Developing an evidence base for osteopathic healthcare: an exploration of osteopathic healthcare to inform the design of an appropriate methodology to investigate its effectiveness

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Developing an evidence base for osteopathic healthcare

An exploration of osteopathic healthcare to inform the design of an appropriate methodology to investigate its effectiveness.

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25th October 2017
I certify that the work presented in this thesis is, to the best of my knowledge and belief, original, except as acknowledged in the text, and that the material has not been submitted, either in whole or in part, for a degree at this or any other university.

I acknowledge that I have read and understood the University's rules, requirements, procedures and policy relating to my higher degree research award and to my thesis. I certify that I have complied with the rules, requirements, procedures and policy of the University (as they may be from time to time).

Signed …………………………………………… Date ……………………………
Synopsis

Osteopathy is an international health service and osteopaths appear to utilise a range of therapeutic interventions, but there is a need for foundational research to establish a valid description of its intervention. Health services require an evidence base to provide certainty to users and third party payers, to make comparisons with other services, to provide consumer choice and to establish a scientific foundation and to influence practice. The process of establishing evidence has evolved alongside the development of scientific principles, and the current gold standard of evidence for healthcare is the randomised controlled trial. There are questions regarding whether this method is suitable for complex interventions like osteopathy and whether the findings reflect real-world practice.

This thesis aimed to establish an authentic model of osteopathic healthcare from the perspective of practitioners and patients, to review its evidence and to develop a clinical trial methodology that could test its effectiveness. Within a philosophical framework of pragmatism, an explanatory sequential mixed methods approach was used combining a practitioner survey with a patient snapshot of one day in practice, a patient survey and interviews, and a systematic literature review. Results from each of these studies were synthesised to develop a model of osteopathic healthcare, and a pragmatic clinical trial method was developed on the basis of the model using a Delphi panel.

The model of osteopathic healthcare demonstrated that it is consumer driven and health focused, has biopsychosocial foundations and manages patients who predominantly present with pain in multiple regions. The intervention is complex and follows a patient-centred model including a primary care assessment, individually tailored manual therapies, exercise and lifestyle advice, and includes cross disciplinary referrals with the health team. The randomised single blind controlled pragmatic trial method that was developed to test the effectiveness of osteopathic healthcare on the most common presentation, chronic non-specific low back pain, reflected this model with broad inclusion and specific exclusion criteria, an authentic intervention package and follow up, functional outcome measures and analysis by intention to treat.
This thesis has achieved its aims, and the results have professional, educational and research implications for the future of the osteopathic profession. The process used in this thesis of developing a practice model and a clinical research method for a complex intervention can guide researchers in other fields. Completing a pragmatic clinical trial based on the method developed in this thesis will be a major step in the development of an evidence base for osteopathic healthcare.
Acknowledgements

This work has required assistance and guidance from many people. My family and loved ones have excused me from being present (in body and more commonly in mind) at days of fun and exercise while I had intense concentration on this project. My girls, Sachi and Gabrielle, have come to accept I have had another child being born that required attention – the PhD. I have inhabited Sachi’s room where my surrogate desk was located to birth this new child, which I thank her for. I will make sure I replace the boring office furniture with teenage girl styles. Monique Lewis played a major role in keeping the girls happy during this time, was assistant researcher and transcriber in the patient interviews, and did a brilliant copy edit – thank you. In the early studies, I had assistance from the fellow members of the research council of the Australian Osteopathic Association who helped critique the survey and methods. The association also funded that first study. I am a proud osteopath and long term member of the profession, and love being around colleagues pushing the profession onwards. The osteopathic academic team at Southern Cross University have also heard my laments about this work for years and like most people I know, have probably become sick and tired of hearing about it – thanks for your patience. I pulled together a team of supervisors who each had their own expertise, which suited a project of mixed methods. Professor Iain Graham has pushed me to read for a doctorate rather than just complete projects, and lent me a text on western philosophy in the early days that made me realise the importance of the depth of enquiry that is required, and also my lack of training in that field. Professor Stephen Tyreman is a fair dinkum professor of osteopathy and a mentor to me from my first foray into teaching osteopathic foundations, whether he knew it or not. He has been a great questioner and pushed me to engage in a critique of those foundations despite being across the other side of the earth, and I made big leaps in my thesis when we spent time together in Europe and the UK on my study leave and at conferences. Associate Professor Sandra Grace has been a valued colleague at the coal-face over years and has an incredible ability to dig into the written document for meaning, continuity and clarity – her supervision has taken my work from a disjointed jumble of projects to what is a connected argument. Finally Professor Stephen Myers is a long-time friend and colleague who was there at the beginning and is very much there at the end. He is a visionary and has kept me positive and on-task, and I am indebted to him for getting me to the finishing line.
Publications

Included as part of this thesis


Others


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## Abbreviations

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<th>Description</th>
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<tbody>
<tr>
<td>CER</td>
<td>Comparative Effectiveness Research</td>
</tr>
<tr>
<td>CONSORT</td>
<td>Consolidated Standards of Reporting Trials</td>
</tr>
<tr>
<td>EBM</td>
<td>Evidence-Based Medicine</td>
</tr>
<tr>
<td>EBP</td>
<td>Evidence-Based Practice</td>
</tr>
<tr>
<td>GOsC</td>
<td>General Osteopathic Council (UK)</td>
</tr>
<tr>
<td>HVLA</td>
<td>High Velocity Low Amplitude (thrust technique)</td>
</tr>
<tr>
<td>ITT</td>
<td>Intention To Treat</td>
</tr>
<tr>
<td>MET</td>
<td>Muscle Energy Technique</td>
</tr>
<tr>
<td>OA</td>
<td>Osteopathy Australia</td>
</tr>
<tr>
<td>OMT</td>
<td>Osteopathic Manipulative Therapy</td>
</tr>
<tr>
<td>PCC</td>
<td>Patient- (or Person-) Centred Care</td>
</tr>
<tr>
<td>PRISMA</td>
<td>Preferred Reporting Items for Systematic Reviews and Meta-Analyses</td>
</tr>
<tr>
<td>SMT</td>
<td>Spinal Manipulative Therapy</td>
</tr>
<tr>
<td>STROBE</td>
<td>Strengthening the Reporting of Observational Studies in Epidemiology</td>
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Chapter 1 – Introduction

1.1 Introduction

Osteopathy is a healthcare profession that claims to have a unique philosophy of health (Seffinger et al., 2003). It has an international presence and has developed over the past century to be part of mainstream care in the United States of America, and part of complementary or allied healthcare elsewhere including Australia, New Zealand and the United Kingdom. A number of groups and individuals have explored the definition and description of this profession. These have included individual practitioners, interest groups, groups of researchers and academics, professional associations and governments. The variations in these definitions and descriptions relate to differences in eras of development, jurisdictions, and the aims of the group constructing the definition. The term osteopathy is consistent throughout the history of the profession and refers to the overarching philosophy as described by its founder, with the adjective osteopathic applied to its practitioners, techniques and activities. Osteopathic medicine is the application of that philosophy to medical practice and has been specifically used in the USA to denote the full scope medical practice that graduates of osteopathic training practise in that jurisdiction. Outside of the USA, osteopathic practitioners practise healthcare that is underpinned by the osteopathic philosophy but is limited in scope in comparison to USA physicians (Osteopathic International Alliance, 2013).

To encompass the international nature of the profession, the term osteopathic healthcare will be used in this thesis to refer to the practice of osteopathy by osteopathic practitioners.

In order to set a foundation of this thesis, a comparison of the range of definitions is worthwhile as it produces valuable distinctions between these definitions. The findings from this thesis have implications for the current definition of osteopathy and the descriptions of osteopathic healthcare in the public domain. In Australia, the current Osteopathy Australia definition (2017) is:

Osteopathy is a form of manual healthcare which recognises the important link between the structure of the body and the way it functions. Osteopaths focus on how the skeleton, joints, muscles, nerves, circulation, connective tissue and internal organs function as a holistic unit.
Using skilled evaluation, diagnosis and a wide range of hands-on techniques, osteopaths can identify important types of dysfunction in your body. Osteopathic treatment uses techniques such as stretching and massage for general treatment of the soft tissues (muscles, tendons and ligaments) along with mobilisation of specific joints and soft tissues.

In the UK the statutory body the General Osteopathic Council provides this version (General Osteopathic Council, 2016):

Osteopathy is a system of diagnosis and treatment for a wide range of medical conditions. It works with the structure and function of the body, and is based on the principle that the well-being of an individual depends on the skeleton, muscles, ligaments and connective tissues functioning smoothly together.

The Institute of Osteopathy, the professional body in the UK, provides a different focus (Institute of osteopathy, 2016):

Osteopathy is a method of assessing, treating and preventing a wide range of health problems. Osteopaths use a combination of movement, stretching, targeted deep tissue massage and manipulation of a person’s muscles and joints to improve function, relieve pain and aid recovery.

The commonality in these three definitions is the focus on a range of health (or medical) problems with an aim to lessen pain and improve function of the musculoskeletal tissues by the use of manual therapy.

The Oxford Dictionary definition states that osteopathy treats medical disorders (osteopathy, 2016):

A branch of medical practice that emphasizes the treatment of medical disorders through the manipulation and massage of the bones, joints, and muscles.

The full scope practice within the USA is reflected in the American Osteopathic Association description of osteopathic medicine which states (American Osteopathic Association, 2014a):

Practised by osteopathic physicians (DOs), osteopathic medicine is a complete system of medical care with a philosophy that combines the needs of the patient with the current practice of medicine, surgery and obstetrics; that emphasizes the interrelationship between structure and
function; and that has an appreciation of the body's ability to heal itself.
DOs are fully licensed to prescribe medicine and practise in all specialty
areas including surgery. They are trained to consider the health of the
whole person and use their hands to help diagnose and treat their patients.

Open Universities Australia has a descriptive outline for prospective students (Open
Universities Australia, 2016):

Osteopaths examine patients to determine the nature and extent of
disorders that are caused by interference with the nervous system.
Osteopaths adjust spinal columns, or utilise supplementary measures such
as exercise, water, light and heat to correct problem areas.

As can be seen from this sample of definitions and descriptions, there is not a
consistent osteopathy appearing in the public arena. The distinctions between
definitions include the use or absence of manual therapy, the focus of treatment and
the modalities of practice. Specifically, the use of the word manual, massage and
hands on dominate in the Osteopathy Australia and Institute of Osteopathy versions,
the General Council puts forward that osteopaths treat medical conditions and
wellbeing, and the Open University attempts to attract students by saying it treats
interference in the nervous system by adjusting the spinal column and using water,
light and heat. It is not surprising given these variable and vague statements, that
aren’t necessarily research based and often historical, that the sceptics dictionary
could describe osteopathy as (osteopathy, 2017b):

Osteopathy is a medical practice based on the theory that diseases are due
chiefly to loss of structural integrity which can be restored to harmony or
equilibrium by manipulation. The manipulation allegedly allows the body
to heal itself.

The focus on unclear terms like structural integrity causing disease and restoring
harmony and equilibrium understandably provoke scorn from scientific minds, as
seen in this excerpt from the Rational Wiki site (Osteopathy, 2017a):

Osteopathy is the discipline of (theoretically) treating disease by
stimulating the body to heal itself, with a focus on manipulating muscles
and bones. The idea that the body can be cured by manipulation has never
been proven in any scientific journal and is essentially woo.
From these preceding definitions, it becomes clear that osteopathic healthcare has a lack of clarity in the public domain and is in need of research in order to establish an authentic identity and to create a more stable and clear professional reputation.

The commonality in the definitions from the professional stakeholder groups is the reference to core principles of osteopathy as developed since the formation of the profession. Those core principles were first enunciated by the founder, Doctor Andrew Taylor Still (Jones, 2001; McKone, 2001; Still, 1910), and most recently published by the American Osteopathic Association (American Osteopathic Association, 2014b) as:

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

The identity of the osteopathic profession in large part depends on the characteristics of osteopathic healthcare as it is practised, and whether it can be regarded as different or unique compared to other healthcare services that patients seek. Research into the nature and effectiveness of osteopathic practice has developed relatively recently and is at a preliminary stage. This PhD thesis aims to explore osteopathic healthcare as it is practised, develop an authentic model of the intervention in a common presenting condition, and propose a pragmatic clinical trial method for testing its effectiveness.

Clinicians of osteopathic healthcare rely on research from other similar disciplines for their framework of evidence, for example chiropractic studies on spinal manipulative therapy (SMT), or physical therapy studies on the benefits of prescribed exercises. Osteopaths are able to integrate these findings into practice, but these are only aspects of practice and do not reflect the practice as a whole entity (Earley & Luce, 2010; Licciardone, 2007a, 2007b; Licciardone & Russo, 2006).

The term ‘whole practice/systems’ has been used to describe the integration of all aspects of a healthcare intervention that is faithful to its use in the real world (Dodds et al., 2013; Ritenbaugh, Verhoef, Fleishman, Boon, & Leis, 2003). It is not unique to osteopathic healthcare but has been subject to discussion for a wide range of
healthcare practices. A definition of whole practice/systems has not been established in the healthcare literature, but research utilising this concept has been described as (Ritenbaugh et al, 2003):

Whole systems research entails the intention to include conceptually as part of the investigative context all aspects of any internally consistent approach to treatment, including its philosophical basis, patients, practitioners, setting of practice, and methods/materials used. Whole systems research acknowledges unique patient, family, community, and environmental characteristics and perspectives.

Despite this approach to research being nascent in healthcare literature, it has been used as a stimulus to this thesis with its aims of exploring authentic practice and developing rigorous methods to examine its effectiveness. Authentic is defined as ‘based on facts; accurate or reliable (authentic, 2017), and in this context refers to real world osteopathic practice, the experiences of the osteopathic practitioners and patients, and the activities that occur when they meet in a healthcare consultation.

Attempting to describe a phenomenon that has been reduced to its parts is reminiscent of the fable of the Hindustani blind men and the elephant (Figure 1), who were asked to describe the object in front of them as they approached an elephant. Each described the part they have found and extrapolated about what they believe the object to be. The tail is a rope one declared, another stated the leg is a pillar, and for one other the ear is a fan. Six different subjective descriptions, but none described the elephant as a whole.

And so these men of Hindustan disputed loud and long, each in his own opinion exceeding stiff and strong, though each was partly in the right and all were in the wrong. (Saxe, John Godfrey. "The Blind Men and the Elephant". The poems of John Godfrey Saxe. Wikisource).
This thesis aims to avoid the error of the blind men, and explore osteopathic healthcare to develop an understanding of the whole practice/system. Certain initial questions arise from this approach: what is osteopathic healthcare as it is practised - a medicine, an idea, an approach to healthcare based on a philosophy? Does it involve spinal manipulation, manual therapy, massage, lifestyle management?

Medicine and healthcare services have moved into an era of evidence based practice, which urges the professions to draw on proof of the effectiveness of their interventions in order to give patients and third party payers improved informed choices for their healthcare (Franke, 2010; Nolan, 2004; Pager, Holden, & Golenko, 2012; Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996). Healthcare professions like osteopathy are ethically required to provide evidence of the benefits and risks of their practices to their various stakeholders (Gevitz, 2001; Lucas & Moran, 2007b). These stakeholders include patients, other health professionals, third party funding agencies, government organisations, educational institutions and members of the profession themselves (Osteopathy Australia, 2012; Pickstone et al., 2008).

The gathering of evidence in healthcare takes many forms, but the gold standard of testing the effect of a clinical intervention is the randomised controlled trial (RCT) (Oxford Centre for Evidence-Based Medicine - Levels of Evidence Working Group, 2011). Systematic reviews of multiple RCTs increase the strength of the evidence. A critical literature has developed regarding the dominant use of the RCT and the

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**Figure 1** The blind men and the elephant
(accessed from https://i.ytimg.com/vi/evGn3Dm_fYM/maxresdefault.jpg)
hierarchy of evidence in medicine, including the financial inequity involved in mounting RCTs, a perceived neglect of external validity, and issues of publication bias and commercial influence (Greenhalgh, Howick, & Maskrey, 2014; Miles, 2009; Tonelli, 2010; Zimmerman, 2013). These issues will be further discussed in Chapter 2.

The structure of RCTs suits certain types of interventions, but has limitations where the condition is multifactorial and the intervention is complex (Silverman, 2009; Song, Sandelowski, & Happ, 2010). Developing a clinical trial methodology for a complex intervention requires a model of the intervention to be developed through a systematic research process, in order to establish its real-world authenticity, or in clinical trial terms, its external validity (Craig et al., 2008; Song et al., 2010). Song and colleagues (2010, p729) describe “qualitizing the clinical trial” in order to make a meaningful inclusion of the experiences and outcomes in patient-centred interventions. A more detailed discussion of the meaning of evidence and the use of clinical trials will follow in Chapter 2.

This thesis supports the development of a pragmatic clinical trial method to test the effectiveness of the osteopathic intervention in a real-world setting. This development first requires research to establish the nature of the osteopathic healthcare intervention, the degree of its complexity, and its application in common clinical presentations. This research had not been done in Australia at the commencement of this study.

1.2 Background of this study

Research into osteopathy as a healthcare profession is relatively scarce. As yet the profession has not developed coherent research strategies to establish the effectiveness of its particular approach to healthcare. It also varies in the way it is practised internationally; in the USA for example, osteopaths are full scope medical physicians, while in the UK, Australia, New Zealand, Europe and in other countries, they are limited scope primary health care practitioners. This means that while they can be first or primary point of contact for a patient in the healthcare system following the definition in the WHO 1978 Alma Ata Declaration on Primary Health Care (World Health Organisation, 1978a), they have a scope of practice that is limited to neuro-musculoskeletal conditions by their training and lack of access to public health facilities. The defining features of osteopaths is that they are taught to uphold a set
of philosophical tenets, and to prioritise the health of the somatic tissues that are often treated with a specific set of manual therapies.

At the time of commencing this study in 2004, the activities of osteopaths in practice was little known. Workforce studies had been carried out in Australia (Jamison, 1991a, 1991b; Mullen, 1997), New Zealand (Jamison, 1991c; McGrath, 1995) and the United Kingdom (General Osteopathic Council, 2001), but were undertaken in small samples and were not up to date. Despite the osteopathic profession having a unique and distinct history for 120 years in the USA and Australia and the UK for 100 years, it remains little known in mainstream society and among conventional healthcare workers. The fact that osteopathic healthcare has continued to attract people to its service for much of its existence has been driven predominantly by word of mouth networks (see Figure 2).

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**Figure 2** An illustrative fictional conversation in an Australian street regarding how patients find an osteopath (based on actual patient descriptions reported in this thesis)
The biological underpinning of the theories of the osteopathic approach to healthcare were examined in the 1950s, but has not been repeated or reconceptualised in the light of current scientific understanding (Gevitz, 2001; Heath, 2002; Licciardone, 2007b). The clinical effectiveness of the osteopathic intervention has not been established with high quality research, despite many anecdotal reports over decades of the profession’s existence. The profession claimed to be unique in medicine and healthcare, but had not been proactive in researching itself (Gevitz, 2006). It has been caught in the vulnerable situation of claiming a specific role in healthcare service provision, while being unable to define and establish that role in an era of evidence based medicine (EBM). This has left osteopathy open to criticism, not only regarding the claim that it is a unique healthcare practice (Gevitz, 1994; Johnson & Kurtz, 2001; Mychaskiw, 2006; Teitelbaum, 2003), but also that its diagnostic theories lack validity and that its approach to healthcare does not result in clinically relevant outcomes compared to any other similar healthcare services. A detailed discussion of the history and progression of the osteopathic profession will follow in Chapter 2.

Despite this lack of evidence, the profession itself appears to prioritise this clinical outcome component as critical to its research strategy, that of testing the clinical effectiveness of its intervention (Osteopathy Australia, 2012; Rushton, Fawkes, Carnes, & Moore, 2014). In order to establish the clinical evidence for a practice, it is vital that initial exploratory research is carried out in order to carefully describe and characterise the service. In a recent themed edition of the International Journal of Osteopathic Medicine, Tyreman (2013) posited that the answer to the question, ‘What is osteopathy?’ will be revealed by describing and analysing what osteopaths do in practice, and what their mental processes are as they practice. This exploratory approach to researching the profession would ensure that further clinical research is based on an authentic intervention as it is practised in the real world, rather than any specific singular therapy, for instance a spinal manipulation or a prescribed medicinal drug.

The testing of an intervention using the whole practice/systems approach described earlier in in this chapter (1.1), is consistent with a strategy described as comparative effectiveness research (CER) (Coulter, 2011; Coulter, Lewith, Khorsan, Kirk, & Mittman, 2014; Manchikanti, Falco, Boswell, & Hirsch, 2010; Slutsky, Atkins, Chang, & Sharp, 2010), and this approach supports the development of pragmatic clinical trials as an appropriate method to test two interventions from the real world.
Pragmatic trials are designed to ‘evaluate the effectiveness of interventions in real-life routine practice conditions, whereas explanatory trials aim to test whether an intervention works under optimal situations’ (Patsopoulos, 2011). Pragmatic trials have been reported to produce results that can be generalised and applied in normal practice settings (Godwin et al., 2003; MacPherson, 2004).

At the time of the commencement of this research (2004) there had been no attempts to construct an authentic real world model for testing the osteopathic healthcare intervention in a pragmatic clinical trial. There are examples of pragmatic trials that use a whole practice model, for example in naturopathic medicine (Szczurko et al., 2007) and acupuncture (Shi et al., 2015), but these do not explain how the intervention was developed and established as authentic to real practice. A series of research studies exploring osteopathic healthcare as it is practised would establish a foundation for pragmatic clinical research to be attempted based on an authentic model. In the era of EBM, health professions are ethically required to provide evidence for their service to patients, and in this thesis I argue that the development (and implementation) of a clinical trial method to test a real world model of osteopathic healthcare is essential for its survival as an independent modern health profession.

1.3 Statement of the problem

Given the discussion above, the problem facing the osteopathic profession is the lack of evidence for its unique intervention. This problem can be stated as: Osteopathy is a health profession that does not have a well-developed evidence basis for its clinical effectiveness, despite existing for over a century and now the profession needs to find its place in an era of evidence based practice.

1.4 Purpose of the Study

To address this problem an authentic model of osteopathic healthcare needs to be developed that could be tested rigorously with appropriate methods to establish the extent of its effect in patient populations. This will be undertaken by practitioner and patient surveys, a practitioner focus group and patient interviews. Then using this data, a pragmatic clinical trial method will be developed to test the effectiveness of osteopathic healthcare on a common presentation which will be refined by an expert
Delphi panel. The intent of this body of work is to lay a stable foundation for an evidence base for osteopathic healthcare.

1.5 **Aim of thesis**

Clearly stating the problem and clarifying the purpose allows the aim to emerge. The aim of this thesis is to explore osteopathic healthcare as it is practised, develop an authentic model of the intervention in a common presenting condition, and propose a pragmatic clinical trial method for testing its effectiveness.

1.6 **Research questions**

This stated aim gives rise to a broad range of research questions: what do osteopaths do in practice, what members of the community consult them, and with what conditions? How is this practice experienced by practitioners and patients? These broad questions were formalised as the research questions of the thesis:

- What is the nature of osteopathic practice in Australia?
- What are the common workplace characteristics regarding patient presentations, assessment practices, and patient management?
- What is the quality and currency of the evidence for authentic osteopathic healthcare applied to chronic non-specific low back pain, the most common presenting problem based on the workplace findings?
- What is the experience of practitioners managing the common presenting problem of osteopathic healthcare?
- What is the experience of patients with the common presenting problem of osteopathic healthcare?
- What is an appropriate pragmatic clinical trial method to test the effectiveness of osteopathic healthcare for the most common presenting problem?

1.7 **Methodology**

The assumptions underpinning this research are that osteopathic healthcare has established itself to be effective for musculoskeletal pain presentations through patient choice and word of mouth; that there is some consistency to what patients receive from osteopathic healthcare; that there is an identifiable philosophy underpinning osteopathic healthcare; and that a well-designed pragmatic clinical trial
will be the most appropriate method to answer the question of the effectiveness of osteopathic healthcare in the most common problem.

In order to answer these research questions, a mixed methods approach was employed to describe and analyse the features of osteopathic healthcare from a number of positions and perspectives – the professional workplace, the opinion of practitioners, the experience of patients and the opinion and consensus of clinical researchers. The type of mixed methods used in this thesis is an explanatory sequential design (Cresswell, 2011), as the Stage one quantitative data set the framework for the further qualitative stage. It is a participant-selection variant of this design (Cresswell, 2008; Morgan, 1998), as the qualitative stage had at least equal importance to the quantitative stage. A full explanation of the rationale for this methodology is in Chapter 3. A simple structure of the research studies that comprise this thesis is presented in Figure 3.
Figure 3 Flowchart of research questions, methods and outcomes
1.8  Philosophical and paradigmatic underpinning of the thesis

Before embarking on the research journey it is important to clarify the philosophical and paradigmatic underpinning of the thesis and explore any inherent bias in the process. The primary aim of research is to uncover truth. This search for truth is a fraught activity, as whenever new knowledge is discovered all previous truths have to be reconsidered in light of it. Truth is dynamic, relative and dependent on the question that has been posed (Heidegger, 1948; Russell, 1961).

The first step in a study such as this is to establish and state the underpinning paradigm that leads to the methodology to be followed. Broadly, a paradigm can be described as a set of beliefs that contribute to the development of a worldview that shapes the way an environment may be interpreted and understood (Nolan, 2004). Denzin and Lincoln (2008) describe paradigm from a research specific perspective as:

the net that contains the researcher’s epistemological, ontological, and methodological premises may be termed a paradigm … all research is interpretive; it is guided by the researcher’s set of beliefs and feelings about the world and how it should be understood and studied (p22).

Nolan (2004) argues that in order to establish an appropriate structure for any research activity, an ontological position should be taken, which then influences the epistemology and methodology of the activity. The central ontological question is whether reality is something fixed and external, or variable and interpreted internally. The polarity of these views is a continuation of the ancient debate between the absolutists like Plato and Socrates, who viewed reality as unchanging, and the relativists like Heraclitus who argued that it is fluid and always changing (Johnson, 2010).

The epistemological question then deals with what counts as knowledge, what justifies our beliefs, and what standard of evidence is needed to establish a truth. This question fuels the quantitative/qualitative paradigm debate that emerged in the twentieth century following the rise of qualitative methods (Johnson, 2010; Nolan, 2004). Finally, the methodological question that follows is how that knowledge
would be obtained. These questions are influenced by two differing philosophical perspectives - rationalism and empiricism. Rationalists such as Descartes, Leibnitz and Spinoza argued that we can use facts, or accepted principles, to reason deductively to establish “a priori” knowledge (Russell, 1961). The Empiricists such as Locke, Berkeley and Hume posit that knowledge can only be gained through direct sense experience and inductive reasoning, and that only what could be systematically observed by a human could be called truth (Russell, 1961). Hume became sceptical of the pure inductive approach as, despite systematic observation he reasoned that one was never able to produce absolute certainty (Johnson, 2010). In the early nineteenth century Kant set out to resolve the conflict between this philosophical divide by taking a realist position that some phenomena are knowable by the senses, but that the true nature of the world is not knowable. Kant also later argued that quantity and quality are both important aspects of human understanding (Johnson, 2010); in fact Johnson and Gray (2010) refer to Kant as a proto-mixed methods thinker.

During this same period of the early to mid-nineteenth century, the scientific experimental research method was formally developed and became based on a positivist paradigm, described as a realist position that there is a reality of the world that can be studied and understood (Denzin, 2008; Ellis, 2004). The twentieth century saw a further distillation of this paradigmatic approach into the stance of logical positivism, which is described in the Merriam-Webster dictionary as holding that “all meaningful statements are either analytic or conclusively verifiable or at least confirmable by observation and experiment” (logical positivism, 2011).

The original stance put by Hume and the empiricists that nature and truth must be established by systematic observation underpins modern scientific medicine (DePoy, 1994), and this stance has been seen in a critical light as reflecting a hegemonic dominance of biomedicine with regards to what is valued as evidence for interventions in healthcare (Borgerson, 2009; Filc, 2004). The direction taken by the logical positivists inevitably led to a removal of the variable and context-laden effect of the human relationship and practitioner-patient interaction. In service fields like healthcare this approach strips away a large component of the activity, to the point that it is no longer describing the reality. The epistemological assumption that there is a single reality that can be discovered by reducing it into its parts runs counter to the worldview of the naturalistic/holistic paradigm. The naturalistic/holistic
paradigm posits that nature is based on individual interpretation, and due to the complexity of human life, healthcare should be practised with each patient’s individual context taken into account (Ellis, 2004). This worldview is integral to the osteopathic healthcare practice of the author of this thesis, and influences the stance of this thesis.

The stance taken by the logical positivists, that only a particular kind of science can reveal the truth, has been described as the dominant use of “scientism” in healthcare practice (Miles & Loughlin, 2011b). In this paradigm, there is a dualistic distinction made between subjective and objective claims, and an epistemological stance that only science reveals the true nature of the world. The sequelae of this stance in healthcare has been a somewhat distorted use of the principles of the EBM movement, which was described by its modern founders thus (Sackett et al, 1996):

Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.

Despite this definition by one of the founders of EBM placing clinical expertise on equal footing with external evidence, the EBM movement has progressed to promote a hierarchy which places the RCT and systematic reviews of multiple RCTs at the pinnacle of truth for the efficacy of an intervention. While this component of EBM does use a reductionist approach in order to control variables such as patient context (Miles, 2009; Tonelli, 2010), a distortion occurs when a logical positivist stance is taken that ignores the integration of this evidence with individual clinical expertise as recommended by Sackett et al (1996). The debate over the meaning of evidence and its relationship with practice is further discussed and analysed in Chapter 2.

The philosophical paradigmatic stance taken in this thesis is that of pragmatism. Pragmatism is oriented toward solving practical problems in the real world (Feilzer, 2010), and comes from the writings of Peirce, Dewey and James in the nineteenth and early twentieth centuries and Rorty in the late twentieth century (Hall, 2013). Pragmatism has been defined as a bridge between paradigm and methodology, or a stance at the “interface between philosophy and methodology” (Greene, Caracelli, & Graham, 1989). One of the founders of pragmatism, John Dewey, conceived thought as an evolutionary process (Russell, 1961), and all reality as temporal. Dewey puts
the process of *inquiry* as central to logic, aimed at converting a so called indeterminate situation into a unified whole (Russell, 1961). This reflects the process applied in this thesis.

The current study primarily follows a subjective stance, which has emerged from the experience of the researcher as a healthcare professional, where empirical observation has revealed that individual context drives effective care of human beings. Taking this stance allows a flexible but rigorous analytical approach to be used to help describe a phenomenon under study. The methodological stance that follows is pluralistic, and leads naturally to an inductive interpretive approach to explore and describe the subject in focus – that of osteopathic healthcare.

1.9 Conceptual Framework for the Thesis

The conceptual framework sets the stage for the thesis, positions it in a larger framework of literature and aims to show how the variables in the studies connect with one another (Ellis, 2004). Inherent to this conceptual framework is the knowledge and experience that healthcare is a complex and multifaceted phenomenon. There are a broad set of factors affecting a person’s health and the practice of healthcare professionals including social, cultural, economic and educational influences (Australian Institute of Health and Welfare, 2016). Many of these are beyond the scope of this thesis. For this thesis the central concepts are the history and culture of the osteopathic profession, the influence of science and philosophy on this profession, and how these variables affect the practice of osteopathic healthcare. These concepts are outlined in Figure 4.
The history of osteopathy begins in the late 19th century in a post-civil war America. The founder, Dr Andrew Taylor Still, was a physician who became disenchanted with the medicine of the day and had a number of insights into a more natural approach to health and healing. He was charismatic and a spiritual seeker, and the foundations of the profession were set by him and his writings (Baer, 1987; Still, 1908; Still, 1910). Osteopathy has been described by Dr Still and others as an art and a science, and as a philosophical approach to the practice of medicine (Littlejohn, 2000; Still, 1908; Still, 1910; Stone, 2000; Wales, 1953). This can be seen as an attempt to amalgamate a number of poles – art and science, the inductive and deductive, the interpretive and positivist, the subjective and objective – and makes the subject of osteopathy a difficult one to explore from a single research perspective. The history and culture of osteopathy is discussed in Chapter 2.
The science that underpins osteopathy is derived from a broad study of normal structure and function of the body – anatomy and physiology, as well as a detailed examination of the function and disturbance of blood and nerve supply. This is clearly outlined in Still’s original definition of osteopathy and also in its underpinning tenets, or so-called philosophy. How these sciences are applied to supporting the biological mechanism of osteopathic techniques, and how they are integrated into practice is the subject of analysis in the underpinning literature review in Chapter 2. For this current study, the research questions emerge from the need to explore the scientific aspect of osteopathic healthcare with reference to this reported philosophical basis for the practice.

Against this background, the initial exploratory research questions arose: what is the nature of osteopathic practice in Australia; what are the common practices, presentations and therapies used in the workplace; what is the current evidence for authentic osteopathic healthcare applied to the most common presenting problem based on workplace findings? The answers to these questions would most likely be expressed as numbers, percentages and proportions, which is an exploratory approach, as very little was known of osteopathic practice at the time of commencement. When the aim progresses to developing a testable model of authentic osteopathic healthcare, there is a need to go deeper into the meaning of these data. Further questions arise: how do osteopathic practitioners describe their management of patients with a common presenting problem, and what is the experience of patients with the common presenting problem of osteopathic healthcare? The study has then moved to a more inductive and interpretive stance to deepen understanding of the phenomena under study.

This study is best described as an integrated research design – establishing a model of osteopathic healthcare through exploratory quantitative data collection from practitioners, as well as using qualitative methods to explore meaning from patients and practitioners. The study uses a mixed methods approach in order to answer the research questions and sub-questions. Mixed Methods Research (MMR) is well suited to the ontological position of pragmatism - where multiple forms of data are collected and used to answer the research question(s) (Cresswell, 2007). Further in-depth discussion of the mixed methodology that arises from this philosophical stance of pragmatism will be covered in Chapter 3.
Chapter 1 – Introduction

1.10 Theoretical Framework for the study

The theoretical framework for a study provides an outline of the variables involved that have been substantiated by previous research. For this thesis (Figure 6) these variables are patient-centered care, evidence in healthcare, and professional scope of practice.

![Theoretical Framework](image)

Figure 5 Theoretical Framework

The questions of what is osteopathic healthcare as it is practiced and how the practice has developed requires an analysis of these current theories of healthcare practice.

1.10.1 Patient Centred Care

Patient-centred care (PCC) is thought to be the future of effective healthcare, although many agencies prefer the term person-centred care (Parsons et al., 2007; Dwamena et al., 2012; Luxford, 2012). This approach deeply involves patients in their own care, where education and shared knowledge forms the basis of a
partnership with their practitioner. There is no global definition of PCC. The theory of PCC appears to have developed from research conducted by the Picker Institute and the Harvard School of Medicine in 1993, who commissioned a systematic review of nine models and frameworks (Schaller, 2007). The researchers found the core elements of PCC most frequently cited were:

- Education and shared knowledge
- Involvement of family and friends
- Collaboration and team management
- Sensitivity to non-medical and spiritual dimensions of care
- Respect for patients’ needs and preferences
- Free flow and accessibility of information

At the time of commencement of this study no research had explored osteopathic healthcare as a patient-centred approach, although this theory of care is assumed in some historical writings and modern promotional material (Seffinger et al., 2003). In this thesis, this approach is termed patient/person-centred care to refer to the individual, rather than the plural people-centred care.

1.10.2 Evidence in healthcare

Evidence-based medicine is a movement arising from a number of influences: the modernisation of healthcare, the progress of scientific method, and the need for third party payers to subsidise therapies that are known to work (Pager et al., 2012; Sur & Dahm, 2011). There has always been demand for practitioners to have an understanding of the evidence of the effect of their therapies, but the EBM movement has created a clearer hierarchy of evidence, and aims to bring more user-friendly information to the practitioner in the exponentially increasing amount of research information being produced and published (Oxford Centre for Evidence-Based Medicine - Levels of Evidence Working Group, 2011).

The EBM movement has generated some debate and criticism, reflecting the conflict between research paradigms. A number of authors have been critical of EBM (Greenhalgh et al., 2014; Miles & Loughlin, 2011a; Sur & Dahm, 2011) for the perceived diminution of the practitioners’ and patients’ values and context. The
current definition of EBM does include patient choice and clinician judgement, but authors like Gelhaus (2011) and Thornton (2011) are critical of the weighting of evidence based practice guidelines that may in Gelhaus’ words create ‘robot decisions’ (p883). These issues are further explored in Chapter 2.

1.10.3 Professional scope of practice

What defines whether an occupational group is a profession is a controversial issue. It depends on the philosophical perspective one takes. Historically, the first three learned professions were law, medicine and the clergy (Hilton, 2007). Hilton (2007) states that professions have a number of characteristics that individually may be shared with other social groups, but when present collectively distinguish the group as a profession. These characteristics are:

- a body of specialist knowledge and skills;
- a commitment to high standards of service;
- varying degrees of self-regulation and autonomy;
- moral and ethical standards of behaviour.

Schein (reported in Hilton, 2007) outlined three components of what constituted professional knowledge:

- an underlying discipline or basic science component upon which the practice rests, or from which it is developed;
- an applied science component from which many of the day to day diagnostic procedures and problem solutions are derived;
- a skills and attitudinal component that concerns the actual performance of services to the client, using the underlying basic and applied knowledge.

Schon (1983) also pointed to this application of scientific theory in order to solve problems of practice, and noted that the knowledge base of a profession has the four properties of being specialised, firmly bound, scientific and standardised (Schon, 1983). A health professional scope of practice is defined in the McGraw-Hill Concise Dictionary of Modern Medicine (2002) as ‘the range of responsibility, types of patients or caseload and practice guidelines that determine the boundaries within which a physician or other professional practices’. The scopes of health professionals have tended to develop on historical and educational grounds (Saks, 2012), and then
become defended by professional guilds and associations in order to protect their ‘turf’. There have been arguments for a more flexible scope, especially with nursing and allied health groups seeking roles that have traditionally been part of the primary care medical professional practice scope. A national council of nursing boards in the US took a patient-centred approach and stated that scope of practice changes should have a foundational basis within four areas: 1) an established history of the practice scope within the profession, 2) education and training, 3) supporting evidence, and 4) appropriate regulatory environment (National Council of State Boards of Nursing, 2006). If a profession can provide supportive evidence in these areas, the council concluded that changes in scope of practice are likely to be in the public’s best interest.

There is a literature that has developed that challenges any rigid boundaries of scope, and modern jurisdictions tend to legislate only title, not specific roles. Legislation of title is a simple designation of the specific discipline. This approach to loosening any defined scope of practice promotes a multifaceted health professional workforce (Australian Council for Safety and Quality in Health Care, 2004). The issues of scope of practice in osteopathy is explored in this context in Chapter 2.

1.11 Researcher’s background and statement of bias

An important component of the qualitative method approach is to record the history and philosophical position of the researcher as a strategy designed to consider the possibility of the bias that can arise in the research and to consider how to minimise it.

I have had entry-level training and practised in three distinct health professions in Australia – nursing, naturopathy and osteopathy. I practised as a Registered Nurse in tertiary care hospitals for five years following a three year certificate, practised as a naturopath in a private clinic following a four year diploma, and have now practised as a registered osteopath for twenty-seven years following a four and a half year diploma. I have been employed as an academic in public universities in both naturopathy and osteopathy for 23 years. I completed a Master of Applied Science by research using quantitative methods, and have a postgraduate qualification in higher education teaching.
As a practitioner and teacher I use the underpinning holistic philosophy found in the practices that have developed within the field of Complementary Medicine; that the body and mind are interconnected, that nature has inherent self-healing mechanisms and that the promotion of health and prevention of disease is the primary aim of therapy. My clinical and educational reasoning process integrates this biopsychosocial model into my practice, and I have found it to be the primary driver in my approach to patient care. I do not know whether this is true for other practitioners in the field, and in my experience I have observed that osteopaths appear to hold to these tenets, and that their approach is different from practitioners of other disciplines. Patients also report their experiences to me when they navigate the pathways and options within healthcare. I share the naturalistic and holistic worldview that nature is based on individual interpretation, and that due to the complexity of human life, healthcare should be practised with each patient’s individual context taken into account.

I have potential for bias arising from this experience as a practitioner in the field under study. I can only gain impressions from the patients that visit my practice and from discussions with colleagues at meetings, and this is likely to be limited. I can observe the response in my patients, but this does not result in generalisable assumptions. I genuinely hope that osteopathy is helpful in patients, but this can bias the researcher to ignore negative findings.

In order to limit bias, a number of strategies have been used. All findings have been compared to other similar studies completed by independent researchers and differences have been noted. The main findings have been published after rigorous peer review in international journals. I have used bracketing in the analysis of interview data, and had assistant researchers to review the thematic analyses in the interviews and focus group in order to minimise any personal bias on the data.

1.12 Scope and Limitations of the study

This study will concern itself only with the practice of registered osteopaths in Australia, although there will be comparisons with other jurisdictions. Detailed discussions of limitations are included in each publication and phase and also in the discussion chapter.
1.13 Thesis outline

This thesis is organised in a way that integrates four publications that have resulted from projects within the study. There is an introductory chapter, then a literature review chapter dealing with the two major foci – osteopathy and evidence. That is followed by an overarching methodology chapter, Chapter 3. Chapters 4-7 include the five research projects that resulted in four peer reviewed publications and one prepared for publication. Each project has a self-contained introduction, methods, results and discussion. The references from each paper are integrated into one list in the references section at end. Finally, Chapter 8 presents a discussion of the findings, and the conclusions and implications drawn from this thesis.

A brief overview of the thesis is as follows:

Chapter 1 Introduction
This chapter outlines all aspects of the thesis, including the background, the development of the research questions, the philosophical underpinnings, the conceptual and theoretical frameworks and structure of the thesis.

Chapter 2 Background/Literature
This chapter explores and reviews the literature that supports the need for this study in two sections:

Osteopathic Healthcare
This section explores the definition, origin and current status of osteopathy internationally. There is an examination of its status and progress as a healthcare profession and the issues that are central to both stakeholders and the profession itself. The profession will be considered in the light of the concepts of philosophy and science and exploring their role in practice.

Evidence in Healthcare
The use of scientific method in healthcare and medicine is explored in this section, as well as the development of evidence based medicine, the structure and application of its use including clinical trial methodologies. It also considers the status of evidence in healthcare, CAM, and osteopathy.
Chapter 3 Methodology
This chapter details the methodological approach that has guided the research and the methods of data gathering and analysis. Firstly the research aim is stated and then the epistemological stance of pragmatism is discussed. The paradigmatic stance is linked to the methodological approach of mixed methods. Next, the research design is outlined followed by a discussion of the limitations of this over-arching methodology and design.

Chapter 4 Stage 1
This chapter was an initial stage designed to address the questions:

- What is the nature of osteopathic practice in Australia?
- What are the common workplace characteristics regarding patient presentations, assessment practices, and patient management?

Two publications reporting the results of a national workforce survey of practising osteopaths in Australia:


Chapter 5 Stage 2
This chapter was designed to answer the question:

- What is the quality and currency of the evidence for authentic osteopathic healthcare applied to chronic non-specific low back pain, the most common presenting problem based on the workplace findings?
A Systematic Review of the evidence for the osteopathic healthcare in the most common presentation from the workforce survey – Chronic Non-Specific Low Back Pain (CNSLBP). Published as:

Chapter 6  Stage 3
This stage was designed to answer the questions:

- What is the experience of practitioners managing chronic non-specific low back pain, the most common presenting problem based on the workplace findings?

- What is the experience of patients with chronic non-specific low back pain, the most common presenting problem based on the workplace findings?

A practitioner focus group was completed in this stage to explore experienced practitioners’ opinions and approaches for managing patients with CNSLBP in the light of the evidence. This is unpublished and is structured in a publication style.

