude
- **OCF**: higher score=more knowledge of OCF (less naievity)
- **Prev OCF**: if participant has previously had any OCF treatment: 1=no, 2=yes
- **Pain**: % (levels as scored by participant)
- **Dysfn**: % (levels as scored by practitioner)
- **Recep**: % (levels as scored by practitioner)
- **HNF Mil**: number of mild injuries to the head, neck and face
- **HNF Mod**: number of moderate injuries to the head, neck and face
- **HNF Sev**: number of severe injuries to the head, neck and face
- **Ax Mil**: number of mild injuries to the axial structures
- **Ax Mod**: number of moderate injuries to the axial structures
- **Ax Sev**: number of severe injuries to the axial structures
- **Trau Mil**: total number of mild injuries
- **Trau Mod**: total number of moderate injuries
- **Trau Sev**: total number of severe injuries
- **Chr Mil**: total number of mild chronic illnesses
- **Chr Mod**: total number of moderate illnesses
- **Chr Sev**: total number of severe chronic illnesses
### Descriptive Statistics for Potential Predictor Variables

#### Table 14a Descriptive Statistics for Categorical Potential Predictor Variables

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<tr>
<th>Variable</th>
<th>Category</th>
<th>Number of participants</th>
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<td><strong>Gender</strong></td>
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<tr>
<td></td>
<td>Female</td>
<td>N=15 participants (50%)</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>N=15 participants (50%)</td>
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<tr>
<td><strong>Practitioner delivering the CV4</strong></td>
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<tr>
<td></td>
<td>Practitioner 1</td>
<td>N= 11 participants (37%)</td>
</tr>
<tr>
<td></td>
<td>Practitioner 2</td>
<td>N= 9 participants (30%)</td>
</tr>
<tr>
<td></td>
<td>Practitioner 3</td>
<td>N= 10 participants (33%)</td>
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<tr>
<td><strong>Response to touch control</strong></td>
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<tr>
<td></td>
<td>‘Touch responders’</td>
<td>N= 13 participants (43%)</td>
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<tr>
<td></td>
<td>‘Non touch responders’</td>
<td>N= 17 participants (57%)</td>
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<tr>
<td><strong>Participants previous experience of OCF</strong></td>
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<tr>
<td></td>
<td>Previous experience</td>
<td>N= 13 participants (43%)</td>
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<tr>
<td></td>
<td>No previous experience</td>
<td>N= 17 participants (57%)</td>
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Table 14 b  Descriptive Statistics for Continuous Potential Predictor Variables

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<tr>
<th>Variable</th>
<th>Range</th>
<th>Mean (SD)</th>
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<td>33.0 (9.2)</td>
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<tr>
<td>Height (cm)</td>
<td>156.0-184.5</td>
<td>172.5 (7.6)</td>
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<td>Body Mass Index</td>
<td>19.9-36.0</td>
<td>24.3 (3.1)</td>
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<td>Current Pain Levels</td>
<td>0.0-37.0</td>
<td>6.8 (9.6)</td>
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<td>Dysfunction (practitioner assessed)</td>
<td>13.0-82.0</td>
<td>44.1 (19.3)</td>
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<td>Receptivity (practitioner assessed)</td>
<td>25.0-99.0</td>
<td>71.6 (17.5)</td>
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<td>SF-36 Score</td>
<td>48.6-100.0</td>
<td>78.9 (13.0)</td>
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<tr>
<td>PSS Score</td>
<td>18.8-83.3</td>
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<td>HCAMQ Score</td>
<td>58.2-100.0</td>
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<td>Naievity to OCF</td>
<td>5.0-100.0</td>
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<td>Baseline HRV (LF/HF ratio)</td>
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<td>1.8 (2.1)</td>
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<td>0.3 (0.5)</td>
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<tr>
<td>Chronic Illness – Moderate</td>
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<td>2.2 (1.9)</td>
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<td>Trauma – Severe</td>
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<td>0.5 (0.9)</td>
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<td>HNF – Moderate</td>
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<td>HNF – Severe</td>
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Appendix 7

Scoring Criteria and Instructions for ‘Physical Trauma or Injury’ and ‘Chronic Illness’ Questionnaires

