Effects of an Osteopathic Clinical Based Approach for the Treatment of Chronic Non-Specific Low Back Pain in Factory Workers: A single cohort, pilot study

Simon Yardley

A research project submitted in partial requirement for the degree of Master of Osteopathy, Unitec Institute of Technology, 2009
Declaration

Name of candidate: Simon John Yardley

This research project is submitted in partial fulfilment for the requirements for the Unitec degree of Masters of Osteopathy.

The regulations for the degree are set out in the Masters of Osteopathy programme schedule and are elaborated in the course handbook.

Candidate’s declaration

I confirm that:

• This research project represents my own work

• The contribution of supervisor’s and others to this work was consistent with the Unitec regulations and policies.

• Research for this work has been conducted in accordance with the Unitec Ethics committee policy and procedures, and has fulfilled any requirements set for this project by said committee.

Candidate signature: ........................................ Date: December 12th 2009

(Simon John Yardley)

Student number: 1186023
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Abbreviations and Terminology

**ACC:** Accident Compensation Corporation.

**Active:** A technique that requires the patient to undertake physical movements at the direction of the practitioner.

**Acute LBP:** Short term, less than three months in duration.

**AUD:** Australian Dollars.

**Chronic LBP:** Long term, greater than three months in duration.

**BLT:** Balanced Ligamentous Tension.

**BMI:** Body Mass Index.

**Direct technique:** A technique where the force used is applied to the barrier.

**FLR:** Fascial-Ligamentous Release.

**FPR:** Facilitated Positional Release.

**GP:** General Practitioner.

**HVLA:** High Velocity Low Amplitude technique.

**HRQoL:** Health Related Quality of Life.

**ICC:** Intraclass Correlation Coefficient.

**Indirect technique:** A technique where force used is applied away from the barrier.

**INR:** Integrated Neuromuscular Release.

**LBP:** Low Back Pain, either acute or chronic.

**LAS:** Ligamentous strain articular technique.

**MANTIS:** Manual Alternative and Natural Therapy Index System.

**MCIC:** Minimum Clinically Important Change.

**MEDLINE:** Medical Literature Analysis and Retrieval System Online.

**MET:** Muscle Energy Technique.

**MR:** Myofascial release.
NICE: National Institute for Clinical Excellence.
NSLBP: Non specific low back pain.
NZ: New Zealand.
NZD: New Zealand Dollars.
OCF: Osteopathy in the Cranial Field.
OMT: Osteopathic Manipulative Treatment.
Passive: A technique that requires no involvement from the patient.
QBPDS: Quebec Back Pain Disability Scale.
RCT: Randomized Controlled Trial.
ROM: Range of motion.
SD: Standard Deviation.
SDD: Smallest Detectable Difference.
SEM: Standard Error of Measurement.
sham: A ‘fake’ treatment with minimal or no treatment effect.
SCS: Strain Counter Strain technique.
SMT: Spinal Manipulative Treatment.
SF-12: Short form 12 question, general health questionnaire.
TSE: Trunk Stretching Exercises.
UK: United Kingdom.
USA: United States of America.
VAS: Visual Analogue Scale.
VT: Visceral Technique.
SECTION I - LITERATURE REVIEW
Introduction to the dissertation

Chronic non-specific low back pain (NSLBP) is a major cause of lost work hours in the western world (2004; Dagenais, Caro, & Haldeman, 2008; Feuerstein, Hartzell, Rogers, & Marcus, 2006; Licciardone, King, Hensel, & Williams, 2008; Melloh, et al., 2008). Studies show that the high incidence of chronic NSLBP is not restricted to the western world, for example, it is also common throughout Africa (Louw, Morris, & Grimmer-Somers, 2007). In New Zealand in 2001, chronic NSLBP accounted for 70% of all NSLBP, and in 1999 it was the fourth most costly worker complaint for large corporations in the United States (Goetzel, Hawkins, Ozminkowski, & Wang, 2003). Reported lifetime prevalence rates in the western world for chronic NSLBP in adults ranges from 50 to 84%, with no difference in prevalence between males and females in the adult population (Airaksinen, et al., 2006; Cohen, Argoft, & Carragee, 2008; Walker, Muller, & Grant, 2003).