A waiting room patient survey followed by interviews with patients with the target condition of CNSLBP was completed to answer the second question of this phase. This study was published as:


Chapter 7 Final Stage
The final stage reports the main two outcomes:

- a model of osteopathic healthcare that has been developed from the previous studies, and presented as a series of converged data and a new definition;

- a proposed clinical trial method in answer to the question “what is an appropriate pragmatic clinical trial method to test the effectiveness of osteopathic healthcare for the most common presenting problem?”, developed in a Delphi Panel of international clinical researchers.

Chapter 8 Discussion
This chapter summarises the findings from the projects, and considers how these findings intersect. The development of a clinical model of osteopathic healthcare is presented, and contextualised to current healthcare and evidence. Conclusions are drawn and the implications for the osteopathic profession, researchers, educational programs and the wider healthcare field are stated and future directions pointed out.
1.14 Conclusion

This chapter has established the background, purpose and aim of this thesis. The aim led to a set of research questions that have been outlined in section 1.6. In order to build a research design, the philosophical and paradigmatic underpinnings of research was discussed, and the stance of pragmatism was described. An introduction to mixed methods research followed, with more detail to be provided in Chapter 3. The conceptual and theoretical frameworks were described in sections 1.9 and 1.10, which set the map and literature review directions of the thesis. The researcher’s background and statement of bias is included, in order for the reader to understand the context of the development of the argument in the thesis and the possible influences on the included research studies. Finally the scope and limitations of the study are discussed and an outline of the structure of the thesis is provided.
Chapter 2 – Background

2.1 Chapter introduction

This chapter provides a general background to the two major aspects to this thesis – osteopathic medicine and evidence in healthcare. These are presented in order to understand how these two subjects relate to one another in the context of the development of the research questions and the context for the discussion that follows.

2.2 Introduction to Osteopathic Medicine

2.2.1 Definition and principles of practice

The definition of osteopathy and osteopathic medicine varies slightly based on the jurisdiction and local scope of practice (outlined in 1.1). The difference between the profession in the USA and elsewhere has been the subject of debate and recent analysis, leading to the international group, the Osteopathic International Alliance (2014), stating that:

An osteopathic physician is a person with full, unlimited medical practice rights and who has achieved the nationally recognized academic and professional standards within his or her country to practice diagnosis and provide treatment based upon the principles of osteopathic philosophy. Individual countries establish the national academic and professional standards for osteopathic physicians practicing within their countries. An osteopath is a person who has achieved the nationally recognized academic and professional standards within his or her country to independently practice diagnosis and provide treatment based upon the principles of osteopathic philosophy. Individual countries establish the national academic and professional standards for osteopaths practicing within their countries.

The core osteopathic principles are the common link in these varying descriptions of practice, and they have evolved over time as language and knowledge have changed. Stark (2013) outlined how the descriptions have been inconsistent over the 140 years of the profession’s existence. Stark (2013) had been unable to uncover any evidence
to confirm that AT Still, the founder of osteopathy, recorded a specific list of principles, despite using that term in many of his writings. It appears that current records are from students of the American College of Osteopathy who recorded their interpretation of Still’s teachings, and individual osteopaths who published their own version. In 1953 a revision, or more correctly a ‘tentative formulation’ of the principles, was published by a committee of osteopaths in the US (Kirksville College of Osteopathic Medicine, 1953). This work was completed at the original home of the American School of Osteopathy at Kirksville, Missouri and became the profession’s foundation for a period of time. At that time the osteopathic principles were described as:

1. The human being is a dynamic unit of function.
2. The body possesses self-regulatory mechanisms that are self-healing in nature.
3. Structure and function are interrelated at all levels.
4. Rational treatment is based on these principles.

A further proposal in 2002 used the term tenets and distinguished them from principles for patient care (Rogers, 2002). The ‘basic tenets’ were listed as:

1. A person is the product of dynamic interaction between body, mind, and spirit.
2. An inherent property of this dynamic interaction is the capacity of the individual for the maintenance of health and recovery from disease.
3. Many forces, both intrinsic and extrinsic to the person, can challenge this inherent capacity and contribute to the onset of illness.
4. The musculoskeletal system significantly influences the individual’s ability to restore this inherent capacity and therefore to resist disease processes.

The principles for patient care in that same proposal had a patient and practice focus:

1. The patient is the focus for healthcare.
2. The patient has the primary responsibility for his or her health.
3. An effective treatment program for patient care is founded on these tenets and:
a. incorporates evidence-based guidelines;

b. optimises the patient’s natural healing capacity;

c. addresses the primary cause of disease; and

d. emphasises health maintenance and disease prevention.

This proposal came from a group of well-published researchers in osteopathic medicine in the USA, and reads as an attempt to modernise the language of the original principles while keeping the historical focus on the natural healing capacity of the body and on the importance of the musculoskeletal system in health. This 2002 list of tenets avoids certain controversial statements like the relationship of structure and function in the cause of disease, a view that has been seen by some authors as a divisive, dated concept that is not evidence based (Evans, 2013; Hoover, 1963).

The question of how these osteopathic principles and philosophy affect practice has not been systematically studied. The chapter on osteopathic philosophy in the international textbook ‘Foundations for Osteopathic Medicine’ (Seffinger et al., 2003) includes a statement:

The osteopathic philosophy, deceptively simple in its presentation, forms the basis for osteopathic medicine’s distinctive approach to health care.
The philosophy acts as a unifying set of ideas for the organization of scientific knowledge in relation to all phases of physical, mental, emotional, and spiritual health, along with distinctive patient management principles. As such, its concepts form the foundation for practicing osteopathic medicine.

This places the philosophy as an underpinning organiser of scientific knowledge, and seems to support the idea of osteopathy as art and science. How this practice is studied in an era of scientific medicine creates a challenge for the profession and its researchers. Gevitz (2006) has explored the integration of the principles into practice as the central idea that the osteopathic profession may claim as its uniqueness, noting that the osteopathic profession in the US, while being described as parallel to the main medical profession, in effect performs the same roles as non-osteopathic physicians. He urges the need for the profession to explore and provide proof that osteopathic healthcare is distinct because of the integration of a philosophy (Gevitz, 2006). There is some debate in the US about whether osteopathy can remain
Osteopathy was originally created as a radical alternative to what was seen as a failing medical system. Its success at moving into the mainstream may have come at a cost - the loss of identity. Most people - including physicians - know very little about the field (most people know more about chiropractic). Many people - even osteopaths - question what osteopathy has to offer that is distinctive.

This demonstrates the identity issues of osteopathy in the US and the need for the worldwide profession to explore and research its place in the healthcare system. More recently a number of authors have discussed the need for a modernisation of the principles in a special edition of the International Journal of Osteopathic Medicine (Evans, 2013; Paulus, 2013; Tyreman, 2013). Paulus argued that the principles as they stand are vague and do not identify a unique osteopathic foundation, and proposed a set of ten principles that underpin the osteopathic philosophy. He claimed to base these on extensive reading of the historical writings of AT Still and ‘the writings of the early osteopathic pioneers’ (p12). Paulus included the structure and function relationship, and attempted to identify the specific use of osteopathic manipulative hands-on treatment as integral to the practice. He also included a metaphysical concept as his Principle 9, where osteopathic diagnosis and treatment could be perceived from a ‘non-material field’ that is ‘invisible and refers to the subjective bioenergetics elements that underlie the material form. The non-material field is the expression of subtle functions or inherent forces’ (p15). This illustrates the diversity of individual opinion about what underpins the osteopathic principles.

Tyreman (2013) agrees with the argument by Paulus that the principles do not identify a unique osteopathic approach to healthcare, and suggests there is a need for research into the values-based practice of osteopathy in order to understand what current osteopathy is based upon. In pointing the direction forward, Tyreman posits that the answer to the question, ‘What is osteopathy?’ will be revealed by describing and analysing what osteopaths do in practice, and what their mental processes are as they practise.

The history and evolution of the osteopathic profession and its principles, as well its current status and scope is explored further in the following sections, in order to establish the rationale behind this thesis.
2.2.2 Historical context

Osteopathic medicine was founded in the United States in 1874 following a period of development by its founder Andrew Taylor Still. Still was a physician trained in the apprenticeship method of the time, who became disillusioned by the conventional medicine of the day. He lost a number of members of his family to a meningitis epidemic during 1864, and also had traumatic experiences during the Civil War. He established the first osteopathy training in 1892 at the American School of Osteopathy in Kirksville Missouri (Peterson, 2003; Seffinger et al., 2003).

The fact that the formation of osteopathy occurred in the late nineteenth century in the US is notable, as it was a time of unregulated pluralistic medicine (Baer, 1987; Peterson, 2003). The rise of biomedicine during the early period of its development had significant effects on the osteopathic professions progress in different countries – inclusive and mainstreaming in the USA, and sidelining and marginalisation in other countries including Australia and the UK (Baer, 2006, 2009; Gevitz, 2006).

After a minimal presence in Australia, osteopathy grew alongside the rise of the holistic health movement in the 1960s and 70s, and became associated with alternative therapies. As Baer describes it, the diffusion and development of osteopathy outside the US had ‘distinct evolutionary trajectories shaped by the larger political economies of these countries’ (Baer, 2009, p26).

The first osteopaths practising in Australia are reported as Edgar Culley and Florence McGeorge who graduated from the American School of Osteopathy under AT Still in 1900 (Hawkins, 1990; Willis, 1991). Overseas trained osteopaths also migrated, especially from the UK, which operated under the same legal framework that allowed alternative medicine practitioners freedom to practise. During these early years, the profession was under pressure from the mainstream establishment, in one instance leading to charges against the aforementioned Edgar Culley in 1926 for using the courtesy title “doctor” (Hawkins, 1990). This was overturned on appeal the following year. Preliminary signs of professionalisation were evident in 1941 with the establishment of the Australian Osteopathic Association by Alistair McGown, David Evans & Leon Van Straten. Gradually the number of locally trained osteopaths grew, mainly through graduates of private colleges that combined osteopathy with
chiropractic and naturopathy. Such early colleges included the Health Academy in Melbourne (later renamed as the Chiropractic and Osteopathy College of Australia) founded by FG Roberts in 1959, and the Sydney College of Osteopathy founded by Alfred Kaufman in that same year (Goetjes, 2011).

The professions continued to grow, with chiropractic outstripping osteopathy, and following public and medical urging a Committee of Inquiry was set up by the Federal Minister of Health Dr Everingham in 1974. The inquiry, named after the chair, Professor EC Webb, produced a report that recommended statutory registration for chiropractic and osteopathy and the setting up of tertiary training (Webb, 1977). Acts were passed in each state, starting in Victoria in 1978, closely followed by NSW in 1979 and then other states. These acts and the boards governing them were commonly named chiropractic alone. In many cases this progressed to chiropractic and osteopathic, and finally in the 1990s the professions became separate in Act and governing boards. The osteopathic profession was nationally registered and the Osteopathy Board of Australia was formed as the Health Practitioner Regulation National Law Acts that were passed in 2009-2010.

The emergence of unorthodox medical systems like osteopathy in Australia during the 1960s and 1970s was in direct contrast to the rise of the dominance of biomedicine in western societies (Baer, 2009). Both osteopathy and chiropractic were labelled alternative medicine during this period of development. As osteopathy and chiropractic were related in both educational institutions and regulatory bodies, a perception of their being the same profession emerged. As these professions became known for their use of manual therapy for painful musculoskeletal problems, they developed a more ‘complementary’ position in the health workforce, a term that had less political divisiveness than ‘alternative’ (Coulter, 2007). Osteopathy separated from chiropractic to form a more clear identity and in the last two decades has occupied what Baer calls “a niche between biomedicine and complementary medicine” (Baer, 2009, p28).

2.2.3 Professional scope of practice

The concept of a scope of practice is an essential part of a profession’s role in a pluralistic health service. It is defined in the McGraw-Hill Concise Dictionary of Modern Medicine (2002) as:
The range of responsibility, the types of patients or caseload, and practice guidelines that determine the boundaries within which a physician, or other professional, practices.

So the definition differs depending on the level and type of regulation within a jurisdiction. Health professionals who are regulated by statute may have their title and/or activities protected by law, and penalties exist for non-regulated professions who trespass into the scope of practice of registered professions or use their title unlawfully (Weir, 2000). In recent times, registered health professionals have expanded their practices to encompass tasks that are required by the healthcare sector, so the rigid boundaries of scopes based on activities have become less well defined (Wardle, 2016).

The development of osteopathy differs between the profession that is inside and outside its founding nation (as discussed in Chapter 1). In the US, osteopathy developed within a relatively unregulated medical system until the Flexner Report of 1910 (Baer, 1987; Peterson, 2003). This report was the pivot for a revolution of standards in medical education and pushed all medical schools towards curricula underpinned by biomedical science, causing a rift in the osteopathic community, including a banishment of its founder AT Still to the periphery (Peterson, 2003). His spiritualist leanings were not considered a proper fit for an emerging school of medicine although his definition of osteopathy reflected his respect for science: ‘osteopathy is that science which consists of such exact, exhaustive, and verifiable knowledge of the structure and function of the human mechanism…’ (Still, 1908).

Baer (2006) described the historical development of osteopathy in the US as a parallel system, whereas in Australia it evolved into a full professionalised heterodox (i.e. not conforming to the mainstream) medical system.

Many proponents of osteopathy have pointed out that scientific theory does and should underpin practice (Fryer, 2008; Lucas & Moran, 2007a). This is especially true of the scientific disciplines of anatomy and physiology in the formative years, and the prioritising of science continues today. In the post-war years of the 1950s-60s research was seen as a vital ingredient in the progress towards full scope medical practice in all states of the union in the US (Earley & Luce, 2010; Licciardone, 2007a). Stakeholders in osteopathy like the national professional associations and regulatory bodies are unanimous about the need for knowledge generation, investigation of current research and integration of these into practice (Australasian...
2.2.4 Current status and challenges for the future.

A worldwide survey was conducted in 2012-13 by the Osteopathy International Alliance, an organisation of educational and professional stakeholders in osteopathy (Osteopathic International Alliance, 2013), that established the profile of the global profession for the first time. The survey encompassed all of the countries where osteopathy was a licensed or registered profession and included unregulated jurisdictions, although some unregulated countries with very small numbers of osteopaths did not respond. The OIA developed a two tiered system for the profession due to the differing scope of practices of US and non-US osteopaths, where osteopaths are the limited scope tier, and osteopathic physicians are the full scope tier. The report estimated that there were 130,850 osteopaths worldwide, of whom 87,850 were osteopathic physicians with full medical license. There was an estimated tripling of worldwide numbers in the preceding decade, predominantly in the US and France.

The international profile of the osteopathic profession is progressing in terms of practitioner numbers and geographic locations. It appears as both a parallel medical profession in the US and a marginalised healthcare profession elsewhere, and there is evidence that it is undergoing a process of mainstreaming (Baer, 2009), for example the establishment of university education, profession-specific peer reviewed international journals, and subsidy in public health systems (Orrock, Lasham, & Ward, 2015). There is a clear challenge for the osteopathic profession if it is to establish its place as a modern healthcare profession. There needs to be foundational work on the underpinning philosophy and how it influences the application of science as well as ongoing development of knowledge that is specific to the osteopathic profession. Providing a clinical service with satisfied clients, and cherry picking of other professions’ research findings is insufficient to meet the requirements of a modern health profession, as the very definition of a profession includes having a specialised body of knowledge (Hilton 2007). This is particularly true in an era of healthcare that has identified an evidence base as vital to ensure patients receive the best and most cost-effective care in an expanding marketplace of healthcare providers.
2.3 Evidence in healthcare

2.3.1 Introduction

The concept of evidence is an ancient one, and forms the basis for all activities involving justice. The Oxford Dictionary (2016) defines evidence as ‘the available body of facts or information indicating whether a belief or proposition is true or valid’, and the word is derived from the Latin *evidentia*, from *evident* - obvious to the eye or mind.

What is obvious to the eye or mind depends on the epistemological stance one takes with regards to the level and type of evidence required to demonstrate a truth. What evidence is needed to establish the risks and benefits of a healthcare intervention is in part an ethical question, as the delivery of healthcare to a population should be based on ethical principles. This principle of ‘to do good, and not to do harm’ was thought to be first outlined in late fifth century BC by the so-called father of modern medicine, Hippocrates in his ‘History of Epidemics’ and at the very least this requires that each intervention should have a consideration of the risk and benefits of its application (Sokol, 2013). Although this phrase does not appear in the Hippocratic Oath, and there is some controversy about the origin of the exact phrase (Sokol, 2013), the reference to prioritising respect and care for patients and minimising the harm are foundations of modern healthcare. These bioethical standards are included in the principles of beneficence for giving benefit, and non-maleficence for doing no harm. Sokol (2013) states that there is commonly harm in medical interventions, and argues that harm-benefit analysis will involve value judgments about what constitutes an acceptable risk or an acceptable quality of life. The most ethical solution to a dilemma in clinical practice varies greatly based on the patient context, and Sokol (2013) suggests that “first do no net harm” might be a better aphorism (Sokol, 2013).

Building evidence of benefit and harm of medical and health interventions has not always been based on scientific principles. A summary of the history of evidence in healthcare is warranted to understand the modern concept of evidence based practice.

2.3.2 History of evidence

Before the Renaissance truth was the preserve of the clergy and authority was the only source of new knowledge. In the era of pre-scientific medicine and healthcare,
practitioners relied on experience to make decisions - the more experienced, the more likely an expert would be to know how to solve a clinical problem – a model of “eminence-based practice” (Isaacs, 1999 p1618). The Greek philosopher and physician Galen of Pergamon (129-219AD) explored the conflict between practising based on either reason or experience alone in his essay On Medical Experience, concluding that both were needed for good outcomes (Daly, 2000). The literature base in medicine and healthcare depended on textbooks written by esteemed clinicians, and each edition of the text was updated with new knowledge derived from their practice experiences. As increasing scientific appraisal and experimentation occurred, textbook information became rapidly out of date. This dependence on experience was flawed as individual practitioners could have biases and habitual practices (Hoffman, 2010; Oxman & Guyatt, 1993). Common errors of reasoning can arise from heuristics (mental shortcuts that can result in faulty decision making) and biases (faulty beliefs that lead to incorrect decisions) (Elstein, 1999, 2009). Examples include practitioners underestimating the prevalence of conditions because they are ordinary and overestimating the prevalence of unusual or well publicised ones. Bias can occur when gathering information from the patient: for example, the order in which it is collected can affect how much weight it is given (Elstein, 1999), or there can be confirmation bias where the questions are seeking to confirm a hypothesis rather than expanding the scope of questioning to challenge it.

The modern birth of the use of evidence in healthcare practice is reportedly the result of the work of both the French physician Pierre Louis (1787-1872) and the English doctor Thomas Beddoes (1760-1808) (Goodman, 2003; Morabia, 2009). Dr Louis questioned the 2000 year tradition of the use of venesection, or bloodletting for the treatment of diseases like pneumonia and tuberculosis. He used a simple statistical method to compare outcomes of patients using a control group, proving that it was harmful practice. In a similar era, Dr Beddoes established a scientific analysis in his study of the use of medical gasses, and criticised the expert-based medical practice of the day (Goodman, 2003).

This period of the rise of science in medicine challenged the historical role of the expert. Goodman (2003) explored the use of expertise in the context of evidence in healthcare, and pointed out the perennial distinction between knowledge and skills that has engaged philosophers from Plato to Chomsky. The issue is that vast reservoirs of knowledge in an expert may not translate into practice, and in many
cases an individual is designated an expert by a group or committee of already designated experts, which can lead to a bias. Clinical expertise is the practical arm of the knowledge base that precedes and integrates with it, especially in the speed and accuracy of solving complex problems.

A major figure in the focus on evidence in medical practice in the twentieth century is the Scottish physician Dr Archie Cochrane (1909-1988). Dr Cochrane was interned as a prisoner of war in Greece and Germany in the second World War and worked as a camp physician. He became dissatisfied with the interventions he had to use, stating ‘I knew that there was no real evidence that anything we had to offer had any effect on tuberculosis, and I was afraid that I shortened the lives of some of my friends by unnecessary intervention’ (Cochrane, 1972, p6). He witnessed the surprising level of ‘re recuperative powers of the body’ (p5) despite the lack of medicines and technical interventions in the camps, and also the side-effects of interventions that were dangerous and had a weak evidence base. Cochrane went on to a career in clinical and public health in the UK following the war, and developed many of the core concepts of clinical epidemiology, including promoting the importance of the randomised controlled trial (RCT). He was also part of the team who published the first RCT of the use of aspirin in vascular disease (Elwood et al., 1974). Cochrane was explicitly focused on the importance of producing evidence of both harm and benefit in order to avoid using dangerous interventions that had little proof of effectiveness, and felt that evidence was to be used to make decisions about whether an intervention would be necessary at all. He was also committed to social justice and found evidence for the negative health effects of lower socio-economic status (Cochrane, 1972; Greenhalgh et al., 2014; Zimmerman, 2013).

Cochrane’s advocacy of RCTs and the need for easily accessible reviews of multiple RCTs led to the setting up of the Cochrane Centre in 1992 in Oxford, funded by the British National Health Service under the directorship of Ian Chalmers (Chalmers, Dickersin, & Chalmers, 1992). This was followed by the establishment of the Cochrane Library database and the development of the international Cochrane Collaboration in 1993, all in his name. This latter development, now named simply Cochrane (http://www.cochrane.org/about-us), is a network of researchers, practitioners and stakeholders, and has 37,000 contributors from over 130 countries.
With the rapid accumulation of RCTs and the development of systematic reviews in this and other databases, along with the technological revolution and freely available information on the world-wide web, the challenge became translation of research into clinical practice in order to influence bedside care. An important series of publications that prepared the ground for the integration of science into practice was physician and mathematician Alvan Feinstein’s series in the Annals of Internal Medicine that defined the field of clinical epidemiology (Feinstein, 1968a, 1968b, 1968c; Sur & Dahm, 2011). Another pivotal publication that established guidelines for translating bio-statistical findings from scientific research into clinical practice was a textbook published in 1982 called Clinical Epidemiology: The Essentials authored by Suzanne Fletcher and Robert Fletcher, and now in its fifth edition (Fletcher, 2013; Sur & Dahm, 2011). As the inclusion of this new discipline of clinical epidemiology into medical curricula grew, a movement began to take shape at McMaster’s University in Canada in the 1990s.

2.3.3 Evidence-based medicine

One of the medical academics at McMaster University, Dr Gordon Guyatt, coined the term evidence-based medicine (EBM) to encompass the scientific and critical appraisal skills he was teaching his students. The work of the academic group at McMaster, led by clinician and biostatistician David Sackett, resulted in the first published definition of EBM in 1996 (Sackett et al., 1996, p71). A full quotation is offered here in order to discuss and critique aspects of this definition:

Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care. By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centred clinical research into the accuracy and precision of diagnostic tests (including the clinical
examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens.

The words ‘conscientious’, ‘explicit’, and ‘judicious’ refer to being systematically thorough, clear-cut and using good judgement in the use of the evidence. These words leave the control over the use of the published evidence in the hands and mind of the educated reader. The definition has been concisely summarised as three intersecting circles of practising EBM (Spring, 2007) (see Figure 6).

![Figure 6 Three aspects of evidence-based clinical practice](adapted from Spring (Spring, 2007)

The weighting of each of these three aspects of EBM is not clear and has been much debated. A conflict has emerged between those who have been educated under the eminence-base of experts and the new guard of clinicians who have been trained in the use of critical evidence-based literature (Karthikeyan & Pais, 2010; Miles, Loughlin, & Polychronis, 2008). Some authors argue that the patients context can be so complex and individualised that simple algorithmic clinical reasoning may result in limited, and some would say erroneous, care (Greenhalgh et al., 2014; Sur & Dahm, 2011). It has also been pointed out that the three intersecting circle description of EBM misses the integration of characteristics of the practice in which the clinician works (Hoffman, 2010).

A hierarchy of levels of evidence developed within EBM based on work done in clinical epidemiology during the 1980s, in order to guide clinicians about judging the ‘best available research evidence’. The hierarchy ranks the various sources of evidence (an example is provided in Figure 7), and places systematic reviews of
multiple RCTs at its highest level. In early versions, there was a focus on intervention studies for diseases and conditions, but the most recent versions include diagnostic processes and risk of harm from interventions. These hierarchies have many variations, depending on the research question and the type of data produced (Oxford Centre for Evidence-Based Medicine - Levels of Evidence Working Group, 2011; Sackett & Wennberg, 1997).

![Hierarchies of Research Designs & Levels of Scientific Evidence](image)

**Figure 7 Levels of Evidence (Forrest and Miller, 2002)**

The middle levels of the pyramid have a number of observational clinical research methods that may not have the full rigour of randomisation or control, like case series and cohort studies. Cohort studies examine a group of people who are linked together by a factor under analysis — for example by disease, their age, or treatment received. The cohort is followed for a length of time to explore outcomes. This approach can be retrospective or prospective, and is non-randomized and so is less rigorous for outcome studies compared to RCTs. Matched cohort studies are considered valuable scientific evidence when exploring risk factors for disease, but they require large group numbers and long time periods to establish valid results (Anglemeyer et al, 2016).

A debate has followed the implementation of such a hierarchy of evidence. Murad and colleagues (2016) have pointed out that systematic reviews should not be a layer of the pyramid as they are not research studies but are methods for synthesizing research. Others have argued that complex interventions such as those from CAM do not fit neatly into the levels due to methodological issues inherent in RCTs (Walach
et al, 2006). The lack of qualitative studies has also attracted criticism (Merlin et al, 2009), and more current approaches to EBM have turned away from a hierarchy to tabulated forms of differing forms of evidence (Oxford Centre for Evidence-Based Medicine - Levels of Evidence Working Group, 2011).

Translating published findings into practice depends on the clinician being able to read and critique published reports. This activity requires, in particular, the skills of critical thinking and literature appraisal. A series of twenty five educational articles supporting these skills appeared in the Journal of the American Medical Association between 1993 and 2000, starting with an introduction by the founders (Oxman, 1993). Hoffman and co-authors (Hoffman, 2010) have summarised the elements that need to be critically appraised in the research literature as internal validity, impact and applicability. Internal validity refers to the trustworthiness of the evidence in relation to how the study’s methodology was established and applied – this is further discussed in the next section. Impact is concerned with the importance of the findings in relation to its clinical application. Finally, applicability is whether the findings can be applied to an individual patient - this step can be called external validity or generalisability. The time, effort and skill required to assess multiple papers is beyond many clinicians, hence the summaries and guidelines that have been developed that summarise risks, benefits and costs.

2.3.4 Evidence-based practice

The term evidence-based practice (EBP) appears to have been used interchangeably with EBM, with more focus on patient care and in professions other than medicine (Hoffman, 2010). Some authors have suggested variations to the terms EBM and EBP, including evidence-informed practice. There is some evidence that practitioners have positive attitudes towards EBP, but the translation of its use into practice has been mixed (Lizarondo, Grimmer-Somers, & Kumar, 2011). This translation is difficult in areas of healthcare that are “research emergent”- those where there is a paucity of evidence available to support or refute its use in practice, especially when the research evidence does not match the real-world of practice. It is reported that this lack of research evidence can be due to lack of funding, a lack of solid foundation in training of researchers in the field (Pager et al., 2012; Pickstone et al., 2008). A number of authors have also discussed the problems of translation into practice where evidence does exist (Kallassian, Dremsizov, & Angus, 2002).
Kalassian (2002) outlined three barriers to translation of research into practice. First, where no evidence based guidelines exist, second where the clinician may not have the skill to interpret the evidence, and third where the clinician rejects the evidence as not applicable to their practice. The Cochrane collaboration and EBM movement have focused on the first two barriers with some success. Lack of credibility in research findings, particularly where the clinician struggles to apply the findings with the practice and individual patient context, remains a major problem to solve (Ioannidis, 2006; Wallace, 2013). The lack of evidence for or against an intervention or service is not the same as evidence of a lack of benefit or harm. The clinician in an era of EBM is primarily being prompted to be aware of what evidence exists and, where appropriate, apply and integrate that knowledge into the clinical reasoning for each patient.

2.3.5 Criticism of EBM

Critics of the EBM movement have focused on a range of issues. A number of articles were published in the Lancet criticising both the authoritarian nature of the movement (Fernandez et al., 2015) and methodology issues such as the strong focus on internal validity of RCTs while appearing to neglect external validity and generalisability (Rothwell, 2005). Others point out that proponents of novel or non-commercial interventions can struggle to mount the funds required for large clinical trials, and so may be considered non-evidence based (Greenhalgh et al., 2014; Sur & Dahm, 2011). There is some evidence that industry funding of RCTs produce more positive outcomes and that a publication bias towards positive outcomes exists (Bekelman, Li, & Gross, 2003). A movement to solve this publication bias has resulted in the CONSORT (Consolidated Standards of Reporting Trials) guidelines to ensure that only the complete results of listed clinical trials will be published (Moher et al., 2010).

Other reported problems with the EBM movement include that third party payers may use the EBM movement principles to refuse claims for treatments that may be reported as beneficial for a specific patient cohort, but not supported by evidence that ranks higher in the hierarchy of evidence (Fernandez et al., 2015; Sur & Dahm, 2011). Others argue that the practice of EBM reduces the evidence pool in a skewed way where only explanatory RCTs become reliable evidence (Fernandez et al., 2015). The hierarchy of evidence in EBM has RCTs at a high point predominantly because they are a method that purports to reduce bias. However, Borgerson (2009)
points out that cohort studies which are placed lower on the evidence hierarchy than RCTs can manage bias just as well, and that bias may be limitless, which refutes the need for a hierarchy (Borgerson, 2009).

Greenhalgh and colleagues made the point in 2014 that a renaissance of the EBM mission is required in order to allow more contextualisation of research findings, and to give guidance to clinicians so that evidence can be more usable (Greenhalgh et al., 2014). The authors urge a move towards deeper research into the patient experience of healthcare, and increased respect for the primacy of the therapeutic relationship and the individualisation of the patient’s management based on clinician judgement (Greenhalgh et al., 2014). Kelly et al (2015) argue that values are neglected in the EBM movement, and have demonstrated ways in which values influence many aspects of how EBM can be practised. An example is whether the common public good is considered when the choice is made about what research questions to ask when much clinical research is funded by corporations for specific profitable interventions – two of the founders of the EBM movement wrote a humorous satirical piece in the British Medical Journal addressing this very concern of profit-based science (Sackett, 2003). Another example is the inherent epistemic consequence of trials that may prove a solution for the statistical majority, but not the minority (Kelly, 2015). This ethics-based critique is backed by an editorial in the American Medical Associations Journal of Ethics (Rysavy, 2013). Rysavy (2013) explores a number of ethical problems with the EBM approach, including the inherent authority of the producers and disseminators of evidence, and reminds his readers of the William Osler quote, that medicine is ‘a science of uncertainty and an art of probability’.

In a highly critical series of articles, including the tenth Thematic Edition in Volume 13 of the Journal of Evaluation in Clinical Practice, published in August 2007, Miles and fellow authors deconstructed the EBM movement, and found that it is not evidence-based itself. A number of authors state that the movement is based on scientism and reductionism, and that statistical findings neglect the person and the centrality of the healthcare consultation. They conclude that (Miles et al., 2008, p641):

The advent of patient centredness and shared clinical decision making and the rise in importance of genomics and translational sciences is rapidly marginalising EBM, so that the concept of EBM is losing influence as the promises and potential of personalised medicine are increasingly
Recognised. EBM was initially known as ‘clinical epidemiology’, the application of epidemiological data to clinical practice. That is what it was, what it always has been and that is what it remains.

Researchers and practitioners from the field of complementary and alternative medicine have also raised criticisms of the methodology of RCTs, where the active intervention is limited to singular aspects of practice and outcome measures may not be broad enough to encompass more holistic results from therapy (Barry, 2006; Fonnebo et al., 2007). Clinicians using more holistic approaches to healthcare have struggled with how to quantify a complex outcome such as wellness, and this is reported as a significant barrier to constructing outcomes from RCTs (Barry, 2006).

Despite these criticisms, a well-designed and executed RCT has remained the gold standard of establishing the efficacy or effectiveness of healthcare interventions internationally (Fletcher, 2013; Hoffman, 2010; Kelly, 2015; Moher et al., 2010; Therapeutic Goods Administration, 2014). As a result of the evolution of the EBM movement over the past two decades, there has been a more concerted focus on the design of RCTs and the skill of translation of those findings into a clinical reasoning model (Sniderman, LaChapelle, Rachon, & Furberg, 2013) that encompasses the three aspects as the founders of EBM had proposed.

The following sections of this chapter look at the principles of the RCT method and seek to explore the status of clinical evidence of the osteopathic approach to healthcare, with particular reference to its applicability, external validity and generalisability.

2.3.6 Clinical Trials

2.3.6.1 Introduction

The gold standard of establishing the effect of a clinical intervention has become the RCT. Jadad (1998) reported that the earliest recorded clinical trial was by Daniel of Judah around 600BC, who compared a vegetarian diet with the standard Babylonian diet over 10 days, although this trial was not a RCT and had multiple biases, and was published in the Holy Bible. In 1747 James Lind established that an intake of oranges and lemons was an effective way of preventing scurvy in sailors (although it took 50 years for the Royal Navy to follow the evidence and supply lemons to its ships) (Jadad, 1998). A famous trial conducted by Ignaz Semmelweis in 1847 demonstrated
a 50% drop in maternal mortality by the simple practice of comprehensive hand washing of the physicians and students who moved between the cadaver laboratory and the birthing rooms (Jadad, 1998).

The basic elements of a RCT are that the researchers (investigators) recruit a group of people from a population (participants or subjects) to examine whether an intervention changes certain events (outcomes) compared to another intervention (control) or a pretend intervention (placebo or sham). The results are expressed in numbers, so it is called a quantitative study. The RCT is termed an experimental comparative study because the investigators influence the method of administering the intervention. If the investigators do not influence this aspect of the trial, it becomes an observational study, where the data can be gathered from the past (retrospective), planned for the future (prospective), or from a sample of the population (cross-sectional). Examples of this type of research are cohort studies, case control studies and surveys. Research can also be conducted based on qualitative methods that seek to observe and interpret events in the natural setting in order to develop an understanding of the meaning of events and the experience of participants (DePoy, 1994; Hoffman, 2010; Jadad, 1998, 2008). This thesis utilises both quantitative and qualitative methods and this will be outlined in the following chapter. As the RCT is the gold standard of clinical research it will be the focus of this section of the thesis, and despite having advantages for an emerging research base, the observational studies will not be analysed so the focus can be on the gold standard.

The main goal of the RCT method is to minimise the bias that can influence results from both the investigators’ and subjects’ behaviours and actions – a central principle of the scientific method that gives the results more certainty (Jadad, 1998, 2008). Bias can arise from a number of aspects of a RCT (Hoffman, 2010):

- Sampling bias – where the subjects recruited and selected differ systematically from the population under study, prevented by careful sampling;
- Allocation bias – where the subjects allocated to active and control groups are systematically different, prevented by randomisation;
- Maturation bias – where changes in subjects happen naturally over time, prevented by having a control and randomisation;
- Measurement (ascertainment) bias – errors and expectations from investigators – prevented by blinding all involved;
- Attrition bias – subjects who withdraw are different from those who stay – prevented by reducing attrition and analyse by intention-to-treat;

- Placebo effect – improvement by expectation – prevented by blinding and control receiving a very similar intervention;

- Hawthorne effect – improvement by attention from investigators – prevented by treating all groups the same.

Various aspects within the RCT method work to minimise these and other biases. The following section outlines the principles of the RCT in further depth in order to analyse the arguments in this thesis.

2.3.6.2 Design

There are a number of factors that affect the design of a RCT, including what aspect of the intervention is being evaluated, how the intervention is given, and the number of participants available. With regards to the aspect of the intervention being studied, an RCT can either be explanatory or pragmatic. Explanatory trials address whether an intervention works or not in experimental conditions – they are designed to test the causal relationships in the hypothesis. This design looks to achieve a clear result with very strict inclusion criteria, using placebos as much as possible, and an outcome measure that is highly valid and reliable. Pragmatic trials, on the other hand, while still looking to determine that an intervention works, place it in conditions that mimic normal real-world clinical practice. This design includes a broad group of subjects, has an active control in order to clarify choice between interventions, and includes broad outcome measures (Godwin et al., 2003; MacPherson, 2004).

A primary difference between these research designs is the balance between internal and external validity. Internal validity relates to the trial design and its rigour in minimising bias, and external validity relates to the strength of the applicability or generalisability of the findings to the general population (Godwin et al., 2003; Rothwell, 2005). An explanatory trial will aim for a high level of internal validity, but as the method is simplified to reduce bias it can lose external real world validity. On the other hand, if designed on the basis of the usual clinical practice pragmatic trials will reach high external validity, at the expense of some aspects of the internal rigour (Patsopoulos, 2011; Rothwell, 2005; Zwarenstein et al., 2008).
The contrast between these designs brings forward the difference between the aim of establishing either efficacy or effectiveness of an intervention. Efficacy is most often investigated in an explanatory trial, as it tests the intervention in ideal circumstances, where the intervention and inclusions are tightly controlled. Effectiveness is more commonly investigated in pragmatic trials as it is tested in real life (Hoffman, 2010; Jadad, 2008).

Guidance for researchers designing pragmatic trials has progressed over the past decade. There are a number of quality indicator guides published that provide templates for researchers to strengthen their design: the PRECIS-2 (Loudon et al, 2009) and the pragmatic extension to the CONSORT statement (Zwarenstein et al, 2008). Examples of design issues that require specific attention are recruitment and outcome measures. Recruitment in pragmatic trials can require a different approach as subjects receiving their normal care may have modified informed consent requirements, and practitioners delivering the intervention have to be monitored for their adherence to the protocol (Ford and Norrie, 2016). Outcome measures in pragmatic designs can suffer from increased missing data compared to explanatory trials because of the commonly used mailed or web-based surveys, and designers need to offer alternative methods of collecting data to ensure robust response rates (Ford and Norrie, 2016).

Designs can be parallel, cross-over or factorial with regard to how an intervention is applied (Jadad, 2008). In parallel design each participant only receives one of the interventions (active or control); in cross-over design the participants receive both interventions in successive periods, and a factorial design is when two or more interventions are used in various combinations of one another. Parallel designs are most common as they are more simplified and clearer in results. The results of a crossover design can be weakened by the carry-over effect of the first intervention into the second period with the new intervention, making it difficult to separate the individual effects (Hoffman, 2010; Jadad, 1998). If the researcher can examine this carry-over effect and account for it, the crossover design can provide strong evidence for effectiveness, as it allows comparison at an individual level (Elbourne et al., 2002). Also, it can reduce the number of participants in a trial (Elbourne et al., 2002).

Finally, the RCT design is affected by the number of participants. There are trials of one participant (n-of-1), which use a crossover design on one patient, up to trials of
many subjects (mega-trials) with a pragmatic design on large populations (Jadad, 2008). The sample size can be fixed at a certain number if a statistical calculation (power) is able to be used on the variability of the outcome measure.

2.3.6.3 **Blinding**

Blinding is when investigators and subjects in the trial are unaware of what group allocation each subject is in. One assistant can manage the allocation sequence, but should be uninvolved from then on and keep the allocation secret. The people administering the interventions, the subjects, and the people who assess and record the outcomes could all be blinded making a triple blinded study. Because these same people often carry out two of these tasks, many trials are able to be double-blinded (Hoffman, 2010; Jadad, 2008). There are also open RCTs, where everybody knows which intervention is given, for example in trials of surgery. In trials where one of the groups of individuals are blinded (a single blinded RCT) it is usually the subjects or the assessing investigators who are able to be blinded. This is common in trials of hands-on interventions, where the people treating will be fully aware of what is an active treatment and cannot be blinded. The concept of dual blinding has been introduced (Caspi, Millen, & Sechrest, 2000), where the subject and the assessor are blinded when the person treating cannot be blinded, but this has not appeared to have gained any momentum in the published literature.

2.3.6.4 **Randomisation**

This process ensures that all subjects have the same chance of being allocated to each of the study groups, thus minimising the risk of ascertainment bias and placebo effect. The purpose is to create homogenous (similar in characteristics) groups at the baseline or commencement of the trial. Randomisation can be stratified if it is important in the study design - for example, if there needs to be similar numbers in age categories. There are pseudo-random methods, for instance, allocated on their odd or even birth year, but these designs cannot be called RCTs and run the risk of being predicted by people involved in the trial. Randomisation can be as simple as flipping a coin or more technical using computer-generated sequences (Jadad, 2008).

2.3.6.5 **Control**

The use of a control is common in much experimental scientific method. In RCT design, establishing a control group has the effect of minimising the influence of
confounding variables as one group receives the intervention and one does not, making the results of the experiment valid. The types of control can be negative (no effect expected) or positive (predictable effect established). In drug/medication trials, a placebo pill that is matched to the active drug is a common and effective method. Control is more difficult in other interventions where the subject can recognise whether they are in an active group or not, for example in hands-on interventions (Birch, 2006). Control groups should have a number of characteristics: the control intervention should be acceptable to the subjects to ensure blinding, it should not have any curative potential or small effects not related to the study outcome measures, and all the conditions should be the same as for the active group (Lin, Chen, Huang, & Chen, 2012).

Sham interventions have been used in manual therapy trials, with variable credibility (Licciardone & Russo, 2006; Noll, Degenhardt, Stuart, McGovern, & Matteson, 2004). In a study of the effect of osteopathic manipulative therapy on residents of an aged-care home, Noll et al. (2004) studied whether the subjects knew if they were in the active or sham groups and found no difference in outcomes from that knowledge, advising that sham controls need to be carefully designed. The results can be confounded if the subject knows they are receiving the active treatment, thus weakening the blinding, and care should be taken to ascertain whether the subject has previous experience with the active treatment and recognises it (Licciardone & Russo, 2006). There is also the wait list control design where the subjects in the control group have no intervention until the active group have completed the intervention, and then receive the active treatment (Hart & Bagiella, 2012). This has attracted criticism owing to potential over-estimation of intervention effects as subjects expect to get the active treatment if they wait, and so improve (Cunningham, Kypri, & McCambridge, 2013).

2.3.6.6 Outcome measures

The decision about what measures will be used to assess the efficacy or effectiveness of an intervention requires a number of considerations. Chapman et al. (2011) in a systematic review of outcome measures for chronic low back pain advised that appropriate measures should be chosen that are valid, reliable and responsive to change, ones that are most important to patients, and with a careful consideration of the number of measures required and their costs. The issue of using multiple outcome
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measures has some critics (Choudhary & Garg, 2011), with the CONSORT statement explicitly warning that multiple primary outcome measures can result in errors of interpretation (Moher et al., 2010). The more outcomes that are assessed, the greater the risk of the study reporting false positives and there may be a bias towards reporting only positive results (Jadad, 1998). Most RCTs have a single primary and multiple secondary measures (Choudhary & Garg, 2011).

Research into pain interventions generally have primary measures of the level of pain using the numerical rating scale (NRS), but when the focus is on chronic pain the outcome measures often include an assessment of quality of life as there is evidence that these measures are more central to the recovery of patients (Dworkin et al., 2005; Maughan & Lewis, 2010; Williams et al., 2007). The most important risk factors for back and neck pain are reported as psychosocial (Waddell, Main, Morris, Di Paola, & Gray, 1984), with the result that many modern RCTs of interventions in pain syndromes include outcomes like psychological distress (Maughan & Lewis, 2010). There is some evidence for a psychological effect from manual therapy (Bishop et al., 2015), and researchers have been urged to include secondary measures in this domain (Bishop et al., 2015; Dworkin et al., 2005). There are also patient-centred outcome measures that allow subjects to design individualised expected results (O’Brien et al., 2010). For example, O’Brien et al. (2010) developed outcomes based on the level that subjects with fibromyalgia and back pain expected to reach for a treatment to be deemed successful in domains of pain, fatigue and distress.

Economic outcome measures are used regularly in comparative trials to assist in questions of healthcare utilisation and lost productivity, especially in patients with back pain (Dagenais, Roffey, Wai, Haldeman, & Caro, 2009; Kim et al., 2016; Tsertsvadze et al., 2014). A number of authors suggest that all costs associated with the intervention, the level of absenteeism from work, the follow up and adjunctive treatment costs should all be included to obtain a valid comparison (Dagenais et al., 2009; Tsertsvadze et al., 2014).