Trauma – Question 13 (Medical History Form)
History of injury/physical trauma (including surgery) for which the participant sought treatment from a health care professional
Assessed in the context of the impact the trauma had on the participant’s ability to perform their usual daily activities
Score each individual injury and add scores. Group as follows: a) Total score; b) Head, face and neck; c) Chest, back, abdomen, hip; d) Extremities
0 = absent
1 = mild: no time off work/school, still able to perform usual activities eg: mole removed under local anesthetic or sprained ankle requiring strapping but not crutches
2 = moderate: 1-10 days off work/school/until able to perform usual daily activities again eg: tonsillectomy or straightforward leg fracture
3 = severe: > 10 days off work/school/until able to perform usual daily activities again eg: bowel resection or ACL rupture

Chronic Illness - Question 14 (Medical History Form)
Defined as: a long-term illness, dysfunction, disorder, medical condition or disability lasting for a period of 3 months or more.
Assessed in the context of the impact of the illness in the person’s whole life to date
Score each illness separately and add scores together
0 = absent
1 = mild eg: well controlled asthma or dysmenorrhea
2 = moderate eg: depression, 4 yrs duration, daily symptoms, required medication but participant able to work or chronic fatigue, unable to work for 18 months, now resolved
3 = severe eg: progressive rheumatoid arthritis, 7 years duration or cancer requiring chemotherapy/multiple surgeries

OCF - Question 13 - 17 (Participants’ Questionnaire)
Question 13
Score ½ a point for one or more of the following: Osteopathy, osteopathic medicine, cranial osteopathy, cranio-sacral therapy. 1 point if heard of OCF, 1 ½ points if heard of BOCF (max score of 3 points for this question).

Questions 14 – 16
0 = No
1 = Yes
Question 17
0 = no knowledge
1 = little knowledge
2 = moderate knowledge
3 = a lot of knowledge
4 = formal education/ training
Appendix 8

New Values for the *Combined Trauma* Variable

Table 15  *Combined Trauma* Variable Values (from principal components analysis)

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Appendix 9

Predictors Variables Not Included in the Regression Based on Poor Univariate Association with Response

Table 16  Predictor Variables Not Included in the Regression

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<th>Significance (2-tailed)</th>
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<td>Severe Head, Neck and Face Trauma</td>
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<td>Severe Chronic Illness</td>
<td>0.200</td>
<td>0.288</td>
</tr>
<tr>
<td>Health and Wellbeing (SF-36 score)</td>
<td>0.139</td>
<td>0.463</td>
</tr>
<tr>
<td>Perceived Stress Levels (PSS score)</td>
<td>-0.061</td>
<td>0.748</td>
</tr>
<tr>
<td>Attitudes and Beliefs (HCAMQ score)</td>
<td>0.052</td>
<td>0.784</td>
</tr>
<tr>
<td>Naivety to OCF</td>
<td>0.013</td>
<td>0.947</td>
</tr>
<tr>
<td>History of Previous OCF Treatment</td>
<td>-0.009</td>
<td>0.962</td>
</tr>
<tr>
<td>Response to Touch Control Phase</td>
<td>0.199</td>
<td>0.291</td>
</tr>
</tbody>
</table>
Appendices for the Research Project
Appendix A

Notification of Ethics Approval

Kim Collard
PO Box 60236
Titirangi

30 June 2008

Dear Kim

Your file number for this application: 2008-848
Title: Which factors may serve to predict an individual's immediate physiological response to a common osteopathic technique?

Your application for ethics approval has been reviewed by the Unitec Research Ethics Committee (UREC) and has been approved for the following period:

Start date: 30 June 2008
Finish date: 30 June 2009

Please note that:
1. the above dates must be referred to on the information AND consent forms given to all participants
2. you must inform UREC, in advance, of any ethically-relevant deviation in the project. This may require additional approval.

You may now commence your research according to the protocols approved by UREC. We wish you every success with your project.

Yours sincerely

Deborah Rolland
Deputy Chair, UREC

cc: Rob Moran
Cynthia Almeida

Appendix B

Recruitment Advertisement
**Research Participants Needed**

We are investigating the influence of a cranial osteopathic technique on physiological function.

Males and females aged between 18 and 50 years old are required. All we need you to do is answer a 20 minute questionnaire and attend a one hour session to receive a gentle cranial osteopathic technique. You simply lie back on a treatment table and relax while an experienced practitioner applies gentle pressure to the back of your head.