The majority of existing research for manual therapy treatment of NSLBP has been performed by physiotherapists and chiropractors. Most of these studies have investigated ‘manipulative’ treatments that involve a ‘thrust’ delivered to the spinal joints rather than ‘non-manipulative’ manual therapy techniques (e.g. non-thrust mobilisation) (Assendelft, et al., 2004; N. Bogduk, 2004; Di Fabio, 1992; Haldeman & Dagenais, 2008; Hancock, Maher, Latimer, Herbert, & McAuley, 2008; P. Kent & Herbert, 2005; Koldas Dogan, Sonel Tur, Kurtais, & Atay, 2008; Licciardone, 2004; Licciardone, Brimhall, & King, 2005; Raspe, 2008). These studies report contradictory findings about whether manual therapy (e.g. osteopathic, chiropractic and physiotherapy), have a clinically important effect on chronic NSLBP (Assendelft,
et al., 2004; Chou & Huffman, 2007; Licciardone, et al., 2005). Further, these studies have utilized a small subset of the potential treatment options available to the manual therapist, and have frequently focused their attention on ‘somatic dysfunction’ of the cervical, thoracic and lumbar spine. Osteopathic philosophy acknowledges that ‘somatic dysfunction’ may be a common strain pattern in the presentation of acute cases of NSLBP (Lee, 2005; Littlejohn, 1900; Parsons & Marcer, 2006), however other osteopaths (Barral & Croibier, 1999; Stone, 2007a; Weiselfish-Giammatteo & Giammatteo, 2003) argue that such dysfunction may not be as important in chronic NSLBP. In chronic cases there may be a variety of reasons why NSLBP experienced by sufferers may not be directly related to the site of their pain. In these cases treatment of the perceived symptomatic area may be of limited value in resolution of their NSLBP, instead, a broader based treatment approach that incorporates more than thrust manipulation may be more successful. Further, osteopaths argue that in these scenarios of complex, multi-factorial NSLBP a global treatment perspective may be more appropriate and successful in addressing the problem.

Licciardone and Russo (2006); and Machado, Kamper, Herbert, Maher and McAuley (2008), have criticised previous studies for their uniform treatment approach and poor study design, which they have suggested as possible reasons why manual therapy treatment has demonstrated only modest effectiveness in treating chronic NSLBP studies.

The primary purpose of this study was to investigate the effectiveness of a short course of ‘clinically styled’ osteopathic manipulative therapy (OMT) on pain intensity, in a homogeneous population of symptomatic participants with chronic
NSLBP. The study used a single cohort, repeated measures design, where all participants received three tailored sessions of OMT. Assessment of functional disability and general health were secondary outcome measures.
Scope of literature search

A search of MEDLINE, SCOPUS, MANTIS and OSTMED databases since 1996 was performed. The search covered studies since the comprehensive Cochrane review on low back pain by Assendelft et al. (2004), with a focus on systematic reviews and randomised controlled trials (RCT). Combinations of the following key words were used: manual therapy for chronic NSLBP, pragmatic manual therapy studies, osteopathy and NSLBP, epidemiology of chronic NSLBP, minimally clinically important change (MCIC) and NSLBP, reliability measures and NSLBP, and statistical analysis of pre-post designs.

The strategy involved an initial electronic search extracting all systematic reviews in the date range that matched the search criteria. Each selected review was then manually checked against the search criteria, and if still a match, all cited references for RCTs were retained. A second search was made extracting all RCTs from the cited references, and these were added to the previous ‘hit’ list of RCTs. The systematic reviews and RCTs found by this process comprised the body of literature used for this literature review. Finally, well known studies within the osteopathic research group at Unitec were included – if they had been missed by the search criteria of the above literature databases (e.g. student theses).
Definition of Chronic Non-Specific Low Back Pain

Low back pain has been described as:

“Local or referred pain at the base of the spine caused by a sprain, strain, or osteoarthritis, ankylosing spondylitis, neoplasm or a herniated intervertebral disc. Low back pain is a common complaint and is often associated with poor posture, obesity, sagging abdominal muscles, sitting for prolonged periods of time, or improper use of body mechanics.” (Andersson, 1999; Cassidy, Carroll, & Cote, 1998)

As Airaksinen et al. (2006) suggest, chronic non-specific low back pain is not attributable to any specific pathology (e.g. inflammation, infection, tumour, osteoporosis, fracture, nerve root pain, or cancer), and must have persisted for at least twelve weeks. As opposed to acute low back pain which would have persisted for less than twelve weeks (Airaksinen, et al., 2006).