Researchers in the CAM field have reported that the effects of the interventions used can be broad and encompass such concepts as quality of life and general wellness (Sikorskii, Wyatt, Victorson, Faulkner, & Rahbar, 2009). Whilst there are established tools for measuring quality of life (or health-related quality of life for the focus of this thesis), such as the Roland–Morris disability questionnaire (RMDQ) and the
Oswestry disability index (ODI) (Maughan & Lewis, 2010), there are no well validated tools for such an ill-defined concept as wellbeing (Parkinson, Sibbritt, Bolton, van Rotterdam, & Villadsen, 2013; Sikorskii et al., 2009). Hsu, Bluespruce, Sherman, and Cherkin (2010) found a number of unanticipated results from CAM interventions in back pain, including increased hope, positive changes in emotional states, changes in thinking that increased the ability to cope with back pain, increased energy, and dramatic improvements in health or well-being, and advise that a broad range of outcomes should be assessed.

Researchers investigating outcomes from osteopathic intervention have encompassed both pain outcomes and, more recently, quality of life measures (Cerritelli, Verzella, & Barlafante, 2014), and have explored methods of evaluating these broader outcomes (Licciardone, 2007b; Licciardone & Russo, 2006). An analysis of research into osteopathic healthcare follows (see 2.3.8).

### 2.3.6.7 Limitations of the RCT

The RCT is a powerful tool to research the effect of clinical interventions and is evolving in the era of EBM. It has been pointed out by a number of authors that the RCT in its pure form suits testing a research question that requires a statistically significant effect from a simple intervention in a homogenous subject group (Glasziou, Meats, Heneghan, & Shepperd, 2008; Jadad, 1998, 2008). As reported earlier in this chapter, critics of the EBM movement have focused on perceived deficiencies in the RCT, noting that in the real world of clinical practice people present with a number of complaints and co-morbidities, that the non-specific effects of the consultation including the environment and the therapeutic relationship play large roles in outcomes, and that clinicians often use multiple interventions to solve the multi-layered problem of the patient in front of them (Greenhalgh et al., 2014; Hawe, Shiell, & Riley, 2004; Miles & Loughlin, 2011a; Sniderman et al., 2013).

### 2.3.7 Researching complex interventions

This complexity of clinical practice has generated a discussion about the design of the RCT in the literature (Campbell et al., 2000; Glasziou et al., 2008; Hawe et al., 2004), and the term complex interventions has emerged as a focus for clinical researchers (Campbell et al., 2000; Paterson, Baarts, Launsø, & Verhoef, 2009; Paterson & Britten, 2004). Work has been done by the Medical Research Council in...
the UK which developed a framework for design and evaluation of complex interventions in 2000 (updated in 2008) that outlined a pathway for researchers to maximise both internal and external validity of RCTs in less simple clinical scenarios (Craig et al., 2008; Medical Research Council, 2000). The process included an initial phase called ‘modelling’, where a deep and systematic understanding of the complex intervention and its components is developed. The authors of this guideline advised investigators to use multiple methods like focus groups, preliminary surveys, case studies, or small observational studies (Medical Research Council, 2000). In this way the RCT would be designed on an authentic model of practice and aim to solve one of the critical problems in the practice of EBM - the transferability of findings from RCTs to clinical practice (Glasziou et al., 2008).

The focus of this current study is osteopathy and its evidence base. An analysis of the profession’s level of evidence and understanding of the specific components of the osteopathic intervention is important to underpin the aims of this current research.

2.3.8 Research into osteopathy

Osteopathy has developed primarily on the basis of eminence-based medicine from its foundation (Gevitz, 2001). It is odd that there has been a lack of clinical evidence to scientifically evaluate the osteopathic intervention, when the study of science and research has been present in the development of osteopathy since its early days, as expressed in this statement by Still (1910, p10):

An osteopath must be a man of reason and prove his talk by his work. He has no use for theories unless they are demonstrated.

The curriculum of osteopathic training institutions have included the basic and medical sciences since the advent of formal education (Lucas & Moran, 2007a), but the use of science to underpin practice has not appeared to create a quantum of clinical research specifically into osteopathic healthcare. This is especially true of research into the manual therapy techniques employed by osteopathic practitioners, termed Osteopathic Manipulative Treatment (OMT). Researching OMT as a singular intervention does not reflect whole osteopathic healthcare practice, but it is an identifiable characteristic of the profession internationally and it would make sense to focus on that component in a research strategy.
Earley and Luce (2010) described the history of research into osteopathy, reporting that in the first half of the twentieth century, a number of osteopathic researchers explored the diagnostic finding named by AT Still as the osteopathic lesion, or what is now termed somatic dysfunction. Louisa Burns did investigations during the first two decades of the twentieth century into neurology using rabbits to explore the reflex relationship of spinal lesions to visceral function, and JS Denslow and IM Korr completed seminal work during the 1940-50s on identifying palpatory findings in skeletal muscle that related to neurological reflex changes in the spinal cord (American Academy of Osteopathy, 1979). These projects were innovative and influential with regards to the biological underpinning of osteopathic diagnosis of somatic dysfunction, and were influential in osteopathic thinking for many decades into the later twentieth century. The findings of a neurological model for osteopathic diagnosis have been brought into question by a number of researchers recently (Fryer, Bird, Robbins, Fossum, & Johnson, 2010; Fryer, Morris, Gibbons, & Briggs, 2006; Van Buskirk, 1990) and there has not been significant work completed since on this aspect of osteopathic diagnosis.

Evidence for the clinical effectiveness or efficacy of osteopathic manipulative therapy (OMT) has been attempted over its history. A systematic review in 2011 (Posadzki & Ernst, 2011) looking for evidence in any musculoskeletal pain from the inception of the main databases up to 2010 found a lack of high quality trials that found a positive effect of OMT, and concluded that 'collectively, these data fail to produce compelling evidence for the effectiveness of osteopathy as a treatment of musculoskeletal pain’ (p290).

This review prompted a number of criticisms (Licciardone, 2011; Schwerla, 2012). Licciardone (2011) accepted that the findings for general musculoskeletal pain were weak, but claimed that his systematic review that found positive effects of OMT specifically in low back pain (Licciardone, Brimhall, & King, 2005) had more validity than what Posadzki and Ernst (2011) reported. Posadzki and Ernst (2011) replied that Licciardone’s review and meta-analysis included some weak and heterogeneous trials, and claimed that theirs had better validity. Schwerla (2012) stated that Posadzki and Ernst (2011) did not systematically search the trial databases and that they used a biased instrument in assessing quality. The Jadad scale that was used (Furlan, Pennick, Bombardier, & van Tulder, 2009) does rank the level
of blinding, which as mentioned in section 1.2.6.3 is difficult in trials of hands-on therapy and results in a lower score for those studies. Posadski and Ernst (2011) refuted the criticisms from Licciardone and Schwerla and stood by their findings.

The difficulty with blinding of the clinician will always weaken the internal validity of trials on manual therapy, and decreases the Jadad risk of bias score (Lewith, Walach, & Jonas, 2002; Licciardone & Russo, 2006). Strategies to reduce the variability of the intervention applied by each individual clinician can mitigate this variable, by training and creating a consistent intervention. Another strategy is to manage the subjects’ expectation and awareness of the active treatment compared to the control, by intake and end of trial interviews (Licciardone & Russo, 2006). The lack of a meta-analysis in the Posadski and Ernst (2011) review is a weakness of their conclusions, as a meta-analysis combines the effects from different trial sizes more rigorously than a simple vote count. The two trials that Posadski and Ernst (2011) did not include had positive effects of OMT on LBP, but one was a package of manual therapy and not OMT (Burton, Tillotson, & Cleary, 2000). The contrasting results of these two systematic reviews means that evidence for OMT in LBP is inconclusive.

OMT has been utilised for a number of conditions over its history apart from musculoskeletal pain, and some promising areas have emerged. There is moderate evidence for reducing the use of medication in pneumonia and preventing relapses in otitis media (Perez, Sneed, & Eland, 2012), but limited evidence for any other conditions.

A recent systematic review that looked more broadly at the evidence for manual therapies (Bronfort, Haas, Evans, Leininger, & Triano, 2010) concluded that spinal manipulation/mobilisation is effective in adults for spinal pain and headache, but inconclusive for other conditions, and that massage is effective in adults for chronic low back pain and chronic neck pain but inconclusive for other conditions. This systematic review was updated and extended in 2014 (Clar et al, 2014) and confirmed the majority of the Bronfort et al (2010) findings. The researchers found three exceptions where evidence moved from inconclusive to moderate: manipulation/mobilisation with exercise for rotator cuff disorder; spinal mobilisation for cervicogenic headache; and mobilisation for miscellaneous headache (Clar et al, 2014). For osteopaths, these findings help support their practice, but a clinician using
OMT may have a concern that spinal manipulation/mobilisation and massage individually do not reflect the full range of their practice.

A number of issues have been debated that act as hurdles to researching OMT as an intervention, well outlined by Licciardone and Russo (2006). The issue of being unable to blind the person who administers a hands on therapy means that single blind trials are common. The control arm of the trial has to be accepted as credible by the subjects, and could create a confounding influence if the subjects expected a hands-on therapy, so a sham control has to be carefully designed. The authors also point out that if an intervention normally embraces components of the therapeutic relationship and a range of psychosocial and lifestyle factors, separating the manual therapy of OMT from these aspects reduces the generalisability of the findings, and could be a barrier to transferability of the findings.

Many of these concerns regarding clinical evidence are similar to the CAM professions (Lewith et al., 2002), and a discussion of the merits of comparative effectiveness research and pragmatic trials has emerged (Coulter, 2011; Fonnebo et al., 2007). Researchers in CAM have been urged to establish foundational research in the philosophical basis and the characteristics of real-world practice before launching clinical trials and the search for biological mechanisms (Fonnebo et al., 2007).

A leading researcher in osteopathic medicine, John Licciardone, has put forward that the two priorities for the modern scientific progress of the osteopathic profession should be somatic dysfunction and the effects of OMT (Licciardone, 2007a, 2007b, 2008). In an editorial of the International Journal of Osteopathic Medicine, Lucas and Moran (2007b) stated:

> Without research the profession would not have begun, and without continued research there will be threats to professional autonomy, professional development, and to the ongoing viability of our education programmes.

There are a number of researchers in the field of clinical medicine pointing out that interventions need to be tested realistically, while still utilising the scientific method underpinning the RCT (Degenhardt & Stoll, 2011; Milanese, 2007). There are also questions of how to establish and apply a protocol in a pragmatic RCT that reflects
osteopathic practice (Kirsch, 2011) and is patient-centred (Moran, 2013). Osteopathic leaders are urging an evidence-informed practice to ensure the future of the profession (Degenhardt & Stoll, 2011; Leach, 2008; Lucas & Moran, 2007b; Orrock & Myers, 2013; Patterson, 2003). The profession requires urgent establishment of the whole nature of its particular approach to healthcare and a robust testing of its clinical effectiveness in common conditions.

2.4 Conclusion

The history and development of the osteopathic health profession has been outlined and an argument was put forward of the need for its evidence base to be developed further in order to establish the profession’s distinct place in healthcare delivery. I have explored the concept of evidence and placed it into the era of EBM, and looked specifically at the gold standard of clinical evidence, the RCT.

It is evident that the osteopathic profession requires a careful research strategy that includes establishing its clinical effectiveness that reflects its practice in the real world. The evidence of what the osteopathic healthcare service entails was lacking when this thesis commenced, so the foundations needed to be made. This led to the initial research question of what were the characteristics of this service, and this was answered in part by the findings reported in Chapter 4. Further questions followed from those initial findings regarding what evidence does the osteopathic profession have for its effectiveness in common presenting complaints, and what is the experience of practitioners and patients with the common presenting problem of providing and receiving osteopathic healthcare? This sequence of questions required a research design that was appropriate to supply answers, and this is explored in the next chapter.
Chapter 3 – Research Design, methodology and methods

3.1 Introduction

This chapter presents the overarching methodology that underpins this thesis and a summary of methods used in each study. The next four chapters 4-7 pertain to specific research studies and the specific methods of each study are described in those chapters in detail.

3.2 Philosophical assumptions that underpin the methodology

The epistemological stance that this thesis takes is one of empiricism with regards to how truth is discovered, and is based on the paradigm of pragmatism. Pragmatism can be seen as an extension of the radical empiricism described by one of its founders, William James (Hookway, 2016) as it places experience at the centre of the search for meaning, but rejects the dualistic choice between subjectivism and objectivism. Instead pragmatists view knowledge as both constructed and based on the world in which an individual lives (Teddlie, 2009). The aim of research within this paradigm is to see what works, what solves problems and what answers questions. As the first pragmatist Charles Sanders Peirce (1839-1914) expressed, pragmatism is concerned with the practical effects of what we discover (Hookway, 2016).

Pragmatism can be considered a stance at the interface between philosophy and methodology (Greene, 2003). The methodology that follows is pluralistic, taking aspects from both interpretive/subjective and objective methods of inquiry. Pragmatism has a dominant philosophical foundation in the mixed methods and methodological pluralism communities (Cameron, 2011; Johnson, 2010), and suits the real-world focus of this thesis – that of exploring the issue of producing evidence of authentic practice.

Taking an empiricist stance is logical when exploring healthcare practice, given that it is based on close observation of the characteristics and outcomes of people with health issues to resolve. The use of the word empirical has an interesting conflicting use in the modern day argument between proponents of conventional and non-
conventional (commonly termed Complementary and Alternative Medicine or CAM) health practices. Modern conventional medicine in fact has its historical roots in rationalism, using previously established facts and principles to reason. Modern biomedical science veered towards a strict version of empiricism in the latter twentieth century following the rise of clinical epidemiology (Fernandez et al., 2015; Newton, 2001), where only empirical research findings should be used in claims of benefit (Miles, 2009; Preference Collaborative Review Group, 2008). In this context empirical evidence meant findings that are based on the most rigorous clinical trial methods that remove any risk of bias and non-specific effects of the participants. On the other hand, non-conventional advocates from the CAM field have made their stance firmly in a broader based empiricism, claiming that evidence exists in the realm of practitioners who observe and record benefits in their patients, and over time develop a practice that is valid, as in the example of thousands of years of traditional Chinese medicine. Both use the term empirical but with very different interpretations of the meaning. Despite that apparent conflict in the use of the terms, empirical research is a guiding principle in all clinical research, as it includes random and then systematic observation of effect of interventions by individual practitioners, which leads to the development of questions, hypotheses, and a design of a testable intervention for clinical trials. This process has been termed the Empirical Cycle and was first enunciated by chess master and psychologist Adriaane de Groot in 1969 (de Groot, 2014) (see Figure 8). This continuum needs to integrate the observation and experience of practitioners in the development of research questions that are valid and in order for a clinical trial method to be authentic and translate to practice, as the originators of the evidence based medicine movement have declared (Sackett et al., 1996).

![The de Groot empirical cycle.](image from Tesseund/Daan/Wikimedia Commons)
Conducting mixed methods research with a stance of pragmatism has become more common and accepted (Hall, 2013; Johnson, 2010; Johnson, 2004; Morgan, 2007) as it allows a flexible analytic approach to be used to help describe the phenomenon under study. The linking of pragmatism and the methodology of mixed methods centres on what Morgan (2007) terms an abduction-intersubjectivity-transferability approach, in which reasoning moves back and forth between induction/deduction and subjectivity/objectivity, illustrating a pragmatic approach to the research practice itself. The following section looks more closely at mixed methods research, including its development and its applicability to this thesis.

3.3 Mixed Methods Research (MMR)

3.3.1 Introduction

MMR has been termed a third methodological movement, and has developed over the last three decades. The movement was underpinned by the need to resolve tensions between the two opposed methodologies in the paradigm wars (Gage, 1989) of the twentieth century – quantitative and qualitative methods. Rather than claiming to replace either of those dominant methods, proponents of MMR aim to draw on the strengths of both, while minimising their weaknesses (Johnson, 2004).

As far back as the late eighteenth century, Kant attempted to reconcile empiricism and rationalism in what has been called a proto-mixed methodological stance (Johnson, 2010), but it took until the mid- to late- twentieth century and the rise of qualitative methods in sociological and psychological research for the concept of MMR to gain impetus (Johnson, 2010). A comprehensive and commonly cited definition comes from Cresswell (2007, p5):

Mixed methods research is a research design with philosophical assumptions as well as methods of inquiry. As a methodology, it involves philosophical assumptions that guide the direction of the collection and analysis of data and the mixture of qualitative and quantitative data in a single study or series of studies. Its central premise is that the use of quantitative and qualitative approaches in combination provides a better understanding of research problems than either approach alone.

The claim that MMR can gain improved insight into a research subject is a central argument of the movement, and has been taken up by professionals from practice disciplines dealing with complex problems that simple deductive logic fail to solve.
Proponents of MMR claim that this approach can provide impetus for research in those disciplines dealing with complexity by acknowledging context, recognising individuality, being sensitive to recurrent patterns and seeking multidimensional results (Cresswell, 2011; Evans et al., 2011). These are all aspects of modern healthcare, especially with more complex interventions (Craig et al., 2008; Medical Research Council, 2000). Investigators in health services research were early supporters of MMR based on the perceived limitation of the quantitative method to deal with the complexity of modern healthcare (O'Cathain, Murphy, & Nicholl, 2007).

Cresswell (2011) outlined a number of research problems that suit taking a MMR approach. The researcher may face a situation where using one data source is insufficient to tell the whole story, or to give a full solution to the problem. Additionally, there may be a need to explain initial results, especially if they are incomplete or provide only basic descriptive data. Exploratory findings may need a second method to provide enhanced external validity and generalisability. These problems can result in a multiphase project that gradually deepen the answer to the research question.

(Bryman, 2006, p98) puts forward central questions to be considered by the investigator as preliminary steps that help guide their choice of research design:

- Are the quantitative and qualitative data collected simultaneously or sequentially?
- Does the quantitative or the qualitative data have priority?
- What is the rationale for integrating the data – for example, triangulation, explanation, or exploration?
- At what stage(s) in the research process does multi-strategy research occur?
- Is there more than one data strand?

The investigator needs to clarify these issues in order to design an appropriate method that will best answer the research question. Following Bryman’s questions for this current study, the research questions were developed and the data collected sequentially, the data sets had equal priority, the rationale for integration was done for triangulation (this will be explained in the next section), the use of multi-strategy occurred following the initial quantitative data collection, and there is more than one
data strand. The following section looks at the process of integration of the strands in MMR.

3.3.2 Integration of data

The process of MMR is characterised by the fact that at some stage the quantitative and qualitative strands will be integrated. Bazeley (2009) describes the interaction of the two dominant methodologies as a continuum, and discusses the value of integrating the two. Woolley (2009, p7) defines integration in MMR with a strongly pragmatic stance:

Integration can be said to occur to the extent that different data elements and various strategies for analysis of those elements are combined throughout a study in such a way as to become interdependent in reaching a common theoretical or research goal, thereby producing findings that are greater than the sum of the parts.

Using MMR with these multiple data sets to add validity or trustworthiness to results is a central aim of the process, and the process of integrating the findings has been termed triangulation. Erzberger (2003) outlined the process of using triangulation when seeking a fuller and more complete picture of the phenomenon, like pieces of a jigsaw puzzle. Triangulation has been widely used in social research and its value in MMR has been the subject of some criticism. For instance, Morgan (1998) thought that terms like convergence or cross-validation were more precise. The term triangulation is based on a trigonometry process in navigation of using two points to locate a position. In contrast, the term has been used in research to denote using additional data sets in order to validate, check, review or add to initial findings, whether using mixed or similar methods (Hammersley, 2008). Denzin (2008) originally defined the difference between four different types of triangulation – data, methodological, investigator and theory triangulation. Most common, and the way triangulation is used in this thesis, is methodological triangulation – the use of multiple methods to solve a problem.

As a recently emerging field, a number of different types of MMR have evolved and more are still evolving (Evans et al., 2011). Morgan (1998) outlined a priority-sequence model to clarify different ways to combine studies in a MMR design. Using this model the researcher states whether it is principally quantitative or qualitative.
(and places the abbreviated principle method in capitals), and the method comes first or complementary as follow-up. For example, a series of qualitative focus groups exploring patient’s views of their experience of visiting a healthcare provider group followed by a national quantitative survey of patient satisfaction based on the earlier findings would be abbreviated qual→QUANT. Following Morgan’s model, the research design of this current thesis is QUANT→QUAL, as both data sets had equal importance and the patient interviews and focus group followed the survey.

Cresswell (2007) then extended this approach to establish a typology to describe these variants:

- Convergent parallel design – where the strands are concurrent through the same phase of the process;
- Explanatory sequential design – where the phases are distinct and the quantitative strand is first and qualitative second;
- Exploratory sequential design - where the phases are also distinct but the qualitative strand is first and quantitative second;
- The embedded design – where one strand is collected within the other;
- The transformative design – where both strands emerge under a transformative theoretical framework;
- The multiphase design – where there is a combination of sequential and concurrent strands over time to reach a programme aim.

Following this more current typology, the research design of this thesis is an explanatory sequential design (Cresswell, 2011), as the Stage 1 quantitative data set and analysis prompted further research questions that set the framework for further qualitative stages. It is a participant-selection variant of this design (Cresswell, 2008; Morgan, 1998), as the qualitative Stage 3 had at least equal importance as the first. The quantitative survey established a number of aspects of osteopathic practice in Australia to explore more deeply – the common presentation of chronic low back pain, the wide variety of diagnostic and therapeutic skills used, and the general practice patterns of the workplace.

Bryman (2006) analysed 232 social science articles published in the years 1994-2003 that used a mixture of methods. The two most commonly used strategies were surveys and semi-structured interviews. The studies that are integrated in this thesis
mirrored this pattern as it includes quantitative surveys, qualitative (phenomenological) interviews, as well as a focus group and an expert Delphi panel. The approach to the integration of these data is discussed in the next section which outlines the research design.

3.4 Research Design

In this explanatory sequential design, the Stage 1 quantitative data set the framework for the qualitative Stage 3, by helping to identify and select the participants and aspects to explore and for later stages (the nature of osteopathic practice and management, patients with the common presenting problem and practitioners managing these patients). Also the qualitative Stage 3 had equal priority to the Stage 1 data, because in the researcher’s conceptual framework of patient-centred healthcare, the therapeutic relationship is an equal power sharing between practitioner and patients and their opinions and experiences become central to the thesis.

The data sets were integrated using methodological triangulation or convergence, the key goal being (Greene et al., 1989, p257):

to measure overlapping but different facets of a phenomenon, yielding an enriched elaborated understanding of the phenomenon….. seeking elaboration, enhancement, illustration, clarification of the results of one method with the results from the other method .

The following Figure 9 illustrates the sequential process.
RESEARCH QUESTIONS

- What is the nature of osteopathic practice in Australia?
- What are the common workplace characteristics regarding patient presentations, assessment practices, and patient management?
- What is the quality and currency of evidence for authentic osteopathic healthcare applied to the chronic non-specific low back pain?
- What is the experience of practitioners managing the common presenting problem of osteopathic healthcare?
- What is the experience of patients with the common presenting problem of osteopathic healthcare?
- What is an appropriate pragmatic clinical trial methodology to test the effectiveness of osteopathic healthcare for chronic non-specific low back pain?

QUANTITATIVE
- Practitioner survey
- Patient snapshot

QUALITATIVE
- Practitioner focus group
- Patient interviews

Systematic Review of Evidence

Authentic Model of Practice

Delphi Panel

Pragmatic Clinical Trial Methodology

Figure 9  Outline of the explanatory sequential design of this thesis
3.4.1 Limitations

A criticism of pragmatism is that it could be seen as being simply eclectic and result in a research process where any approach could be used as long as it works (Greene, 2003). Russell (1961) outlined his criticism of the pragmatism of James and Dewey as being just interested in the effects of truth, not a theory of truth. The pragmatic stance does require a solid rationale for its overarching use (Greene, 2003), and the researcher needs to ensure that the method used in each phase links clearly to the research aims and is well suited to answer the question(s). In this thesis the single focus is on osteopathic healthcare as it is practised, and the aim of each phase had methods chosen specifically to answer each question guided by pragmatism.

There are some issues and controversies regarding the use of MMR, none more so than the incompatibility thesis. The theoretical differences between the two methods were presented as the incompatibility thesis during the paradigm wars of the 1980s and 1990s. Blaikie (1991) was an early critic of the attempt to combine methods and triangulate data, arguing that empiricism, interpretivism and realism are fundamentally different philosophical orientations. Hammersley (2008) pointed out that these epistemological and ontological assumptions are not necessarily built into the methods used, and there is a difference between the overarching philosophy of the research and the methods used to collect data. Guba (1994) points out that researchers in MMR need to settle on a single paradigmatic stance underpinning the research, and each phase of research may use different methods to answer the question. Other authors have argued that many of the issues that have been considered incompatible are not limits to research in either domain (Bergmann, 2008; Tashakkori A., 2003). In the best examples, the reported quantitative belief in a single reality, the necessity of separating the knower from the known, the generalisability of findings and the emphasis on deductive reasoning from universal laws are all reported as highly variable in actual research projects, and (Bergmann, 2008) suggests that the only identifiable feature of quantitative research is that results relate to a statistical analysis.

Cresswell (2008) has outlined methodological issues that may arise with the sampling, participant selection, data collection and analysis when using the sequential design in mixed methods. Sampling is different in size and scope with
quantitative and qualitative designs, and care must be taken to consider the differences.

Finally, there can arise contradictory findings between data sets and the researcher needs to decide what strategy to use with these. The primary approach used in this research study was to identify and discuss any differences between the findings, as differing results could lead to further research. The heterogeneity between the various samples means there will be different perspectives and results, and this is likely in an MMR approach. For example, patients and practitioners come to a healthcare consultation with different expectations, and differences in their experience can be used to focus on problems to solve. The following section outlines the stages of research.

3.5 Stage 1: Quantitative workforce survey and patient snapshot

The initial research study asked the broad questions: “What is the nature of osteopathic practice in Australia?” and “What are the common workplace characteristics regarding patient presentations, assessment practices, and patient management?” In order to answer these questions a national postal survey was conducted, which had two sections – the first an exploration of details of osteopathic practitioners’ work and professional life, and the second a snapshot recording of a single day’s patients – their demographics, presenting complaints, and management approaches. This resulted in two peer-reviewed publications that are included in Chapters 4.1 and 4.2. Each has its own background literature, methods, results and discussion.

3.6 Stage 2: Systematic Review of evidence

Following analysis of the workforce survey, the findings prompted the next research question, “What is the current evidence for authentic osteopathic healthcare applied to chronic non-specific low back pain, the most common presenting problem based on the workplace findings?” As the survey in Stage 1 revealed that the most common patient complaint presenting to that sample was chronic non-specific low back pain (CNSLBP), this became the focus of a systematic review of the published evidence following the Cochrane Collaboration guidelines. This work resulted in a peer-reviewed publication that is included in Chapter 5. The systematic review contains a literature review, methods, results and discussion.
3.7 Stage 3: Qualitative focus group and interviews

The third stage had two studies designed to deepen the understanding of the characteristics of osteopathic practice from two perspectives. The first was from the perspective of the osteopathic practitioner and to help answer the question, ‘How do osteopaths manage patients?’ with a focus on those patients with the target presenting symptom (CNSLBP). Findings from a practitioner focus group of osteopathic practitioners designed to answer this question is reported in Chapter 6 in pre-publication format. This paper contains its own literature, methods, results and discussion.

The second perspective in this stage was from osteopathic patients who had the target condition of CNSLBP. A waiting room survey and semi-structured interviews of patients of osteopaths were conducted to answer the question, ‘What is the experience of osteopathic healthcare for patients with CNSLBP?’ This resulted in a peer-reviewed publication that is included in Chapter 6. This paper has its own literature, methods, results and discussion.

3.8 Final Stage: Delphi Panel

Following the three stages of data gathering, a model of the osteopathic intervention in the management of CNSLBP emerged and a proposal for a pragmatic clinical trial was drafted in order to test that authentic model. To answer the final question, “What is an appropriate pragmatic clinical trial methodology to test the effectiveness of osteopathic healthcare for CNSLBP?” a Delphi panel of experts was formed to consider and critique the draft method. Relevant literature, methods, results and discussion are included in a pre-publication format in Chapter 7.

All stages of the research are brought together in Chapter 8, where a synthesis of findings is described and analysed.

3.9 Quality Indicators

Quality indicators were chosen for each type of study undertaken in this thesis to provide objective criteria to assess the quality of the work and how it was reported. The tools used are outlined below and reported in the discussion of the relevant
research. The STROBE (strengthening the reporting of observational studies in epidemiology) checklist for cross sectional and survey research (STROBE, 2017) was used for the workplace survey and patient snapshot reported in Chapter 4.

The PRISMA (preferred reporting items for systematic reviews and meta-analyses) checklist was used for the Systematic Review in Chapter 5 (Moher, Liberati, Tetzlaff, & Altman, 2009).

The COREQ (consolidated criteria for reporting qualitative research) was used for the focus group and patient interviews reported in Chapter 6 (Tong, Sainsbury, & Craig, 2007).

The Delphi panel followed advice from the literature, as no formulated quality indicator tool was able to be found, despite the Delphi method being used in the development of many quality checklist tools.

3.10 Conclusion

This chapter has explored the methodological underpinning of this thesis, the epistemology of empiricism and the paradigm of pragmatism. The overarching method of MMR was introduced and critiqued for its applicability to answer the research questions. The research design has been outlined - a participant selection variant of an explanatory sequential mixed methods study to address the research questions. The following chapters 4, 5, 6 and 7 report the studies that make up Stages 1, 2, 3 and Final Stage of the thesis. An introduction in each chapter explains the sequence of the studies and reflects on the influence of the findings on the actions and approaches that followed.
Chapter 4 – Stage 1 - Quantitative

4.1 Chapter introduction

This chapter presents the first stage of data gathering- a national workforce survey of practitioners designed to answer the questions of what is the nature and characteristics of osteopathic practice in Australia, and what are the common presentations, assessment practices, and patient management strategies and interventions?

The following are two peer reviewed publications that are self-contained describing their aims, rationale, methods results and conclusions. The first part of the national workforce study aimed to explore the practitioner’s workplace and practice characteristics. The second part aimed to establish and describe the patient presentations and management from a single day of practice in those surveyed practices. The following two publications are the final proofs that were published in International Journal of Osteopathic Medicine in 2009. The survey instrument is included in the appendix.

These publications established a workforce benchmark for the profession in Australia. At the time, previous smaller and less representative samples had provided limited data about the practices of osteopaths, but the Osteopathic Census 2004 outlined in these papers gave specific details of the practitioners’ activities, their modes of practice and the patients they see. These publications are regularly cited and many of the findings have been confirmed in more current studies – these are outlined in the discussion at the end of the chapter.
4.2 Profile of the members of the Australian Osteopathic Association: Part one – the practitioners.


Funding

The National Fund for Research into Osteopathy (NFRO) funded the development of the census, printing and correspondence.
4.2.1 Introduction

Workforce surveys provide vital foundations upon which to build a profession’s knowledge of itself and its directions for the future. The Research Council of the Australian Osteopathic Association (AOA) recognised the need for a workforce survey as a high priority for the Australian osteopathic profession, as there needed to be a solid database of the profession. Members of the Research Council identified the need to clarify the characteristics of members of the Australian profession, and their patients in order to: 1) identify and characterise the profession for government, insurers, the public and intra-professionally; 2) plan future developments in training and service provision; 3) support any enquiry into scope of practice issues; 4) prioritise research on the basis of common clinical presentations. Other health professions regularly undertake workforce surveys of their members (Anderson, Ellis, Williams, & Gates, 2005; Chiropractic Association of Australia, 2005). In terms of the currency and coherence of this professional identity, lack of data can become a barrier to arguing convincingly for presence in the mainstream healthcare system (Jamison, 1991a).

The Australian osteopathic profession has been surveyed previously (Jamison, 1991b; Mullen, 1997). A survey by Jamison undertaken in the early 1990s (Jamison, 1991b), and Delphi study which supported it (Jamison, 1991a), appear to be the first such analyses of the osteopathic profession in Australia since the profession attained statutory registration following the Federal Government committee of inquiry into non-conventional medical practices, the Webb Report in 1977. Both of these investigations targeted members of the AOA, a subset of the total population of osteopaths in Australia. The osteopathic profession has also been surveyed in New Zealand in 1991 and 1995 (Jamison, 1991c; McGrath, 1995) using a similar range of questions, with the 1995 one including a snapshot of patients. In 2001, the General Osteopathic Council (GOsC), the governing body of the osteopathic profession in the United Kingdom (UK), undertook a survey of the 3161 registrants (General Osteopathic Council, 2001). The results of the GOsC survey indicate trends between...
1994 and 2001 regarding the practice of osteopathy in the UK and characteristics of patients consulting osteopaths.

This article (in two parts) is a report of the descriptive findings of this census and includes selected comparative and temporal trends with reference to previous surveys of the profession locally and internationally, and also with other professionals in the manual therapy field, chiropractic and physiotherapy. This report also highlights some of the issues that arise from the data.

4.2.2 Methods

4.2.2.1 Development

Survey questions were adapted from those used in surveys of other healthcare professions (Bensoussan, 1996; General Osteopathic Council, 2001; Hale, 2002a; Jamison, 1991b), and sought information about practitioner demographics, qualifications, work patterns and clinical activities. The survey instrument was formatted to allow commercial electronic scanning (NRS Pearson Pty Ltd). Face validity was established with the help of two groups of osteopaths within the AOA—the Research Council of five members, and the Federal Council of seven members. The draft questions were also distributed to an external educationalist with expertise in questionnaire methodology. These 13 people were asked to provide feedback on the relevance and clarity of the questions and questions were amended to accommodate feedback where appropriate. Approval for the project was provided by the Human Research and Ethics Committee of Southern Cross University.

4.2.2.2 Administration of census

The census was distributed by mail to the 656 Australian resident, financial, practising members of the Australian Osteopathic Association in March 2004. A strategy of publishing information about the survey in the newsletter of the AOA was used to improve the response rate. The number of Australian registered osteopaths at the time of distribution was 945 (Osteopaths Registration Board of NSW, personal communication). This meant that the membership of the AOA was 69.4% of the total registered osteopathic population nationally.
4.2.2.3 **Statistical analysis**

The data was inputted onto spreadsheets (Microsoft Excel) and analysed using SPPS v11.0 for Windows (SPSS Inc, Chicago, IL). Descriptive statistics were used to explore the data. Correlations were computed for the variables of years since graduation and estimated patient number to explore growth of income over time. Brief text answers to open ended questions were grouped by the author using simple thematic analysis.

4.2.3 **Results**

The response rate from surveyed members of the Australian Osteopathic Association for Part One was 52% (n=341). Response rates for individual questions varied between 46-52% as all respondents did not complete every question.

4.2.3.1 **Age, gender and experience**

Sixty eight percent of the respondents were aged between 20-39 yrs, with 12.7% over the age of 50. 53.8% of all respondents were female. The sample was an average of 9.8 years since graduation, and the mode of years since graduation was four years.

4.2.3.2 **Qualifications**

The variations of first osteopathic qualification reported and the institutions awarding these qualifications are listed in Table 1. Thirty five percent of respondents (n=118) claimed they had a second osteopathic qualification. These are listed in Table 2, along with the institutions granting these awards.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>First osteopathic qualification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qualification and institution</td>
<td>Number (% of positive respondents)</td>
</tr>
<tr>
<td>Diploma</td>
<td>n=124; 36.3%</td>
</tr>
<tr>
<td>Bachelors degrees</td>
<td>n=154; 45.1%</td>
</tr>
<tr>
<td>Bachelor (Honours)</td>
<td>n=4; 1%</td>
</tr>
<tr>
<td>Graduate Diploma</td>
<td>n=1; 0.3%</td>
</tr>
</tbody>
</table>
Missing n=58; 17%

From the following institutions:
Royal Melbourne Institute of Technology n=111; 32.5%
Victoria University n=72; 21.1%
British School of Osteopathy n=26; 7.6%
University of Western Sydney n=20; 5.8%
International Colleges of Osteopathy n=18; 5.2%
Pacific College n=13; 3.8%
NSW College n=12; 3.5%
Philip Institute of Technology n=12; 3.5%
European School of Osteopathy n=12; 3.5%
British College of Naturopathy and Osteopathy n=3; 0.8%
Windsor College n=2; 0.5%
ICO and COS (France) n=2; 0.5%
South Australian College of Osteopathy n=1; 0.3%

Table 2  Second osteopathic qualification

<table>
<thead>
<tr>
<th>Qualification and institution</th>
<th>Number (% of positive respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Masters degree</td>
<td>n= 78; 66%</td>
</tr>
<tr>
<td>Bachelors degree</td>
<td>n=24; 20.3%</td>
</tr>
<tr>
<td>Graduate Diploma (Paed)</td>
<td>n=7; 5.9%</td>
</tr>
<tr>
<td>Bachelors (Honours)</td>
<td>n=4; 3.4%</td>
</tr>
<tr>
<td>Graduate Certificate</td>
<td>n=3; 2.5%</td>
</tr>
<tr>
<td>Diploma Osteopathy</td>
<td>n=1; 0.8%</td>
</tr>
<tr>
<td>Fellow Societie Osteopathique</td>
<td>n=1; 0.8%</td>
</tr>
</tbody>
</table>

Institutions granting these awards were:
Victoria University n=55; 46.6%
Royal Melbourne Institute of Technology n=32; 27.1%
University of Western Sydney n=18; 15.3%
University of Westminster n=4; 3.4%
International Colleges of Osteopathy n=1; 0.8%
NSW College of Osteopathy n=1; 0.8%
British College of Osteopathic Medicine n=1; 0.8%
Oxford Brooks University n=1; 0.8%
University of Greenwich/ESO n=1; 0.8%
VUT/Middlesex University n=1; 0.8%
Missing n=3; 2.5%

4.2.3.3  Practice characteristics

The main practice characteristics are listed in Table 3. The respondents stated that they saw their patients for the whole consult (n=325; 95.6%).

Table 3  Practice characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Amount</th>
<th>Number (% of positive respondents)</th>
</tr>
</thead>
</table>

4.2.3.4 Diagnostic practices

The subjects were asked to estimate the number of times over the last week that they considered certain systems as part of their physical examination of the patient. This is summarised in Table 4.

<table>
<thead>
<tr>
<th>Hours practice /week</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>24-32</td>
<td>76</td>
<td>23%</td>
</tr>
<tr>
<td>32-40</td>
<td>104</td>
<td>31.4%</td>
</tr>
<tr>
<td>40+</td>
<td>74</td>
<td>22.4%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Practice locations</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>one</td>
<td>196</td>
<td>59%</td>
</tr>
<tr>
<td>two</td>
<td>113</td>
<td>33.8%</td>
</tr>
<tr>
<td>three</td>
<td>23</td>
<td>6.9%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Consults /week</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-20</td>
<td>44</td>
<td>13.1%</td>
</tr>
<tr>
<td>21-40</td>
<td>156</td>
<td>46.2%</td>
</tr>
<tr>
<td>41-60</td>
<td>95</td>
<td>28.2%</td>
</tr>
<tr>
<td>61-80</td>
<td>30</td>
<td>8.9%</td>
</tr>
<tr>
<td>81-100</td>
<td>6</td>
<td>1.8%</td>
</tr>
<tr>
<td>100+</td>
<td>6</td>
<td>1.8%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Consultation length (minutes)</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultation length (minutes)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;15</td>
<td>1</td>
<td>0.3%</td>
</tr>
<tr>
<td>15-30</td>
<td>23</td>
<td>6.9%</td>
</tr>
<tr>
<td>30-45</td>
<td>135</td>
<td>40.5%</td>
</tr>
<tr>
<td>45-60</td>
<td>148</td>
<td>44.4%</td>
</tr>
<tr>
<td>&lt;60</td>
<td>26</td>
<td>7.8%</td>
</tr>
<tr>
<td>Consultation length (minutes)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Returning patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;15</td>
<td>6</td>
<td>1.8%</td>
</tr>
<tr>
<td>15-30</td>
<td>76</td>
<td>23.1%</td>
</tr>
<tr>
<td>30-45</td>
<td>218</td>
<td>66.3%</td>
</tr>
<tr>
<td>45-60</td>
<td>27</td>
<td>8.2%</td>
</tr>
<tr>
<td>&lt;60</td>
<td>2</td>
<td>0.6%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Consultation fee (AUD)</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>New patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35-50</td>
<td>25</td>
<td>7.7%</td>
</tr>
<tr>
<td>51-60</td>
<td>94</td>
<td>29.2%</td>
</tr>
<tr>
<td>61-70</td>
<td>109</td>
<td>33.9%</td>
</tr>
<tr>
<td>71-80</td>
<td>50</td>
<td>15.5%</td>
</tr>
<tr>
<td>81-100</td>
<td>34</td>
<td>10.6%</td>
</tr>
<tr>
<td>100+</td>
<td>9</td>
<td>2.8%</td>
</tr>
<tr>
<td>Consultation fee (AUD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Returning patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35-45</td>
<td>21</td>
<td>6.5%</td>
</tr>
<tr>
<td>46-55</td>
<td>143</td>
<td>44.5%</td>
</tr>
<tr>
<td>56-65</td>
<td>100</td>
<td>31.1%</td>
</tr>
<tr>
<td>66-75</td>
<td>47</td>
<td>14.6%</td>
</tr>
<tr>
<td>76+</td>
<td>10</td>
<td>3.1%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recording system</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Papers/cards</td>
<td>222</td>
<td>65.1%</td>
</tr>
<tr>
<td>Computerised</td>
<td>18</td>
<td>5.3%</td>
</tr>
<tr>
<td>Combination</td>
<td>84</td>
<td>24.6%</td>
</tr>
</tbody>
</table>
Table 4  Estimate of systems physical examination

<table>
<thead>
<tr>
<th>System</th>
<th>Number of times/week</th>
<th>Number (% of positive respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orthopaedic</td>
<td>0-5</td>
<td>n=54 (17%)</td>
</tr>
<tr>
<td></td>
<td>6-10</td>
<td>n=58 (18.3%)</td>
</tr>
<tr>
<td></td>
<td>11-20</td>
<td>n=73 (22.8%)</td>
</tr>
<tr>
<td></td>
<td>21-40</td>
<td>n=91 (28.3%)</td>
</tr>
<tr>
<td></td>
<td>40+</td>
<td>n=42 (13.0%)</td>
</tr>
<tr>
<td>Neurological</td>
<td>0-5</td>
<td>n=132 (42.8%)</td>
</tr>
<tr>
<td></td>
<td>6-10</td>
<td>n=53 (17.1%)</td>
</tr>
<tr>
<td></td>
<td>11-20</td>
<td>n=61 (19.8%)</td>
</tr>
<tr>
<td></td>
<td>21-35</td>
<td>n=24 (7.7%)</td>
</tr>
<tr>
<td></td>
<td>35+</td>
<td>n=38 (12.6%)</td>
</tr>
<tr>
<td>Cardiac</td>
<td>0-5</td>
<td>n=217 (80.6%)</td>
</tr>
<tr>
<td></td>
<td>6-10</td>
<td>n=29 (10.7%)</td>
</tr>
<tr>
<td></td>
<td>11+</td>
<td>n=23 (8.5%)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>0-5</td>
<td>n=202 (75.9%)</td>
</tr>
<tr>
<td></td>
<td>6-10</td>
<td>n=30 (11.2%)</td>
</tr>
<tr>
<td></td>
<td>11-20</td>
<td>n=18 (6.6%)</td>
</tr>
<tr>
<td></td>
<td>21+</td>
<td>n=16 (6.3%)</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>0-5</td>
<td>n=202 (73.2%)</td>
</tr>
<tr>
<td></td>
<td>6-10</td>
<td>n=38 (13.8%)</td>
</tr>
<tr>
<td></td>
<td>11-20</td>
<td>n=10 (3.7%)</td>
</tr>
<tr>
<td></td>
<td>21+</td>
<td>n=26 (9.4%)</td>
</tr>
<tr>
<td>Other –text answers</td>
<td>Genitourinary</td>
<td>n=12 (3.2%)</td>
</tr>
<tr>
<td>(n= 56; 16.6% of sample)</td>
<td>Psychological</td>
<td>n=6 (1.6%)</td>
</tr>
<tr>
<td></td>
<td>Endocrine</td>
<td>n=6 (1.6%)</td>
</tr>
<tr>
<td></td>
<td>Dental</td>
<td>n=6 (1.6%)</td>
</tr>
<tr>
<td></td>
<td>Lymphatic</td>
<td>n=6 (1.6%)</td>
</tr>
<tr>
<td></td>
<td>Ear Nose and Throat</td>
<td>n=5 (1.4%)</td>
</tr>
</tbody>
</table>

Subjects were also asked to estimate the frequency of their referral for diagnostic testing in undefined categories of never, rarely, often and always (see summary in Table 5).