If you are interested in participating, please contact:

Kim Collard
Master of Osteopathy Student
Home: 816 9371
Mobile: 021 645 867
Email: kim@mcorp.co.nz
Appendix C

Participant Consent Form

Responses to cranial osteopathy

This research project investigates the immediate effects of a cranial osteopathic technique on part of the nervous system known as the autonomic nervous system. The research is being undertaken by Kim Collard, a Master of Osteopathy student at Unitec NZ and will be supervised by Dr Craig Hilton and Robert Moran.

Name of Participant: ___________________________

I have seen the Participant Information Sheet dated 1st June 2008 for people taking part in the project titled ‘Responses to cranial osteopathy’. I have had the opportunity to read the contents of the information sheet and to discuss the project with Kim Collard, and I am satisfied with the explanations I have been given. I understand that the anonymised data from his project will be held indefinitely for the purposes of future analysis and research. I understand that taking part in this project is voluntary (my choice) and that I may withdraw from the project at any time prior to commencement of data analysis (10th September 2008) and this will in no way affect my access to the services provided by Unitec NZ, or the Unitec Osteopathic Clinic.

I understand that I can withdraw from the study if, for any reason, I want to do so.

I understand that I can withdraw from the study at anytime up until the date of the last data collection session.

I understand that my participation in this project is confidential, and no material that could identify me will be used in any reports of this project.

I acknowledge that any materials collected during the study will be stored securely so that only the researchers may access them.

I have had enough time to consider whether I want to take part.

I know whom to contact if I have any questions or concerns about the project.

The principal researcher for this project is Kim Collard.

Contact details: kim@mcorp.co.nz 021 645 867 09 186 9371

Signature: _____________________________ (participant) Date: __________________

Project explained by Kim Collard.
Signature: _____________________________ Date: __________________

The participant should retain a copy of this consent form.

UREC REGISTRATION NUMBER: (2008-848)

This study has been approved by the UNITEC Research Ethics Committee from 30 June 2008 to 30 June 2009. If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (ph: 09 815-4321 ext 7248). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

Appendix D

Participant Information Sheet
Responses to cranial osteopathy.

**About this research**
You are invited to take part in a study undertaken within the Master of Osteopathy Degree at Unitec NZ. This research investigates a branch of manual therapy known as Osteopathy in the Cranial Field, looking at individual’s responses to a common cranial osteopathic technique (CV4). Both males and females are needed between the ages of 18 and 50 years old.

*Participants in this project will be required to:*
- Attend a brief appointment to:
  - Ensure that the inclusion and exclusion criteria are met, and that they are eligible for the project.
  - Sign a consent form.
  - Answer several questions about any previous injuries and long term illnesses.
- Answer a questionnaire at home within 24 hours prior to the data collection session. This should take 15-20 minutes.
- Attend one 60 minute data collection session.
  - Avoid any stimulants, such as caffeine, energy drinks etc. in the 2 hours prior to the data collection session.
  - Lie on their back on a treatment table for approximately 45 minutes.
  - Allow ECG leads to be attached to both wrists and right ankle and galvanic skin response electrodes to be wrapped around index and middle fingers of the right hand. A small temperature sensor will be taped at the base of the neck, and an elasticated band will be secured around the lower chest at the level of the base of the sternum.
  - Relax on the treatment table for the period of data collection. During this time, an osteopathic practitioner will be gently holding the head.
- Consent to the research team’s use of the research data in preparing both a research project dissertation and an article for publication.

**The researchers**
The primary researcher is Kim Collard. This project is being supervised by Robert Moran and Craig Hilton.

**Participation and consent**
We would greatly appreciate your participation in this study. If you’re interested in participating please complete a consent form (attached) for this project and return it to Kim Collard.

*You have the right not to participate, or to withdraw from this research project at any time prior to commencement of data analysis. This can be done by emailing us, phoning us, or telling us when we contact you that you do not want to participate.*

**Getting help**
Please contact any one of us should you have any queries or require any help with this research project.

Kim Collard: kim@mcorp.co.nz 09 816 9371 021 645 867
Robert Moran: rmoran@unitec.ac.nz 09 815 4321 x8642
Craig Hilton: chilton@unitec.ac.nz 09 815 4321 x8601
Participant Information Sheet (continued)

Information and concerns
If you would like further information about the project you can call or email the above addresses. If at any time you are confused or concerned about the research project, you can contact Kim Collard, the primary researcher, on the details above.
If you have any concerns about the way in which the research is being conducted, you can contact the following:
Health Advocates: Advocates Network Services Trust, Phone (09) 6235799, (0800)205555, Fax (09)6235798, PO Box 9983, Newmarket, Auckland.