In back pain research it is important to distinguish between acute and chronic NSLBP, as pain intensity in acute NSLBP is more likely to reduce over the course of six weeks than chronic NSLBP (Bombardier, Hayden, & Beaton, 2001; Kovacs, et al., 2007; Ostelo & de Vet, 2005; Salaffi, Stancati, Silvestri, Ciapetti, & Grassi, 2004). In acute NSLBP, reductions in pain intensity may be due to a ‘natural recovery’, the tendency for the person to naturally recover from a recent injury. Thus any treatment intervention applied to acute NSLBP participants may receive an additional benefit from this effect. In the case of participants with long term chronic NSLBP of a
number of years, their pain is more likely to be in a ‘steady state’; where any short term change in pain intensity would be unlikely. In these long term chronic NSLBP cases, a further effect to be considered is known as ‘regression towards the mean’; where a participant’s pain intensity is more likely to return to their long term or ‘mean’ pain level (Field, 2009). Thus participants with long term chronic NSLBP are more likely to return towards their long-term pain level, rather than towards improved health. To avoid the ‘natural recovery’ effect for intervention trials on NSLBP, it would be prudent to use participants with NSLBP pain duration of greater than six-weeks.
Epidemiology of non-specific low back pain

Prevalence and incidence

In the general adult population there is no difference in prevalence rates for NSLBP between males and females, with a lifetime prevalence rate of approximately 80% (Jones & Macfarlane, 2005). Workers involved with intensive heavy manual labour, or people suffering from psychosocial distress have been identified at increased risk of chronic NSLBP, and have higher prevalence rates (Borenstein, 2000; Shelerud, 2006; Toomingas, Theorell, Michelsen, & Nordemar, 1997).

Chronic NSLBP is common to all areas of the world with high rates present in several countries of the western world (see Table 1). Reported lifetime prevalence rates for NSLBP have been quoted at 50 to 84% in adults, and show the least variation with an 80% agreement between studies (Cole & Grimshaw, 2003; Ebrall, 1994; P. M. Kent & Keating, 2005; Louw, et al., 2007; McBride, Begg, Herbison, & Buckingham, 2004; Walker, et al., 2003). No difference has been found in rates between males and females in the adult population (Airaksinen, et al., 2006; Cohen, et al., 2008; Walker, et al., 2003). Lifetime prevalence rates higher than 50 to 84% range have been observed in workers and individuals who experience greater psychological distress (Borenstein, 2000; Shelerud, 2006; Toomingas, et al., 1997). Point prevalence rates (twelve-month prevalence rate), show a wider variation than lifetime prevalence rates at 25% to 68%.
Cost

One of the largest healthcare expenditures and a large economic burden for western societies results from costs related to NSLBP, particularly from medical treatments and lost worker hours (Dagenais, Caro, et al., 2008; Walker, et al., 2003). In the case of chronic NSLBP a small number of cases appear to be responsible for an inversely large proportion of the health care budget (Dagenais, Mayer, Haldeman, & Borg-Stein, 2008). In the USA in 1999 NSLBP was the fourth most costly health condition reported in a study of over 370,000 workers from six different corporations (Goetzel, et al., 2003). In 2001 in New Zealand and Australia, direct healthcare costs were calculated at NZ$98 million, and greater than AUD$1 billion respectively (McBride, et al., 2004; Walker, et al., 2003). The cost to the New Zealand economy in 2004 was estimated at NZ$500 million per annum (McBride, et al., 2004).
Severity
Non-specific low back pain and particularly chronic NSLBP, can in some cases be a very disabling condition. The extent of personal disability varies with the individual and may be related to their own physical, emotional and environmental circumstances (N. Bogduk, 2006a; Dagenais, Caro, et al., 2008; Kuchera, 2007; Shelerud, 2006). Shelerud et al. (2006) has suggested that psychosocial factors may be more important than physical disability in the case of factory workers in the USA. This may explain why self-reported pain scores did not demonstrate any correlation with the severity of structural dysfunction demonstrated on imaging results (Cohen, et al., 2008). A large proportion of patients with no pain had imaging results suggestive of trauma to their low back, and thus might have expected to be in pain.