Table 5  Estimated referrals for diagnostic testing

<table>
<thead>
<tr>
<th>Diagnostic method</th>
<th>Estimate</th>
<th>Number (% of positive respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plain radiology</td>
<td>Never</td>
<td>n=2 (0.6%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=146 (43.3%)</td>
</tr>
<tr>
<td>Procedure</td>
<td>Never</td>
<td>Rarely</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-------</td>
<td>--------</td>
</tr>
<tr>
<td>Computerised Axial Tomography</td>
<td>n=65</td>
<td>n=198</td>
</tr>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>n=81</td>
<td>n=208</td>
</tr>
<tr>
<td>Thermography</td>
<td>n=271</td>
<td>n=29</td>
</tr>
<tr>
<td>Ultrasonography</td>
<td>n=84</td>
<td>n=200</td>
</tr>
<tr>
<td>Blood pathology</td>
<td>n=153</td>
<td>n=140</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>n=228</td>
<td>n=78</td>
</tr>
<tr>
<td>Cultures/microbiology</td>
<td>n=257</td>
<td>n=50</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Often</th>
<th>n=185 (54.9%)</th>
<th>Always</th>
<th>n=4 (1.2%)</th>
</tr>
</thead>
</table>

4.2.3.5 Therapeutic modalities

Figure 1 displays the frequency of estimated use of the osteopathic manipulative treatment (OMT) modalities described in the survey. The most commonly used OMT by respondents were ‘soft tissue’, ‘muscle energy technique’ and ‘articulation techniques’.
4.2.3.6 Prescriptions

Respondents report regular prescription of modalities other than Osteopathic Manipulative Treatment (see Table 6).

Table 6 Estimates of prescription modalities

<table>
<thead>
<tr>
<th>Prescription</th>
<th>Estimate</th>
<th>Number (% of positive respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise</td>
<td>Never</td>
<td>n=2 (0.6%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=146 (43.3%)</td>
</tr>
<tr>
<td></td>
<td>Often</td>
<td>n=185 (54.9%)</td>
</tr>
<tr>
<td></td>
<td>Always</td>
<td>n=4 (1.2%)</td>
</tr>
</tbody>
</table>
Chapter 4 – Stage 1 - Quantitative

4.2.3.7 Adverse events

Respondents were presented with three choices of severity and four choices of undefined frequency of adverse events in their practice life, presented in Table 7.

<table>
<thead>
<tr>
<th>Event severity</th>
<th>Estimate of frequency</th>
<th>Number (% of positive respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>n=13 (3.9%)</td>
<td></td>
</tr>
<tr>
<td>Rarely</td>
<td>n=184 (55.6%)</td>
<td></td>
</tr>
<tr>
<td>Occasionally</td>
<td>n=115 (34.7%)</td>
<td></td>
</tr>
<tr>
<td>Frequently</td>
<td>n=19 (5.7%)</td>
<td></td>
</tr>
<tr>
<td>Requiring referral/treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>n=180 (56.1%)</td>
<td></td>
</tr>
<tr>
<td>Rarely</td>
<td>n=128 (39.9%)</td>
<td></td>
</tr>
<tr>
<td>Occasionally</td>
<td>n=13 (4.0%)</td>
<td></td>
</tr>
<tr>
<td>Serious</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>n=297 (92.8%)</td>
<td></td>
</tr>
<tr>
<td>Rarely</td>
<td>n=22 (6.9%)</td>
<td></td>
</tr>
<tr>
<td>Occasionally</td>
<td>n=1 (0.3%)</td>
<td></td>
</tr>
</tbody>
</table>

4.2.3.8 Interprofessional relationships

Subjects described their referral patterns in estimates, see Table 8.
**Table 8  Outward referral patterns**

<table>
<thead>
<tr>
<th>Referral to:</th>
<th>Estimate of frequency</th>
<th>Number (% of positive respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Practitioners</td>
<td>Never</td>
<td>n=2 (0.6%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=39 (11.7%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=228 (68.5%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=64 (19.2%)</td>
</tr>
<tr>
<td>Massage therapist</td>
<td>Never</td>
<td>n=17 (5.1%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=92 (27.4%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=162 (48.2%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=65 (19.3%)</td>
</tr>
<tr>
<td>Naturopaths/herbalists</td>
<td>Never</td>
<td>n=32 (9.6%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=117 (35.0%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=145 (43.4%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=40 (12.0%)</td>
</tr>
<tr>
<td>Podiatrists</td>
<td>Never</td>
<td>n=29 (8.6%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=115 (34.1%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=160 (47.5%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=33 (9.8%)</td>
</tr>
<tr>
<td>Counsellor</td>
<td>Never</td>
<td>n=69 (20.7%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=194 (58.3%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=70 (21.0%)</td>
</tr>
<tr>
<td>Psychologist</td>
<td>Never</td>
<td>n=122 (36.6%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=146 (43.8%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=63 (18.9%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=2 (0.6%)</td>
</tr>
<tr>
<td>Dietician</td>
<td>Never</td>
<td>n=144 (44.2%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=128 (39.3%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=52 (16.0%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=2 (0.6%)</td>
</tr>
<tr>
<td>Personal trainer</td>
<td>Never</td>
<td>n=125 (37.5%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=138 (41.4%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=63 (18.9%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=7 (2.1%)</td>
</tr>
<tr>
<td>Medical specialist</td>
<td>Never</td>
<td>n=56 (17.2%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=96 (29.4%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=157 (48.2%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=17 (5.2%)</td>
</tr>
<tr>
<td>Chinese Medicine practitioner</td>
<td>Never</td>
<td>n=77 (23.1%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=144 (43.2%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=91 (27.3%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=21 (6.3%)</td>
</tr>
<tr>
<td>Another osteopath</td>
<td>Never</td>
<td>n=19 (5.3%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=147 (44.0%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=141 (42.2%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=27 (8.1%)</td>
</tr>
</tbody>
</table>
Referals were almost exclusively from other patients, see Table 9.

### Table 9  
**Inward referral patterns**

<table>
<thead>
<tr>
<th>Referral from:</th>
<th>Estimate of frequency</th>
<th>Number (% of positive respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other patients of practice</td>
<td>Rarely</td>
<td>n=1 (0.3%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=12 (3.6%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=320 (96.1%)</td>
</tr>
<tr>
<td>General Practitioners</td>
<td>Never</td>
<td>n=23 (6.9%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=93 (27.8%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=160 (47.9%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=58 (17.4%)</td>
</tr>
<tr>
<td>Massage therapist</td>
<td>Never</td>
<td>n=4 (1.2%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=43 (13.0%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=163 (49.2%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=121 (36.6%)</td>
</tr>
<tr>
<td>Podiatrist</td>
<td>Never</td>
<td>n=95 (38.3%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=117 (43.8%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=97 (28.9%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=27 (8.0%)</td>
</tr>
<tr>
<td>Counsellor/ Psychologist</td>
<td>Never</td>
<td>n=175 (52.6%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=105 (31.5%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=48 (14.4%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=5 (1.5%)</td>
</tr>
<tr>
<td>Dietician</td>
<td>Never</td>
<td>n=259 (78.2%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=61 (18.4%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=10 (3.0%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=1 (0.3%)</td>
</tr>
<tr>
<td>Personal trainer</td>
<td>Never</td>
<td>n=111 (33.3%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=110 (33.0%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=85 (25.5%)</td>
</tr>
<tr>
<td></td>
<td>Frequently</td>
<td>n=27 (8.1%)</td>
</tr>
<tr>
<td>Medical specialist</td>
<td>Never</td>
<td>n=167 (50.6%)</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
<td>n=103 (31.2%)</td>
</tr>
<tr>
<td></td>
<td>Occasionally</td>
<td>n=49 (14.8%)</td>
</tr>
</tbody>
</table>
Some respondents reported utilising other disciplines of medicine as part of their practice (apart from the prescription modalities mentioned previously). These were nutritional medicine (14.4% of respondents), naturopathic medicine (8.5%), acupuncture (7%) and herbal medicine (6%). Respondents also reported working alongside practitioners of other disciplines in their practices, including acupuncturists (20.8% of respondents), herbal medicine practitioners (20.2%), nutritional medicine practitioners (15.8%) and naturopaths (8.5%).

### 4.2.3.9 Continuing Education

Respondents were asked to describe their attendance at different types of continuing education over the previous twelve months, and also to give a level of importance of the activities to them. Table 9 outlines the attendance data. Two activities stood out - the AOA evening seminars were considered “very” or “extremely” important (41.4% and 17.1% of respondents respectively), with 2-3 day osteopathic seminars also “very” (48.0%) or “extremely” (25.1%) important.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number attending (% of positive respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AOA evening seminars</td>
<td>N=183 (53.7%)</td>
</tr>
</tbody>
</table>

---

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number attending</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chinese Medicine practitioner</td>
<td>n=11 (3.3%)</td>
</tr>
<tr>
<td></td>
<td>n=148 (45.1%)</td>
</tr>
<tr>
<td></td>
<td>n=104 (31.7%)</td>
</tr>
<tr>
<td></td>
<td>n=61 (18.6%)</td>
</tr>
<tr>
<td></td>
<td>n=15 (4.6%)</td>
</tr>
<tr>
<td>Another osteopath</td>
<td>n=12 (3.6%)</td>
</tr>
<tr>
<td></td>
<td>n=140 (42.3%)</td>
</tr>
<tr>
<td></td>
<td>n=144 (43.5%)</td>
</tr>
<tr>
<td></td>
<td>n=35 (10.6%)</td>
</tr>
<tr>
<td>Physiotherapist</td>
<td>n=190 (56.5%)</td>
</tr>
<tr>
<td></td>
<td>n=102 (30.4%)</td>
</tr>
<tr>
<td></td>
<td>n=38 (11.3%)</td>
</tr>
<tr>
<td></td>
<td>n=6 (1.8%)</td>
</tr>
<tr>
<td>Chiropractor</td>
<td>n=221 (67.0%)</td>
</tr>
<tr>
<td></td>
<td>n=79 (23.9%)</td>
</tr>
<tr>
<td></td>
<td>n=26 (7.9%)</td>
</tr>
<tr>
<td></td>
<td>n=4 (1.2%)</td>
</tr>
</tbody>
</table>
4.2.3.10 Opinion of training

Participants were requested to complete an open question in regards to whether their training could be improved in certain aspects. 70% (n=239) of practitioners answered this question, and the issues mentioned are listed in Table 10.

Table 11 Opinion of training

<table>
<thead>
<tr>
<th>Theme</th>
<th>Number mentioning theme (% of positive respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No improvement needed</td>
<td>N=60 (18.7%)</td>
</tr>
<tr>
<td>More business management skills</td>
<td>N=52 (16%)</td>
</tr>
<tr>
<td>More exercise prescription and rehabilitation skills</td>
<td>N=17 (5%)</td>
</tr>
<tr>
<td>Increased numbers of patients/clinical training</td>
<td>N=17 (5%)</td>
</tr>
<tr>
<td>More observation of practicing osteopaths</td>
<td>N=17 (5%)</td>
</tr>
<tr>
<td>Enhanced patient interaction/psychology skills</td>
<td>N=17 (5%)</td>
</tr>
<tr>
<td>Increased numbers of acute and seriously ill/hospitalised patients</td>
<td>N=14 (4%)</td>
</tr>
<tr>
<td>Enhanced osteopathic philosophy/principles/art of practice</td>
<td>N=14 (4%)</td>
</tr>
<tr>
<td>Increased knowledge of other professionals</td>
<td>N=10 (3%)</td>
</tr>
<tr>
<td>More knowledge of nutrition</td>
<td>N=7 (2%)</td>
</tr>
<tr>
<td>More soft tissue techniques</td>
<td>N=7 (2%)</td>
</tr>
<tr>
<td>More OCF/indirect methods</td>
<td>N=7 (2%)</td>
</tr>
</tbody>
</table>

4.2.3.11 Professional issues

The respondents were surveyed for their opinion regarding the most important issues facing the profession. The issues considered most important were: (1) public perception/ignorance of osteopathy (very important n=86, 25.5%; extremely important n=235, 69.7%); (2) health practitioners’ perception/ignorance of
osteopathy (very important n=90, 26.7%; extremely important n=230, 68.2%), and (3) a full supply of quality graduates (very important n=135, 40.5%; extremely important n=140, 42.0%). The respondents also thought that the need for evidence of the efficacy of osteopathic management was relatively important (very important n=139, 41.2%; extremely important n=136, 40.4%).

The issue of expanded practice rights revealed a polarity, with diagnostic rights reported as very important (n=123, 37.0%) or extremely important (n=124, 37.3%), but prescription rights as not important (n=123, 37.6%) or mildly important.

4.2.4 Discussion

The response rate of 52% of the target AOA group was above the range expected from mail surveys, and allows some generalisability only with regards to the national membership of the AOA, as over 30% of the registered osteopaths in Australia at the time of the census were not members, and were not sent the census (Ornstein, 1998).

4.2.4.1 Previous surveys

The 1991 survey of members of the AOA had a response rate of 53% (Jamison, 1991b). The questions asked were similar to the current study, but did not have a snapshot of patients. There were more detailed opinions of members in the Delphi study that preceded the 1991 survey (Jamison, 1991a). The 1996 survey (Mullen, 1997) returned a response rate of 37.5%, at a time when the membership represented 70% of registered osteopaths in Australia. Whilst that survey contained similar questions and a snapshot of patients, it had a stronger focus on comparing graduating characteristics and screening for contraindications to high velocity cervical manipulation. The osteopathic profession has also been surveyed in New Zealand (Jamison, 1991c; McGrath, 1995) using a similar range of questions, with the 1995 one including a snapshot of patients.

In 2001, the General Osteopathic Council (GOsC), the governing body of the osteopathic profession in the United Kingdom (UK), undertook a snapshot survey of the 3161 registrants. The response rate of the survey was 26.9% (n=852) (General Osteopathic Council, 2001). The results of the GOsC survey indicate trends between
1994 and 2001 regarding the practice of osteopathy in the UK and characteristics of patients consulting osteopaths.

The differences in years between this census and the New Zealand and UK surveys (9 and 3 years respectively) may create error in some comparisons, as the profession grows and change over time. The data used were the most current available.

### 4.2.4.2 Age, gender and experience

This sample had six individuals over 60 years of age – in 1991 they were slightly older (66% between 31-50 yrs) (Jamison, 1991b). The gender in the current sample had a more balanced mix, as in 1991 and 1996, the bias was towards males (71% and 57% respectively) (Jamison, 1991b; Mullen, 1997). A comparison with physiotherapy, which is the dominant allied health manual therapy profession in Australia, reveals a marked difference. There is a history of female bias and by 2001, despite increases in males entering that profession, still with a minority (35%) of them (Anderson et al., 2005).

Newer graduates filled in the survey in larger numbers (44% - less than 5yrs after graduation) and the mean duration since graduation was similar in the 1991 and 1996 Australian samples (Jamison, 1991b; Mullen, 1997).

### 4.2.4.3 Qualifications

The original trainings in osteopathy were undergraduate single qualifications obtained in private colleges, but in the recent decade the structure has shifted towards the undergraduate bachelor degree plus postgraduate masters qualification. These survey data demonstrate that respondents were newer graduates and therefore from the university programmes, in contrast to the 1996 survey (Mullen, 1997) when there were no graduates from postgraduate osteopathic programmes. The honours degree is an undergraduate upgrade degree, and not defined as postgraduate.

The proportion of British graduates in the AOA in 2004 at 13.6%, has fallen sharply over the time surveyed – it was at 25% in 1991 (Jamison, 1991b) and 28% in 1996 (Mullen, 1997). This trend may be related to the change of registration requirements
in the late 1990s for overseas applicants from automatic registration for graduates of proscribed UK institutions to registration examinations for all overseas applicants.

4.2.4.4 Practice characteristics

The working week in number of hours and patient consultations has changed little since 1991 (Jamison, 1991b). The consultation length has also remained stable for the sample group (Jamison, 1991b). The average consultation fee charged by practitioners has only risen by approximately AUD$10 (20% over 13 years or 1.5% per annum), which is below the accumulated Consumer Price Index rate from 1991-2004 (Australian Bureau of Statistics, 2006b). The average gross income per annum (48 week) extrapolated from these figures is A$100,800.

The New Zealand data reflect a similar working week to the Australian respondents in terms of numbers of patients and fees charged (McGrath, 1995). In the UK, the average number of patient consultation in one patient snapshot survey was 7.6 consultations per day, and the practitioners worked a similar number of hours in a week to the current sample (General Osteopathic Council, 2001). This data reveals a consistency in practice characteristics unaffected by the passage of time and the location in different continents.

4.2.4.5 Diagnostic practices

Osteopaths are considered to be part of the primary health care provider team, as evidenced by their inclusion in the Australian Government’s Enhanced Primary Care system within Medicare, which is the national health funding scheme (Department of Health and Ageing, 2007). The World Health Organisation’s definition of primary health care includes roles in health promotion, illness prevention, treatment and care of the sick (World Health Organisation, 1978b), so skill in the use of multi-system screening examination should be in evidence in a primary contact osteopathic practice (Grace, Vemulpad, & Beirman, 2006). The current data demonstrates that the respondents estimate that they use a broad spread of examinations in body systems, but with limited frequency outside of the orthopaedic system. This aspect of practice appears to have expanded over time, as the diagnostic activities were
limited to a full history plus a regional history and examination in the 1991 survey (Jamison, 1991b). Evidence of a diagnostic screen limited to patient history and regional examination was present in New Zealand in 1991 (McGrath, 1995).

With regards to diagnostic testing, plain radiology is the most common form of imaging modality undertaken with 54.9% regularly referring and 43.3% rarely. The referrals for CT (16.8% regularly) and MRI (5% regularly) are interesting and further exploration of referral patterns by osteopaths for advanced imaging appears justifiable. Data regarding the incidence of positive findings following referral to advanced imaging would be useful in considering the rights of direct referral for these investigations. Most commonly, CT and MRI imaging are referred through a medical practitioner, demonstrating the importance of professional links to medical practitioners. The referral rate for radiology has risen markedly since 1991, when only 6% of practitioners regularly requested x-rays, and 0% regularly for CT scans (Jamison, 1991b). In 1996, 11.5% of practitioners used “x-ray examination to assist diagnosis” (Mullen, 1997) (frequency not specified). New Zealand osteopaths referred just 5% routinely and 10% often for radiographs, and 0% for CT in the same categories in 1991 (McGrath, 1995). The impact of university training in diagnostic imaging with specialist academics and textbooks in the field (Yochum, 2004) has most likely driven this trend.

The low use, and request, of blood pathology (50% never and 45.8% rarely) and microbiology/cultures (83.7% never and 16.3% rarely) highlights the limited scope of practice of osteopaths in Australia, and this is consistent in the historical literature. It must be mentioned that there is no public subsidy for osteopath referred diagnostic testing (apart from spinal plain film x-rays), and this may present a barrier to referral for investigations that would involve the patient bearing the full cost of such investigations.

4.2.4.6 Therapeutic modalities

There is a broad spread of the thirteen modalities estimated in this survey. This spread of modality use has remained markedly stable since 1991. The practice of osteopathy in Australia appears to be highly eclectic, where a majority of respondents practise
five main modalities (soft tissue, muscle energy, high velocity, non-high velocity, stretching) over 60% of the time. There are interesting pockets of highly regular modality use, with the most prominent being that for 90-100% of the time 13% of respondents use osteopathy in the cranial field, 7% use strain counterstrain and 6% use functional technique. New Zealand osteopaths in 1991 estimated a similar breakdown of modality use - soft tissue (74% all /most of the time), articulation (78% all/most) and high velocity manipulation (68% all/most), although there was significantly lower use of muscle energy (McGrath, 1995).

4.2.4.7 Prescriptions

There is a dominant use of exercise prescription and dietary intervention amongst the respondents, and this was similar in 1991 in both Australia and New Zealand (Jamison, 1991b, 1991c). The change in nutrient prescription, which at 6.3% is significantly less than the 28% prescribing these in 1991 (Jamison, 1991b), is marked, possibly reflecting a change in focus of practice and educational curriculum. The New Zealand group had a higher use of these supplements - 40% routinely/often in 1991 (Jamison, 1991c).

The use of “other” prescriptions (nutritional medicine, herbal medicine, behavioural therapy) is interesting, as the census revealed low levels of training in these disciplines outside of the primary osteopathic qualification(s). There is less than 20% of the sample with other qualifications, and of this only half were clinically oriented, mostly naturopathy. Before the establishment of university based training, many osteopaths had training at diploma level in the modalities of nutrition, naturopathy, herbal medicine and acupuncture. The low figures for other qualifications in this survey may simply reflect the more specialised focus on osteopathy modalities in current training programmes, or the lack of opportunities to complete further training. In order to be safe and competent in clinical application, proper training and supervision is required, and this is the same for all practitioners.
4.2.4.8 Adverse events

Adverse events are known to occur in osteopathic practice (Ernst, 2001; Gibbons & Tehan). Of concern is that 6.9% of practitioners report rare serious adverse events. The term “rarely” was not defined in this survey instrument, but this finding underlines the need for research into the epidemiology of adverse events following osteopathic treatment.

4.2.4.9 Inter-professional relationships

Close contact with other health professionals has been a consistent feature in osteopathy in Australia. In 1991, 24% of respondents practised in multidisciplinary practices (Jamison, 1991b), and in 1996 41% of the practitioners practised at least part of their week in this setting, and received 12% of their referrals from GPs (Mullen, 1997). The main inter-professional contacts in 1996 were identified as GPs (24% of all contacts), radiologists (16%), podiatrists (11%), physiotherapists (8%), naturopaths (6%) and masseurs (6%) (Mullen, 1997). The current survey demonstrates that osteopaths in Australia have the strongest referral networks with GPs, masseurs, naturopaths and podiatrists, and therefore these groups are important components in the network of an osteopathic practice in Australia. Efforts to further enhance awareness and professional links with these groups may be justifiable. The UK data shows a trend of increasing referrals from GPs and consultants – up to 26% in 2001 from 22% in 1997, but like Australia and New Zealand, the majority are self-referred (General Osteopathic Council, 2001).

4.2.4.10 Continuing Education

The respondents regularly attended and placed importance on continuing education. The 1991 survey had a similar finding - 98% of respondents claimed that they routinely spent time each week on self-education, and 97% had undertaken more formal professional education since graduation (Jamison, 1991b). The sample group were all members of the AOA, and are therefore likely to be biased towards education events run by that organisation.
4.2.4.11 Opinion of training

The standout issue that respondents reported in regards to opinion of training appears to be gaining skills in operation of a small business. The practices are mixed between sole practitioner, osteopathic group practices and multidisciplinary practices, and these have different business models operating. The curriculum of the entry level training institutions and the continuing education activities of the professional association might be reviewed in the light of this data to ensure competent and successful business practice. Further qualitative research is required to validate this data.

4.2.4.12 Professional issues

Questions regarding ‘professional issues’ drew responses from the current study that are similar to the issues raised by respondents in the 1991 studies (Jamison, 1991a, 1991b), where research into cost effectiveness and efficacy of osteopathic management, and education of the public and other health practitioners about osteopathy were considered to be important issues.

The importance of expanded practice rights appeared to exhibit a trend away from the responses gathered in the 1991 survey, where a scope of practice including the prescription of medicines was emphasised (Jamison, 1991a).

4.2.4.13 Graduate success – temporal patterns of patient numbers and income

Looking at the estimated patient numbers, and categorising the sample into years since graduation (Figure 2), it is possible to estimate weekly and annual income. This analysis suggests that new graduate income from patient consultation fees in the first two years after graduation is A$80,640 gross per annum (before business expenses and overheads), and is well above the average annual professional income in Australia in 2003 of A$57,200 (Australian Bureau of Statistics, 2006d). Income appears to plateau, possibly under the influence of part time work and other income activities (eg academic work was not counted), but after 20 years of experience the curve results in a gross income of A$141,120pa. Average chiropractic net income in
Australia is A$216,358, which is higher than osteopaths possibly due to seeing an average of 103 patients per week for 21 minutes per consult (Chiropractic Association of Australia, 2005).

4.2.4.14 Lower Socio-economic access

The main patients of osteopathic practices in Australia pay private fees, and with only 50% of the Australian public having private health insurance (Australian Bureau of Statistics, 2006c), this highlights the issue regarding access to this service for lower socio-economic groups. A majority (n=276, 82.4%) of the respondents use concession rates, and this may reflect an attempt to promote wider access. There are no public funded osteopathic outpatient services in Australia, although the teaching clinics of the universities offer consultations at rates that are less than the prevailing market rates.

4.2.5 Conclusion

The osteopathic profession in Australia is a young and growing profession, with high levels of tertiary qualification and commitment to continuing education. The practitioners earn a moderately high professional salary and graduates appear to earn above the average salary within 2 years of graduation. These health professionals practice within a multidisciplinary network, utilise the diagnostic skills of primary care in a limited way, and have a limited scope of practice due to restricted access to diagnostic technology and prescription rights. The most important issues facing the profession as reported by the respondents were an apparent ignorance of osteopathy in the public and professional domain, and increasing the evidence for the efficacy of osteopathic treatment.
4.3 Profile of the members of the Australian Osteopathic Association: Part two – the patients


**Funding**

The National Fund for Research into Osteopathy (NFRO) funded the development of the census, printing and correspondence.
4.3.1 Introduction

Workforce surveys provide vital foundations upon which to build a profession’s knowledge of itself and its directions for the future. The Research Council of the Australian Osteopathic Association (AOA) recognised the need for a workforce survey as a high priority, as there needed to be a solid database of the professional association. Members of the Research Council identified the need to clarify the characteristics of patients who consult members of the Australian Osteopathic Association, in order to: 1) identify and characterise members of the professional association for government, insurers, the public and intra-professionally; 2) plan future developments in training and service provision; 3) support any enquiry into scope of practice issues; 4) prioritise research on the basis of common clinical presentations.

In Australia, osteopaths are members of the allied health grouping that includes chiropractors and physiotherapists. Osteopathy in Australia is a registered health profession, and governed by Registration Boards in each state. Training is currently offered through three universities. The largest peak body independent of government is the Australian Osteopathic Association.

Members of the Australian Osteopathic Association has been surveyed previously (Jamison, 1991a, 1991b; Mullen, 1997). The one by Jamison published in 1991, the Delphi study which supported it and the 1995 Mullen survey targeted members of the AOA, a subset of the total population of osteopaths in Australia. Members of the New Zealand Register of Osteopaths were surveyed in 1991 (Jamison, 1991c) as well as in 1995 (McGrath, 1995) – a project which also included members of the International Society of Osteopathic Practitioners and a snapshot of their patients (McGrath, 1995). In 2001, the General Osteopathic Council (GOsC), the governing body of the osteopathic profession in the United Kingdom (UK), undertook a survey of the 3161 registrants (General Osteopathic Council, 2001). The results of the GOsC survey indicate trends between 1994 and 2001 regarding the practice of osteopathy in the UK and characteristics of patients consulting osteopaths.
This article focuses on the snapshot of a day of practice, which was the second part of the Osteopathic Census 2004. The first part focused on the practitioners and was previously reported in this journal (Orrock, 2009a).

4.3.2 Methods

4.3.2.1 Development

Survey questions were adapted from those used in surveys of healthcare professions (Bensoussan, 1996; Hale, 2002a, 2002b; Jamison, 1991b; Mullen, 1997), and sought information about practitioner demographics, qualifications, work patterns and clinical activities including the snapshot of patients. The survey instrument (see Appendix) was formatted to allow commercial electronic scanning (NRS Pearson Pty Ltd). Face validity was established with the help of two groups within the AOA - the Research Council consisting of five members, and the Federal Council consisting of seven members. The draft questions were also distributed to an external educationalist with expertise in questionnaire methodology. These 13 people were asked to provide feedback on the relevance and clarity of the questions, and questions were amended to accommodate feedback where appropriate. The Human Research and Ethics Committee of Southern Cross University provided approval for the project.

4.3.2.2 Administration of census

The survey was distributed by mail to the 656 Australian resident practising members of the Australian Osteopathic Association in March 2004, and part 2, the snapshot of patients, was filled in on a single day – 11th May 2004. A strategy of publishing information about the survey in the newsletter of the AOA was used to improve the response rate. The number of Australian registered osteopaths at the time of distribution was 945 (Osteopaths Registration Board of NSW, personal communication). This meant that the membership of the AOA represented 69.4% of the total number of registered osteopaths in Australia.
4.3.2.3 Statistical analysis

The data was entered into spreadsheets (Microsoft Excel) and analysed using SPSS v11.0 for Windows (SPSS Inc, Chicago, IL). Descriptive statistics were used to explore the data. The occupational groupings were based on the Australian and New Zealand Standard Classification of Occupations (Australian Bureau of Statistics, 2006a). All patients were enrolled in the study by the practitioner and filled in an informed consent, and were free to refuse participation.

4.3.3 Results

This part of the census was completed by 255 (75%) of the responding practitioners, which means 85 (25%) who completed part one did not complete part two.

4.3.3.1 Age, gender and type

The 255 respondents saw 2238 patients on that day in May - an average of 8.7 patients. 18.9% of them were new patients, and 62.5% of them female. They were mostly aged in the 30-39 (23.25%) or 40-49 (23.15%) age groups, but there was a large range from 0-80+years (see Figure 1). 89% were private paying patients. The patients were from a broad cross-section of occupational groupings, outlined in table 1.
### Figure 11  Distribution of age categories

#### Table 12  Occupations of patients

<table>
<thead>
<tr>
<th>Occupational grouping</th>
<th>Number (% of positive respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional</td>
<td>n=363 (16.5%)</td>
</tr>
<tr>
<td>Technicians and Trades</td>
<td>n=307 (14.0%)</td>
</tr>
<tr>
<td>Managers</td>
<td>n=302 (13.8%)</td>
</tr>
<tr>
<td>Clerical and Administrative</td>
<td>n=246 (11.2%)</td>
</tr>
<tr>
<td>Retired</td>
<td>n=215 (9.8%)</td>
</tr>
<tr>
<td>House duties/parent</td>
<td>n=178 (8.2%)</td>
</tr>
<tr>
<td>Student</td>
<td>n=159 (7.2%)</td>
</tr>
<tr>
<td>Sales</td>
<td>n=124 (5.6%)</td>
</tr>
<tr>
<td>Community and personal service</td>
<td>n=106 (4.8%)</td>
</tr>
<tr>
<td>Labourers</td>
<td>n=65 (2.9%)</td>
</tr>
<tr>
<td>Child</td>
<td>n=58 (2.6%)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>n=32 (1.5%)</td>
</tr>
<tr>
<td>Machine operator/driver</td>
<td>n=31 (1.5%)</td>
</tr>
<tr>
<td>Disability</td>
<td>n=9 (0.4%)</td>
</tr>
<tr>
<td>Missing</td>
<td>n=43</td>
</tr>
</tbody>
</table>
4.3.3.2 Presenting complaints

The census gave the opportunity to list and describe three presenting symptoms, in an attempt to capture a wide scope of patient characteristics. The predominant first presenting symptom was pain (82.7%) with a small (7.8%) group of patients complaining primarily of immobility. The location of these symptoms was overwhelmingly in the lumbar spine (27.3%) and neck (24.5%) (see Figure 2), followed by head (9.8%) and then other spinal regions, with less frequency of appendicular presentations (see Figure 2).

![Figure 12: Location of 1st presenting symptom](image)

The second presenting symptom, reported present in 60% (n=1343) of patients, was still most commonly of pain in the neck (18.8%) and lumbar spine (16.8%). Immobility was more frequent as a symptom type (14.1%) and the thoracic spine as a location (13.8%) in the second presenting symptom, and head as a location was
lower (5.9%) than the first presenting symptom pattern. For the third presenting symptom, reported in 22.9% (n=514), the patterns were the same as for the second presenting symptom.

Wide ranging “other” symptoms were reported under each category. Although generally below 10% of complaints, there were presentations of headaches (6 to 6.5% - overlapping with “pain” and “head” in the main answers), and childhood development check-ups (n=45, 2%). There is a small osteopathic presence in the management of systemic disorders, mainly respiratory and gastrointestinal (1.3 – 1.5%).

The primary presenting complaint had a history commonly longer than 12 weeks (see Table 2). Of the total patients recorded, 18.9% were new patients. Of these, 6.9% were patients of another osteopath, but were new to the practice. This question was completed for 92.3% of the patients.

<table>
<thead>
<tr>
<th>Duration</th>
<th>Number</th>
<th>% of positive respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-3 wks</td>
<td>561</td>
<td>27.8</td>
</tr>
<tr>
<td>3-12 wks</td>
<td>424</td>
<td>21.0</td>
</tr>
<tr>
<td>12+ wks</td>
<td>1034</td>
<td>51.2</td>
</tr>
<tr>
<td>Missing</td>
<td>219</td>
<td></td>
</tr>
</tbody>
</table>

For the previous patients, the length of time they had been seen by this practitioner for any complaint (answered for 64% of patients) was evenly spread over less than one month to more than 5 years - 42% of patients have been seen for over 12 months (see Table 3). The number of previous patients returning to the practice with a new complaint was 25.3%.
Table 14 Length of time seeing the practitioner for any complaint

<table>
<thead>
<tr>
<th>Duration</th>
<th>Number</th>
<th>% of positive respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 month or less</td>
<td>300</td>
<td>21.1</td>
</tr>
<tr>
<td>1-3 months</td>
<td>192</td>
<td>13.5</td>
</tr>
<tr>
<td>3-6 months</td>
<td>164</td>
<td>11.6</td>
</tr>
<tr>
<td>6-12 months</td>
<td>167</td>
<td>11.8</td>
</tr>
<tr>
<td>12-24 months</td>
<td>211</td>
<td>14.9</td>
</tr>
<tr>
<td>2-5 years</td>
<td>213</td>
<td>15.0</td>
</tr>
<tr>
<td>more than 5 years</td>
<td>172</td>
<td>12.1</td>
</tr>
<tr>
<td>Missing</td>
<td>819</td>
<td></td>
</tr>
</tbody>
</table>

With regards to the number of subsequent consults for the presenting complaint (answered by 65.7%), the majority of these (68.1%) were below seven consults. The number of patients who had been seen more than thirty times for this complaint was 7% (n=103) (see Table 4). A majority (57%) of people have sought previous treatment from another practitioner for their presenting symptoms, and 62.4% have been unsatisfied with that previous treatment.

Table 15  Subsequent consult number for presenting complaint

<table>
<thead>
<tr>
<th>Consult number</th>
<th>Number of positive respondents</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 3</td>
<td>608</td>
<td>41.3</td>
</tr>
<tr>
<td>4 to 6</td>
<td>395</td>
<td>26.9</td>
</tr>
<tr>
<td>7 to 10</td>
<td>161</td>
<td>10.9</td>
</tr>
<tr>
<td>11 to 15</td>
<td>87</td>
<td>5.9</td>
</tr>
<tr>
<td>16 to 20</td>
<td>63</td>
<td>4.3</td>
</tr>
<tr>
<td>21 to 30</td>
<td>54</td>
<td>3.7</td>
</tr>
<tr>
<td>31 to 40</td>
<td>35</td>
<td>2.4</td>
</tr>
<tr>
<td>41 to 100</td>
<td>55</td>
<td>3.7</td>
</tr>
<tr>
<td>100 plus</td>
<td>13</td>
<td>0.9</td>
</tr>
<tr>
<td>Missing</td>
<td>767</td>
<td></td>
</tr>
</tbody>
</table>

The referral pattern (answered by 92.8% of patients) shows the major source is self (70.5%) – whether this is from friends and family or general knowledge. The incidence of referrals from general practitioners was 4.9% and from other practitioners was 10.1%. Yellow pages and advertising (8.6%) was the only other significant source (see Figure 3).
4.3.3.3 Diagnosis

The frequencies of physical examination carried out and the number of times that the practitioner made a positive finding on examination are summarised in Table 5. The musculoskeletal system was examined most commonly (78% of patients) followed by the neurological system (43%). The gastrointestinal (13%), cardiovascular (12%) and respiratory (10%) systems were also present, with the frequency of positive findings following the same order. The practitioners chose one or more diagnoses from a list, the most common being somatic dysfunction (74% of patients), postural dysfunction (46%), trauma (29%), psychogenic/stress (16.3%) as well as lower levels of organic disease (8.9%) and nutritional dysfunction (2.5%).

Figure 13 Source of patient referral
Table 16  Physical examination performed and positive findings

<table>
<thead>
<tr>
<th>System examined</th>
<th>Number (% of positive respondents)</th>
<th>Number of positive findings (% of positive respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Musculoskeletal</td>
<td>n=1735 (78%)</td>
<td>n=1566 (70%)</td>
</tr>
<tr>
<td>Neurological</td>
<td>n=951 (43%)</td>
<td>n=302 (13.5%)</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>n=271 (13%)</td>
<td>n=56 (2.5%)</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>n=264 (12%)</td>
<td>n=20 (0.9%)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>n=231 (10%)</td>
<td>n=33 (1.5%)</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>n=131 (6%)</td>
<td>n=0</td>
</tr>
</tbody>
</table>

* Results do not equal 100% as respondents could choose more than one system

4.3.3.4  Treatment modalities

Techniques employed were: soft tissue (71% of patients had this technique used on them), joint articulation (57%), high velocity (51%), muscle energy (50%), exercise prescription (33%), cranial (23%), functional (21%), counterstrain (17%) and myofascial (16%) (see Figure 14).
4.3.4 Discussion

The response rate for Part 2 was 38.9% of the AOA membership and is applicable only to the national membership of the AOA, as over 30% of registered osteopaths in Australia at the time of the census were not members of the AOA, and were not sent the census (AOA Federal Office, personal communication). The membership was seen as an opportunistic sample of the profession in Australia, where all addresses were current, and regular correspondence was established. Surveying all registered osteopaths in Australia would provide a more representative view of the national picture, but data about the patients of non-AOA member registered osteopaths for comparison is not available from the Registration Boards.

The reasons for the lower response rate in Part 2 could be that some practitioners did not normally practice on a Tuesday or were on leave - 10 people reported that they were on leave from the practice for maternity, illness or private holidays. Another reason may be difficulty filling in the patient snapshot section - 2 people reported that the informed consent process was too time consuming in a day of practice.

4.3.4.1 Previous surveys

A comparison of previous surveys that included a snapshot of patients is summarised in Table 17. The 1996 Australian survey (Mullen, 1997) returned a response rate of 37.6%, at a time when the AOA membership represented 70% of registered osteopaths in Australia. Whilst that survey contained a snapshot of patients, it had a stronger focus on comparing graduating characteristics and screening for contraindications to high velocity cervical manipulation. The New Zealand survey of 1995 (McGrath, 1995) profiled members of two professional organisations and their patients, and covered similar characteristics as the current survey. The General Osteopathic Council (GOsC) survey of 2001 (General Osteopathic Council, 2001), had a response rate of 26.9% (n=852) of all registrants in the UK.
The differences in the instrument, the specific questions asked and the years between this census and the New Zealand and UK surveys (9 and 3 years respectively) may create error in some comparisons. Also, the data collected in the UK survey was of all registrants, and not just the subset of members of a professional association.

### Table 17

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Population sample</th>
<th>n</th>
<th>Response rate</th>
<th>Patient number (mean)</th>
<th>Patient Gender (% F)</th>
<th>Age (median category)</th>
<th>New patient %</th>
<th>Primary symptom location</th>
</tr>
</thead>
<tbody>
<tr>
<td>McGrath</td>
<td>1995</td>
<td>NZRO/ISOP members</td>
<td>98</td>
<td>60.8%</td>
<td>12.3</td>
<td>62.5</td>
<td>30-39</td>
<td>19.5</td>
<td>“Neck” 45.7%</td>
</tr>
<tr>
<td>Mullen</td>
<td>1996</td>
<td>AOA members</td>
<td>100</td>
<td>37.6%</td>
<td>11.6</td>
<td>61</td>
<td>30-39</td>
<td>13.3</td>
<td>“Cervical” 44.7%</td>
</tr>
<tr>
<td>GOsC</td>
<td>2001</td>
<td>UK Registered osteopaths</td>
<td>852</td>
<td>26.9%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orrock</td>
<td>2004</td>
<td>AOA members</td>
<td>341</td>
<td>38.9%</td>
<td>8.7</td>
<td>62.5</td>
<td>30-39</td>
<td>18.9</td>
<td>“Lumbar spine” 27.3%</td>
</tr>
</tbody>
</table>

#### 4.3.4.2 Age, gender and type

The mean number of patients seen in a day of practice has decreased since 1996 – down to 8.7 from 11.6, and the predominance of the female gender was the same (Mullen, 1997) (see Table 17). The fact that they were 89% private paying patients demonstrates the low uptake of insurance and public patients in this market. The age range in 1996 was not significantly different to this study in most categories, except that the current practices see double the amount of people 60 years of age and over (n=331, 14.6% of patients). The number of new patients per day has remained similar over that 8 years (1.5-1.6), and currently includes 6.9% of patients who have seen another osteopath. The new patient figure of 18.9% is similar to New Zealand (19.5%) (Jamison, 1991c) and the UK (21%) (General Osteopathic Council, 2001).

Osteopaths in the UK saw a slightly less average number of patients on snapshot day (7.6), but other characteristics were similar to Australia and New Zealand - 60%
female, predominantly self-funded (86%), although the median age category in the UK was older at 40-49 (General Osteopathic Council, 2001). Osteopaths in Australia, New Zealand and the UK have a similar proportion of children up to nine years of age presenting to their practices (3.8%, 4% and 4.5% respectively) (General Osteopathic Council, 2001; McGrath, 1995; Mullen, 1997). The patients are from a broad cross-section of occupational groupings. As mentioned in Part 1 (section 4.2.4.14), just half the Australian population are covered by private health insurance (Australian Bureau of Statistics, 2006c), and osteopathy is not offered in public institutions outside of the student clinics in the universities offering osteopathic programmes. There are no Australian patient data for the professions of chiropractic and physiotherapy available for comparison.

### 4.3.4.3 Presenting complaints

The dominance of painful and immobile low back and neck conditions was predictable in this sample. In 1996, the pattern was similar (Mullen, 1997). The majority of patients had 2 presenting symptoms, usually a mixture of pain in the low back and neck, with a smaller presence of thoracic spine pain and immobility as well as headaches. A quarter of patients had three distinct presenting symptoms, which demonstrates the broad focus of these practices. This presentation of multiple location pain and immobility suggests that osteopaths have a scope of practice that includes the diagnosis and management of complex pain syndromes.

Many of these patients had chronic conditions as the primary presenting symptom. They reported that they had a history of that complaint for over 12 weeks (51.1%), which is classified as chronic (Merskey, 1994). People with chronic pain are known to commonly present with pain in multiple sites, as this survey demonstrates (Carnes, 2007). Also, the number of patients who had been seen more than 30 times for this complaint (7%) also possibly demonstrates a high level of chronicity. This number of consultations may be related to the 12% of patients who have seen this practitioner for longer than 5 years.

The referral pattern highlights the fact that institutional and/or formal referrals to osteopaths are not frequent. The incidence of referrals from general practitioners
(GPs) and registered practitioners is small but visible, and will likely be increased by the Enhanced Primary Care programme under Medicare, which gives GPs the option to send chronically ill people to osteopaths with substantial subsidy (Department of Health and Ageing, 2007).