Confidentiality
Your confidentiality and anonymity will be protected in the following ways:
- Information and data collected from you during this research will be labeled with an identification number for the purpose of anonymously comparing your data.
- All computer records will be accessible only by passwords held only by the researchers.
- Any data derived from the research will be anonymous and your identity will be kept confidential.

A copy of the final report will be available at the Unitec NZ library, and a plain English summary will be available to participants and other interested parties. Summaries and recommendations may be published in research journals.

Finally, we would like to extend our appreciation and thanks to you for your valuable contribution to this research.

UREC REGISTRATION NUMBER: (2008-848)
This study has been approved by the UNITEC Research Ethics Committee from 30 June 2008 to 30 June 2009. If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (ph: 09 815-4321 ext 7248). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.
Appendix E

Guidelines for submission to the *International Journal of Osteopathic Medicine*

Guide for Authors

The journal Editors welcome contributions for publication from the following categories: Letters to the Editor, Reviews and Original Articles, Commentaries and Clinical Practice case studies with educational value.

Online Submission

Submission to this journal proceeds totally online.([http://ees.elsevier.com/ijom](http://ees.elsevier.com/ijom)) you will be guided stepwise through the creation and uploading of the various files. The system automatically converts source files to a single Adobe Acrobat PDF version of the article, which is used in the peer-review process. Please note that even though manuscript source files are converted to PDF at submission for the review process, these source files are needed for further processing after acceptance. All correspondence, including notification of the Editor's decision and requests for revision, takes place by e-mail and via the Author's homepage, removing the need for a hard-copy paper trail.

The above represents a very brief outline of this form of submission. It can be advantageous to print this "Guide for Authors" section from the site for reference in the subsequent stages of article preparation.

Submission of an article implies that the work described has not been published previously (except in the form of an abstract or as part of a published lecture or academic thesis), that it is not under consideration for publication elsewhere, that its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in English or in any other language, without the written consent of the Publisher.

Types of contributions

Letters to the Editor As is common in biomedical journals the editorial board welcomes critical response to any aspect of the journal. In particular, letters that point out deficiencies and that add to, or further clarify points made in a recently published work, are welcomed. The Editorial Board reserves the right to offer authors of papers the right of rebuttal, which may be published alongside the letter.

Reviews and Original Articles These should be either i) reports of new findings related to osteopathic medicine that are supported by research evidence. These should be original, previously unpublished works. The report will normally be divided into the following sections: abstract, introduction, materials and methods, results, discussion, conclusion, references. Or ii) critical or systematic review that seeks to summarise or draw conclusions from the established literature on a topic relevant to osteopathic medicine.
Short review  The drawing together of present knowledge in a subject area, in order to provide a background for the reader not currently versed in the literature of a particular topic. Shorter in length than and not intended to be as comprehensive as that of the literature review paper. With more emphasis on outlining areas of deficit in the current literature that warrant further investigation.

Research Note  Findings of interest arising from a larger study but not the primary aim of the research endeavour, for example short experiments aimed at establishing the reliability of new equipment used in the primary experiment or other incidental findings of interest, arising from, but not the topic of the primary research. Including further clarification of an experimental protocol after addition of further controls, or statistical reassessment of raw data.

Preliminary Findings  Presentation of results from pilot studies which may establish a solid basis for further investigations. Format similar to original research report but with more emphasis in discussion of future studies and hypotheses arising from pilot study.

Commentaries Include articles that do not fit into the above criteria as original research. Includes commentary and essays especially in regards to history, philosophy, professional, educational, clinical, ethical, political and legal aspects of osteopathic medicine.

Clinical Practice  Authors are encouraged to submit papers in one of the following formats: Case Report, Case Problem, and Evidence in Practice.

Case Reports usually document the management of one patient, with an emphasis on presentations that are unusual, rare or where there was an unexpected response to treatment eg. an unexpected side effect or adverse reaction. Authors may also wish to present a case series where multiple occurrences of a similar phenomenon are documented. Preference will be given to reports that are prospective in their planning and utilise Single System Designs, including objective measures.