There has been progress in the prediction of factors that might identify those who suffer from long term (greater than twelve-months) chronic NSLBP (Costa Lda, et al., 2007). Costa Lda, et al. (2007), had identified individuals who were able to recover from chronic NSLBP within one year, from those who still had low back pain after twelve-months. Costa Lda, et al. (2007), found that those who had previously taken sick leave for their NSLBP, had a high degree of disability, a lower level of education, and a self belief that they would not recover from their pain.

Causative Factors
The best predictor of any future incidence of chronic NSLBP is a previous history of low back pain (N. Bogduk, 2006b). Other factors that have been associated with increased risk of future NSLBP include: childhood incident of chronic pain
(Duggleby & Kumar, 1997; Ebrall, 1994; Walker, et al., 2003), poor physical fitness (N. Bogduk, 2004), heavy manual labour (N. Bogduk, 2006a; Dunn & Croft, 2004), low self esteem in the workplace (Dagenais, Caro, et al., 2008; Shelerud, 2006), and an as yet unidentified genetic component. These will now be discussed in more detail.

**Genetic Component to Non Specific Low Back Pain**

Several studies have demonstrated a possible, as yet unidentified, genetic component to NSLBP through examination of identical twins with and without NSLBP (Battie, Videman, Levalahti, Gill, & Kaprio, 2007; Leboeuf-Yde, 2004; Shelerud, 2006). In studies involving identical twins, Shelerud (2006) has found evidence that suggests environmental factors may be outweighed by an individual’s genetics. The study found that identical twins with a large variation in BMI all developed NSLBP in later life. Other investigators have shown a genetic link for NSLBP amongst younger people, a group that is less likely to be affected by environmental factors compared to the elderly due to their age (Hestbaek, Iachine, Leboeuf-Yde, Kyvik, & Manniche, 2004). Research into possible genetic components linked to NSLBP is currently at an early stage but may yet prove to be a valuable predictor of future incidence of NSLBP.
Table 2 - Risk factors associated with low back pain

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Potentially associated with the development of NSLBP</th>
<th>Potentially associated with the persistence of LBP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior episode of low back pain</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Poor job satisfaction or low pay</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Inadequate coping skills</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Fear avoidance behaviour</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Manual labour or physically stressful job</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Obesity</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Older age</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Low educational level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Higher pain intensity or disability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor physical fitness</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Neck pain</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Unidentified genetic component</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Depression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotional distress or trauma</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

From (Cohen, et al., 2008; Dagenais, Caro, et al., 2008; Shelerud, 2006)

Psychosocial Factors

A systematic review by Dunn and Croft (2004) found a strong link between chronic NSLBP and several psychological factors such as smoking, obesity, anxiety, depression, kinesiophobia and somatisation. Shelerud et al. (2006) has found evidence that suggests environmental factors may be outweighed by an individuals genetics, and that psychosocial factors may be more important than physical disability in the case of factory workers in the USA.

Workplace Environment

A great deal of research has been performed on the relationship of NSLBP with occupational roles and health (Garg & Moore, 1992; Karahan, Kav, Abbasoglu, & Dogan, 2009; Shelerud, 2006; Waddell & Burton, 2001). The most common workplace activities responsible for chronic NSLBP have involved activities such as: manual lifting of heavy loads, and prolonged poor posture (Garg & Moore, 1992).
Studies conducted on cable car workers in San Francisco (Borenstein, 2000), railroad workers in the USA (Shelerud, 2006), and hospital workers from Turkey (Karahan, et al., 2009) have shown that job roles involving the heavy manual lifting or the moving of heavy objects on a repetitive basis correlates strongly with the incidence of chronic NSLBP. However, research has argued that the incidence of LBP in these professions is more likely to be predicted by job satisfaction, emotional state and ‘individual freedom’ rather than heavy lifting alone (Shelerud, 2006). The successful treatment reduction of low back pain in the cases reported by Shelerud et al. (2006) was not sufficient to prevent the ongoing re-occurrence of worker complaints, which may suggest non-physical factors may be more important than treatment alone.
Manual therapy treatment of non-specific low back pain

What is manual therapy?

Manual therapy refers to the skilled application of practitioners’ hands to specific areas of the body in order to improve the function of the musculoskeletal system in that area (Greenman, 2003). The term manual therapy can be used to describe disciplines such as physiotherapy, chiropractic and osteopathy. In each of these occupations practitioners can employ a wide variety of ‘hands on’ treatment techniques (Hartman, 1996).