### 4.3.4.4 Diagnosis

The results in terms of the diagnostic categories reflect a broad practice base. The patients were labelled with predictable features of a practice in the musculoskeletal domain - postural dysfunction and trauma, as well as that of an osteopathic practice - somatic dysfunction. The patients were also diagnosed with psychogenic/stress, organic disease and nutritional dysfunction. This points to the primary care responsibility of the osteopath, where a broad scope of diagnostic skill is required to differentiate between dysfunction, disease and psychogenic aetiologies (Grace et al., 2006). Unfortunately, the diagnostic categories used in this study do not readily equate to the New Zealand and UK survey categories, although the New Zealand practitioners did diagnose psychogenic/stress in 7.8%, and pathological disease in 1.2% of the patients (McGrath, 1995), both less than half the incidences in the current survey.

The use of physical examination is one measure of the extent to which a primary diagnosis is being sought. Osteopaths in Australia are primary care limited scope health practitioners, and have an identifiable role in the management of painful musculoskeletal conditions. The use of laboratory and diagnostic technology by osteopaths is limited by the lack of health insurance and/or Medicare subsidy, apart from plain spinal radiographs. The evidence for use of diagnostic methodologies in this census demonstrates the primary care function of some practitioners outside of the predictable neuro-musculo-skeletal domain. This is evidenced in the occurrence of positive examination findings in the cardiac (0.9%), respiratory (1.5%) and gastrointestinal (2.5%) systems, demonstrating an important primary diagnostic role in these practices, albeit small. Patients present to osteopathic practices commonly in the 35-65 years of age range and with chronic painful conditions, which increase the probability of co-morbidities existing in other systems that require diagnosis and
management. This appears to support the teaching of safety and competency in general systems examination.

4.3.4.5 Treatment modalities

The modality use reflects the estimates from Part 1 (section 4.2.3.5), in that soft tissue technique stands out as a consistent feature of osteopathic treatment, amongst the group of techniques used the majority of the time – joint articulation, high velocity thrust and muscle energy. Of interest is the frequency of exercise prescription and lifestyle management, demonstrating a third of patients will leave with educational and lifestyle changes to enhance self-management and prevention. The 1996 survey reported a lower use of articulation, but was no different in the use of the other modalities (Mullen, 1997). The change in training institutions and type of programme in that time does not appear to have changed the blend of treatment modalities. By comparison, New Zealand osteopaths in 1996 appeared to use more craniosacral (31% of the time) and less muscle energy (29% of the time), although the scaling used was different (McGrath, 1995).

4.3.4.6 Limitations

Limitations to this research are predominantly regarding the response rate, where a non-responder bias could be present both from members of the AOA who did not respond to this survey, but also registered osteopaths who are not members of the AOA. This census should be repeated on a five-year cycle, in order to track growth and change. Improvements to this instrument would be:

- To survey the broader registrant group.
- To ensure clarity of proportionate style questions. Respondents may differ in their interpretation that percentage based answers must add to 100%.
- To survey member categories separately (eg semi-retired, academic), as the group of people who did not practise on the snapshot day may bias the sample questions from the first part.
- To capture less data in text form, as it is awkward to compile, and requires interview based qualitative methodology to extract valid meaning.
• People can present to osteopaths for maintenance and check-up style appointments, and this should be an option for presenting complaint, best termed “reason for appointment”.

• Diagnostic categories (and other questions) need to be made consistent for ease of international comparisons.

4.3.5 Conclusion

Members of the Australian Osteopathic Association complete approximately two million consultations a year, which for the vast majority are paid by the individuals themselves with minimal public health subsidy. These consultations are often with patients who suffer chronic conditions causing pain of their spinal regions as well as headaches, and they are treated with a variety of manual techniques, lifestyle and exercise management. Osteopaths utilise primary care diagnostic skills, and a small but significant group of patients have co-morbidities in systems outside of the predictable musculoskeletal domain. Members of the AOA see patients from a broad cross section of occupational groups. Limitations of this survey were in the relatively low response rate, the possibility of a non-responder bias and the variability inherent in self-reporting. Further analysis of this data will be presented in future to ascertain relationships of the variables age, gender and patient type with diagnosis and treatment characteristics.
4.4 Discussion

The two publications that resulted from the preceding workforce survey demonstrated details of the practice and patients of a significant sample of members of the Australian Osteopathic Association (52%), which represented 38.9% of Australian osteopaths at that time. Comparisons were made to New Zealand and the United Kingdom which are similar jurisdictions and that had completed similar workforce surveys. Since those publications, there have been a number of further studies to enable comparisons to this data (Burke, Myers, & Zhang, 2013; Xue, 2008). It is worthwhile to firstly assess this additional literature to allow a comprehensive synthesis of the similarities in the data to be made.

Xue (2008) conducted brief phone interviews in 2005 with 1067 individuals in Australia randomly selected by a representative sampling method, and inquired about their utilisation of CAM therapies in the last 12 months. They reported specifically on the data regarding acupuncture, chiropractic and osteopathy. People visiting osteopathic practitioners were the lowest number of the three professions at 4.6% (n=51) and they were in a lower socioeconomic group comparatively. They presented to osteopaths most commonly for back pain, but also significantly for general health and wellbeing and to improve their ability to perform activities of daily living. The interviewees were asked about their perception of the level of outcomes and reported highly positive outcomes overall – for osteopathy they reported less pain (79.5%), improved ability to undertake daily activities (60.5%) and improved wellbeing (45.6%). This data came from a small number of subjects (n=51), so the comments on satisfaction and outcomes cannot be generalised to any great extent. Similar caution should be applied to the difference in the studies regarding the age group of patients, where Xue et al (2008) found the dominant age range to be older than that found in the data in this chapter’s studies that was on a larger sample (65+ compared to 30-39 found in 4.1). The dominant cause of visiting an osteopath was given as “back pain” (48.4%) which, despite not clarifying if it included both lumbar and thoracic complaints, coincides with the finding in the surveys reported in this chapter of the most common complaint being pain the lumbar spine (27.3%). The finding on the number of osteopathic consultations over the previous 12 months was 5.7 in the
Xue et al (2008) study for undefined problems, and this is similar to the results of the patient snapshot (most commonly 4-6 consultations for the presenting complaint). The focus group and the patient survey and interviews (reported in Chapter 6) also reported that patients require ongoing care for chronic non-specific low back pain that was estimated at between 6-10 consultations. This data was considered by the Delphi panel (reported in Chapter 7) who agreed that the number of follow up consultations should be based on focus group data, and that four outcome measurement points should be scheduled over 26 weeks in order to capture the effectiveness of osteopathic healthcare on people with chronic non-specific low back pain over time.

Burke et al. (2013) completed a cross-sectional study of Australian osteopaths that collected a sample of longitudinal data of patient management. The response rate was very small at 3.4% of the population of registered osteopaths at that time (2010-11), compared to 38.9% for the workforce study and 26.9% for the snapshot of patients reported in this chapter, but the demographics and geographical spread was similar to that found in the survey in this chapter and to the national registration authority data. The age of patients was in the same category in both data sets (30-39), and the dominant primary presenting symptom was pain in the lumbar spine in both studies. The patients reported the presence of more than one symptomatic region in both the Burke et al (2013) (68.2% had three) and Orrock (2009b) studies (60% had two, and 22.9% had three). These findings support the findings in practitioner focus group and patient interviews (reported in Chapter 6) that the scope of practice of osteopathic healthcare includes complex pain presentations that require multi-regional assessment. There were co-morbidities present in 37.9% of the Burke et al (2013) sample, most commonly in cardiovascular system, mental health frequency in the snapshot had patients being examined regularly in non-musculoskeletal systems – gastrointestinal (13%), cardiovascular (13%), and respiratory (10%) systems. These findings demonstrate that osteopathic healthcare practice has presentations at primary care level that require broad diagnostic assessment of the patient’s presentation, and consideration of cross disciplinary referral.
Inward referral patterns reflect that word of mouth is dominant; Burke et al found it at 71.3%, the snapshot at 70.5%, and with similar general practitioner referral (Burke et al 7.3%, snapshot 4.9%). These patterns were supported in practitioner focus group and patient interviews, where the relationship between osteopaths and medical practitioners was evident. Outward referrals in the snapshot again showed common medical referral (occasionally/frequently 87.7%), but also a multidisciplinary pattern. Osteopathic healthcare from these studies is a collaborative practice in a healthcare team.

From the Burke et al (2013) study, and the data in this thesis, osteopathic healthcare involves the use of a wide range of manual therapies – with soft tissue, articulation, high velocity thrusts and muscle energy techniques all used above 10% of the time reported in the surveys. Education and advice (11.9%/6.9%) and exercise therapy (5.7%/8.6%) are both used as modalities of practice in the Burke et al (2013) and Orrock (2009a and 2009b) studies respectively, and this was confirmed in practitioner focus group and patient interviews. Synthesising the data from this thesis and other research demonstrates that osteopathic healthcare intervention is multimodal and includes self-management strategies for patients.

Data on osteopathic practice from the UK was collected by the National Council for Osteopathic Research in 2009 using a standardised collection survey (Fawkes, 2013; Fawkes, Leach, Mathias, & Moore, 2014). This was a pilot study gathering information from 9.4% of the osteopaths in the UK (n=342), and again the results of the 1,630 patient data sets supported many of the characteristics from the Australian data. Lumbar region pain was the most common presenting symptom (36%), a large number (48.8%) of patients reported co-morbidities including hypertension (11.7%) and asthma (6.6%). The age range was the same as Orrock (2009b) at 30-39yrs, and self-referral was dominant at 79.9%. The intervention was a similar range of manual techniques – soft tissue (78%), articulation (72.7%), high velocity thrusts (37.7), education (35.8%) and exercise (22.6%). There was a difference in the stage of the presenting complaint between this data and the Australian, with the majority (51.1%) presenting with acute pain. The most common treatment side effects for 48 hours after treatment were reported as increased stiffness (18%) or pain (14%). This is
similar to reports in the literature (Carnes, Mars, Mullinger, Froud, & Underwood, 2010; Rajendran, Bright, Bettles, Carnes, & Mullinger, 2012), and the practitioner survey reported in this chapter – mild adverse events reported as 40.4% occasionally/frequently.

The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist for quality in cross sectional and survey studies was closely adhered to in these publications. The only discrepancy was that the survey was not formally piloted, but was based on a previous national survey that had been piloted and the author had direct advice on improvements from the authors and developers of the original survey. The individual questions were tested on a small group of practitioners as reported in the publication. The risk in neglecting a formal piloting of the survey is that some respondents may read questions differently and respond inconsistently.

Workforce studies of this kind face a number of challenges, including achieving high response rates, validity and replicability (Lieder et al, 2016). There is evidence of respondent burden in some health workforce surveys due to an increase in the number of surveys, time constraints and lack of tailoring and relevance to every practitioner. The survey in this study was specifically designed for osteopathic clinical practitioners, and this was the first national survey of its kind and achieved a reasonable response rate. The survey instrument requires robust psychometric testing to ensure validity and reliability, especially in order to replicate the study. This current study was based on a previous national survey tool, but only had a small sample of practitioners to test the questions and format. This meant that further studies (Burke et al, 2015) had some incompatible data.

In summary, the data reported in this chapter outlines osteopathic healthcare as a primary care practice dealing with complex pain presentations of the musculoskeletal system, commonly chronic non-specific low back pain. The patients are predominantly self-referred, have co-morbidities, undergo multisystem assessment and are given education and advice for self-management and treated with manual therapy and exercise therapy over a series of consultations, with short-term mild side
Chapter 4 – Stage 1 - Quantitative

effects of treatment experienced. There is regular cross referral to medical and other practitioners. As a result of this work, these features of osteopathic healthcare have enhanced validity as they are based on research and synthesized with other data, rather than being anecdotal. This data led directly to the question of exploring the level of evidence for the effectiveness of osteopathic healthcare in what was found as the most common presenting complaint – chronic non-specific low back pain.
Chapter 5 – Stage 2 – Systematic Review

5.1 Chapter introduction and data synthesis

This stage follows the quantitative Stage 1, which revealed that a sample of practitioner members of the Australian Osteopathic Association reported that the most common presentation to them was chronic low back pain, and that the osteopathic healthcare intervention had a multi-modal character – a range of manual therapies, exercise and lifestyle advice. That data was compared to more recent studies and international data.

This Stage 2 aims to establish if robust clinical evidence exists to support the practice that was revealed in Stage 1, and is designed to answer the third question: what is the current evidence for authentic osteopathic healthcare applied to the most common presenting problem based on the workplace findings – chronic non-specific low back pain?

Following is a peer reviewed publication that was published in the journal BMC Musculoskeletal Disorders. The systematic review reported in this chapter updated the level of evidence for osteopathic healthcare in chronic non-specific low back pain, and specifically excluded studies that did not reflect osteopathy as it is practiced based on the previous workforce study. This was a unique approach at the time, and prompted a further systematic review which added more recent trial evidence – this is discussed further in section 5.3.
5.2 Osteopathic intervention in chronic non-specific low back pain: a systematic review

Peer reviewed and published as: Orrock PJ, Myers, SP. Osteopathic intervention in chronic non-specific low back pain: a systematic review. BMC Musculoskeletal Disorders 2013,14:129.

Author contribution: Paul J Orrock and Stephen P Myers planned the systematic review and developed the methodology. Paul J Orrock was the principal investigator, completed the literature search, wrote the body of the paper, and was one of the reviewers. Stephen P Myers was the other reviewer, contributed to the interpretation of the results, edited the paper and co-wrote the discussion. Both authors read and approve the final manuscript.
5.2.1 **Background**

5.2.1.1 **Rationale**

Chronic Low Back Pain (CLBP) is pain that is located between the costal margin and buttocks and has persisted for longer than 3 months. Patients suffer physical disabilities and psychological distress concurrently with the pain (Bogduk, 2004). The condition has a high incidence and prevalence. International back pain researcher Gordon Waddell (1996) described CLBP as a twenty-first century epidemic. In 2007, 13.8% of Australian population (2,846,400) stated they had a back pain/problem, and/or a disc disorder (Australian Bureau of Statistics, 2009). These disorders are categorised as musculoskeletal conditions, and in 2004–05, musculoskeletal conditions were more prevalent than any other of the National Health Priority Areas (NHPAs), with 31% of Australians suffering from one or more of these conditions (Australian Bureau of Statistics, 2009). Arthritis and musculoskeletal conditions were also responsible for the main disabling condition in more than one in three Australians with a disability (Australian Institute of Health and Welfare, 2005), and were a major area of health expenditure in 2001–02, with around $4.6 billion spent on the conditions.

Non-specific low back pain is described in a recent review of national guidelines (Koes et al., 2010) as a diagnosis of exclusion, where pain caused by a suspected or confirmed serious pathology (‘red flag’ conditions such as tumour, infection or fracture) or presenting as a radicular syndrome have been ruled out (Koes et al., 2010). The review states that some guidelines, for example the Australian and New Zealand guidelines, do not distinguish between non-specific low back pain and radicular syndrome.

Osteopathic Medicine is a medical system of diagnosis and therapy based on a set of overarching principles that give osteopathic medicine a holistic basis for its practice (Seffinger et al., 2003). It is practised worldwide, predominantly in developed western nations, and the practice varies from full medical scope in the US to allied/adjunctive health in the UK, Australia and New Zealand amongst others. A major foundation of osteopathic medicine worldwide is an evaluation of
the somatic tissues for signs of dysfunction which is treated with a broad range of manual therapies and adjunctive care.

Osteopaths manage a range of patients depending on the jurisdiction and scope of practice. Because of utilising the holistic diagnostic model and a broad range of manual techniques, Osteopathic Manipulative Treatment (OMT) cannot be confined to a single intervention. Osteopathic medicine is one of the registered professions legally allowed to use Spinal Manipulative Therapy (SMT), defined as manual loading of the spine using short or long leverage methods (Waddell, 1996), and SMT as a single modality has been heavily researched (Assendelft, Morton, Yu, Suttorp, & Shekelle, 2004; Bronfort, Haas, Evans, & Bouter, 2004). John Licciardone, principal author of the only systematic review of OMT in chronic low back pain and a senior clinical academic, warns that OMT is not chiropractic or simple SMT, but a complex intervention based on a multi-factorial diagnostic work up (Licciardone et al., 2005).

The results of a sample of 2238 patients presenting to 255 Australian osteopathic practices (Orrock, 2009b) demonstrate that chronic low back pain is a common presenting problem to these practices, and that the interventions are multi-dimensional. The most common primary presenting symptom was pain located in the lumbar spine (27.3%), and 51.2% of the primary presenting complaints were classified as chronic. The osteopathic intervention on this subset of patients was predominantly soft tissue techniques (78% received this modality), joint articulation (65%), muscle energy (58%), high velocity manipulation (synonymous with SMT) (55%) and exercise advice (42%) (Orrock, 2009b).

The results of a pilot study surveying 342 osteopathic practices in the United Kingdom that collected data on 1630 patients (Fawkes et al., 2014) demonstrated that pain located in the lower back was the most common presenting symptom (36%), and that 37.7% of patients presenting had chronic complaints. The most common osteopathic interventions for these patients were soft tissue techniques (78% received this modality), joint articulation (72.7%), high velocity manipulation (37.7%) and education (35.8%).

There is a need to evaluate the effectiveness of this service to these patients using rigorous research that can be applied to practice. A comparative review of the clinical trial literature of SMT or massage or osteopathy in the treatment of low
back pain reveals an evidence base for SMT and massage, both modalities in use by osteopaths, but a lack of research into whole osteopathic practice as demonstrated in the survey data mentioned. A Cochrane review of SMT in low back pain concluded that despite over 800 publications addressing this issue, evidence for the effect on low back pain is equivocal (Assendelft et al., 2004). The Cochrane review of 13 clinical trials of massage found that there is evidence that it may be beneficial for subacute and chronic low back pain in conjunction with exercise (Furlan, Imamura, Dryden, & Irvin, 2009). A systematic review and meta-analysis of osteopathic clinical trials up to 2003 (Licciardone et al., 2005) concluded that patients had significant improvements from osteopathic intervention, but that many of the results are from trials with small numbers and the intervention is often a single modality or technique.

The question that arises is what is the clinical trial evidence for the osteopathic intervention in CNSLBP, and does the research translate into clinical practice by testing the intervention as it is applied in the everyday practice? Osteopathic intervention for this study is defined specifically as manual intervention and lifestyle advice applied by an osteopath which would be considered by the osteopathic community to be consistent with osteopathic practice. An updated systematic review is warranted to include more recent studies, to apply a rigorous risk of bias assessment, and also to examine the evidence of authentic multidimensional osteopathic intervention, and not simply extrapolating from single modality evidence.

5.2.1.2 Objective

This current systematic review of clinical research into osteopathic intervention in chronic non-specific low back pain aims to focus on the quality of the evidence and its applicability to practice. Factors underpinning this objective are: to focus on a study condition that commonly presents to this professional group; to use a rigorous mainstream assessment of quality; and finally to review studies that reflect what is known of authentic osteopathic practice.
5.2.2 Methods

5.2.2.1 Eligibility

The inclusion criteria for the initial search were papers that reported clinical trials, tested the effectiveness and/or efficacy of an osteopathic manual therapy intervention and had a study condition of low back pain. Additional inclusion criteria for the final analysis were: adult subjects; authentic (multidimensional) OMT as the intervention; osteopath as the practitioner; and a study condition of chronic non-specific low back pain.

5.2.2.2 Search process

The literature was searched up to August 2011 using the following databases: AMED, CINAHL Plus, Cochrane Central Register of Clinical Trials, MEDLINE Plus, EMBASE, MANTIS, OSTMED, PEDro, ScienceDirect. Multiple search terms were used: osteopathy/osteopathic, osteopathic manipulative technique, OMT, Spinal Manipulative Therapy, SMT, clinical trial, back pain, chronic back pain, in various combinations. The reference lists of all articles were searched for other studies, and authors of incomplete or unpublished articles were contacted up till December 2011 requesting details of their trials.

5.2.2.3 Study selection

The process of selection followed a broad search to identify trials in SMT as well as OMT, because of the possible overlap in the interventions. Abstracts were read to exclude duplication and trials with no relationship with osteopathy. Studies that appeared to test the research question were then subjected to an analysis of the full text. Included trials were then subjected to a formal systematic review.

5.2.2.4 Data collection and risk of bias analysis

The two authors independently used data extraction tables and risk of bias analysis based on the Systematic Review Guidelines of the Cochrane Back Review Group (Furlan, Pennick, et al., 2009). The extraction tables described each study’s design, participants, randomisation, level of blinding, dropout rate, inclusion and exclusion criteria, treatment, control group, outcome measures and results. The
risk of bias criteria are outlined in Table 18 – one point was given for each affirmative answer. Before commencing the formal review, the two authors tested their rating consistency by independently reviewing an unrelated clinical trial paper and discussed any minor differences in their interpretation of the guidelines.

### 5.2.2.5 Synthesis of results

The study results would be pooled and a meta-analysis performed following the guidelines in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins, 2011). For this study, the factors established for inclusion in a meta-analysis were that the studies had homogeneity in subjects, study condition, intervention and outcome measures.

The a priori criteria for determining the superiority (and inferiority) of one treatment compared to another would need to be demonstrated by statistical significance ($\alpha < 0.05$) in a high quality randomised appropriately controlled study. Non-inferiority and equivalence would have needed to have been demonstrated in a study specifically designed to determine these effects with appropriate statistical analytical methods (Julious, 2004). In the situation that multiple studies existed they would be subject to a meta-analysis. If the studies were too heterogeneous to warrant a meta-analysis; then the evidence for superiority, non-inferiority or equivalence would be assessed for consistency across the studies. Where the studies were equivocal, weighting would be given to those studies with higher methodological validity and statistical power.

**Table 18 Assessment for sources of risk of bias (Furlan, Pennick, et al., 2009)**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Yes/No/Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Randomisation adequate?</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td>2</td>
<td>Concealed treatment allocation?</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td>3</td>
<td>Patient blinded?</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td>4</td>
<td>Care provider blinded?</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td>5</td>
<td>Outcome assessor blinded?</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td>6</td>
<td>Drop out rate described?</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td>7</td>
<td>Participants analysed within group?</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td>8</td>
<td>Free of selective outcome reporting?</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td>9</td>
<td>Groups similar at baseline?</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td>10</td>
<td>Co-interventions avoided/similar?</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td>11</td>
<td>Compliance acceptable?</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td>12</td>
<td>Timing of outcome similar?</td>
<td>Yes/No/Unsure</td>
</tr>
</tbody>
</table>
5.2.3 Results

5.2.3.1 Study selection

The initial search terms and article elimination processes are outlined in Figure 15. The authors of one unpublished trial were contacted but the results were not released for this review due to the publication peer review being currently underway. After the application of the specific inclusion criteria, two articles remained.

![Flowchart of paper selection](image)

Figure 15 Flowchart of paper selection

5.2.3.2 Study characteristics

The two articles that remained are summarised in Table 19. There was one study added to the most recent Systematic Review in 2003 (Licciardone, et al.,
Randomisation was consistently applied, but there was a range of outcome measures and intervention characteristics. The Licciardone et al. (2003) study used the SF-36 as the primary outcome measure, whereas the Chown (2008) study used the Oswestry Disability Index. The package of osteopathic manual interventions that were applied with discretion by the treating osteopaths were similar, but were applied at different intensities and frequencies.

5.2.3.3 Risk of bias within studies

The included studies were analysed for risk of bias and the results are summarised in Table 19. The scores ranged from 7/12 to 9/12, demonstrating they had a low risk of bias (Furlan, Pennick, et al., 2009), with the criteria most commonly lacking dealing with blinding of those involved, and a lack of patient compliance.

<table>
<thead>
<tr>
<th>Author</th>
<th>Licciardone, 2003 [21]</th>
<th>Chown et al., 2008 [26]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>N=91, 21-69yo</td>
<td>N=239, 18-65yo</td>
</tr>
<tr>
<td>Randomised</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Blinding</td>
<td>Patients</td>
<td>Patients and Assessors</td>
</tr>
<tr>
<td>Inclusion</td>
<td>NSLBP for 3 months</td>
<td>NSLBP for 3 months</td>
</tr>
<tr>
<td>Exclusion</td>
<td>Red flags, neurological signs, surgery, workers comp, pregnancy, recent manipulation</td>
<td>Red flags, radiculopathy, surgery, anti-coagulants</td>
</tr>
<tr>
<td>Intervention detail</td>
<td>Senior osteopathic students</td>
<td>One osteopath</td>
</tr>
<tr>
<td></td>
<td>Choice of soft tissue, MET, Art, HVT, SCS, cranio-sacral, myofascial technique</td>
<td>Choice of soft tissue, MET, Art, HVT, functional, exercise, education, psychosocial, nutritional advice</td>
</tr>
<tr>
<td></td>
<td>Seven sessions over 5 months</td>
<td>Five sessions over 3 months</td>
</tr>
<tr>
<td></td>
<td>Follow up at 1, 3 and 6 months</td>
<td>Follow up 6 weeks and 12 months</td>
</tr>
<tr>
<td>Control</td>
<td>Sham or no treatment</td>
<td>Manipulative PT or group exercise</td>
</tr>
<tr>
<td>Outcome measures</td>
<td>SF-36, VAS, RM, ODI, satisfaction questionnaire</td>
<td>ODI, EuroQoL, Shuttle walk test, satisfaction questionnaire</td>
</tr>
<tr>
<td>Main results</td>
<td>1 month OMT &gt; control (p=0.03)</td>
<td>ODI - 5.0 (95% CI 1.6 – 8.4; SD 10.5; p&lt;0.01):</td>
</tr>
<tr>
<td></td>
<td>3 months Sham &gt; OMT/control (p=0.01)</td>
<td>EQ-5D 0.11 (CI 0.02 to 0.19; SD 0.24; p&lt;0.05):</td>
</tr>
<tr>
<td></td>
<td>6 months Sham &gt; OMT/control (p=0.03)</td>
<td>Group comparison not done</td>
</tr>
<tr>
<td></td>
<td>VAS pain:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 month OMT/Sham &gt;control (p=0.01/0.003)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 months OMT/Sham &gt;control (p=0.001/0.001)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6 months OMT/Sham &gt;control (p=0.02/0.02)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RM no differences</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OMT less co-treatments (p=0.03)</td>
<td></td>
</tr>
<tr>
<td>Risk of Bias score /12</td>
<td>Detail of point loss</td>
<td>Quality Issues</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Randomization processes not fully described</td>
<td>Patients not blinded</td>
<td></td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>---------------------</td>
<td></td>
</tr>
<tr>
<td>Drop out rate not fully described</td>
<td>Care provider not blinded</td>
<td></td>
</tr>
<tr>
<td>Compliance not acceptable</td>
<td>Care provider not blinded</td>
<td></td>
</tr>
<tr>
<td>Co-interventions not avoided</td>
<td>Compliance not acceptable</td>
<td></td>
</tr>
<tr>
<td>Compliance not acceptable</td>
<td>Sample size reduced</td>
<td></td>
</tr>
<tr>
<td>Confounders in sham techniques, co-treatments</td>
<td>Statistical analysis incomplete</td>
<td></td>
</tr>
</tbody>
</table>
5.2.3.4 Results of individual studies

The two trials included which investigated osteopathic manual interventions by osteopathic clinicians in chronic non-specific lower back pain in adults differed in their conclusions; one concluded that the osteopathic intervention was similar in effect to a sham intervention (Licciardone et al., 2003), and the other suggests similarity of the effect of osteopathic intervention with exercise and physiotherapy (Chown, 2008). The trials used different comparators with regards to the primary outcomes, the number of treatments, the duration of treatment and the duration of follow-up. Licciardone et al. (2003) compared osteopathic intervention to sham intervention (range of motion, light touch and simulated techniques) and a non-treatment; the primary outcome was the Medical Outcomes Study Short Form-36 Health Survey (SF-36); provided seven treatments over five months; and assessed the difference between baseline and six months. Chown (2008) compared osteopathic intervention to group exercise and physiotherapy; the primary outcome was the Oswestry Disability Index (pain intensity and effects on daily living); provided five treatment sessions to be undertaken within a three month duration; and assessed the difference between baseline and six weeks; and six weeks and follow-up at 72–79 weeks.

The Licciardone et al. (2003) trial had a systematic exclusion procedure ensuring the patients had non-specific lower back pain. Whilst it was reported that applicants were excluded if they had ever been a patient at the trial clinic site, it was not reported whether the subjects had any previous experience of OMT which could affect their blinding with regards to the sham control. The randomisation process was performed using sequentially sealed envelopes in order to establish a balance of OMT and non-OMT groups, but this was not fully described – it was unclear whether this was this a system of alternates for each subject allocation, or that the envelopes were shuffled between allocations, or some other method. As the authors discussed, the osteopathic assessor and treating practitioners were pre-doctoral students and this relative inexperience may have affected the result. The drop out/attrition rate was relatively high at 27.5%, and the specific reasons for this attrition were only
given for two dropouts from the intervention group. The usual care group used more co-treatments - these were not described and could have included medication, physical and exercise therapy, massage and other interventions that are similar to the OMT intervention, and as the authors mentioned, may have attenuated its effects.

The Chown (2008) trial attracted a large recruitment base but had a significant attrition, especially in the exercise group. The first two interventions appeared to be delivered by single therapists, which reduces the generalisability of the results to the broader professional groups. The subjects were not blinded to the interventions, and it was unclear whether they knew the difference between physiotherapy and osteopathy, nor whether they had experienced these interventions before.

5.2.3.5 Synthesis of results

The heterogeneity between these two studies meant that the planned meta-analysis was not performed because of both clinical and methodological diversity (Higgins, 2011). While there is significant differences between these two trials, one trial concluded that the osteopathic intervention was similar in effect to a sham intervention, and the other suggests similarity of effect between osteopathic intervention, exercise and physiotherapy. This is in contrast to the systematic review of 2003 that found that OMT significantly reduced low back pain compared to controls (Licciardone et al., 2005). The authors of both included studies recommend that larger scale clinical trials be undertaken with care given to recruitment and retention of participants and also to the experience of the treating clinicians.

5.2.4 Discussion

5.2.4.1 Summary of evidence

These findings clarify the current state of research on the effect of the osteopathic intervention in the treatment of chronic non-specific lower back pain in adults. This condition in the adult population has been identified as one of the most prevalent presentations to osteopathic clinicians; and as such, needs to be seen as a key research priority for the osteopathic profession. The results of this review suggest that there is a paucity of quality clinical trials that assess the
effectiveness of osteopathic medicine intervention in this condition in the adult population, with only two trials included. These suggest that OMT appeared similar to sham intervention (Licciardone et al., 2003), and exercise and physiotherapy (Chown, 2008).

This review differs in its conclusions from the previous Systematic Review of 2003 (Licciardone et al., 2005), which concluded there was a positive effect from OMT in patients with low back pain. There were a number of trials included in the 2003 review that were not included in the current one for a number of reasons. The Hoehler (Hoehler, Tobis, & Buerger, 1981), Gibson (Gibson et al., 1985) and Andersson (Andersson et al., 1999) trials did not fit the criteria of testing only chronic low back pain, the Burton trial (Burton et al., 2000) did not fit the criteria of testing non-specific low back pain and the Cleary trial (Cleary & Fox, 1994) did not specify the type of back pain.

One of the difficulties of research in osteopathic medicine where there are only a small number of intervention trials is the lack of consistency in the methodology used. The lack of consensus on what is appropriate methodology remains a substantive barrier to understanding the role of osteopathic medicine in chronic non-specific lower back pain, which forms a major presentation to osteopathic clinical practice. The benefit of consistent methodology is the capacity to better compare clinical trials and where appropriate to use meta-analysis to provide a statistical assessment of a number of smaller homogenous clinical trials grouped together. Failure to develop an effective methodological consensus may leave this question of the effectiveness of osteopathic medicine in non-specific lower back pain unanswered.

A number of the methodological issues have been discussed by researchers in the field (Caspi et al., 2000; Coulter, 2011; Fonnebo et al., 2007; Licciardone & Russo, 2006). These include: the problem of blinding the subject and the treatment provider to the intervention, the subjects’ knowledge and perceptions of the intervention, and the difficulty of control in trials of manual therapy, particularly the credibility of sham treatment. Although both included studies were considered to have a low risk of bias according to the Cochrane Back Review Group (Furlan, Pennick, et al., 2009), both had methodological weakness in blinding of participants and patient compliance, which appear to be
common issues in trials of manual therapy interventions (Licciardone & Russo, 2006). Licciardone and Russo (2006) point out that the influence of a number of non-specific treatment effects on clinical outcomes present a major challenge to raising the evidence base of OMT and constructing appropriate clinical trials.

Another methodological issue that arises from this systematic review is whether the randomised clinical trial that aims to test efficacy suits a complex intervention like osteopathic medicine in a multifactorial condition like chronic non-specific LBP (Fonnebo et al., 2007). The emergence of comparative effectiveness research (Coulter, 2011), including the pragmatic trial approach, may point the way to solving the difficulties that researchers have had in meeting the requirements of evidence based medicine and the hierarchy that places systematic reviews of rigorous RCTs at its pinnacle.

5.2.4.2 Limitations

As in any systematic review, it is possible that there are clinical trials that were not found in the search process. The aim of focussing strictly on CNSLBP limited the number of studies, as many had mixed back pain populations. The requirement of having an authentic osteopathic intervention, which was based on studies of practice in Australia and the United Kingdom, may limit the generalisability of these findings to other jurisdictions.

5.2.5 Conclusions

In summary, there is a paucity of quality clinical trials testing the osteopathic intervention in adult patients with chronic non-specific low back pain, and more data is required. Two trials were included that differed in their conclusions. One trial concluded that the osteopathic intervention was similar in effect to a sham intervention, and the other suggests similarity of the effect of osteopathic intervention to exercise and physiotherapy. Further clinical trials into this subject are required that have consistent and rigorous methods. These trials need to include an appropriate control and utilise an intervention that reflects actual practice.
5.3 Discussion

This Stage 2 was a study to question whether there is any evidence of the osteopathic healthcare intervention in the most common patient complaint found in the workforce study outlined in Chapter 4 – chronic non-specific low back pain. The rationale for this systematic review was to link the argument in this thesis about the osteopathic profession requiring evidence that supports their practice, and is authentic to what this intervention is in the real-world to what is present in the research literature. Applying a criteria of authenticity to the paper selection reduced the included studies to two only. This illustrates the paucity of evidence that has been produced. The trials that were included used different comparators with regards to the primary outcomes, the number of treatments, the duration of treatment and the duration of follow-up, and so a meta-analysis could not be performed, as they were too heterogeneous. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) quality indicator checklist was used for this publication, and was followed closely with no discrepancies.

Since this systematic review was published in 2013 (reviewing data up to the end of 2011), two important additions to the literature on this subject have been published. The first was Licciardone and co-authors’ randomised controlled trial with 455 subjects (Licciardone, Minotti, Gatchel, Kearns, & Singh, 2013) that found OMT was significantly better at reducing CNSLBP compared to sham OMT and ultrasound therapy. The OMT was delivered over six sessions and included high-velocity low-amplitude thrusts, moderate velocity moderate-amplitude thrusts, soft tissue techniques, myofascial stretch and release, positional treatment of myofascial tender points and muscle energy techniques. This package of therapy mirrored the workplace findings reported in Chapter 4 and was delivered using osteopathic physicians, and so would have been included in the systematic review reported in this chapter as authentic OMT if it has been reported and/or published earlier.

Following the positive findings in this clinical trial, another systematic review into the effect of OMT on non-specific low back pain was conducted in 2013 (Franke, Franke, & Fryer, 2014) that included the Licciardone et al’s (2013) findings and also smaller trials that were not published in English. It also included acute and chronic nonspecific low back pain. For chronic NSLBP the authors found clinically relevant
improvements in pain and functional status for OMT against a number of different controls based on a meta-analysis of the trials. These authors included trials that were excluded from the systematic review in this chapter; Anderssen et al (1999) included subacute pain, Gibson et al (1995) described the OMT as spinal manipulation only, and Mandara (2008) did not provide enough detail to ensure low bias.

The level of evidence for an authentic osteopathic healthcare intervention that reflects whole practice is still uncertain from these findings. There is potential in conducting larger pragmatic trials with high quality design in order to answer the question more completely. Deepening the understanding of the osteopathic healthcare intervention by qualitative studies involving practitioners and patients would enhance the external validity of any real-world model and be of benefit to designing such a trial method (Campbell et al., 2000; Medical Research Council, 2000).
Chapter 6 – Stage 3 - Qualitative

6.1 Chapter introduction and data synthesis

Stage 1 revealed that a sample of practitioner members of the Australian Osteopathic Association report that the most common presentation to them was chronic low back pain, and that the osteopathic healthcare intervention had a multi-modal character – a range of manual therapies, exercise and lifestyle advice. Stage 2 revealed that despite a large research literature on aspects of the osteopathic healthcare intervention in CNSLBP, there were few RCTs testing a model of the intervention similar to how it is practised in the real-world, and trials up to 2011 did not demonstrate superiority compared to sham or other interventions. Research conducted between 2011 and 2014 has demonstrated a limited effect of OMT on CNSLBP, but there is a risk of bias and an incomplete osteopathic intervention in some of this research. A more complete model of the osteopathic healthcare intervention based on research findings was required to establish a real-world intervention that could be tested in a pragmatic clinical trial.

The development of a model of healthcare that is not based on a simple intervention requires a broad range of perspectives (Campbell et al., 2000; Craig et al., 2008). The results of research into osteopathic healthcare practice thus far reveal that it appears as a complex, multimodal intervention. The practitioner survey data established a foundation, but the voices and experiences of the main participants in any healthcare encounter – that of the practitioners and the patients, should be heard, analysed and added to any model if it is to be authentic and complete (Medical Research Council, 2000).

This third stage of data gathering utilised qualitative methods to answer the questions of what is the experience of practitioners managing the most common presenting problem of osteopathic healthcare, and also of the patients who have that problem?

The following incudes two studies: the first is a practitioner focus group which is unpublished, and the second is a patient survey and interviews that has been published in the peer reviewed literature in the journal Manual Therapy.
6.2 **Focus group of osteopathic practitioners**

6.2.1 **Introduction**

What defines whether an occupational group is a profession depends on the philosophical perspective one takes. There are a number of defining characteristics, but one that is common to many is a need to develop foundational principles and elements of a body of specialist knowledge and skills that can be tested (Cruess, Johnston, & Cruess, 2004; Hilton, 2007; Professions Australia, 2012). For professional health practice the highest ranked testing methods in evidence based medicine are clinical outcome studies (Hoffman, 2010; Oxford Centre for Evidence-Based Medicine - Levels of Evidence Working Group, 2011). Osteopathy has been described as a patient-centred, evidence-based approach to healthcare (Baer, 2009), using a holistic approach to diagnosis and a broad range of therapeutic interventions to achieve improved health (Seffinger et al., 2003). Very little is known of the actual clinical encounter in osteopathic practice, resulting in a paucity of authentic clinical research (Licciardone et al., 2005; Licciardone, 2007b). Some recent survey data about the Australian osteopathic profession (Burke at al, 2013; Orrock, 2009a, 2009b) delivered predominantly quantitative data about Australian osteopaths and their patients. Further exploratory research is required to enhance the content validity of this data (Glenn, 2010). This is particularly important with regards to the opinions and approaches of the clinicians from the real-world of practice, who can give more depth to the question of how osteopaths manage common patient problems like chronic non-specific low back pain (CNSLBP) – reportedly the most common presentation to Australian osteopaths (Orrock, 2009b). The aim of this research was to answer the question of what is the experience of practitioners managing patients with the common presenting problem of osteopathic healthcare?

6.2.2 **Methods**

Using a qualitative method such as a focus group following a quantitative survey is a common Mixed Methods Research (MMR) strategy (Cresswell, 2011), and is reported as providing useful insights that might not be made clear from either method alone (Bryman, 2006). Combining these research methods enables the researcher to check the accuracy of conclusions on the basis of the findings from each method; qualitative research can be used to provide hypotheses that can be tested using
quantitative methods, and both methods can be combined to derive a more holistic understanding of the phenomenon being investigated (van Krieken, 2000). Surveys can be combined with interviews of groups or individuals to establish reliability and validity between the data (Cresswell, 2008; Neumann, 2000).

Qualitative data collection methods such as interviews and focus groups of key stakeholders are reported as effective ways of researching the nature of health practice (Higgs, 2009). Focus groups are defined as the explicit use of the group interaction to generate data, with an aim of encouraging interaction and discussion amongst group participants, rather than individuals separately responding to a moderator (Kitzinger, 1994; Kitzinger, 1995). They are also an efficient method for gathering information about peoples’ views and perceptions quickly (Paterson & Higgs, 2005). Focus groups also enable researchers to gather a concentration of experts in a particular field for specific research in their area of expertise. Pre-existing groups or ‘natural clusterings’, like members of a profession, are appropriate and useful for focus group research (Kitzinger, 1994). Within a MMR approach, this is termed a FG-QUAL design (Teddlie, 2009). The optimal characteristics of focus groups are reported as numbering between 5-10 participants who are homogeneous, the group interview is conducted by a moderator with an assistant, and the focus is on a singular topic of interest (Teddlie, 2009). The weaknesses of focus groups have been reported as the possible expense, that the discussion may be dominated by one or two participants, and the possible bias of the moderator (Leung & Savithiri, 2009).

The methods of this focus group closely followed the COREQ guideline for reporting qualitative research (Tong et al, 2007) (Appendix 2). A focus group of osteopathic practitioners was established by advertising for expressions of interest by posting to the database of osteopaths in Southern Cross University’s clinical footprint region. It was aimed that six to eight practitioners would be recruited who work in busy team based general practice (ie non-specialised) osteopathic clinics. These practitioners were recruited on a first-come basis with a limit of two per clinic to reduce selection bias. A set of guide questions (see Table 20) was mailed to the practitioners along with an information sheet and a consent form, clearly stipulating all aspects of the research. These practitioners were invited to attend a two-hour focus group where the principle investigator and author of this paper acted as the moderator, and led a guided discussion that was recorded with their consent. Transcripts from the focus group were de-identified and data were analysed using a descriptive phenomenology approach.
approach to inquire into the practitioners’ lived experience of how they manage these patients – their clinical priorities and reasoning process (Higgs, 2009). The level of agreement across the group was ranked by the moderator as 3 where only one individual expressed the issue, 2 where a majority of the group agreed, and 1 where there was unanimity on the issue. Thematic analysis was carried out on the group comments, key themes from the transcribed focus group data were identified using a series of sub-themes, and these were then categorised into meta-themes. This data was compared to workforce survey data to look for areas of commonality, was reviewed in the context of current evidence of the management of the study condition, and led to further exploring the osteopathic healthcare intervention from the patients’ perspectives.

Table 20 – Guide questions for practitioner focus group
Focus group title: Exploring the osteopathic healthcare intervention on chronic non-specific low back pain using a whole practice model.

- What is chronic non-specific low back pain?
- What is your experience of how common these patients are in your practice?
- What are the underlying principles you consider when managing chronic low back pain patients as an osteopath?
- What factors influence the prognosis, diagnosis and therapy in your management of these patients? (are there subcategories – what are they?)
- What are the most effective interventions in these patients? Why?
- In your experience, how effective is osteopathy generally in these patients?
- How many consultations on average are necessary in these patients?
- What are the factors that influence these patients’ outcomes in your experience?
- What are the aims/goals of osteopathic management in these patients?
- What referrals are necessary in these patients care (if any)?
- Do you know of the level of evidence for osteopathic management of chronic non-specific low back pain?
- What is your opinion of the research into the management of this condition?

This focus group design included a research assistant observing participants’ verbal activity to illustrate any dominance. A reflective logbook was used by the moderator to reveal any of his own biases and/or reactions to the discussion. Data from both of these are reported in results. The participants all knew of the background of the moderator and had a professional relationship with him.