The aim of the Case Problem is to provide a more thorough discussion of the differential diagnosis of a clinical problem. The emphasis is on the clinical reasoning and logic employed in the diagnostic process.

The purpose of the Evidence in Practice report is to provide an account of the application of the recognised Evidence Based Medicine process to a real clinical problem. The paper should be written with reference to each of the following five steps: 1. Developing an answerable clinical question. 2. The processes employed in searching the literature for evidence. 3. The appraisal of evidence for usefulness and applicability. 4. Integrating the critical appraisal with existing clinical expertise and with the patient's unique biology, values, and circumstances. 5. Reflect on the process (steps 1-4), evaluating effectiveness, and identifying deficiencies.

Presentation of Typescripts

Your article should be typed on A4 paper, double-spaced with margins of at least 3cm. Number all pages consecutively beginning with the title page.

To facilitate anonymity, the author's names and any reference to their addresses should
only appear on the title page. Please check your typescript carefully before you send it off, both for correct content and typographic errors. It is not possible to change the content of accepted typescripts during production.

Papers should be set out as follows, with each section beginning on a separate page:

**Title page**
To facilitate the peer-review process, two title pages are required. The first should carry just the title of the paper and no information that might identify the author or institution. The second should contain the following information: title of paper; full name(s) and address(es) of author(s) clearly indicating who is the corresponding author; you should give a maximum of four degrees/qualifications for each author and the current relevant appointment only; institutional affiliation; name, address, telephone, fax and e-mail of the corresponding author; source(s) of support in the form of funding and/or equipment.

**Keywords**
Include three to ten keywords. These should be indexing terms that may be published with the abstract with the aim of increasing the likely accessibility of your paper to potential readers searching the literature. Therefore, ensure keywords are descriptive of the study. Refer to [http://www.nlm.nih.gov/mesh/meshhome.html](http://www.nlm.nih.gov/mesh/meshhome.html) for the MeSH thesaurus.

**Abstract**
Both qualitative and quantitative research approaches should be accompanied by a structured abstract. Commentaries and Essays may continue to use text based abstracts of no more than 150 words. All original articles should include the following headings in the abstract as appropriate: **Background, Objective, Design, Setting, Methods, Subjects, Results, and Conclusions.** As an absolute minimum: **Objectives, Methods, Results, and Conclusions** must be provided for all original articles. Abstracts for reviews of the literature (in particular systematic reviews and meta-analysis) should include the following headings as appropriate: **Objectives, Data Sources, Study Selection, Data Extraction, Data Synthesis, Conclusions.** Abstracts for Case Studies should include the following headings as appropriate: **Background, Objectives, Clinical Features, Intervention and Outcomes, Conclusions.**

**Text**
The text of observational and experimental articles is usually, but not necessarily, divided into sections with the headings; introduction, methods, results, results and discussion. In longer articles, headings should be used only to enhance the readability. Three categories of headings should be used:

- major ones should be typed in capital letter in the centre of the page and underlined
- secondary ones should be typed in lower case (with an initial capital letter) in the left hand margin and underlined
- minor ones typed in lower case and italicised

Do not use 'he', 'his' etc. here the sex of the person is unknown; say 'the patient' etc. Avoid inelegant alternatives such as 'he/she'. Avoid sexist language.

**Statement of Competing Interests**
When submitting a Research report you will need to consider if you, or any of your co-
authors, are an Editor or Editorial Board member of the International Journal of Osteopathic Medicine. If this is the case you will need to include a section, at the end of your manuscript immediately before the reference section, called "Statement of Competing Interests". Example statement, which may require editing, is as follows: {Name of author} is an Editor of the Int J Osteopath Med; {Name of author} is a member of the Editorial Board of the Int J Osteopath Med but was not involved in review or editorial decisions regarding this manuscript.

References
Responsibility for the accuracy of bibliographic citations lies entirely with the Authors.

Citations in the text: Please ensure that every reference cited in the text is also present in the reference list (and vice versa). Avoid using references in the abstract. Unpublished results and personal communications are not recommended in the reference list, but may be mentioned in the text. If these references are included in the reference list they should follow the standard reference style of the journal and should include a substitution of the publication date with either "Unpublished results" or "Personal communication" Citation of a reference as "in press" implies that the item has been accepted for publication.