History of manual therapy and non-specific low back pain

Until recent times in the United Kingdom (UK), Australia and New Zealand, patients who consulted their General Practitioner (GP) for NSLBP would have usually been referred to a physiotherapist. Even before GPs started to refer patients to osteopaths and chiropractors, NSLBP patients had started to seek treatment from these professions. With the introduction of Accident Compensation Corporation (ACC) provision to the chiropractic and osteopathic professions in New Zealand it is now common for GPs in New Zealand to refer directly to an osteopath (Duke, 2005).

Traditional treatment advice for NSLBP from GPs in the UK included activities such as back rest (bed rest), exercise avoidance, muscle relaxants, anti-inflammatory and analgesic medicines (Cohen, et al., 2008). The prescription of such activities represents a conservative strategy, which mainly addressed control of the symptoms rather than resolution of the ‘root’ cause.
Osteopathic approach to diagnosis and treatment

Osteopathic treatment utilises an individualised medical diagnostic model combined with manual therapeutic treatment strategies to enhance the homeostatic mechanisms of the patient (Kuchera, 2007). This approach is based on the osteopathic philosophy outlined by the founder of osteopathy, A. T. Still, and his four main principles: the body is a unit, structure and function are reciprocally related, the rule of the artery is supreme, and that the body possess self-regulatory and self-healing mechanisms (Lee, 2005).

The osteopathic manual therapy practitioner performs a thorough medical history and a skilled palpatory examination of the patient to diagnose possible causes for their condition (Sammut & Searle-barnes, 1998; Ward, 2003). Production of a short list of potential causes for the patients chronic NSLBP can be facilitated by the use of an osteopathic differential diagnosis. A differential diagnosis may be created from an analysis of a physical examination of the patient coupled with their medical history. The differential diagnosis would then ‘drive’ the osteopathic practitioner’s treatment plan, where one of several treatment models may be employed. Within each treatment model the practitioner may apply any number of treatment techniques, until the practitioner observes the desired patient response (Kuchera, 2007). The diagnostic models and treatment techniques discussed by Kuchera (2007), are explained in detail in a number of well regarded osteopathic books (Hartman, 1996; Parsons & Marcer, 2006; Stone, 1999; Ward, 2003).
The National Institute for Clinical Excellence (NICE) in the UK has recently published guidelines on NSLBP. These encourage the patient to first seek manual therapy and acupuncture treatment before approaching their GP (NICE, 2008), and follows recent similar decisions in Europe (Airaksinen, et al., 2006). The reason for these changes in the UK and European Union have been based on the latest evidence based medicine. For example the evidence includes discussion on: (1) no correlation between low back imaging data and NSLBP, (2) the benefits of exercise, manual therapy, psychological intervention, and acupuncture, and (3) the need for education in the avoidance of poor posture (NICE, 2008).
Benefits of an osteopathic approach in the treatment of chronic non-specific low back pain

One of the potential benefits of an osteopathic palpatory examination can be the insight the practitioner may gain into the underlying state of the patients tissues and physiology (Kuchera, 2007). The information received by the practitioner from the patient examination may give further insights into the cause of the condition, not just the symptomatic findings, and suitable therapeutic techniques that may help (Kuchera, 2007). Any of the selected techniques may be applied to regions of the patients body that are distant from the site of their original symptoms. Examples could include the forearm extensor muscles in the case of chronic hand pain, or trigger points in the serratus anterior muscle in the case of chronic shoulder pain. In these two examples it is possible that pharmacological medication and/or application of treatment local to the hand or shoulder, may only produce short-term relief from pain (Chauffour & Prat, 2002; Myers, 2001).

A further example of this broad, pragmatic treatment approach available to osteopaths would be the opportunity of the osteopath to consider diagnosis and treatment of visceral organs of the body (e.g. liver, kidney) for chronic pain (Barral & Mercier, 2005; Stone, 2007b). Very few other manual therapy professions treat the viscera of the body.
Literature review of the manual therapy techniques for non-specific low back pain

The manual therapy techniques identified from the literature were taken from two general sources: manual therapy textbooks, and secondly, journal papers. A list of osteopathic and manual therapy techniques were compiled from a number of widely available osteopathy textbooks: Foundations of Osteopathic Medicine (Ward, 2003), Osteopathy (Parsons & Marcer, 2006), and Handbook of Osteopathic Technique (Hartman, 1996). Further techniques were chosen based on the most common clinical approaches used by American osteopaths from a study by Johnson and Kurtz (2003), and secondly from previous RCTs (see Table 3).