All participants were provided with copies of the results and discussion, giving an opportunity to check and add to their comments before report finalisation and/or publication. This study was approved by the Southern Cross University Human Research and Ethics Committee (approval number ECN-11-273).
6.2.3 Results

Recruitment resulted in seven osteopaths consenting to participate and they gathered in a university meeting room for two hours. Each participant was given a numerical identifier to use when speaking in order to enable the transcription to be organised by speaker. Characteristics of the participants are outlined in Table 21, illustrating a mix of gender, training background, experience and practice location.

<table>
<thead>
<tr>
<th>Code</th>
<th>Gender</th>
<th>Training institution</th>
<th>Years in practice</th>
<th>Practice location</th>
</tr>
</thead>
<tbody>
<tr>
<td>FG5</td>
<td>M</td>
<td>University of Western Sydney</td>
<td>6</td>
<td>Regional town</td>
</tr>
<tr>
<td>FG6</td>
<td>M</td>
<td>University of Western Sydney</td>
<td>7</td>
<td>City/metropolis</td>
</tr>
<tr>
<td>FG3</td>
<td>F</td>
<td>British School of Osteopathy, UK</td>
<td>20</td>
<td>Regional town</td>
</tr>
<tr>
<td>FG7</td>
<td>M</td>
<td>RMIT</td>
<td>19</td>
<td>City</td>
</tr>
<tr>
<td>FG2</td>
<td>M</td>
<td>International Colleges of Osteopathy</td>
<td>25</td>
<td>Regional town</td>
</tr>
<tr>
<td>FG4</td>
<td>F</td>
<td>Victoria University</td>
<td>9</td>
<td>City/metropolis</td>
</tr>
<tr>
<td>FG1</td>
<td>M</td>
<td>Victoria University</td>
<td>12</td>
<td>Regional city</td>
</tr>
</tbody>
</table>

Discussion was focused on the guide questions and the results of the thematic analysis are outlined in Table 22. The meta-themes that emerged were: the definition of CNSLBP, the prevalence of CNSLBP, patients’ motivation to visit an osteopath, factors influencing prognosis and management, therapeutic approach, and the focus on psychosocial issues. These meta-themes will now be outlined.

<table>
<thead>
<tr>
<th>Meta-theme</th>
<th>Sub-themes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition of chronic non-specific low back pain</td>
<td>Diagnosis of exclusion&lt;br&gt;Lack of clarity regarding “non-specific” label&lt;br&gt;Lack of clarity when becomes not chronic</td>
</tr>
<tr>
<td>Prevalence</td>
<td>Common presentation&lt;br&gt;Worse from cold weather&lt;br&gt;Common as co-morbidity</td>
</tr>
<tr>
<td>Patients’ motivation to visit an osteopath</td>
<td>Tried everything else</td>
</tr>
<tr>
<td>Factors influencing prognosis/management</td>
<td>Co-morbidity presence and severity&lt;br&gt;Age&lt;br&gt;Degenerative status&lt;br&gt;Occupational aggravators</td>
</tr>
</tbody>
</table>
6.2.3.1 Definition of chronic non-specific low back pain (CNSLBP)

The group reached full agreement on what chronic low back pain was, and on the fact that non-specific denoted that no red flags or serious medical conditions could be identified. There was discussion whether osteopathic labels of dysfunction should be included under the non-specific label, as they reported that elements of biomechanical and functional disturbance could be found when there is no pathology present. As one participant said about this diagnostic problem:

So long as you can exclude pathology you’re dealing with altered physiology. (FG2)

There was general concern that if no osteopathic diagnosis could be found in the presence of pain, that would be rare, but;

A worry, (FG3)

as referral for investigation would be needed.

In terms of making a prognosis when the cause of pain is not established, all agreed that false or unfounded claims are not acceptable, but after a comprehensive
assessment a short trial of treatment noticing how the tissue responds and with the hindsight of clinical experience, they are able to make a reasonable prognosis.

6.2.3.2 Prevalence

The group reported that this was a common condition, estimates ranging between 25-60% of all patient presentations, and that it is very common as a co-morbidity in other presentations. The majority agreed that 50% of the low back pain presentations are non-specific in diagnosis. They reported that this complaint was more common in colder months of the year.

6.2.3.3 Patients choosing osteopathy

The group agreed unanimously that patients come referred by word of mouth after they have tried everything else for their problems. For this group osteopathy is:

A last port of call. (FG2)

6.2.3.4 Factors influencing prognosis/management

The group reported a number of factors that influence their approach in these patients. Age, co-morbidities, level of degeneration are all taken into account when assessing the patient. A number of sub-categories of patient were agreed upon after discussion:

- The “destabilised” (FG3) who have loss of muscle tone via pregnancy, sedentary lifestyle and microtrauma/repetition of strain;
- The ones with “psychological overlay” (FG2) who may be in an insurance claim, or have been told negative information about the condition;
- Those with occupational issues – labourers/builders have certain patterns of dysfunction (FG5)
- The “weekend warriors” (FG6) – people who overdo it thinking they can stay young by vigorous activity;
- The obese – considered a major factor in aetiology and prognosis;
- The non-compliant to exercise and lifestyle change - how this greatly effects management, self-management and prognosis.
6.2.3.5 Therapeutic approach

There does not appear to be a singular protocol for management in these patients, and it was reported by respondents as highly individualised based on age, occupation, chronicity, psychological state, and motivation to self-manage. Points were made that the outcomes from management should be functional, not theoretical. For example:

(aims from treatment could be that the patient can) play 6 holes of golf,
stand at sink for 30 minutes, sit watching television for 50 minutes. (FG5)

Having patient-centred outcome measures brings it back to that whole
individualistic approach. And it’s osteopathy in a nutshell. (FG3)

The approach was broad and instinctual

Instinctive .. feeling how the tissue changes under your guidance, (FG5)

and:

An evolutionary process. (FG1)

One participant who had over 20 years of practice related this individualised
osteopathic approach to healthcare to first principles and an autonomy of decision making:

What we’re taught in osteopathic principles are our core knowledge - our
anatomy, our neurology … our functional understanding of biomechanics
underpins our understanding of how bodies work … how bodies work in
health, and in disease, and therefore you can apply techniques and
treatment strategies from a wide number of modalities because you
understand them, and you can think, and you don’t need a protocol or a
guru to guide you in a treatment strategy. (FG3)

And the most experienced of the group agreed:

Look at the patient in totality.. osteopathically, for lack of a better term,
and individualise their treatment – that’s the protocol. (FG2)

There was general agreement on a reasonable intervention plan of an initial
comprehensive assessment, two consultations in week one, weekly sessions for two
or three weeks and then a full review to establish a clear prognosis.
6.2.3.6 Psychosocial issues

There was a lengthy discussion about the chronic pain patient, and how a number of difficult issues effect the management. Their patients have often been told they have to live with it and have lost hope:

When you know your patient is going to get better and they don’t believe you. (FG3)

The group unanimously agreed that as the patients come from therapy that hasn’t met their expectations, their role may be instilling hope and managing their expectations through careful management of their psychological state:

Using the placebo effect to enhance the person’s wellbeing, and I guess what I’m referring to there, though is giving them a light at the end of the tunnel. You know, as soon as they have hope — just having some hope can change their response. (FG5)

and:

So by educating them and explaining or trying to get their expectations to be more realistic, you’re already helping their mental state. (FG5)

6.2.3.7 Moderator reflection logbook

As a moderator with long clinical experience in the osteopathic discipline, I found myself agreeing with much of the discussion points made. They seemed consistent to me, and I was satisfied that my experience was being mirrored. I became concerned when one less experienced participant expressed difficulty in the management of the patient when they had non-specific pain, as the osteopathic diagnostic skill was not well-developed. Like other experienced practitioners in the group, I felt that his training may have been deficient in that aspect.

The main issue of reflection arose when the research and evidence base was discussed. The more recently graduated were more evidence informed and had more advanced knowledge of chronic pain, whereas the experienced practitioners were silent on the evidence base of managing chronic pain. As an academic and researcher, this disappointed me, but was understandable given the major shift in training in Australia from private college clinical based education to university masters level in the last 20 years.
Chapter 6 – Stage 3 - Qualitative

The assistant’s observation demonstrated a good amount of spread of dialogue from all participants, but there were relatively numerous direct responses and interaction between one of the newer graduates (FG5) and one of the more experienced practitioners (FG3). This was predominantly around the evidence and the perceived lack of osteopathic skills when the patient has non-specific pain, and possibly demonstrates the gap between current evidence and practice-based reasoning.

6.2.4 Discussion

This focus group revealed a number of characteristics of osteopathic practitioners’ experience of managing patients with CNSLBP. The sample had a broad base in terms of age, experience and training background and practice location. Despite this they agreed that the presentation of patients with CNSLBP is common, and this is supported by workforce surveys in the UK and Australia (Fawkes, 2013; Orrock, 2009a, 2009b). The description of sub-categories of these patients is also supported in the literature in terms of degeneration, comorbidities and psychological state (Turk, 2005; Turk, Swanson, & Tunks, 2008). The agreement amongst members that referral for psychological evaluation is central to their practice reflects a cross disciplinary network, which is supported by the evidence for managing people with chronic pain (Kaiser et al., 2013). It is well reported that people who have an insurance claim will have delay in healing and return to work (Newton-John & McDonald, 2012; Rohling, Binder, & Langhinrichsen-Rohling, 1995), and this group reflected that trend in reporting.

An interesting subtheme in the experience of these practitioners is that they report non-pathological dysfunctions present in the musculoskeletal system that they diagnose and treat even when these patients have been seen by other practitioners and not improved. The evidence for these osteopathic diagnostic labels is lacking (Fryer et al., 2010), and there have been calls for a review of the osteopathic approach to healthcare from within the profession (Lucas & Moran, 2007b). There was a sign in this data that the more experienced practitioners were willing to diagnose and treat on that older model, and at least one of the new graduates was uncomfortable with it. This aspect of a generation gap in the profession has not been researched to a great extent, but a range of clinical reasoning approaches has been reported recently from practitioner interviews in the UK, illustrating that experienced osteopaths tended to
reason outside a standard method, depending on the level of patient involvement (Thomson, Petty, & Moore, 2013a).

There is a challenge in testing this multimodal intervention in a clinical trial as it appears to be practised, as the individualising process would make results hard to analyse (Jadad, 2008). A pragmatic trial would be appropriate as it allows practitioner discretion and reflects the range of modalities, the repetition, and the outcome measures that occur in real-world practice (MacPherson, 2004).

The limitations in this study were that it was a single focus group that will have weak generalisability. The aim was to compare the findings of this single focus group with other research in larger samples, and so caution is advised with making general conclusions from this data. The possibility of moderator bias was minimized by bracketing during the running of the focus group, and discussed in the reflection. The dominance from more experienced members of the focus group did not appear to reduce other members participation, and strategies were employed to minimise these and were reported. The findings relating to a possible generation gap reflected this dominance with regards to the use of evidence and the treatment approach in the management of chronic pain.

6.2.5 Conclusion

This single focus group of osteopathic practitioners revealed aspects of their experience in managing patients who present with the common condition of CNSLBP. Some of these aspects confirm previous findings from workplace surveys, and some are more unique to this data. Further focus groups from a wider population may strengthen the validity of these findings. These findings assisted the process in this thesis as the second part of the qualitative Stage 3 was aimed at exploring the osteopathic healthcare intervention with the other main stakeholder in this therapeutic encounter - the patients.
6.3 The patient experience of osteopathic healthcare.

Peer reviewed and published as:


There was no funding and no contributing author.
6.3.1 Introduction

Osteopathy is an approach to healthcare underpinned by guiding principles that place importance on the interconnectedness of the structure and function of the body (Seffinger et al., 2003). In Australia osteopathy is a primary care limited scope practice, and the practitioners and patients of osteopathic practices have been researched in a limited way (Adams, Easthope, & Sibbritt, 2003; Burke et al., 2013; Orrock, 2009a, 2009b; Xue, 2008). Current knowledge of this practice, based on workplace surveys, suggest that osteopaths in Australia see patients who self-refer, present with pain and stiffness in various regions, of which chronic lower back pain is a dominant presenting symptom, and that the osteopathic intervention includes a range of manual therapies, exercise and lifestyle advice (Burke et al., 2013; Orrock, 2009b; Xue, 2008). The validity of the data from these surveys is limited, with relatively small samples, and is dependent on the practitioner’s recall, which may be biased or incorrect (Newell, 2011). Evidence suggests that osteopathic practice in Australia is similar in many aspects to that in the UK (Fawkes et al., 2014; Froud, Rajendran, Fossum, Collins, & Mullinger, 2008; Leach et al., 2013; Rajendran et al., 2012; Strutt, Shaw, & Leach, 2008) and other countries - particularly in Europe, but different from the US - where osteopaths are primary care physicians.

The expectations and experiences of patients of osteopaths have been studied in the UK, in both private (Leach et al., 2013) and teaching clinics (Rajendran et al., 2012; Strutt et al., 2008). Themes emerging from these studies identified the importance of the therapeutic relationship and communication, the development of trust and hope, outcome measures of pain relief and quality of life, and the incidence of treatment after-effects. There has been no similar direct research of patients in Australia. Osteopathy has been reported as one of the fastest growing allied health professions in Australia (Australian Bureau of Statistics, 2008; IDA Economics, 2008), and further detail of this practice is necessary to deepen the understanding of a clinical intervention that has not as yet established an evidence base.

The research questions were:

- what is the lived experience of osteopathic healthcare for patients with non-specific low back pain, and
are patients’ experiences of osteopathic healthcare consistent with characteristics suggested by previous survey results?

The preliminary survey was to provide directions of inquiry for interviews and also to recruit patients with a target condition of chronic non-specific low back pain.

6.3.2 Methods

A qualitative approach to researching the experience of patients of a health service is appropriate to establish the nature of that experience (Bryman, 2006; Glenn, 2010; Grady, 2007; Higgs, 2009; Neumann, 2000; van Krieken, 2000). The patients’ perspective is a fundamental foundation in any patient-centred service (Luxford, Safran, & Delbanco, 2011; Patwardhan, 2012; Reuben & Tinetti, 2012), and the factors influencing consumer choice need to be explored with regards to osteopathy, which is predominantly a private fee-paying service (Burke et al., 2013; Orrock, 2009b).

6.3.2.1 Study design

The project employed a mixed methodology, using an explanatory sequential design described by Creswell (2011), where a quantitative survey was followed by qualitative semi-structured interviews. The initial survey had questions that were designed to seek information about patient demographics, referral patterns, condition history, improvement level, characteristics of the consultation and management, and outcomes experienced.

The methodology for the interviews was descriptive phenomenology, which is appropriate to explore the core commonalities and meaning, structure and essence of the patients’ lived experiences (Higgs, 2009; Patton, 2002; Starks & Trinidad, 2007; Wojnar & Swanson, 2007). The Human Research and Ethics Committee of Southern Cross University provided approval for the project.

6.3.2.2 Participants

Survey

The survey was distributed to five osteopathic practices, involving nine practising osteopaths. This was a convenience sample in the geographical region of the researcher, selected to ensure a range of practitioner gender (2 female, 7 male), experience level (ranged from 4 to 21 years of clinical experience) and training
background (NSW, Victoria, UK, Germany). Inclusion criteria for patients responding to the survey were adults (over 18 years of age) who were returning patients who could speak and read English. Internal validity was established with feedback from a senior academic, five osteopathic clinical teaching staff, and a sample of three osteopathic patients. These nine people were asked to provide feedback on the relevance and clarity of the questions, and questions were amended to accommodate feedback.

**Interviews**

A purposive sample of patients who responded on the survey that they had chronic low back pain that had been treated by the osteopath and were willing to be interviewed were contacted and screened to confirm the target condition. Respondents were excluded if they had a confirmed diagnosis of a pathological cause of the pain. Those included were then sent the information, guide questions and consent forms. The guide questions were:

- Why did you go to an osteopath in the first place?
- How would you explain osteopathy to a friend? To your doctor?
- What is it like being treated/managed by an osteopath?
- Can you describe the treatment session for me?
- In your experience, what aspects of your healthcare are managed by the osteopath?
- In your experience, what are the effects of osteopathic treatment?

**6.3.2.3 Data collection and analysis**

**Survey**

Patients were invited to read the survey information and complete the survey. Completed surveys were held in a private box and collected by the researcher after three weeks. Data were entered into the statistics package (IBM SPSS Statistics version 20.0.0). Descriptive statistics were used to explore the data. The results from this analysis informed the approach to the interview questions and areas of inquiry by clarifying details of the clinical assessment and therapy employed during the consultation.
Interviews

After screening and consent checking, the enrolled subjects were interviewed by phone for 30-40 minutes. Probe questions were used to seek clarification. The interviews were recorded and transcribed, and the data were analysed using an approach informed by the seven-step thematic analysis described by Collaizzi (Wojnar & Swanson, 2007), outlined in Table 23. The researcher was aware of previous survey results and employed a strategy of “bracketing” – putting aside preconceptions by maintaining a constant sense of caution regarding bias, and by the use of an assistant researcher (Wojnar & Swanson, 2007). The researcher categorised themes as they became apparent by repetition during multiple readings into two levels (sub- and meta-) and the process was reviewed and audited by an assistant researcher to ensure they were both well represented in the transcripts and were plausible. The number of participants was not predetermined, and by the eleventh interview there were no new themes apparent. This was considered to be theoretical saturation. Individual summaries and initial sub-themes based on verbatim transcripts were sent to each participant for their feedback.

Table 23  Summary of Collaizzi’s method of analysis for Descriptive Phenomenology
(Wojnar & Swanson, 2007)

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Reading and rereading transcriptions to acquire general feeling for experience</td>
</tr>
<tr>
<td>2</td>
<td>Extracting significant statements to generate information pertaining directly to phenomenon studied</td>
</tr>
<tr>
<td>3</td>
<td>Formulating meanings to illuminate meanings hidden in various contexts of the phenomenon</td>
</tr>
<tr>
<td>4</td>
<td>Categorizing into clusters of themes and validating to identify experiences common to all informants with original text</td>
</tr>
<tr>
<td>5</td>
<td>Describing to generate a prototype of a theoretical model</td>
</tr>
<tr>
<td>6</td>
<td>Returning to participants to validate the findings</td>
</tr>
<tr>
<td>7</td>
<td>Incorporating any changes based on the informants to present a theoretical model that comprehensively reflects the feedback universal features of phenomenon</td>
</tr>
</tbody>
</table>

6.3.3  Results

The results of the survey and interviews will be presented separately for methodological clarity and then integrated.
6.3.3.1 Survey

Completed surveys (n=161) were collected. A summary of respondent characteristics is presented in Table 24. Activities commonly reported by respondents were: questioning about the detail of the presenting problem; assessment of both the presenting problem and other areas; soft tissue, stretching and manipulative techniques to multiple regions; and exercise advice. Common outcomes reported were reduced pain, increased flexibility/range of motion, the ability to complete daily tasks and improved posture. These findings helped structure the interviews.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Survey respondents n (%)</th>
<th>Interview subjects n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>66 (40.7)</td>
<td>5 (45.5)</td>
</tr>
<tr>
<td>Female</td>
<td>94 (58.0)</td>
<td>6 (54.5)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-29</td>
<td>11 (6.8)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>30-39</td>
<td>36 (22.2)</td>
<td>2 (18.2)</td>
</tr>
<tr>
<td>40-49</td>
<td>45 (27.8)</td>
<td>3 (27.3)</td>
</tr>
<tr>
<td>50-59</td>
<td>34 (21.0)</td>
<td>4 (36.3)</td>
</tr>
<tr>
<td>60-69</td>
<td>30 (18.5)</td>
<td>2 (18.2)</td>
</tr>
<tr>
<td>70+</td>
<td>5 (3.1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Condition – number treated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>One</td>
<td>43 (26.7)</td>
<td>2 (18.2)</td>
</tr>
<tr>
<td>Two</td>
<td>42 (26.1)</td>
<td>2 (18.2)</td>
</tr>
<tr>
<td>Three</td>
<td>24 (14.9)</td>
<td>3 (27.3)</td>
</tr>
<tr>
<td>Four or more</td>
<td>52 (32.3)</td>
<td>4 (36.3)</td>
</tr>
<tr>
<td>Main condition – time since onset</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1day-12 weeks</td>
<td>54 (33.5)</td>
<td></td>
</tr>
<tr>
<td>Over 12 weeks</td>
<td>107 (66.5)</td>
<td>11 (100)</td>
</tr>
</tbody>
</table>

6.3.3.2 Interviews

Thirty people responded to the request for an interview. Twelve of these respondents were unable to be contacted, four were unavailable during the data collection period, two did not pass screening for the target condition and one was a new patient. The eleven remaining all consented and phone interviews proceeded. A summary of their characteristics is presented in Table 25. The participants reviewed their interview summaries and all agreed that the points reflected their experience.

Twenty sub-themes emerged from the data and were grouped into meta-themes (Table 3). The meta-themes were:
• Patient decision-making
• Patient shared experiences of the osteopathic encounter
• Tailored patient-centred care
• Therapeutic relationship in healthcare

These meta-themes and sub-themes will now be described in more detail with salient quotes from the transcripts.

**Table 25  Thematic analysis – sub themes grouped into meta-themes**

<table>
<thead>
<tr>
<th>Meta-themes</th>
<th>Subthemes</th>
</tr>
</thead>
</table>
| Patient decision making              | Trusting word of mouth referral  
Choosing after tried all else  
Alternative to chiropractic  
GP referrals driven by patient choice |
| Patient shared experiences of the osteopathic encounter | Holistic  
Making musculoskeletal connections with presenting complaint  
Comprehensive assessment and review at each session  
Searching for a cause  
Consistently applied manual and adjunctive therapies  
Education about the condition and lifestyle advice for self-management |
| Tailored patient-centred care        | Encounter is tailored to patient  
Individualised plan is matched to patient  
Goals of plan are patient centred  
Helps body to help itself  
Plan is a negotiated partnership  
Co-management |
| Therapeutic relationship in healthcare | Personal story is valued  
Extensive communication  
Encounter described as trusting, caring, gentle and instilling hope  
Supportive ongoing relationship if required |

**Patient decision-making**

Participants engaged in an autonomous process of deciding about their healthcare, having explored various options and finding their own way to the osteopath. They consulted the osteopath usually after trying other healthcare professions for their problem, and most were not clear initially about what osteopathy was. There was a dependence on word of mouth referral, most commonly by friends and family:

She was recommended to me by a lady at the newsagency. (PI4)

My mother persuaded me. (PI10)
Participants had commonly visited chiropractors and/or physiotherapists before seeking osteopathy. Six of the eleven participants specifically mentioned that they visited an osteopath as a choice after chiropractic care had not met their expected outcomes. One stated:

I was seeing a chiropractor ten years earlier … and they didn’t massage before they manipulated … and I wasn’t getting any better, I was getting worse. (PI6)

There were reports of general practitioner (GP) referral, with a number stating that they gained referral from their GP through their own request, for example:

My doctor recommended I go and see the physio, but I got (the GP) to write out a referral for the osteopath instead. (PI3)

Patient shared experiences of osteopathic healthcare

A commonality of experiences emerged from the data about the approach taken by the osteopathic practitioners. This theme encompasses both the interpretation of osteopathy as an holistic form of healthcare, as well as descriptions of activities and methods used in the consultation.

Participants consistently described the experience as holistic, but they had mixed views regarding what that meant to them. Some described it in purely physical terms based on the connection made between their presentation and the muscular and skeletal structures. For example one reported that:

It’s a discipline about musculoskeletal connectivity. (PI1)

Others felt that the experience was holistic because broad aspects of their healthcare were considered, including the engagement with their psychological state. One stated that the osteopath explored:

Everything from the endocrinology side to the mental side of things, as chronic pain can lead to depression and vice-versa. (PI10)

Another interpretation was reflected in the following quotation, where holism meant searching for the cause:

I would say it’s a little more holistic, they look a little more at what’s causing it. (PI2)
It was commonly reported that a thorough assessment of the presenting condition and related regions was carried out, as well a consideration of its possible causative factors. The range of inquiry and assessment was summarised by one respondent:

She asks how is it interfering (with life), then she looks at my feet and shoes, how I walk, about the desktop ergonomics, even sexual function and such; so she asks questions and I give her the answers. (PI4)

The respondents experienced that the intervention involved education about the condition, multiple manual therapies and adjunctive techniques as well as lifestyle advice, which included advice regarding exercise rehabilitation, ergonomics and stress reduction. One participant expressed this as:

a combination of information, communication, and treatment; a complete package. (PI8)

**Individualised patient care**

The respondents experienced osteopathic healthcare as tailored to their context, where the activities of each consultation was based on the patient presentation at each encounter. This individualisation of the intervention was reported as being negotiated between patient and practitioner, and was present in assessment, treatment and outcome planning. Tailoring of the intervention was evident for one respondent as a range of techniques used in different situations:

He might expand upon his repertoire and do a whole lot of different things. (PI3)

Another experienced that there was flexibility in how the practitioner responded to a review of previous management outcomes,

When a certain technique’s not working, osteopaths are happy to look elsewhere and try new things. (PI10)

The respondents reported that their expectations of outcomes from treatment were considered. These outcomes were most often reduction in pain and increased mobility, but also included improved general functionality, ability in daily tasks, and general wellbeing. These quotes illustrate the broad range of outcomes reported:

It effects my personal wellbeing. (PI1)

Puts my energy and my strength up, I’ll sleep right through again. (PI2)
Improved breathing. (PI7)
Like taking off a heavy coat. I’d gone from nothing to two kilometres (walking). (PI8)

The focus of care was not solely on externally applied manual therapy, but was reported by many to be on education and progress towards self-management, for example:

They give me ideas and things to help myself rather than expecting someone else to fix it. (PI2)
Empowering you a little bit better to enable you to make things right. (PI7)

As a corollary to these themes on individualisation, education and self-management, there appears to be a partnership between these patients and practitioner, described by two as:

It was more a joint effort. (PI6)
He just listens to everything that you have to say, and what you want done. (PI1)

Finally, a common theme emerged regarding the relationship with other practitioners. Respondents experienced inward and outward referrals between the osteopath and other practitioners, including with mainstream medical practitioners. One respondent regarded the osteopath and GP as:

completely linked. (PI8)

This extended to co-managing with medical specialists:

She did my pre-surgery and post-surgery rehab, in conjunction with talking to the surgeons, so she’s open minded to mainstream. (PI4)

**Therapeutic relationship in healthcare**

The interviewees felt that their personal stories were heard and respected. It appears that osteopathic consultations comprised a substantial level of communication and dialogue, with a therapeutic relationship built on trust and respect. One respondent stated that their aim was:

to have a meaningful one-to-one sort of truth-based direct, frank relationship with the therapist. (PI1)
and another used the consultation to express issues about his health,

    It’s good to get a few concerns off your chest talking to (the osteopath).

    (PI4)

The practitioners’ listening skills, professionalism and knowledge were reported as key aspects of the relationship. Many patients present to osteopaths with chronic pain, and the need for understanding and information becomes paramount, as explained by two participants:

    I use him as a sounding-board. (PI10)
    With knowledge comes hope a lot of the time. I am not alone in the fight.

    (PI10)

Respondents placed importance on trust, caring and hope, and many experienced these aspects as they began to gain control over their chronic condition. Two responses illustrate the depth and stability of the therapeutic relationship experienced:

    Its someone I trust. (PI4)
    He got me through it. (PI9)

6.3.4 Discussion

Most of the respondents reported that they choose to visit an osteopath only after already consulting physiotherapists and/or chiropractors, and depended on word of mouth referral. The lack of awareness of osteopathy could stem from the fact it is the smallest allied health profession in Australia (Australian Bureau of Statistics, 2008; Australian Institute of Health and Welfare, 2013; IDA Economics, 2008) and is not available in the public health system. In 2012 there were 20,081 physiotherapists (10,131 in a musculoskeletal scope of practice), 4029 chiropractors and 1543 osteopaths (Australian Institute of Health and Welfare, 2013).

The finding that these patients are acting autonomously in exercising their right of choice of a health practitioner matches a central principle of the Australian healthcare system, with a recent review stating the goal was to “develop a ‘person-centred’ approach to health care, enabling consumers to be at the centre of their own care” (p42) (Department of Health and Ageing, 2009). This is also an issue in other developed nations, as healthcare systems have to allow for choices being made by
increasingly educated consumers who make unique decisions in a competitive environment (Fotaki et al., 2008; Victoor, Delnoij, Friele, & Rademakers, 2012).

Patient-centered care (PCC) is thought to be the future of effective healthcare (Dwamena et al., 2012; Luxford, 2012; Parsons et al., 2007). There is no global definition of PCC. The Picker Institute has been researching PCC since the early 1990s, and commissioned a systematic review of nine models and frameworks (Schaller, 2007), which found the core elements of PCC most frequently cited were:

- Education and shared knowledge
- Involvement of family and friends
- Collaboration and team management
- Sensitivity to non-medical and spiritual dimensions of care
- Respect for patients needs and preferences
- Free flow and accessibility of information.

There are a number of findings from this data that support the proposition that these patients experienced osteopathic healthcare as patient-centred. The intervention was reported as tailored to the patient context. Patients with chronic pain are heterogeneous (Turk et al., 2008), especially with regards to their cognitive impairment (Kreitler, 2007; Turk, 2005). Respondents reported that there was regular review, a search for causative factors, and different techniques were employed. The patients felt engaged in the relationship, based on being autonomous in choosing osteopathy, feeling that they were listened to, and being partners in decision-making. A number of participants reported that their overall wellbeing and mental state were explored and supported during the consultations. These are all reported aspects of collaborative PCC.

Findings from this study, along with workplace and patient surveys (Adams et al., 2003; Burke et al., 2013; Leach et al., 2013; Orrock, 2009a, 2009b; Rajendran et al., 2012; Strutt et al., 2008; Xue, 2008) further suggests that osteopathic healthcare involves a multi-modal approach. The participants experienced an internal consistency to the experience that included assessment of the whole musculoskeletal system, linking of multiple regions, a depth of inquiry, multiple manual therapies, education about their condition(s), and advice on exercise and lifestyle strategies.
Current best evidence demonstrates that the use of self-help strategies including exercise, the consideration of co-morbidities, the involvement of the mental state of the patient, education and reassurance need to be used in the management of people in chronic pain (International Association for the Study of Pain, 2010; Schnitzer, 2006). Findings from this and other studies appear to support that osteopathic healthcare encompasses these aspects.

In Australia, osteopathy emerged as part of complementary and alternative medicine (CAM), a field of healthcare that has experienced substantial increases in utilisation in the past two decades (Xue, Zhang, Lin, Da Costa, & Story, 2007). The reasons why patients use CAM services have been grouped under push or pull factors (Andrews, 2012). The push factors revealed in this data appear to be a level of dissatisfaction with other manual therapy providers. The pull factors from this data may relate to the participant experience that osteopathic healthcare was holistic and engaged the patient at more depth of understanding of their problem. A number of researchers (Bishop, Yardley, & Lewith, 2007; Furnham, 2000) suggest that the people who attend CAM practitioners can be classified into three groups: those who believe in CAM on principle, those who are frustrated with the mainstream health services, and a third group who simply shop around to find an effective approach. The participants in this research appear to fit into the latter two groups, although the respondents who found their way to osteopathy after chiropractic could be seen to be finding the alternative to the alternative. The finding that a number of interviewees experienced osteopathic healthcare as holistic suggest elements of the biopsychosocial (BPS) model of health (Engel, 1980). Penney (2013) argues that the osteopathic principles are interchangeable with the BPS approach to healthcare, which is widely accepted as a comprehensive framework for the management of chronic conditions (World Health Organisation, 2013).

A focus on quality of life and functional outcome measures is apparent in the reports of these survey respondents and the experience of interviewees. Patients with this target condition have expectations that they improve in a number of domains (Parsons et al., 2007; Sanderson et al., 2012). Hsu et al. (2010) reported on unanticipated effects of interventions in CAM trials for low back pain, finding that there were a number of non-standard results from the intervention, like increased hope, energy and general wellbeing (Hsu et al., 2010). Xue et al. (2007) found similar outcomes from osteopathic management.
The value and depth of the therapeutic relationship emerged as a theme in this research. Placing importance on this relationship is inherent in the BPS model of healthcare (Penney, 2013; Toye & Barker, 2012). Exploring aspects of the patient’s psychosocial history demands a substantial consultation time and an advanced level of communication skill (Mauksch, Dugdale, Dodson, & Epstein, 2008). These respondents reported that trust, hope and reassurance were important elements in their consultations with the osteopath. How the practitioner communicates with patients is known to have an impact on therapeutic outcomes (Darlow et al., 2013). A relevant example of this is a practitioner suggesting to a patient with chronic musculoskeletal pain that their body is vulnerable and should be protected, which may promote the development of a fear-avoidance belief and limit outcomes (Rainville et al., 2011). The provision of cognitive reassurance through explanations and knowledge about the condition, as well as affective reassurance through empathy and showing interest is known to influence outcomes (Pincus et al., 2013), and this was apparent in this study.

The valuing of the therapeutic relationship under a BPS or holistic approach to healthcare is not unique to osteopathy. Interventions like reassurance and hope, while central to the development of a therapeutic relationship, are considered non-specific effects in terms of clinical research. Although this data suggest that the osteopathic intervention includes this focus, it is known that the observed positive effects of an intervention may be due to the non-specific effects of the therapeutic relationship on the belief of the patient that they will improve, and not the effect of the technical intervention (in this case the manual therapy techniques) which may be placebo (Foot, 2012; Kaptchuk et al., 2008; Mitchell, 1998).

Another common aspect of the experience of this sample was that there was a focus on self-help. Self-management is a vital link in the long-term outcome of people with chronic pain (Carnes et al., 2012; National Institute of Clinical Excellence, 2009), although in isolation has recently been shown in meta-analysis to have small effects compared to minimal intervention (Oliveira et al., 2012). The patients who finally arrive at the osteopathic clinic may be a self-selecting group of motivated people, who are searching for help and have not come to the osteopath as their first choice. This has been discussed with regards to patients of CAM, that they want to participate in their treatment and believe that lifestyle changes are essential in healing (Bishop et al., 2007).
The limitation in this research is primarily responder bias as only returning patients and those willing to fill in the survey in the waiting rooms were included in the survey and as interviewees. Even though the completed surveys were kept from the practitioners, the responders may have been hesitant to report negative aspects of the service and their outcomes. The limitations of the survey was that it was a convenience small sample of patients, and the people who consented to be interviewed were likely to have responder bias as satisfied clients. As with any qualitative data, the interviews and themes emerging are subjective experiences of the interviewees and the interviewer. The use of an assistant researcher checking the coding of transcripts, the use of mixed methods and the comparison with other research results strengthen the generalisability of the findings.

6.3.5 Conclusion

The detail of patients’ lived experience reported in this sample reflects and deepens previous survey data. These patients experienced that osteopathic healthcare is a late health choice, involves regular assessment, a range of manual therapies at multiple regions, therapeutic advice regarding exercise and posture, and education about the proposed aetiology of their main problem. Their experience reflects a patient-centred approach to healthcare. These results also reflect elements of an evidence-based management of the chronic pain patients common in these practices (International Association for the Study of Pain, 2010; National Institute of Clinical Excellence, 2009). The lack of formal clinical evidence supporting the specific osteopathic intervention is concerning. This data contributes to what is known about osteopathic healthcare from the patients’ experience of it, and triangulated with other data can assist in developing an authentic model of osteopathic healthcare that may be tested for its effectiveness. Complex interventions like osteopathy require a carefully planned research strategy in order to establish its evidence, including ensuring authenticity before major clinical trials are attempted (Coulter, 2011; Luce et al., 2009; Medical Research Council, 2000).
6.4 Discussion

The two parts of this qualitative Stage 3 of this thesis inquired into the experience and opinions of practitioners and patients about the osteopathic healthcare intervention in CNSLBP. The two parts were linked by the research design, as the practitioner focus group gave a perspective about the management of these patients that gave structure and direction to the patient survey and interviews. The workforce survey of Stage 1 gave the foundation of data that drove the direction of inquiry in Stage 3.

The COREQ quality checklist was used for these two qualitative studies (see appendices 2 and 3). The patient interviews and focus group both followed closely the requirements in the checklist, apart from the reporting of the coding tree. For the patient interviews, a documented and validated method of coding in the thematic analysis was used and included in the publication, which was accepted by the peer reviewers. The lack of reporting a coding tree gives rise to the question of inconsistency and/or bias, but in the project reported in this paper the transcriber (a post doctorate qualitative researcher) acted as a second coder and confirmed the validity of the themes, as reported in the methods. For the focus group, which is not yet submitted for publication, a description of the coding of the subthemes and their relationship to other data will be reported.

These Stage 3 studies had a number of common findings – the uncertainty of the diagnosis of non-specific, the breadth of assessment required, the use of an holistic model, the presence of comorbidities, the application of an individualised or tailored intervention that includes a range of manual therapies, education, lifestyle and exercise advice, and a consideration of the patients psychological state. The consistent positive opinion of osteopathic healthcare emerging from the patient interviews appears as a limit to the generalisability of that data, as there may have been responder bias. The interview questions did not specifically probe for negative consequences but simply asked for the experience to be explored.

The CNSLBP condition appears common as a presenting problem to osteopaths in these samples, and the non-specific label is not clearly defined. Recent definitions are consistent that the non-specific label is one where all identifiable pathological
causes of the pain have been excluded (Airaksinen et al., 2006; National Institute of Clinical Excellence, 2009). Despite the fact that the patients may not have an identifiable pathologic cause of their back pain, they appear to present with a number of co-morbidities based on this data and confirmed by other surveys (Burke et al., 2013; Fawkes et al., 2014; Orrock, 2009b; Xue, 2008) including cardiovascular and mental health issues. This information reveals both the use of a broad holistic or biopsychosocial approach to patient assessment and management, and also prompts the use of such a model, as people in chronic pain are reported to have complex health histories that require multidisciplinary management (Henderson, Harrison, Britt, Bayram, & Miller, 2013; Turk, 2005). These studies provide some evidence that these practices engage in that model.

This data provides some evidence that the osteopathic healthcare in these samples is patient- or person-centred. Questions have been raised about whether osteopathy is patient centered, particularly with the focus on the manual diagnosis of dysfunction – seen as more a reductionist biomedical construct (Thomson, Petty, & Moore, 2013b). Although the current studies did not aim to analyse the specific question of the use of manual osteopathic diagnosis, they do reveal that the patient is a health consumer with free choice to visit an osteopath, that the intervention is individualised/tailored to the patient context and that there is a therapeutic alliance that is integral to the encounter. These all support a patient-centred practice. In an editorial in the International Journal of Osteopathic Medicine, Moran (2013) states that in order to test the patient-centredness of osteopathic practice, a pragmatic trial would be the most appropriate as it allows flexibility in the application of a semi-structured intervention.

The preceding Stages 1 and 3 have collected data about osteopathic healthcare with a focus on a common presenting problem, and a model of the intervention has emerged. Each data set has its own research aims and findings, but have been linked in a mixed method research design that has an overarching aim of finding what is common by triangulation, convergence or synthesis of the findings. The next chapter presents the results of this process as a model of osteopathic healthcare, and applies these findings to a final study developing a pragmatic clinical trial method to test that model.
Chapter 7 – Final Stage – Practice model and trial method

7.1 Chapter introduction and data synthesis

In preceding stages, data has been gathered that were designed to answer questions of the characteristics of osteopathic healthcare from the perspectives of practitioners and patients. The overall aim of this thesis was threefold: 1) to explore the osteopathic healthcare intervention as it is practised; 2) develop an authentic model of the intervention in a common presenting condition; and 3) propose a pragmatic clinical trial method to test its effectiveness. The model that has developed has its foundation in the Stage 1 workforce survey data that explored the characteristics of osteopathic healthcare and the Stage 3 data that deepened the understanding of that practice through qualitative research. This chapter aims to answer the latter two aims – to outline a model of practice, and develop a method to test its effectiveness. What follows in this chapter is a data synthesis of all of the preceding phases that were undertaken to establish a model of practice, this is followed by a full report of a Delphi expert panel that was formed to develop the pragmatic clinical trial method.

7.2 Model of the osteopathic healthcare intervention in CNSLBP

The model of osteopathic healthcare intervention that has emerged from these studies is broader than previously described in textbook and stakeholder definitions. The practitioner surveys and focus group provided insight into their experience of everyday practice. Patients gave deep descriptions during interviews of their experience of receiving this healthcare. These following sections outline the key features of osteopathic healthcare found from the primary findings of these studies. The model that follows is a synthesis of the data with links to the theoretical framework that structures a new definition. The implications of these findings will be discussed further in Chapter 8.

7.2.1 Key feature: patients present to osteopaths with complex somatic pain, the most common of which is chronic non-specific low back pain.

Chronic non-specific low back pain was reported as the most common clinical presentation by the workforce survey of practitioners (section 4.2), the snapshot of
patients (section 4.3) and the focus group of practitioners (section 6.2) (illustrated in Figure 16). This finding was supported by data from the UK (Fawkes, 2013; Fawkes et al., 2014) and a cross-sectional survey of Australian osteopaths (Burke et al., 2013). The *non-specific* label is described in guidelines from a number of countries, but is not fully established internationally. It has appeared to replace an older term *idiopathic*, and was interpreted by the focus group as pain without a pathological explanation, which is consistent with a recent international review (Koes et al., 2010).

Figure 16 Triangulation of data – CNSLBP

7.2.2 Key feature: osteopathic healthcare includes a wide ranging assessment of the patient based on a biopsychosocial model

The practitioner survey, patient snapshot, practitioner focus group and patient interviews all reported that osteopaths employ a wide range of assessment strategies (illustrated in Figure 17). There was evidence for extensive case-taking and physical examination beyond the local area of pain, and including systems examination. The assessment considers the patients’ psychosocial state and influence on the presenting complaint. This reflects a primary care assessment defined in the Merriam-Webster dictionary (primary care, 2016) as where the patient has initial contact with a medical professional and is screened for pathological conditions and need for referral.

Figure 17 Triangulation of data - assessment
7.2.3 Key feature: osteopathic healthcare is patient/person-centred based on the tailoring of management and collaborative co-management

The practitioner focus group and patient interviews revealed that practitioners manage cases of CNSLBP differently depending on certain features in the case and on the individual patient context (illustrated in Figure 18). This could be seen as a patient-centred tailoring process from the patient interview data, and also a sub-grouping from the practitioner focus group data. Issues such as whether the patient needed referral to surgeons, psychologists or allied health practices (e.g. podiatry), and the need for co-management with these colleagues, was a common feature in both sets of data.

![Figure 18 Triangulation of data – patient/person centred](chart.png)

7.2.4 Key feature: the osteopathic healthcare intervention is multi-modal and health focussed

The osteopathic intervention in CNSLBP was revealed to be multimodal and based on a biopsychosocial model in the workforce survey, the patient snapshot, the practitioner focus group and the patient interviews (illustrated in Figure 19). There was consistently reported use of multiple manual therapies, a focus on lifestyle guidance including exercise and diet, education regarding the condition, and referral to other health professionals where necessary.
7.2.4.1 Manual therapy is integral to the intervention

The use of manual therapy was universal in these data (illustrated in Figure 20). The workforce survey and patient snapshot illustrated a range of manual techniques including commonly used HVLA, MET, soft tissue and joint articulation, as well as less frequently used myofascial release, visceral, functional and cranial techniques. The practitioner focus group data confirmed that the same broad range of techniques was utilised, and that their use did not follow any specific protocol. The patient interview data revealed the same variety of techniques could vary from consult to consult, and that other body regions, apart from the main painful focus of the lower back, were also treated with various manual therapies. This was reported in the focus group and patient interviews as an individualisation or tailoring process in the intervention, and reflects a patient-centred approach to healthcare.
7.2.4.2 **Lifestyle and exercise advice is integral to the intervention**

The use of lifestyle advice in osteopathic healthcare was common across all data sets (illustrated in Figure 21). Exercise and postural advice was reported specifically in the surveys, practitioner focus group and patient interviews. Educational strategies including dietary and nutritional advice were also employed as part of management in data from the surveys, focus group and patient interviews. These aspects illustrate the use of a health-focused and preventative healthcare intervention.