Text: Indicate references by superscript numbers in the text. The actual Authors can be referred to, but the reference number(s) must always be given.

List: Number the references in the list in the order in which they appear in the text.

Examples:

Reference to a journal publication:


Reference to a book:


Reference to a chapter in an edited book:


Note shortened form for last page number. e.g., 51-9, and that for more than 6 Authors the first 6 should be listed followed by "et al." For further details you are referred to "Uniform Requirements for Manuscripts submitted to Biomedical Journals" (J Am Med Assoc 1997;277:927-934) (see also [http://www.nejm.org/general/text/requirements/1.htm](http://www.nejm.org/general/text/requirements/1.htm))

Citing and listing of Web references. As a minimum, the full URL should be given. Any further information, if known (Author names, dates, reference to a source publication, etc.), should also be given. Web references can be listed separately (e.g., after the reference list) under a different heading if desired, or can be included in the reference list.
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The text of original research for a quantitative or qualitative study is typically subdivided into the following sections:

Introduction
State the purpose of the article. Summarise the rationale for the study or observation. Give only strictly pertinent references and do not review the subject extensively. Do not include data or conclusions from the work being reported.

Materials and Methods
Describe your selection of observational or experimental subjects (including controls). Identify the methods, apparatus (manufacturer's name and address in parenthesis) and procedures in sufficient detail to allow workers to reproduce the results. Give references and brief descriptions for methods that have been published but are not well known; describe new methods and evaluate limitations.

Indicate whether procedures followed were in accordance with the ethical standards of the institution or regional committee responsible for ethical standards. Do not use patient names or initials. Take care to mask the identity of any subjects in illustrative material.

Results
Present results in logical sequence in the text, tables and illustrations. Do not repeat in the text all the data in the tables or illustrations. Emphasise or summarise only important observations.

Discussion
Emphasise the new and important aspects of the study and the conclusions that follow.
from them. Do not repeat in detail data or other material given in the introduction or the results section. Include implications of the findings and their limitations, include implications for future research. Relate the observations to other relevant studies. Link the conclusion with the goals of the study, but avoid unqualified statements and conclusions not completely supported by your data. State new hypothesis when warranted, but clearly label them as such. Recommendations, when appropriate, may be included.

**Conflict of interest**
At the end of the text, under a subheading "Conflict of interest statement" all authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.

**Ethical considerations**
**Human subjects.** Work on human beings that is submitted to The International Journal of Osteopathic Medicine should comply with the principles laid down in the declaration of Helsinki; Recommendations guiding physicians in biomedical research involving human subjects. Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, the 35th World Medical Assembly, Venice, Italy, October 1983, and the 41st World Medical Assembly, Hong Kong, September 1989. The manuscript should contain a statement that has been approved by the appropriate ethical committees related to the institution(s) in which it was performed and that subjects gave informed consent to the work. Studies involving experiments with animals must state that their care was in accordance with institution guidelines. Patients' and volunteers' names, initials, and hospital numbers should not be used. In a case report, the subject's written consent should be provided. It is the author's responsibility to ensure all appropriate consents have been obtained.

**Patient anonymity.** Studies on patients or volunteers require ethics committee approval and informed consent which should be documented in your paper.

Patients have a right to privacy. Therefore identifying information, including patients' images, names, initials, or hospital numbers, should not be included in videos, recordings, written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and you have obtained written informed consent for publication in print and electronic form from the patient (or parent, guardian or next of kin where applicable). If such consent is made subject to any conditions, Elsevier must be made aware of all such conditions. Written consents must be provided to Elsevier on request.

Even where consent has been given, identifying details should be omitted if they are not essential. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance that alterations do not distort scientific meaning and editors should so note.

If such consent has not been obtained, personal details of patients included in any part of the paper and in any supplementary materials (including all illustrations and videos) must be removed before submission.

**Acknowledgments**
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1) Contributions to conception and design; data acquisition; data analysis and interpretation;
2) Drafting of manuscript, or critical revision for important intellectual content;
3) All authors must have given approval to the final version of the manuscript submitted for consideration to publish.

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Example of suggested format. Note the use of author initials.

*AB conceived the idea for the study. AB and CD contributed to the design and planning of the research. All authors were involved in data collection. AB and EF analysed the data. AB and CD wrote the first draft of the manuscript. EF coordinated funding for the project. All authors edited and approved the final version of the manuscript.*
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