![Figure 21 Triangulation of data – lifestyle advice and education](image)

7.2.5 **Key feature: the osteopathic healthcare intervention includes an ongoing therapeutic relationship**

The osteopathic intervention is applied over a number of consultations and with regular follow-up and review (illustrated in Figure 22). The workforce survey and patient snapshot revealed an ongoing healthcare relationship lasting months to years, with patients re-presenting with different complaints. This gives support for the proposition that the therapeutic alliance is central to patient-centred osteopathic healthcare. The practitioner focus group and patient interviews demonstrated that the care of CNSLBP required weekly to fortnightly consultations over a number of months, and follow up review every few months to adjust treatment and ensure adherence with lifestyle management. This data demonstrates that a common practice is to apply a process of intervention over time and that positive outcomes may not be measurable until later in these chronic pain patients. This data influences the timing of outcome measures in any trial method.
7.2.6 Key feature: outcomes from osteopathic healthcare management are broad and patient-centred

The dominant presentation to osteopathic practice in Australia as revealed by the survey and focus group data was chronic musculoskeletal pain conditions, commonly in the lower back, and it follows that reduction in pain was stated in the practitioner focus group and patient survey and interviews as a primary expectation of outcomes from osteopathic healthcare (illustrated in Figure 23). The practitioner focus group and patient survey and interviews also reported a range of functional outcomes that were both aimed for and experienced, including increased energy, improved breathing, and enhanced capacity for activities of daily living and recreational activities. This data demonstrates that both the assessment and outcomes span a range of the patients’ functions, and supports the practice of a biopsychosocial model.
7.2.7 **New definition**

As a modern health profession, osteopathy has a responsibility to be clear and evidence-based in its presentation to the world and the practice that reflects its definition. The work in this thesis gives raise to a new definition of osteopathy based on the data triangulation and synthesis outlined above.

Osteopathy is a healthcare profession that is underpinned by biopsychosocial and holistic principles, and that focuses on the health and mobility of all tissues of the body. Osteopathic healthcare includes a thorough primary care assessment and the application of a range of manual therapies and health promotion strategies tailored to the individual that aim to optimise both function and health.

The differences from other definitions are that osteopathic healthcare:

- is not just a manual approach

  The practice includes a thorough primary care assessment and health promotion, psychosocial and lifestyle interventions;

- has biopsychosocial principles

  Has holistic osteopathic principles that appear to be integrated into practice as a modernised BPS model

- involves a tailoring/individualisation of the intervention

  The practice has evidence of being person centred in its use of patient context, preferences and needs;

- focuses on functional outcomes

  The outcomes from osteopathic healthcare are aimed at improving function at many levels, both for the activities of daily living and the local tissue health;

- is focused on health rather than disease
Osteopathic healthcare focuses on functional outcomes, and there was no evidence of claims to treat disease;

- has elements of evidence based practice in the domains of chronic pain

The practice of osteopathic healthcare follows elements of the current evidence for managing chronic pain – consideration of psychosocial factors, exercise and lifestyle interventions, team care including referral to medical practitioners and psychologists and self-management.

### 7.2.8 Summary

The key features of osteopathic healthcare outlined above, particularly in the management of CNSLBP, were collected from primary findings of data included in this thesis. Triangulation and synthesis of these data enable the development of a model of osteopathic healthcare based upon these key features (see Table 26) in a new definition that serves two purposes: firstly to illuminate this healthcare practice for stakeholders including third party payers and the profession itself, and secondly, to be used as a construct on which to propose a pragmatic clinical trial method, in order to enhance its authenticity and therefore its transferability to practice. The limitation of this definition is that it is based on the current research and has not been tested on the members of the profession. There may be resistance to certain concepts in this definition and market testing should be carried out to ensure its acceptance by the profession.

The next step in this current project was to develop a pragmatic clinical trial method with the use of an expert Delphi panel.
Table 26 A model of osteopathic healthcare

<table>
<thead>
<tr>
<th>Key features</th>
<th>Primary finding</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumer driven</td>
<td>Patient choice</td>
<td>Workforce survey and snapshot (Orrock, 2009a, 2009b)</td>
</tr>
<tr>
<td></td>
<td>Word of mouth</td>
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<tr>
<td></td>
<td></td>
<td>Crosssectional survey (Burke et al., 2013)</td>
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<tr>
<td></td>
<td></td>
<td>Practitioner focus group (Chapter 6.2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Patient interviews (Orrock, 2015)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>UK data (Burke et al., 2013) (Leach et al., 2013)</td>
</tr>
<tr>
<td>Pain presentations</td>
<td>Somatic pain</td>
<td>Workforce survey and snapshot (Orrock, 2009a, 2009b)</td>
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<tr>
<td></td>
<td></td>
<td>Crosssectional survey (Burke et al., 2013)</td>
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<td></td>
<td></td>
<td>Practitioner focus group (Chapter 6.2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Patient interviews (Orrock, 2015)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>UK data (Burke et al., 2013) (Leach et al., 2013)</td>
</tr>
<tr>
<td></td>
<td>Spinal, trunk and periphery</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chronic non-specific low back pain</td>
<td></td>
</tr>
<tr>
<td>Biopsychosocial foundations</td>
<td>Historical philosophy</td>
<td>Textbook chapter (Seffinger et al., 2003)</td>
</tr>
<tr>
<td></td>
<td>Thorough assessment</td>
<td>Workforce survey and snapshot (Orrock, 2009a, 2009b)</td>
</tr>
<tr>
<td></td>
<td>Consideration of mental state</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Social history</td>
<td>Crosssectional survey (Burke et al., 2013)</td>
</tr>
<tr>
<td></td>
<td>Therapeutic alliance</td>
<td>Practitioner focus group (Chapter 6.2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Patient interviews (Orrock, 2015)</td>
</tr>
<tr>
<td>Person centred</td>
<td>Patient choice</td>
<td>Textbook chapter (Rogers, 2002)</td>
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<tr>
<td></td>
<td>Therapeutic alliance</td>
<td>Workforce survey and snapshot (Orrock, 2009a, 2009b)</td>
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<tr>
<td></td>
<td>Tailored intervention</td>
<td></td>
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<td></td>
<td>Educational focus</td>
<td>Crosssectional survey (Burke et al., 2013)</td>
</tr>
<tr>
<td></td>
<td>Consideration of personal beliefs</td>
<td>Practitioner focus group (Chapter 6.2)</td>
</tr>
<tr>
<td></td>
<td>Collaboration and team management</td>
<td>Patient interviews (Orrock, 2015)</td>
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<tr>
<td></td>
<td>Outcomes matched to patient</td>
<td></td>
</tr>
<tr>
<td>Primary care assessment</td>
<td>Interview includes medical history and systems review and lifestyle</td>
<td>Workforce survey and snapshot (Orrock, 2009a, 2009b)</td>
</tr>
<tr>
<td></td>
<td>Physical assessment of multiple systems and regions</td>
<td></td>
</tr>
<tr>
<td>Interdisciplinary referral</td>
<td>Referrals in and out</td>
<td>Workforce survey and snapshot (Orrock, 2009a, 2009b)</td>
</tr>
<tr>
<td>Tailored manual therapy and lifestyle interventions</td>
<td>Multimodal manual therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exercise advice</td>
<td>Crosssectional survey (Burke et al., 2013)</td>
</tr>
<tr>
<td></td>
<td>Ergonomic advice</td>
<td>Practitioner focus group (Chapter 6.2)</td>
</tr>
<tr>
<td></td>
<td>Dietary advice</td>
<td>Patient interviews (Orrock, 2015)</td>
</tr>
<tr>
<td></td>
<td>Postural aids</td>
<td></td>
</tr>
<tr>
<td>Health focussed</td>
<td>Educational focus</td>
<td>Workforce survey and snapshot (Orrock, 2009a, 2009b)</td>
</tr>
<tr>
<td></td>
<td>Functional outcomes</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Crosssectional survey (Burke et al., 2013)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Practitioner focus group (Chapter 6.2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Patient interviews (Orrock, 2015)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>UK data (Burke et al., 2013) (Leach et al., 2013)</td>
</tr>
</tbody>
</table>
7.3 An international Delphi panel to explore and gain consensus for a pragmatic clinical trial method to test the osteopathic healthcare intervention in chronic non-specific low back pain.

7.3.1 Introduction

An authentic model of practice must be established before designing a pragmatic clinical trial method, especially when testing complex interventions (Craig et al., 2008; Medical Research Council, 2000). Osteopathy is a primary care health profession based on the biopsychosocial model that utilises a multi-modal set of therapies to manage neuro-musculoskeletal pain conditions, of which the most common is CNSLBP (Orrock, 2009a, 2009b). There is a lack of robust clinical evidence for its effectiveness in these presentations (Orrock & Myers, 2013), especially with regards to the whole practice, but recent trial data shows promise (Licciardone et al., 2013). In order to test an intervention in its normal everyday practice setting, it is clear that pragmatic trials are suitable (MacPherson, 2004; Zwarenstein et al., 2008). The value of these trials has been discussed in the literature, with strengths reported as the testing of interventions in chronic conditions, the flexibility in allowing clinicians to treat in response to the presenting individual, and also that they help convince decision-makers about the benefits of a service (MacPherson, 2004; Moran, 2013; Zwarenstein et al., 2008). A pragmatic trial method can result in an improvement in the external validity of the results as it mirrors the real world, but a weakness can result from compromising the internal validity (MacPherson, 2004; Patsopoulos, 2011; Roland & Torgerson, 1998; Zwarenstein et al., 2008).

The Delphi method is a way of systematically gathering the opinions and seeking consensus from a panel of experts about a complex problem or establishing where there is uncertainty about the solution to the problem (Franklin & Hart, 2007; Keeney et al., 2006; Wilde, Ford, & McMeeken, 2007). The technique allows members of the panel to communicate anonymously and without the influence of status and authority. Specific questions are put to the group individually, opinions are collected and summarised, and each panelist comments on the summary in an iterative loop until consensus is achieved. The level of consensus required depends on the criticality
of the question, and ranges from 51\% to 100\% agreement (Keeney et al., 2006; Wilde et al., 2007), with 70\% reported as the most common level (Vernon, 2009).

While there are no rules on the construction of the panel, it is thought that having fewer than 20 members assists in making the process efficient, as long as the panelists have appropriate experience and expertise in the field in question (Keeney et al., 2006; Powell, 2003). There are different ways to commence the cycle, with some authors favouring a qualitative Round 1 to explore the issue, followed by quantitative surveys in Round 2 and onwards. The classic Delphi has the researcher providing a list of solutions to the research question, with panel members ranking these in order of importance (Avella, 2016; Vernon, 2009). A number of modified Delphi methods exist, including commencing with survey findings and refining the questions as the process unfolds. In another version, the researcher proposes solutions based on previous literature and panel members discuss these and agree or propose other solutions (Avella, 2016). Delphi methods have been used to develop consensus about a broad array of issues in healthcare, including diagnosis in musculoskeletal practice (Graham, Regehr, & Wright, 2003; Wilde et al., 2007) and examining for spinal instability (Cook, Brismee, Fleming, & Sizer, 2005).

The Delphi process is made more robust by the panelists’ engagement with the issue without being unduly influenced by the group opinion, by the response rate remaining consistently high throughout the cycles, and by gaining a majority agreement relative to the criticality of the question (Powell, 2003). The disadvantages of the Delphi process include the researcher’s possible bias and/or lack of knowledge in constructing the questionnaire, and the possibility of certain panel members dominating the discussion or dropping out when their opinion is disregarded. The researcher can obtain independent external advice on the questionnaire and maintain open and fair discussion to mitigate these issues (Avella, 2016; Vernon, 2009).

Developing a pragmatic clinical trial methodology to assess an intervention in healthcare requires a number of complex issues to be addressed. These include defining the intervention to be used, developing inclusion and exclusion criteria for subjects and deciding on appropriate outcome measures, while ensuring that the decisions regarding these and other issues are authentic reflections of real-world practice. The Delphi process is an appropriate method to explore these issues. The aim of this study was to develop a pragmatic clinical trial method to test the
effectiveness of osteopathic healthcare for CNSLBP by the use of an international Delphi panel.

### 7.3.2 Method

The method followed an established process for a modified Delphi (Avella, 2016; Keeney et al., 2006; Powell, 2003). An invitation/information letter and consent form were sent via email to a purposive sample of osteopathic practitioners and academics with research experience, based on expertise and publications in the field, a number of experienced clinical researchers in other healthcare fields, and an experienced clinical trial statistician. The aim was to have a panel of 8 members. Once the consent form was received from participants a table of discussion points (Table 27) was sent to each individual as Round 1. This table included a number of proposed solutions to the research question that have emerged from previous literature, and also a list of optional answers to other aspects of the research question. These options were for consideration by the panelists who had a free response to agree or disagree with the proposal(s), and/or providing comment and offering different solutions. All correspondence was handled anonymously with the exception of the researcher. Comments received from the Round 1 discussion paper were thematically analysed and sent back as a summary (with salient quotes and references) to all participants in Round 2, along with the level of agreement to the proposals. This step was to be repeated until a 75% consensus is reached on all aspects of the trial.

<table>
<thead>
<tr>
<th>Background (findings from research)</th>
<th>Effect on methods/questions for panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNSLBP = chronic non-specific low back pain OI = osteopathic intervention OMT = osteopathic manipulative therapy</td>
<td>Ensure broad inclusion criteria?</td>
</tr>
<tr>
<td>CNSLBP is a complex condition with the presence of co-morbidities</td>
<td>Reduce bias by exploring patient knowledge of OI or other manual therapies? How to manage this in design? Exclude those with knowledge OI?</td>
</tr>
<tr>
<td>CNSLBP is the most common presentation for OI</td>
<td>Do intake histories to identify subgroups? Exclude insurance subgroup? Subgroups require acceptable number to power study – how to power this? How to allow variance in: Treatment repetition Blend of therapies/advice Consult number Prognosis?</td>
</tr>
<tr>
<td>Osteopaths individualise the management approach for subgroups: • Degenerative /older group • “Unstable” group (especially post partum) • Insurance claim group (black flag) • Occupational aggravator group (blue flag) • Acute on chronic group (recent injury)</td>
<td></td>
</tr>
<tr>
<td><strong>Clinical trial design</strong></td>
<td>We are considering a parallel design (OI versus Control) Other designs more suitable?</td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td>Is standard GP care the best comparator? Allow GPs to refer to Physical Therapist as part of standard care – does this confound results? What about Sham OMT? How to manage the credibility of the control arm?</td>
</tr>
<tr>
<td><strong>OI is multimodal</strong></td>
<td>How to allow choice of approach? Black box? Package?</td>
</tr>
<tr>
<td><strong>Patients report various outcomes</strong></td>
<td>What validated tools can measure changes in these diverse outcomes? Visual Analogue Scale Numeric Pain Rating Scale Oswestry Disability Index Roland Morris Disability Index Patient interviews Short Form 12, Short Form 36 Do you know of a better Patient Centered Outcomes Questionnaire?</td>
</tr>
<tr>
<td>Pain reduction</td>
<td></td>
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<tr>
<td>Increased flexibility</td>
<td></td>
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<tr>
<td>Enhanced Activities of Daily Living</td>
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<td>Postural normalisation</td>
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<tr>
<td>Educational enhancement</td>
<td></td>
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<td>Self-empowerment</td>
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<tr>
<td>Reassurance</td>
<td></td>
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<tr>
<td>Wellness (sleep, breathing, energy)</td>
<td></td>
</tr>
<tr>
<td><strong>Multiple outcomes reported by patients (including many non-specific effects)</strong></td>
<td>How to encompass this broad range? Does a trial have to nominate a single measure?</td>
</tr>
<tr>
<td><strong>Non-specific effects of therapeutic relationship, educational process, reassurance.</strong></td>
<td>Blinding - subject by credible control (above). Assessor blinded. Add physiological measure (eg performance on task)?</td>
</tr>
<tr>
<td><strong>An effective therapeutic relationship is a key theme in osteopathic management</strong></td>
<td>Manage Hawthorne effect by rotating clinicians in trial arms?</td>
</tr>
<tr>
<td><strong>Effectiveness trial statistics</strong></td>
<td>What is most appropriate for pragmatic design? Clinical Prediction Rule? Intention to Treat? Exploratory Factor Analysis?</td>
</tr>
<tr>
<td>CNSLBP is managed over 6-10 consults/4-6 months (and then 12 months of follow up) to achieve significant results</td>
<td>Outcome measures at 3/6/12/18 months? What to do about withdrawal/attrition?</td>
</tr>
</tbody>
</table>

### Table 27 Delphi Round 1 tabled discussion points

#### 7.3.3 Results

Eight participants were recruited from Australia, Canada, the UK and USA. The recruited panel members all had greater than 10 years’ experience in their field and some had greater than 20 years. They were:

- a medical research professor (Australia);
- an osteopathic clinician and researcher (Australia);
- a statistician and osteopathic clinician (UK);
• a clinical trials researcher (Australia);
• a Chinese medicine clinician and professor (Australia);
• an osteopathic clinician and researcher (Canada);
• an osteopathic clinician and research professor (US);
• a medical researcher and clinician (US).

One participant dropped out after Round 1 with no explanation, leaving seven participants in Round 2. A consensus of 75% was reached after Round 2 on all issues, so no further rounds were required. The themes and discussion that emerged after Round 1 were collated under the following headings.

### 7.3.3.1 Inclusion and exclusion criteria/subgrouping

The response rate to this question was 100% of the second round participants. Broad inclusion criteria were seen as important in pragmatic trials, and all agreed on an intake interview. The definition of non-specific back pain is conflicted in the literature and evolving, and all agreed on using the most recent definition in the inclusion criteria. The panel thought that a severity range should be established to exclude those with either very high or low pain levels – a Visual Analogue Scale (VAS) range of 3-7 was agreed on by 85.7% of the panel. The point was made that the trial should endeavour to include those who were likely to respond well to osteopathic healthcare intervention, and exclude those who were not. Exclusion criteria that were agreed on by 100% were acute pain, severe pain limiting ambulation and/or exercise, co-morbidities that contraindicated manual therapy, post-surgical patients and insurance claimants (workers compensation or concurrent litigation patients). The panel thought that subgrouping participants was costly and inefficient, unless more research was done to define the subgroups and the recruited numbers for each subgroup were high enough for statistical power.

### 7.3.3.2 Managing subjects’ previous knowledge of osteopathy

This issue was raised in Round 1 as a possible confounder, but the panel did not reach consensus on pre-trial interviews. The opinion was that pragmatic trials should include the possibility of treatment expectation, and 80% agreed to doing post trial interviews (from a response rate of 71.4%) – to enquire into the subjects’ perception of the treatment.
7.3.3.3 Design

A parallel design was favoured by 100% of participants in Round 2 after some discussion in Round 1 of the strengths and weaknesses of the cross-over design. The advice was to keep the trial simple, and to test one question at a time, namely the osteopathic intervention compared to control.

7.3.3.4 Control

The Round 1 discussion centred on what is known to be standard care for CNSLBP, and panel members reported international variation in the clinical guidelines. The issue of whether referral for physical therapy was considered standard and whether this would be a confounder in a trial of the osteopathic healthcare intervention was debated. The majority of panelists (85.7%) in Round 2 agreed that physical therapy should be excluded from the control unless the research question compared physical therapy with osteopathic healthcare intervention, and that standard family doctor care including red flag screening, pharmacological prescriptions, education and advice without physical therapy would be the most appropriate control.

7.3.3.5 Intervention

The panel unanimously agreed that the osteopathic intervention should be a package of modalities delivered over a number of consecutive consultations that have emerged from research on real world practice, and that there should be practitioner choice within the package based on the specific needs and context of each subject. The panel agreed that the study protocol for the osteopathic intervention package and its boundaries should be further developed by a clinician focus group.

7.3.3.6 Outcome measures

Panel members advised that patient-oriented outcome measures would be the most appropriate, and warned that some other standard measures are costly and lengthy to administer. Measures discussed were the Roland Morris Disability Questionnaire (RMDQ), the Oswestry Disability Questionnaire, the PROMIS (Patient-Reported Outcomes Measurement Information System) and the Short Form series. All agreed that a patient experience/satisfaction questionnaire should be used. By Round 2 there was 100% agreement on the RMDQ as the primary measure, with PROMIS and VAS pain scoring as secondary measures.
7.3.3.7 Blinding

There was unanimous agreement by Round 2 that the assessor and analyst should be blinded and that a formal assessment of the success of the blinding should be included at the trial end.

7.3.3.8 Effect of therapeutic relationship

There was a proposal in Round 1 to rotate clinicians to avoid a confounder based on the Hawthorne effect of the patient-practitioner relationship (Jadad, 2008). The panel argued against this on the grounds that a pragmatic trial should stay close to normal practice, and 85.7% agreed in Round 2 that each subject has a single clinician and that there should be training to ensure a consistent level of relationship is built during the trial.

7.3.3.9 Statistical approach

A number of statistical approaches were proposed in Round 1, and the panel unanimously favoured Intention to Treat as the primary statistical analysis of results by Round 2. Panel members also agreed that it is important to report effect sizes based on the Cochrane Back Review Group, and minimally important changes.

7.3.3.10 Follow up

The researcher proposed follow-ups at 3, 6, 12 and 18 months in Round 1, and various opinions were discussed. The issues of weekly phone calls and daily diaries were canvassed by some members. In Round 2, the panel reached unanimous agreement on data collection at baseline and 3, 6, 12 and 26 weeks. The opinion was that withdrawals should be followed up if subjects consent. Panelists did not reach agreement on suggestions for either a daily diary (50% agreement) or a weekly phone call (20% agreement) as they were considered time-consuming and costly.

7.3.4 Discussion

Developing a clinical evidence base is a priority in health practice, and osteopathy has limited evidence to support its practice. The development of an authentic model of the intervention that emerges from research, and subsequently designing a pragmatic trial that tests that intervention as it is delivered in the real-world is a solid strategy to address the evidence gap (Craig et al., 2008; Medical Research Council,
The osteopathic healthcare intervention has some evidence that it is complex and multimodal (Burke et al., 2013; Fawkes et al., 2014; Orrock, 2009a, 2009b, 2015), and it has been reported that developing a research plan for complex interventions first requires a detailed description of the intervention (Medical Research Council, 2000).

The Delphi panel was conducted across two rounds with one withdrawal after the first round. The background of panel members was mixed in terms of clinical and academic experience, gender and nationality, so agreement on the issues canvassed may be considered to have minimised bias to some extent. The structure of the trial that has emerged from this Delphi process (see Table 28) gives clear guidance to researchers wishing to design a pragmatic trial that is based on an authentic model of osteopathic practice.

<table>
<thead>
<tr>
<th>Table 28</th>
<th>Pragmatic clinical trial method</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The effectiveness of the osteopathic healthcare intervention in chronic non-specific lower back pain compared to standard medical care</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Trial element</strong></td>
<td><strong>Description of finding</strong></td>
</tr>
<tr>
<td>Design</td>
<td>Parallel</td>
</tr>
<tr>
<td>Inclusion</td>
<td>Broad inclusion, intake interview Adults, severity range VAS 3-7,</td>
</tr>
<tr>
<td>Exclusion</td>
<td>Acute pain, severe pain limiting ambulation and/or exercise, co-morbidities that contraindicate manual therapy, post-surgical patients, insurance claims (workers compensation or concurrent litigation)</td>
</tr>
<tr>
<td>Test condition</td>
<td>Non-specific – use most recent definition</td>
</tr>
<tr>
<td>Control</td>
<td>Standard family doctor care including red flag screening, pharmacological prescriptions, education and advice (excluding physical therapy)</td>
</tr>
<tr>
<td>Intervention</td>
<td>Osteopathic healthcare intervention: package of modalities that have emerged from research Delivered over 6-10 consultations Practitioner choice within the package based on the patient context</td>
</tr>
<tr>
<td>Outcome measures</td>
<td>Roland Morris Disability Questionnaire (primary) PROMIS and VAS (secondary)</td>
</tr>
</tbody>
</table>
| Blinding          | Assessor and analyst
|                  | Formal assessment of the success of the blinding should be included at the trial end. |
| Statistical analysis | Intention to Treat
|                  | Report effect sizes based on the Cochrane Back Review Group |
| Follow up         | At 3, 6, 12 and 26 weeks.
|                  | Follow up withdrawals if the subject is consenting |
Chapter 7 – Final Stage – Practice model and trial method

A wide inclusion criteria suits pragmatic trials and the label NSLBP will include a variety of presentations. There is some consistency in recent definitions of NSLBP with regards to the condition being pain in the defined lower back region and where it is not possible to identify any specific pathological cause (Koes et al., 2010; National Institute of Clinical Excellence, 2009). For example the European Guidelines state (Airaksinen et al., 2006) that NSLBP is:

Low back pain that is not attributable to a recognisable, known specific pathology (e.g. infection, tumour, osteoporosis, fracture, structural deformity, inflammatory disorder (e.g. ankylosing spondylitis), radicular syndrome or cauda equina syndrome) (s208)

People with chronic pain have been found to have disordered thresholds resulting in allodynia and central sensitisation (Woolf, 2011). An intervention solely based on externally delivered manual therapy is unlikely to solve the patient’s pain. The evidence supports the use of exercise therapy, education and some level of mind training in chronic pain, as well as some psychological support for those that require it (National Institute of Clinical Excellence, 2009). The trial that was designed by this Delphi panel dealt with this complexity by ensuring that people who are most likely to respond to the osteopathic healthcare intervention would be included and those who have other primary needs (eg psychological support, surgical intervention) would be excluded.

In designing RCTs, researchers have to deal with a significant confounder when subjects become convinced about whether they are receiving the active treatment or not. For example, confounders like expectancy, where subjects become convinced that they will improve from the intervention, the level of credibility of the intervention and a subject’s previous knowledge of the interventions can create bias and early withdrawal (Licciardone & Russo, 2006). The issue of measuring these beliefs pre-trial was discussed by the panel but rejected in favour of a post-trial analysis. Licciardone and Russo (2006) have argued that researchers in manual therapy have to consider this issue carefully, after they completed a trial of Osteopathic Manipulative Therapy (OMT) compared to a control of sham manipulation on back pain, they found on post-trial analysis that subjects’ judged the credibility of OMT highly over sham.
The fundamental design question resulted in the panel agreeing that a parallel clinical trial design is best when there is a single intervention being tested against a control, and this rationale is supported in the literature (Jadad, 2008). The other point made during the Delphi panel was that a sequential cross-over design requires a certainty about the effects of the intervention over time in order to set the periods of active treatment and avoid a carry-over effect (Mills et al., 2009). The effects of the OMT compared to sham OMT on pain in people with CNSLBP at 12 weeks was reported in a recent randomised controlled trial as moderate ($P<.001$) or substantial ($P=.002$) (Licciardone et al., 2013), but further research to confirm this finding and to assess more long-term effects have not been published.

In pragmatic trials, the control should reflect what patients would commonly receive in the real world. People with back pain are frequent visitors to medical practitioners, for example 18% of visits to general practitioners in Australia deal with musculoskeletal pain and low back pain is the most common complaint in that category (Australian Institute of Health and Welfare, 2016). Guidelines for their management vary between countries (Scott, Moga, & Harstall, 2010). In an overview of international guidelines from thirteen countries, Koes et al. (2010) concluded that the guidelines were similar for the use of diagnostic triage screening for pathological causes and of supervised exercises, cognitive behavioural therapy and multidisciplinary treatment as therapeutic interventions. The authors found discrepancy about the use of spinal manipulation; the Australian and Spanish guidelines do not recommend its use, but the US and Netherlands suggest a short course for people who do not respond to the first line of therapy.

With regards to the intervention, the panel supported the concept of a packaged intervention of therapeutic modalities that have been established by research to be common components of osteopathic healthcare. A weakness of the pragmatic trial design is being unable to determine what part of the intervention had the greatest effect. Proponents of the biopsychosocial model would argue that the combination of therapies has a cumulative effect greater than the sum of its parts (Coulter, 2011; Coulter et al., 2014; Fonnebo et al., 2007), and it appears that osteopathy utilises this model and includes a range of techniques and healthcare strategies to manage chronic pain patients.
The outcome measure that the panel thought best encompasses the functional and general health focus of osteopathic healthcare is the Roland Morris Disability Questionnaire (RMDQ). The group reported that the Oswestry Disability Index took longer to complete, and the Short Form series did not encompass general health as well as the RMDQ. A number of panel members suggested that an evaluation of cost-effectiveness would be a valuable addition if an aim was to influence third party and policy stakeholders (Hlatky, Owens, & Sanders, 2006). The RMDQ is reported to have a good level of reliability and moderate to high correlation with pain intensity scores, and is simple and easy to use (Stevens, Lin, & Maher, 2016).

The issue of blinding in trials that include manual therapy is problematic, and the panel understood that both the subjects and assessor/analyst can be blinded but the practitioner/caregiver cannot be. The term ‘dual blinding’ has been proposed for this problem (Caspi et al., 2000), in order to enhance the integrity of research findings by ensuring that ‘double blind’ only means subjects and practitioner/caregiver are blinded. This weakening of the blinding process compared to the gold standard of double blinding is a limitation in the internal validity of pragmatic trials, but that is counter-balanced by the authenticity and external validity of the method. The Delphi panel members suggested that a post-trial analysis of the extent and success of blinding would be useful, and this could be done by a post-trial interview and/or questionnaire (Licciardone & Russo, 2006).

This weakness of blinding can be linked to the non-specific effect of the therapeutic relationship in clinical trials – where the subject experiences improvement simply by being attended to by a practitioner who engenders hope and certainty (Jadad, 1998). This phenomenon is carefully excluded in gold standard double blind methods as it is considered non-specific and unrelated to the active treatment. The literature on the effect of this relationship in clinical trials is not large, but a systematic review in 2014 found it to be small but significant (Kelley, Kraft-Todd, Schapira, Kossowsky, & Riess, 2014). Again, pragmatic trials are designed to encompass all elements of the practice from the real world, and this includes the relationship between the patient and practitioner. Delphi panel members suggested a strategy of training to ensure that every practitioner gave consistent attention to the relationship with the subjects in order to make this aspect consistent and less of a confounder.
The statistical method of choice was intention to treat (ITT), which is a method to compare patients within their original randomised groups whether they received the allocated treatment or not, for any reason, including dropping out of the trial (Gupta, 2011). This is considered appropriate for pragmatic trial design, as it reflects the real world – and is supported by the CONSORT guidelines (Moher et al., 2010; Zwarenstein et al., 2008). One of the reported problems with ITT is that many researchers have been found to have not fully adhered to the method (Gravel, Opatrny, & Shapiro, 2007). Also, it can dilute the treatment effect if non-compliant and dropout subjects are added to people who are compliant, which can lead to a Type II error – a finding of no significant effect when it was present (Gupta, 2011).

A number of reporting guidelines exist that allow a per-protocol (PP) finding to be added to the ITT analysis while keeping ITT as the primary analysis (Gupta, 2011; Matilde Sanchez & Chen, 2006). PP includes only people who completed the protocol completely in the results (Gupta, 2011; Matilde Sanchez & Chen, 2006). There are a number of proposed modified ITT approaches – for instance excluding subjects who dropout soon after randomisation and before starting the trial intervention, but there is evidence that because there are so many variations, it inherently leads to the possibility of bias (Gupta, 2011; Polit & Gillespie, 2010).

Delphi panel members also suggested that the effect size be reported, which is a statistic that reports on the magnitude of difference between active and control groups, sometimes called a Cohen \(d\) and which follows a Cochrane Back Review Group guideline. Reporting the minimally important difference (MID) was also considered important by the Delphi panel, as it measures the smallest change that a patient can perceive (and report through a measure like the RMDQ) as notable, either positive or negative (Johnston et al., 2015). Finally, the schedule of follow up over 26 weeks that resulted from the practitioner focus group and the experience of osteopathic clinicians on the Delphi panel, appear to be balanced between what the sample of clinicians have experienced, and what the experienced clinical researchers suggested is reasonable for applying the outcome measures in a clinical trial.

7.3.5 There is limitation to these findings, as caution must be applied to the results of a single Delphi panel, as a different group of experts may have diverse opinions. This process should be repeated with different panels to obtain more certainty. This modified Delphi design had the researcher making suggestions about the structure of the trial, and some panellists may have felt constrained by this structure. It would
have been expected that the panel members were aware of new research in the area, and their responses may have been influenced by similar trials of OMT in CLBP, for example Licciardone and colleagues (2013). The proposed trial design needs to be published and available for professional discussion. Following publication and broader professional input a pilot trial needs to be undertaken to ascertain if the design is viable with regards to a number of protocol issues such as recruitment, the definition of the control group, sample size calculation, the method of blinding the assessor and analyst and the training of practitioners to consistently deliver the intervention.

7.3.6 Conclusion

A pragmatic clinical trial method was developed with the use of an expert Delphi panel. The proposals put to the panel regarding the structure of the trial were based on previous research into osteopathic practice in Australia (see Chapters 4 and 6), which improves the external validity of any results from such a trial.

The panel advised that a trial should have a wide range of inclusion criteria and specific exclusions, a parallel design with a control of standard medical care, an intervention package of osteopathic healthcare, a primary outcome measure of the Roland Morris Disability Questionnaire, statistical analysis by Intention to Treat and follow-ups of 3, 6, 12 and 26 weeks. This design gives researchers an evidence-based design for further research into the effects of the osteopathic intervention in CNSLBP that reflects real world practice.
Chapter 8 – Discussion

8.1 Introduction

This thesis has analysed the osteopathic profession and its progress toward building an evidence base for its intervention. The osteopathic profession has existed for over 120 years and despite growing in the number of practitioners and the regions where it is practised, still has very little evidence to support its clinical effectiveness in common patient presentations. The work outlined in this thesis has reached its aims by:

- establishing an authentic model of the osteopathic healthcare intervention in the most common patient problem;
- proposing a new definition of osteopathic healthcare; and
- developing a clinical trial method to test the effectiveness of that intervention.

These results have been achieved by a process of sequential mixed methods research. The approach may give guidance to other researchers aiming to assess a complex healthcare intervention. This research has demonstrated that osteopathic healthcare in the samples studied is a multimodal and complex practice. This practice utilises a biopsychosocial and holistic model to understand a patient problem, and consistently includes thorough whole of health assessment and diagnosis, the use of referral when necessary, education and explanation, application of a broad range of manual therapies and advice regarding lifestyle changes including exercise and dietary interventions.

To develop an authentic model of the osteopathic intervention and a method for testing its clinical effectiveness, the work contained in this thesis explored characteristics of the practices of the osteopathic workforce, the opinions and experience of osteopathic practitioners and their patients, and reviewed the current state of the science in the most common osteopathic intervention. Finally this model was integrated into a pragmatic clinical trial method with the use of an expert Delphi panel. The implications and limitation of these results will now be discussed.
8.2 The philosophical stance and methodology

The philosophical paradigmatic stance taken in this thesis was pragmatism. Pragmatism was well suited to the research questions, as the aim of research within this paradigm is to see what works, what solves problems and what answers questions. In Chapter 1 (sections 1.7 and 1.8), I discussed how pragmatism led me to methodological pluralism, and particularly to mixed methods research. The linking of pragmatism to the MMR approach outlined by Morgan (2007) and Cresswell (2007) allowed the freedom to use a reasoning process to move back and forth between induction/deduction and subjectivity/objectivity.

As outlined in Chapter 3, Cresswell (2008) points out methodological issues that may arise with the sampling, participant selection, data collection and analysis when using the sequential design in mixed methods. Sampling is different in size and scope with quantitative and qualitative designs, and care must be taken to consider the differences. With regards to sampling in this research, the broad pool of registered osteopathic practitioners from the quantitative workforce survey in Stage 1 led to a smaller focus group sample in Stage 3 that would have come from the original population of registered practitioners. The patients that were recruited by the waiting room survey for qualitative interview in Stage 3 may not have been the same patients from the earlier quantitative patient snapshot in Stage 1, but they were patients with the target condition who volunteered and were managed by practitioners who were part of the earlier workforce sample. The samples were also compared to the larger data set and are reported in each paper in Chapters 4-7. The participant (patient) selection in stage 3 was specifically guided by the findings of what was the most common presentation in Stage 1. The practitioners for the focus group were selected by advertising in the region of the researcher, and despite being a broad sample of gender, age, experience and training background, were only a sample and the results cannot be compared to another group as no data of that kind exists. The expert Delphi panel were selected by reputation, qualification and experience, and willingness to participate, as is the normal process with this type of consensus research (Keeney, Hasson, & McKenna, 2006; Powell, 2003).

The conceptual framework that provided a map for this thesis enabled an exploration of the influences of science and philosophy on the history and development of
osteopathic healthcare. This naturally led to an analysis of how these influences impacted on professional practice throughout the twentieth century. In Chapter 2 (section 2.2), I looked at how osteopathic healthcare has evolved in different jurisdictions under these influences, and how the underpinning osteopathic philosophy binds the profession, but the science of its practice is lacking.

The theoretical framework for this research was established and led to exploring the established literatures pertaining to evidence based medicine, professional scope of practice and patient/person-centred care. Each of these theories impact on current practice, and the research included in this thesis has answered questions specifically related to those impacts. This thesis argues that a lack of scientific evidence supporting osteopathic healthcare is a threat to its professional standing and scope of practice in an era of evidence-based medicine. The research in this thesis identified aspects of evidence based practice in the osteopathic healthcare approach to CNSLBP, with the use of the biopsychosocial model, the lifestyle and exercise interventions and the involvement in a multidisciplinary team. Evidence of patient/person-centred care was also identified as central to osteopathic healthcare which provides a more accurate description of what osteopathic healthcare practice is in the real world.

8.3 The model of osteopathic healthcare

This thesis set out to produce an authentic model of osteopathic healthcare from the coalface. The initial questions of this thesis explored the nature of osteopathic healthcare practice in Australia and identified the common patient presentations, assessment and management strategies. This data was then deepened by exploring osteopathic healthcare specifically with regards to the experience of practitioner managing the most common presenting complaint (CNSLBP), and of patients with that complaint who consulted an osteopath.

Gathering real world data about the workforce and their practices is a vital aspect of a profession’s understanding of itself and how it presents to the community at large – including the consumers of healthcare, policy makers and third party payers. The definition of osteopathy becomes more certain and based on evidence from this research. This model changes the way osteopathic healthcare should be described, and a number key features were outlined in Chapter 7 (sections 7.2.1 to 7.2.8) that
have emerged from this work that provide support for the new definition. These keywords are:

**Consumer driven**
The data confirmed that patients choose to visit an osteopathic overwhelmingly by word of mouth and are consumers in a marketplace of healthcare providers. This research has found that patients often seek osteopaths after having visited other practitioners for their problem. Despite the involvement of a few third party payers, for example Medicare in Australia, osteopaths are paid directly by their clients/patients.

**Pain presentations**
Osteopaths in Australia are presented with patients with a broad variety of somatic pain, predominantly in the regions of the spine, trunk and lesser amounts in the periphery. These presentations are dominated by chronic conditions, especially of the lower back.

**Biopsychosocial foundations**
The findings provide support for the proposition that osteopathic practice has elements of a biopsychosocial model of healthcare. The stakeholders who were the subjects in surveys, focus group and/or interviews in this thesis regularly and consistently reported a focus on the psychosocial aspect of the presentation and lives of patients, in addition to and linked with the physical complaint. There were reports from practitioners and patients of links being made between their physical musculoskeletal pain and broader functions including mental state. Education and reassurance was used as modalities in the management of these patients. In his essay *The Biopsychosocial model: Redefining osteopathic philosophy?* Penney (2013) posits that the BPS model and the osteopathic principles have significant congruence. He states that:

> re-defining or integration of osteopathic philosophy with the BPS model
> is one way in which the osteopathic profession can achieve the goal of rational and defensible intervention (p37).

This statement links the osteopathic philosophy of healthcare with its practice model and level of rationality, and this thesis has established evidence to support that there is such an integration. The inclusion of a thorough case interview and assessment that considers individual psychosocial factors and their impact on the patients’ pain, and
the use of a cross disciplinary referral network demonstrates that the osteopathic healthcare practices that were analysed in this thesis follow a biopsychosocial model. The biopsychosocial model is an evidence based approach for chronic disease that promotes a multidisciplinary approach, and based on the findings in this thesis osteopathic healthcare reflects this evidence based management. This runs counter to the critics of osteopathy, who express that it is ‘woo’ (Rational Wiki, 2017) or ‘based on little more than wishful thinking’ (Ernst, 2017).

**Patient/person centred**
The thesis data has also presented some evidence for osteopathic healthcare having aspects of what is termed patient- (or person-) centred care. Elements of PCC outlined in Chapter 1 (section 1.10.1) (Schaller, 2007) that were revealed in the studies in this thesis were:

*Education and shared knowledge.* The patient interview data and practitioner focus group both placed importance on this component of practice in patients with CNSLBP. Patients became knowledgeable about their condition, and felt that they were able to question the osteopath and get reasoned answers that made sense to them.

*Collaboration and team management.* The workforce survey, patient interviews and practitioner focus group all revealed a significant referral practice, and understanding that modern health practice requires an integrated team approach, especially in chronic conditions.

*Sensitivity to non-medical and spiritual dimensions of care.* The biopsychosocial aspects of this data are outlined above. The data from patient interviews and practitioner focus group had elements of considering the patients’ psychosocial situation, their mental state, the need for a therapeutic relationship and reassurance.

*Respect for patients’ needs and preferences.* All the data demonstrated that patients predominantly visit the osteopath by their own choice and pay a fee for service. The focus group and patient interviews revealed that the intervention appeared tailored to the patient, including a consideration of what the findings were on the day of consultation and how the modalities that were used varied between patients and visits. The preferred outcomes from the intervention were reported consistently as depending on the patient’s context – various functions of daily living and including
their pain levels. The PCC approach is a modern movement that is a reaction to the traditional expert driven medicine, and osteopathy already had this patient focus very early in its development.

**Primary care assessment.**
Primary care practice, where a patient can attend with a new complaint for an initial assessment, requires a clinician to have skills and knowledge to screen a patient for the presence of disease and to have the ethical and scientific foundation to guide the patient to the most likely practice/therapy to help them. The data from both practitioners and patients reveal that this occurs, and that the assessment is not a simple analysis of a local area of pain.

**Interdisciplinary referral.**
The referral activity follows on from the primary care assessment outlined, in that the practitioner understands when osteopathic intervention is not necessarily the best path to follow for every presenting patient.

**Tailored manual therapy and lifestyle interventions.**
The osteopathic intervention emerging from this data challenges the assumption that osteopaths are primarily manual therapists. The people presenting to them arrive with complex problems, are assessed under a holistic model, and what naturally results is a complex intervention including manual therapy, education, exercise and health promotion advice and psychosocial support. Because of the extensive enquiry into patients’ health and a consideration of broad aspects of the BPS model, the intervention that results is tailored and individualised to the patient’s context.

**Health focussed.**
The healthcare that emerges from the qualitative data has a focus on maintaining and improving health, whilst still screening for disease and offering an adjunctive therapy to maximise healing.

**8.4 The pragmatic clinical trial method**

This thesis has developed a clinical trial method for testing CNSLBP with an authentic model of the osteopathic healthcare intervention. The method was developed with the use of an expert Delphi panel, and is based on a comparative effectiveness research model.
The parallel design with a control group of standard medical care and broad inclusion criteria reflect the real world of consumer-driven osteopathic healthcare. The exclusion criteria and follow up period are based on the model developed in this thesis, particularly from the practitioner survey and focus group data. The primary outcome measure that is proposed, the Roland Morris Disability Questionnaire, assesses a broad range of patient-centred outcomes that are linked to the data from practitioners and patients in this thesis. Finally, the inclusion of dual blinding and statistical analysis by intention to treat will ensure that the findings from a pragmatic trial that follows this method will be robust and transferable to practice.

Before this trial could be run, certain protocol issues will need to be addressed such as:

- how to manage recruitment,
- further defining the control,
- calculating the sample size,
- defining minimal improvement,
- obtaining ethical approval,
- training of practitioners to deliver the intervention,
- the method of blinding the assessor and analyst.

As the trial developed is a superiority trial design, researchers who wish to test non-inferiority would consider different statistical analysis.

8.5 Limitations

There are a number of limitations in each of the studies included in this research. The aims of the research were focused on the pragmatic outcomes of a model of practice and a clinical trial method. This meant that there were directions of analysis of the data that were beyond the scope of this thesis, for example the socio-political place of osteopathic healthcare. All of the population samples were Australian, and this limits the generalisability of the findings despite the efforts made to compare the findings with other international data, where it exists. The sample sizes in each of the
studies that make up the thesis were small, and limited by availability and response rates. The postal survey achieved a very good relative response rate, but is not current data twelve years later. The profession has more than doubled in the time between the original workforce survey and the current day. Data from two more current Australian surveys that were compared and analysed in section 4.4 (Burke et al., 2013; Xue, 2008), confirmed patient presentations and the range of interventions used. No further studies have been located that examined the same detail of patients and the intervention.

The single focus group had seven practitioners of varying gender, age and experience, which ensured no bias from those characteristics. A single focus group cannot represent a whole profession, but the rich data that resulted from this focus group reached a saturation of themes and was similar to the previous quantitative data, and further focus groups were not deemed necessary. The data collection and analysis were moderated by an assistant and the findings were triangulated with other data in this thesis and other research to improve its external validity.

The phenomenological approach taken in the interviews acknowledged the researcher’s bias and expectations. These were bracketed as much as possible, while accepting the subjective nature of individual views in an interview. The interviews followed a systematic process of questioning in order to keep constancy and setting aside any bias in the interaction.

These different methodological approaches allowed triangulation of the results. The validity of findings has been discussed in each study, and some conclusions were made at the end of Chapters 4, 5 and 6 following the analysis of each study. The final synthesis of these results were presented in Chapter 7. The synthesis of all of this data and the commonalities found using different perspectives, allows some implications to be drawn from these studies.

The model of osteopathic healthcare in CNSLBP and the findings from the Delphi panel have yet to be presented to the profession. This needs to occur through peer reviewed publications and scholarly presentations with ensuing debate in order to test whether the findings from these studies are acceptable to the broader professional community.
8.6 Implications for the profession

The findings from this thesis have implications for the osteopathic profession. In section 1.10.3, I wrote about the specialised, firmly bound, scientific and standardised knowledge base of a profession (Schon, 1983). This thesis has deepened our understanding of how an osteopath practises, and this enables the profession to be certain about its scope and the characteristics of its service.

Many of the findings from this thesis confirm previous definitions of osteopathic healthcare in osteopathic textbooks. However, those descriptions were generated by tradition, anecdote and opinions of committees. This thesis has, for the first time, provided an evidence-based one.

The findings enable third party groups and stakeholders to be better informed about the evidence of the osteopathic healthcare intervention and become more certain about what the patient will receive when consulting with an osteopath. This certainty will have impacts on how osteopathic healthcare is funded by third parties like private health insurance companies and government agencies. These third parties increasingly require evidence from providers of what effectiveness their intervention should have on their clients, as evidenced by a recent review in Australia (Baggoley, 2015). This thesis addressed this urgent requirement by developing an authentic and robust pragmatic clinical trial method to provide a basis to test the osteopathic healthcare intervention in CNSLBP. The mixed method research approach used in this thesis to develop the model and the subsequent pragmatic clinical trial method can be used by other professions and for other presenting complaints.

Finally, the data from this thesis has established that the osteopathic healthcare intervention uses a broad biopsychosocial and holistic approach to healthcare, in its assessment of each patient and in its application of manual and lifestyle therapies. This is well matched to the evidence-based care and management requirements of patients who have chronic pain syndromes, and osteopathic stakeholders now have a valid basis to argue for better access for these patients to osteopathic healthcare.

8.7 Implications for osteopathic education

An outcome of this thesis will be to present the research findings to osteopathic educators, and if the findings are accepted and integrated into curriculum, it may
change the way osteopathy is taught to osteopathic students. The research-based model and definition of osteopathy that has emerged from the work in this thesis can be used to guide the structure of curriculum. Previously, the emphasis has been placed on pathology, palpatory diagnosis and manual therapy, and now the curriculum needs to be expanded to include more patient communication and educational skills, lifestyle management strategies including exercise therapy, nutritional advice and stress reduction. This signifies a move towards a health-based focus rather than a disease-based one, and will require curriculum and assessment renewal.

8.8 Implications for researchers

8.8.1 Whole practice/systems research

One of the primary stimuli for this thesis was a concern about the lack of evidence of osteopathic healthcare as it is practised. In this thesis a ‘whole practice/systems’ approach that leads to trials using a pragmatic approach has been adopted. According to Ritenbaugh et al. (2003, p33):

Whole systems research entails the intention to include conceptually as part of the investigative context all aspects of any internally consistent approach to treatment, including its philosophical basis, patients, practitioners, setting of practice, and methods/materials used. Whole systems research acknowledges unique patient, family, community, and environmental characteristics and perspectives.

This thesis has used such a whole systems approach into osteopathic healthcare, and has developed an authentic model that can be tested.

8.8.2 Researching osteopathic healthcare

A systematic approach to clinical outcome studies has not been well-established in osteopathic research. In exploring this issue, Gevitz (2001) analysed the lack of research in the osteopathic colleges of the US, noting that as far back as the Flexner report of 1910 the colleges were highly criticised for the lack of research development. He noted that the osteopathic colleges’ primary focus was on producing general family physicians, whereas the medical colleges and universities had more focus on producing specialist practitioners and researchers and concluded that the osteopathic colleges have been more focused on knowledge application
rather than its creation (Gevitz, 2001). Also, the osteopathic colleges were not university affiliated until the late 1960s, when the Michigan State University became the first state funded osteopathic programme. University academic staff have a requirement to produce research as part of their employment, which is not necessarily a core activity in private colleges. This limitation of being able to fund the recruitment of qualified scientific research staff in the realm of private education was mirrored in the UK and Australia, and continues today in regions where there is no public funding of osteopathic training. The only state-funded osteopathic programmes outside the USA are in Australia and New Zealand, and the increase in scholarly activity that has resulted from this is evidenced by the growing number of peer reviewed publications like the International Journal of Osteopathic Medicine.

This thesis has introduced the importance of evidence for the progress of a modern health profession, and also focussed on a clinical research method. Producing clinical evidence of therapeutic outcomes from specific common interventions should be a central aim of professions that aim to offer patients a solution to their health issues. Osteopathy needs to produce such evidence. The recent decade has seen a number of researchers turn to large scale clinical trials that are designed to test whole osteopathic practice rather than just aspects of practice, especially the work of John Licciardone and colleagues at the Texas College of Osteopathic Medicine at the state-funded University of North Texas. This thesis specifically aims to provide support for researchers who aim to test an authentic model of practice in pragmatic clinical trial design.

A systematic review of the literature was completed and reported in Chapter 5 of this thesis. The result demonstrated the paucity of clinical research into the osteopathic management of CNSLBP, the most common presentation according to the large workforce survey included in section 4.3. This was the first time that a systematic review included a criterion that the intervention should be based on a researched whole practice model, not on a component of the osteopathic intervention. After that systematic review was published, there have been a number of trials of OMT completed. An example of the improving quality of research into a more authentic osteopathic healthcare was published by Licciardone et al. (2013), which demonstrated positive results for the efficacy of OMT in CNSLBP. The methodology used in this trial was a 2 X 2 factorial design to test OMT compared to two different controls – ultrasound therapy and sham OMT. A number of aspects of this trial
resembled the methodology developed by the Delphi panel in this thesis; the active OMT was broad and included physician discretion of the intervention, the primary outcome measure was pain and the secondary measure included the RMDQ, and the statistical analysis applied was Intention to Treat. The weaknesses in this trial were that the OMT was not specifically linked to research of what physicians would have used for those patients, and sham arms in trials of OMT have proven to be variable in design and effect (Cerritelli, Verzella, Cicchitti, D’Alessandro, & Vanacore, 2016). The trial designed and discussed in this thesis would be more authentic and pragmatic than the Liccardone et al. (2013) trial, using comparative effectiveness to standard family doctor care. Results of such trials will be highly transferable to practice as they reflect what practitioners would normally use in management.

8.8.3 The process of developing a complex intervention for testing

This thesis also developed a process that other researchers can utilise when aiming to test a complex intervention in a clinical trial. A number of guidelines have been published that give guidance for researchers developing and then testing complex interventions. The Medical Research Council (MRC) in the UK have developed a systematic approach to this challenge (Craig et al., 2008; Medical Research Council, 2000), and their process informed the thesis. This was especially true of the early stages outlined in the MRC guidelines, where modelling the intervention from a number of perspectives is advised, as well as completing systematic reviews of the intervention and then developing a trial design that is authentic to the intervention. The guidelines go beyond these early stages to set up evaluation strategies after pilot studies in order to make the intervention replicable for further research (Craig et al., 2008).

The MRC guidelines emphasise that in the development of the method of testing the complex intervention, the developers should ensure that the outcome measures are patient-centred and meet the aims of the intervention (Medical Research Council, 2000; Paterson et al., 2009), and the guidelines advise that a single outcome measure may not capture the full outcome effectively (Craig et al., 2008). This thesis developed this aspect of the pragmatic trial design by the use of mixed methods in collecting and analysing the perspectives of practitioners and patients, and the expert Delphi panel who considered a number of appropriate outcome measures. This thesis
implemented these MRC guidelines in the development of the model of the osteopathic healthcare intervention and the trial method.

My application of a mixed methods approach was successful at exploring a healthcare intervention in the real world and aiming for an authentic model. This was pioneering work that will suit professions that have a multimodal approach to healthcare, especially the research emergent ones that utilise complex interventions.

8.9 Conclusion

This thesis has developed an authentic model of osteopathic healthcare in Australia, with a focus on the most common patient presenting problem; chronic non-specific low back pain. The model of osteopathic healthcare and the pragmatic clinical trial method that have been developed provide a major impetus for building a research base for its practice. The work in this thesis has confirmed a number of aspects of osteopathic healthcare that were based on anecdote and expert opinion, but never systematically researched. A number of new findings were revealed – the extent of evidence-based management strategies in exercise and lifestyle interventions, the coherent use of a biopsychosocial model of healthcare that links to the principles of osteopathy, and a pragmatic trial method that can be used to test the osteopathic healthcare intervention.

The mixed methods approach used in developing this model and the clinical trial method could be used by other health professions using complex interventions to ensure they are authentic and well described before clinical research is attempted. This will support the external validity of any findings, and will promote the transferability of research into clinical practice.

8.9.1 Future research directions

The relationship of the osteopathic principles to the clinical reasoning process employed in practice would be a stimulating direction for further research. The question about whether there is a unique or identifiable osteopathic approach to healthcare needs to be answered. This thesis was able to reveal that the decision-making in osteopathic healthcare involve some aspects of a philosophy of health, but whether this is unique to osteopathy and a reflection of its underpinning principles is yet to be systematically researched.
The primary opportunity for further research arising from this thesis is to conduct the pragmatic clinical trial that was developed. This will allow the effectiveness of osteopathic healthcare intervention in chronic non-specific low back pain to be tested in an authentic way.
Reference list


#


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<th></th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Age</td>
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<tr>
<td>2</td>
<td>Gender</td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>3</td>
<td>In how many locations do you practice?</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>On average, how many hours per week do you practice?</td>
<td>0-4</td>
<td>4-8</td>
</tr>
<tr>
<td>5</td>
<td>How many consults per week?</td>
<td></td>
<td></td>
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<tr>
<td>6</td>
<td>For what % of the consult are you with the patient? (ie use of assistants)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>How long are your consult times? (Average)</td>
<td>less than 15 minutes</td>
<td>15-30 minutes</td>
</tr>
<tr>
<td>8a</td>
<td>What fees do you charge?</td>
<td>Initials</td>
<td>Subsequent</td>
</tr>
<tr>
<td>8b</td>
<td>Do you offer concessions?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>9</td>
<td>What style of recording system do you use?</td>
<td>Paper/cards</td>
<td>Computerised</td>
</tr>
<tr>
<td>10</td>
<td>Estimate the number of times over the last week that you considered the following systems as part of your physical examination.</td>
<td>Orthopaedic</td>
<td>Cardiac</td>
</tr>
</tbody>
</table>

**Instructions:**
- Use a blue/black ballpoint pen or 2B pencil
- Do not use red or felt tip pens
- Do not fold or bend
- Erase mistakes fully
- Make no stray marks
- Where a written answer is required, please write clearly in the boxes provided.

**Please mark like this:**
Example: Please write in boxes here, then mark oval corresponding to the number in each column.
11. Which of the following diagnostic evaluations do you request?

- Plain radiology
- Ultrasound
- Thermography
- CT Scanning
- MRI Scanning
- Blood pathology
- Urinalysis
- Culture

12. Estimate your use of the various modalities of osteopathic care in your practice.

<table>
<thead>
<tr>
<th>Percentage (%)</th>
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<tbody>
<tr>
<td>Lymphatic technique</td>
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<tr>
<td>Soft tissue manipulation</td>
</tr>
<tr>
<td>Stretching</td>
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<tr>
<td>Muscle energy technique</td>
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<tr>
<td>PNF</td>
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<tr>
<td>High velocity manipulation</td>
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<tr>
<td>Non high velocity manipulation (medium/low/articulation/mobilisation)</td>
</tr>
<tr>
<td>Visceral manipulation</td>
</tr>
<tr>
<td>Visceral technique (Barral)</td>
</tr>
<tr>
<td>Cranial field technique</td>
</tr>
<tr>
<td>Functional methods</td>
</tr>
<tr>
<td>Strain/counterstrain</td>
</tr>
<tr>
<td>Fascial/myofascial technique</td>
</tr>
</tbody>
</table>

13. In your whole practice life has a patient ever had an adverse event following your treatment? Estimate the frequency of:

- Minor event that was self limiting
- Event requiring referral and/or treatment to ameliorate
- Serious event requiring immediate referral

14. How often do you prescribe the following?

- Exercise
- Dietary
- Over the counter medication
- Other (specify)

15. Please indicate how often you refer patients to the following:

- Chiropractor
- Counsellor
- Dietician
- General practitioner
- Massage therapist
- Medical specialist
- Naturopath/Herbalist
- Osteopath
- Personal trainer
- Physiotherapist
- Podiatrist
- Practitioner of traditional Chinese medicine
- Psychologist
- Other

16. Please indicate how often you receive referrals from the following:

- The AOA
- Another Osteopath
- Chiropractor
- Practitioner of traditional Chinese medicine
- General practitioner
- Medical specialist
- Physiotherapist
- Counsellor/Psychologist
- Podiatrist
- Dietician
- Personal trainer
- Your other patients
- Massage therapist
- Other

17. Please indicate whether you utilise other health practice modalities in your own practice. *(S) is if you use them yourself *(C) is by co-management by another practitioner in your clinic

- Acupuncture
- Nutritional medicine
- Naturopathy
- Chiropractic
- Herbal medicine
- Psychology
- Hypnotherapy
- Other
18. Please provide all your osteopathic qualification(s): (Other non-osteopathic qualifications to be filled in on page 12)

<table>
<thead>
<tr>
<th>TITLE</th>
<th>INSTITUTION</th>
<th>LENGTH OF COURSE</th>
<th>YEAR COMPLETED</th>
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</table>

19. In your opinion, how well did your osteopathic qualification(s) prepare you for practice? What would have improved the training?

20. Please estimate your years of Clinical experience since graduation as an osteopath: __________ years

21. In the last 12 months, which of the following types of continuing education have you undertaken?

- [ ] AOA evening seminars
- [ ] AOA convocation
- [ ] Special topic/speaker (e.g. Greenman/Barral)
- [ ] SCTF course
- [ ] University course
- [ ] Private college course
- [ ] Other

Name

22. Give the following types of continuing education a level of importance to you.

- Evenings seminars
- 2-3 day osteopathic technique teaching
- 5 day osteopathy theory and technique
- Postgraduate qualification in osteopathic medicine (coursework)
- Postgraduate qualification in osteopathic medicine (research)
- Short training in adjunct therapy (e.g. nutrition, counselling etc)
- Qualification in adjunct therapy
- Identify therapy/training you wish to do (please fill in one oval then specify below)

23. Please estimate the importance of these issues to the osteopathic profession in the next 10 years:

- Public perception/ignorance of osteopathy
- Other health professionals perception/ignorance of osteopathy
- Full supply of quality new osteopathic graduates
- Access to public health institutions e.g. hospital outpatients etc
- Expanded practice rights:
  - Diagnostic test referrals
  - Medication prescription rights
- Evidence of efficacy of osteopathic management
- Evidence of osteopathic diagnostic model
- Any issue not mentioned? (please fill in one oval then specify below)

24. Have you undertaken any AOA service since graduation? Please briefly outline this.


### SNAPSHOT RECORD OF 1 DAY IN PRACTICE - TUESDAY 11 MAY 2004

1. **Patient Number:**

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2. **Postcode**

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3. **What is the patient's occupation?**

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4. **Is this a new patient?**

NP = New Patient (ie never seen an Osteopath before);
PP = Previous Patient of yours (State how long been seeing across all complaints);
PPO = Previous Patient of another Osteopath

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5. **Is this the first consultation for this episode of illness or injury?**

FC = First Consultation
SC = Subsequent Consultation (number)

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6. **Gender**

- Male
- Female

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7. **Age group**

- 0-9
- 10-19
- 20-29
- 30-39
- 40-49
- 50-59
- 60-69
- 70-79
- 80+

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8. **Ethnic origin**

- E = European;
- Ab = Aboriginal;
- As = Asian;
- H = Hispanic;
- I = Indian;
- O = Other

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9. **What type of patient?**

- PP = Private Patient (fee for service);
- I = Insurance (third party payer)

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10. **Presenting Symptom**

Enter one, two or three main presenting symptoms today, using the key below.

**Location:**
- H = Head; N = Neck;
- T = Thorax; A = Abdomen; P = Pelvis;
- UL = Upper Limb; SJ = Shoulder Joint;
- E = Elbow; WH = Wrist and Hand;
- TS = Thoracic Spine; LS = Lumbar Spine;
- LL = Lower Limb; HJ = Hip Joint;
- K = Knee; AF = Ankle and Foot

**Symptom:**
- P = Pain; N = Numbness;
- I = Immobility; O = Other (specify)

Example: Painful wrist and hand with oedema.

1. \(\text{WH}\) Other (specify) Oedema
### SNAPSHOT RECORD OF 1 DAY IN PRACTICE - TUESDAY 11 MAY 2004

<table>
<thead>
<tr>
<th>Patient Number:</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>11. Previous treatment:</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Has the patient seen other health professionals for this complaint?</td>
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<tr>
<td>If yes, were they satisfied with the treatment they received?</td>
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</tr>
<tr>
<td><strong>S</strong> = Satisfactory; <strong>U</strong> = Unsatisfactory</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>12. Duration of presenting complaints</strong></td>
<td>0-3 weeks</td>
<td>0-3 weeks</td>
<td>0-3 weeks</td>
<td>0-3 weeks</td>
<td>0-3 weeks</td>
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<td>3-12 weeks</td>
<td>3-12 weeks</td>
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<td>Over 12 weeks</td>
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<td>Over 12 weeks</td>
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</tr>
<tr>
<td><strong>13. Physical examination you carried out and the result</strong></td>
<td></td>
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<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>P</strong> = Positive; <strong>N</strong> = Negative</td>
<td></td>
<td></td>
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<tr>
<td><strong>14. Diagnosis:</strong> Record your working diagnosis (Mark up to three diagnoses, using the key)</td>
<td></td>
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<tr>
<td><strong>KEY:</strong> <strong>SD</strong> = Somatic Dysfunction;</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>T</strong> = Trauma; <strong>PD</strong> = Postural Dysfunction;</td>
<td></td>
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<tr>
<td><strong>OD</strong> = Organic Disease;</td>
<td></td>
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</tr>
<tr>
<td><strong>PS</strong> = Psychogenic/Stress (PS);</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td><strong>ND</strong> = Nutritional Dysfunction; <strong>U</strong> = Unknown</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td><strong>15. Treatment techniques employed:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>T</strong> = Soft Tissue; <strong>JA</strong> = Joint Articulation;</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>HVT</strong> = High Velocity Thrust;</td>
<td></td>
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<tr>
<td><strong>FT</strong> = Functional Technique;</td>
<td></td>
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<tr>
<td><strong>OCF</strong> = Osteopathy in the Cranial Field;</td>
<td></td>
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<tr>
<td><strong>ME</strong> = Muscle Energy technique;</td>
<td></td>
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<tr>
<td><strong>V</strong> = Visceral; <strong>CS</strong> = Counterstrain;</td>
<td></td>
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<tr>
<td><strong>LSM</strong> = Lifestyle management advice;</td>
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<tr>
<td><strong>C</strong> = Counselling; <strong>EP</strong> = Exercise Prescription;</td>
<td></td>
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<tr>
<td><strong>N</strong> = Nutritional advice; <strong>A</strong> = Acupuncture;</td>
<td></td>
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<tr>
<td><strong>M</strong> = Myofascial technique</td>
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<tr>
<td><strong>O</strong> = Other (please specify)</td>
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</tr>
<tr>
<td><strong>16. Referral – How was the patient referred to your clinic?</strong></td>
<td></td>
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</tr>
<tr>
<td><strong>SR</strong> = Self Referral (eg word of mouth);</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ad</strong> = Yellow pages or other advertisement;</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>GP</strong> = General Practitioner;</td>
<td></td>
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</tr>
<tr>
<td><strong>NP</strong> = Non registered Practitioner (eg Acupuncturist, Naturopath, Massage Therapist etc);</td>
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</tr>
<tr>
<td><strong>RP</strong> = Registered Practitioner (eg Dentist, Physio, Chiro, Acup/TCM);</td>
<td></td>
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</tr>
<tr>
<td><strong>O</strong> = Other (please specify)</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
# Appendix 2

COREQ checklist for Focus Group of practitioners (Tong et al, 2007)

<table>
<thead>
<tr>
<th>Domain 1</th>
<th>Research team and reflexivity</th>
<th>Comment; is it reported in paper?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal Characteristics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interviewer/facilitator</td>
<td>Which author/s conducted the interview or focus group?</td>
<td>Single author; not necessary</td>
</tr>
<tr>
<td>Credentials</td>
<td>What were the researcher’s credentials?</td>
<td>MAppSc (Research) DO; yes</td>
</tr>
<tr>
<td>Occupation</td>
<td>What was their occupation at the time of the study?</td>
<td>Osteopath/academic; yes</td>
</tr>
<tr>
<td>Gender</td>
<td>Was the researcher male or female?</td>
<td>Male; yes</td>
</tr>
<tr>
<td>Experience and training</td>
<td>What experience or training did the researcher have?</td>
<td>Clinician, masters by research; yes</td>
</tr>
<tr>
<td>Relationship with participants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relationship established</td>
<td>Was a relationship established prior to study commencement?</td>
<td>Local colleagues; yes</td>
</tr>
<tr>
<td>Participant knowledge of the interviewer</td>
<td>What did the participants know about the researcher?</td>
<td>That he was a local academic and clinician; yes</td>
</tr>
<tr>
<td>Interviewer characteristics</td>
<td>What characteristics were reported about the interviewer/facilitator?</td>
<td>That he was an osteopath and academic; yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Domain 2</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theoretical framework</td>
<td>What methodological orientation was stated to underpin the study?</td>
</tr>
<tr>
<td>Participant selection</td>
<td></td>
</tr>
<tr>
<td>Sampling</td>
<td>How were participants selected?</td>
</tr>
<tr>
<td>Method of approach</td>
<td>How were participants approached?</td>
</tr>
<tr>
<td>Sample size</td>
<td>How many participants were in the study?</td>
</tr>
<tr>
<td>Non-participation</td>
<td>How many people refused to participate or dropped out?</td>
</tr>
</tbody>
</table>

| Setting | | |
| Setting of data collection | Where was the data collected? | University boardroom |
| Presence of non-participants | Was anyone else present besides the participants and researchers? | Research assistant; yes |
| Description of sample | What are the important characteristics of the sample? | Mixed experience, training background, practice location and gender; yes |

<p>| Data collection | | |
| Interview guide | Were questions, prompts, guides provided by the authors? Was it pilot tested? | Guide questions – not tested; yes |
| Repeat interviews | Were repeat interviews carried out? If yes, how many? | No - saturation; yes |
| Audio/visual recording | Did the research use audio or visual recording to collect the data? | Audio; yes |
| Field notes | Were field notes made during and/or after the interview or focus group? | Yes; yes |</p>
<table>
<thead>
<tr>
<th>Duration</th>
<th>What was the duration of the interviews or focus group?</th>
<th>Two hours; yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data saturation</td>
<td>Was data saturation discussed?</td>
<td>Yes; yes</td>
</tr>
<tr>
<td>Transcripts returned</td>
<td>Were transcripts returned to participants for comment and/or correction?</td>
<td>Thematic summary; yes</td>
</tr>
<tr>
<td><strong>Domain 3</strong></td>
<td><strong>Analysis and findings</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Data analysis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of data coders</td>
<td>How many data coders coded the data?</td>
<td>One; yes</td>
</tr>
<tr>
<td>Description of the coding tree</td>
<td>Did authors provide a description of the coding tree?</td>
<td>No</td>
</tr>
<tr>
<td>Derivation of themes</td>
<td>Were themes identified in advance or derived from the data?</td>
<td>Derived from data and triangulated; yes</td>
</tr>
<tr>
<td>Software</td>
<td>What software, if applicable, was used to manage the data?</td>
<td>Nil</td>
</tr>
<tr>
<td>Participant checking</td>
<td>Did participants provide feedback on the findings?</td>
<td>Yes: yes</td>
</tr>
<tr>
<td><strong>Reporting</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quotations presented</td>
<td>Were participant quotations presented to illustrate the themes/findings? Was each quotation identified?</td>
<td>Yes; yes</td>
</tr>
<tr>
<td>Data and findings consistent</td>
<td>Was there consistency between the data presented and the findings?</td>
<td>Yes; yes</td>
</tr>
<tr>
<td>Clarity of major themes</td>
<td>Were major themes clearly presented in the findings?</td>
<td>Yes; yes</td>
</tr>
<tr>
<td>Clarity of minor themes</td>
<td>Is there a description of diverse cases or discussion of minor themes?</td>
<td>Yes, yes</td>
</tr>
</tbody>
</table>
# Appendix 3

**COREQ checklist for patient interviews (Tong et al, 2007)**

<table>
<thead>
<tr>
<th><strong>Domain 1</strong> Research team and reflexivity</th>
<th>Comment: is it reported in paper?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Personal Characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>Interviewer/facilitator</td>
<td>Which author/s conducted the interview or focus group? Single author</td>
</tr>
<tr>
<td>Credentials</td>
<td>What were the researcher’s credentials? MAAppSc (Research) DO</td>
</tr>
<tr>
<td>Occupation</td>
<td>What was their occupation at the time of the study? Osteopath/academic</td>
</tr>
<tr>
<td>Gender</td>
<td>Was the researcher male or female? Male</td>
</tr>
<tr>
<td>Experience and training</td>
<td>What experience or training did the researcher have? Clinician, masters by research</td>
</tr>
<tr>
<td><strong>Relationship with participants</strong></td>
<td></td>
</tr>
<tr>
<td>Relationship established</td>
<td>Was a relationship established prior to study commencement? No; yes</td>
</tr>
<tr>
<td>Participant knowledge of the interviewer</td>
<td>What did the participants know about the researcher? Nil – introduced by information sheet; yes</td>
</tr>
<tr>
<td>Interviewer characteristics</td>
<td>What characteristics were reported about the interviewer/facilitator? That he was an osteopath and academic doing his PhD; yes</td>
</tr>
<tr>
<td><strong>Domain 2</strong> Study design</td>
<td></td>
</tr>
<tr>
<td><strong>Theoretical framework</strong></td>
<td></td>
</tr>
<tr>
<td>Methodological orientation and Theory</td>
<td>What methodological orientation was stated to underpin the study? Descriptive phenomenology; yes</td>
</tr>
<tr>
<td><strong>Participant selection</strong></td>
<td></td>
</tr>
<tr>
<td>Sampling</td>
<td>How were participants selected? Convenience sample of practices in region; yes</td>
</tr>
<tr>
<td>Method of approach</td>
<td>How were participants approached? Invitation in waiting room; yes</td>
</tr>
<tr>
<td>Sample size</td>
<td>How many participants were in the study? Eleven</td>
</tr>
<tr>
<td>Non-participation</td>
<td>How many people refused to participate or dropped out? Nineteen – five unable at that time, ten no response, four booked but not required</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td></td>
</tr>
<tr>
<td>Setting of data collection</td>
<td>Where was the data collected? By phone; yes</td>
</tr>
<tr>
<td>Presence of non-participants</td>
<td>Was anyone else present besides the participants and researchers? No</td>
</tr>
<tr>
<td>Description of sample</td>
<td>What are the important characteristics of the sample? They had CNSLBP; patients of an osteopath</td>
</tr>
<tr>
<td><strong>Data collection</strong></td>
<td></td>
</tr>
<tr>
<td>Interview guide</td>
<td>Were questions, prompts, guides provided by the authors? Was it pilot tested? Guide questions; yes tested; yes</td>
</tr>
<tr>
<td>Repeat interviews</td>
<td>Were repeat interviews carried out? If yes, how many? No</td>
</tr>
<tr>
<td>Audio/visual recording</td>
<td>Did the research use audio or visual recording to collect the data? Audio; yes</td>
</tr>
<tr>
<td>Field notes</td>
<td>Were field notes made during and/or after the interview or focus group? Yes; yes</td>
</tr>
<tr>
<td>Duration</td>
<td>What was the duration of the interviews or focus group? 30-40 minutes; yes</td>
</tr>
<tr>
<td>Data saturation</td>
<td>Was data saturation discussed?</td>
</tr>
<tr>
<td>-----------------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td>Transcripts returned</td>
<td>Were transcripts returned to participants for comment and/or correction?</td>
</tr>
</tbody>
</table>

**Domain 3 Analysis and findings**

**Data analysis**

- **Number of data coders**: How many data coders coded the data?
  - One; yes

- **Description of the coding tree**: Did authors provide a description of the coding tree?
  - No

- **Derivation of themes**: Were themes identified in advance or derived from the data?
  - Derived from data; yes

- **Software**: What software, if applicable, was used to manage the data?
  - Nil

- **Participant checking**: Did participants provide feedback on the findings?
  - Yes – summary of transcript; yes

**Reporting**

- **Quotations presented**: Were participant quotations presented to illustrate the themes / findings? Was each quotation identified?
  - Yes; yes

- **Data and findings consistent**: Was there consistency between the data presented and the findings?
  - Yes; yes

- **Clarity of major themes**: Were major themes clearly presented in the findings?
  - Yes; yes

- **Clarity of minor themes**: Is there a description of diverse cases or discussion of minor themes?
  - Yes; yes
Appendix 4

Delphi panel
Round 2 discussion paper

**DELPHI PANEL QUESTIONNAIRE #2**

DEVELOPING A CLINICAL TRIAL METHOD TO TEST THE EFFECTIVENESS OF THE OSTEOPATHIC INTERVENTION IN THE MANAGEMENT OF CHRONIC NON-SPECIFIC LOW BACK PAIN

Paul J Orrock

OBJECTIVE OF THIS PANEL

This second round requires you to read the selected quotations (based on recurring themes) and researcher comments on each point and record whether you agree or not with the solution to the original question/proposal.

There is room for further comment, particularly if you have a strong opinion about the issue that needs to be considered further.

CNSLBP = Chronic Non-Specific Low Back Pain

OI = Osteopathic Intervention

<table>
<thead>
<tr>
<th>ISSUE 1 - Broad inclusion criteria?</th>
</tr>
</thead>
<tbody>
<tr>
<td>“quotations” and researcher comments from Round 1</td>
</tr>
<tr>
<td>&quot;Definition of NSLBP is tricky - do cross trial comparisons to ensure consistency (eg UK BEAM).”</td>
</tr>
<tr>
<td>• See exclusions below for cross trial comparisons</td>
</tr>
<tr>
<td>“Broad inclusion is good – make sure the subjects have dysfunctions that can be treated by osteopaths”</td>
</tr>
</tbody>
</table>
“Exclude co-morbidities that would limit successful management”

“Statement to define severity”

“Also ensure comprehensive exclusion criteria. The cohort should have mid-pain score for the CNSLBP (i.e. pain >3 but <7. This will ensure that there is something to treat, that can be seen to be improving and not so significant that it may represent either very acute requiring medical intervention (pain relief) or deep chronicity or complexity”

<table>
<thead>
<tr>
<th>ISSUE 2 – How to manage subjects’ previous knowledge of OI?</th>
</tr>
</thead>
<tbody>
<tr>
<td>“quotations” and researcher comments from Round 1</td>
</tr>
<tr>
<td>“In a pragmatic trial does not matter – its real world Measure/assess it for scientific interest only”</td>
</tr>
<tr>
<td>“No OI in the last 6 months”</td>
</tr>
<tr>
<td>“Good to explore by pre- and post- interviews, but include all”</td>
</tr>
<tr>
<td>“Use wait list control group to control expectations”</td>
</tr>
<tr>
<td>“Clear statement of research aims Target groups who may not have access to OI Clear strong messages about why research needs to be undertaken. Consider wash out period. Cross over, sequential designs”</td>
</tr>
<tr>
<td>“Yes, exclude people with previous experience of OI”</td>
</tr>
</tbody>
</table>
# ISSUE 3 – Sub grouping and inclusion/exclusion criteria

<table>
<thead>
<tr>
<th>“quotations” and researcher comments from Round 1</th>
<th>Proposed solution by researcher</th>
<th>Agree/ Disagree</th>
<th>Further comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Subgrouping is impractical – costly”</td>
<td>Exclusions (ref to BEAM study):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Exclude recent post partum subjects”</td>
<td>• Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Exclude degenerative, acute and unstable”</td>
<td>• Severe pain limiting ambulation and/or exercise</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Exclude insurance claim subjects” (workers/accident claims USA)</td>
<td>• Co-morbidities that contraindicate manual therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Exclude those with recent injury”</td>
<td>• Post surgical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• multiple panel members agree with these exclusions</td>
<td>• Insurance claims (workers/litigation)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Better to aggregate subjects into large groups (risk of groups too small to power and would need to know level of effect for each subgroup)”</td>
<td>Rank prognosis at commencement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Intake histories good for subgroups”</td>
<td>Define and explain sub groups by further expert consensus pre-trial (cross ref BEAM)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• See in Issue 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Sub groups after recruitment, if small numbers effect sizes can be calculated to estimate effects where study power is low”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Establish a range of consult number and semi-standard treatment package”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Record treatment”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Suggest get some principles of standardizing aspects of the treatment.”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Record prognosis and compare at end”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Sub groups are important”</td>
<td></td>
<td></td>
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<tr>
<td>“Planned subgroups should be specified prior to starting a study, and there should be adequate numbers of patients within each subgroup for meaningful analyses.”</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
“Use variance obtained from previous literature – sample size calculation essential.”

<table>
<thead>
<tr>
<th>ISSUE 4 – Design</th>
<th>“quotations” and researcher comments from Round 1</th>
<th>Proposed solution by researcher</th>
<th>Agree/Disagree</th>
<th>Further comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“Keep it simple and cost effective”</td>
<td>Parallel</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>“Possible run in phase (of inert treatment) to weed out major placebo responders?”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>“Parallel or could do a sequential with different treatment strategies”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>“Parallel design is best if only one factor (i.e., OI) is to be studied.”</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>“Factorial design may be preferable if more than one factor is to be studied or if other supplemental treatments are potentially to be used in addition to OI.”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>“Yes, parallel design.”</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
As we do not know the effect of OI, it is impossible to know the extinction period of that effect which makes a cross-over an inappropriate design at this stage.

<table>
<thead>
<tr>
<th>ISSUE 5 – Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>“quotations” and researcher comments from Round 1</strong></td>
</tr>
<tr>
<td>Pragmatic trial by definition includes comparison to “current best practice”</td>
</tr>
<tr>
<td>In UK would include GP referral to Physical Therapist</td>
</tr>
<tr>
<td>Sham is not appropriate</td>
</tr>
<tr>
<td>Multiple panel members agreed with no sham</td>
</tr>
<tr>
<td>“Standard Treatment good”</td>
</tr>
<tr>
<td>Multiple panel members agreed</td>
</tr>
<tr>
<td>Do not allow PT referral, unless you want to compare PT to OI</td>
</tr>
<tr>
<td>“Allow PT if this is standard treatment”</td>
</tr>
<tr>
<td>Proposed solution by researcher</td>
</tr>
<tr>
<td>General Practitioner early management which includes considering:</td>
</tr>
<tr>
<td>• Red flag screening;</td>
</tr>
<tr>
<td>• Pharmacological agents;</td>
</tr>
<tr>
<td>• Advice and education;</td>
</tr>
<tr>
<td>• Refer to one of:</td>
</tr>
<tr>
<td>o Manual Therapy</td>
</tr>
<tr>
<td>o Acupuncture</td>
</tr>
<tr>
<td>o Exercise therapy</td>
</tr>
<tr>
<td>Agree/Disagree</td>
</tr>
<tr>
<td>Further comments</td>
</tr>
</tbody>
</table>
“Examine patient satisfaction and patient perception of effectiveness after the intervention period. GPs might use an information sheet – patients can be told this is the novel aspect under investigation.”

“Objective measures – eg Imaging?”

“Unfortunately, physiological measures are not well validated as viable outcome measures and they are often poorly correlated with the more commonly used outcome measures.”

- NSLBP has no known objective measure

“I recommend measuring treatment expectations prior to delivering the control (and experimental intervention). We have used videos of representative portions of the interventions for patients to view and score.”

“What is standard GP care? The RACGP does not have a guideline for CNSLBP. There are recommendations see Australian Prescriber 2011, European Guidelines 2006 and Royal Melbourne Hospital Guidelines. Generally there is referral for physical therapy. This would potentially confound the study and make it hard to differentiate the effect of OI. If GP care was going to be the control arm it would be important to ensure that GPs manage the problem conservatively and do not refer to a physical therapist.”

For this pragmatic trial – randomize the Manual Therapy referrals to Osteopathy or Physiotherapy .

Include patient satisfaction measure

<table>
<thead>
<tr>
<th>ISSUE 6 – Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>“quotations” and researcher comments from Round 1</td>
</tr>
</tbody>
</table>
"Package agreed on a priori by group of practitioners (refer to UK BEAM trial)" +

"Has to be individualized – categories of intervention may be provided”

"Create a treatment algorithm? OI should not be too diverse."

"Ensure certain key elements are included (based on literature review or consensus) but allow the flexibility to add techniques at the practitioner’s discretion (which they must record).”

"Critical to minimize the treatment variance to pure OI and not OI plus other modalities. For instance no OI and acupuncture. No OI and ingestive therapies.”

"Consultation number should be kept the same, even if some of these may not be standard practice for a specific practitioner. The lower the number of variables that differ between therapists the more meaningful are the results.”

"Algorithmic protocol based on sub group/ diagnostic group”

<table>
<thead>
<tr>
<th>Proposed solution by researcher</th>
<th>Agree/ Disagree</th>
<th>Further comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>OI based on research findings</td>
<td>Disagree</td>
<td></td>
</tr>
<tr>
<td>Package - practitioner choice within boundaries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further establish a study protocol for OI package and boundaries by clinician focus group</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**ISSUE 7 – Outcome Measures**

<table>
<thead>
<tr>
<th>“quotations” and researcher comments from Round 1</th>
<th>Proposed solution by researcher</th>
<th>Agree/ Disagree</th>
<th>Further comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Have to nominate a Primary Measure as forms the basis of sample size calculation”</td>
<td>Primary measure – Roland Morris Disability Questionnaire.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&quot;You will need to pick a single outcome to base your sample size (power) calculations. Which of the measures above is the most sensitive and is least likely to have a floor or ceiling effect.”</td>
<td>Secondary measures – PROMIS-29, cost-effectiveness. Hlatky et al. Cost-effectiveness as an outcome in randomized clinical trials. Clin Trials. 2006;3(6):543-51.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Multiple panel members stated that a single primary and multiple secondary measures would suit</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
“Most common is Roland Morris Q – should be used as Primary”

“We prefer RMDQ to ODI for ease of administration (shorter)”

“Patient interviews are not very efficient in capturing data. We are abandoning the SF series (except SF-6D for cost effectiveness studies) because it is not a very robust measure of general health (i.e., it requires relatively large sample sizes to achieve statistical significance).”

“In the USA, the PROMIS-29 (Patient Reported Outcomes Measurement Information System) has been developed in conjunction with NIH. Additionally, a “minimum dataset” has been developed in 2014 in conjunction with NIH for research on chronic low back pain.”

“Patient Generated Index – use a modified version?”

“Develop a patient nominated outcomes (patients will have different goals)”

“Consider PROMIS. Include work days lost”

- Many panel members advised including patient oriented outcomes

“cost”

“Should include economic measure”

- A number stated that costs/economics should be measured

“Grade improvement (nil, minor, good, excellent) to avoid averages”
### ISSUE 8 – Blinding

<table>
<thead>
<tr>
<th>“quotations” and researcher comments from Round 1</th>
<th>Proposed solution by researcher</th>
<th>Agree/Disagree</th>
<th>Further comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Subject blinding not necessary in pragmatic design”</td>
<td>Blind assessor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Assessor should be blinded”</td>
<td>Blind data assessor/analyst/statistician</td>
<td></td>
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<tr>
<td>“Assessor and statistician should be blinded.”</td>
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<tr>
<td>• Most panel members stated assessor and analyst should be blinded</td>
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<tr>
<td>“Recommend formal post-study assessment of blinding.”</td>
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</tbody>
</table>

### ISSUE 9 – Therapeutic relationship effect

<table>
<thead>
<tr>
<th>“quotations” and researcher comments from Round 1</th>
<th>Proposed solution by researcher</th>
<th>Agree/Disagree</th>
<th>Further comments</th>
</tr>
</thead>
</table>
“Not relevant to rotate clinicians in a randomized pragmatic design”

“Can you make sure clinician has good bedside manner to even things out”

“Both arms have a Hawthorne effect”

“try to maintain continuity of care for each patient by having the same provider throughout the study if possible. The latter better reflects what happens in real life.”

“no to rotation”

Not relevant in a randomized pragmatic trial

<table>
<thead>
<tr>
<th>ISSUE 10 – Statistical approach</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>“quotations” and researcher comments from Round 1</strong></td>
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<tr>
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<tr>
<td>“Intention to Treat is important in pragmatic trials”</td>
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<tr>
<td>• Majority of panel members advised ITT</td>
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<tr>
<td>“Account for clustering (by practitioner/centre)”</td>
</tr>
<tr>
<td>“All outcomes should be reported with effect sizes and minimally important changes”</td>
</tr>
<tr>
<td>“Treatment adherence”</td>
</tr>
<tr>
<td>“Use relative risk for meaningful outcomes (dichotomous variables), with interpretation according to the Cochrane Back Review Group recommendations for small, medium, and large effect size. Recommend sensitivity analysis, including per-protocol results and various imputation techniques to address missing data due to</td>
</tr>
</tbody>
</table>
withdrawal or attrition. Then compare the range of findings with ITT results.

<table>
<thead>
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<th>Agree/Disagree</th>
<th>Further comments</th>
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<tbody>
<tr>
<td>“3, 6 and 12 months”</td>
<td>Baseline, 3wk, 6wk, 12wk, 26wk</td>
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<tr>
<td>“Make sure follow up withdrawals (CONSORT)”</td>
<td>Daily diary</td>
<td></td>
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<tr>
<td>“Find what drop out rate is with other similar trials to choose sample size”</td>
<td>Weekly phone calls</td>
<td></td>
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<tr>
<td>“Baseline , 3 and 6 months”</td>
<td>Follow up withdrawals</td>
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<td></td>
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<tr>
<td>“Some measures during treatment period (1/2 months)”</td>
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<tr>
<td>“Measurements at baseline, 3w, 6w, 12w, 18w and 26w. Provide weekly phone calls to minimize attrition/withdrawal. Also include a daily diary to maximize participant involvement.”</td>
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