The majority of previous RCTs that were of at least moderate methodological quality have employed a wide variety of manual therapy techniques as listed in Table 2 (Aure, Nilsen, & Vasseljen, 2003; Bronfort, Goldsmith, Nelson, Boline, & Anderson, 1996; Licciardone, et al., 2008; Niemisto, et al., 2003). Studies that had a methodological quality score of less than 78 out of 100 (based on systematic reviews), were not included in the literature search for manual therapy techniques as proposed by Assendelft et al. (2004) (Assendelft, et al., 2004; Bronfort, Haas, Evans, & Bouter, 2004; Chou & Huffman, 2007; Ferreira, Ferreira, Latimer, Herbert, & Maher, 2002; Lawrence, et al., 2008).
Table 3 - Manual therapy treatment techniques from RCTs

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment techniques employed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aure, Nilsen, &amp; Vasseljen, 2003</td>
<td>High Velocity Low Amplitude Thrust (HVLA), Mobilisation techniques, stretching techniques.</td>
</tr>
<tr>
<td>Bronfort, et al., 1996</td>
<td>Spinal Manipulative Therapy (SMT) (which includes High Velocity Low Amplitude Thrust).</td>
</tr>
<tr>
<td>Licciardone, et al., 2008</td>
<td>Mobilisation techniques, Balanced Ligamentous Tension (BLT), Cranial Sacral Technique, Facilitated Positional Release (FPR), HVLA, Integrated Neuromuscular Release (INR), Myofascial Release (MR), Soft tissue massage, Ligamentous Articular Strain Technique (LAS), and Visceral Technique (VT).</td>
</tr>
<tr>
<td>Niemisto, et al., 2003</td>
<td>Muscle Energy Technique (MET), Soft tissue massage.</td>
</tr>
</tbody>
</table>

Description of randomised controlled trials that were considered to be of high methodological quality extracted from the original electronic database search.
<table>
<thead>
<tr>
<th>Treatment</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft Tissue Technique</td>
<td>Passive technique applied by the hands, similar to massage, to areas of the body with muscle or tissue tightness. Rhythmical or inhibitory technique. Treatment duration may be several minutes.</td>
</tr>
<tr>
<td>High Velocity Low Amplitude Thrust</td>
<td>Passive technique involving a small thrust force to restricted joints of the body by use of the hands. No cervical manipulation will be undertaken. Treatment duration is approx. 10 seconds.</td>
</tr>
<tr>
<td>Muscle Energy Technique</td>
<td>Active technique applied by the hands to any joint of the body. Treatment duration may be from 30-60 seconds.</td>
</tr>
<tr>
<td>Strain Counter Strain</td>
<td>Passive technique applied by the hands to any joint of the body. Treatment duration of at least 90 seconds, or even longer.</td>
</tr>
<tr>
<td>Myofascial Release</td>
<td>Passive technique applied by the hands to any tissue tightness, or restriction of the body. Treatment duration of 30-90 seconds.</td>
</tr>
<tr>
<td>Articulation</td>
<td>Passive technique applied by the hands to any joint of the body. Treatment duration of approx. 30-60 seconds.</td>
</tr>
<tr>
<td>Functional Technique</td>
<td>Passive technique applied by the hands to any joint of the body. Treatment duration of 1-3 minutes.</td>
</tr>
<tr>
<td>Visceral Technique</td>
<td>Passive technique applied by the hands to any visceral structure (e.g. liver) of the body. Treatment duration of 1-3 minutes.</td>
</tr>
<tr>
<td>Balanced Ligamentous Tension</td>
<td>Passive technique applied by the hands to any tissue restriction of the body. Treatment duration of 30-90 seconds.</td>
</tr>
<tr>
<td>Facilitated Positional Release</td>
<td>Passive technique applied by the hands to any restricted joint of the body. Treatment duration of 30-90 seconds.</td>
</tr>
<tr>
<td>Fascial-Ligamentous Release</td>
<td>Passive technique applied by the hands to any tissue restriction of the body. Treatment duration of 30-90 seconds.</td>
</tr>
</tbody>
</table>

List and description of commonly used manual therapy techniques from a search of osteopathic and manual texts.
Literature review of manual therapeutic interventions chronic for non-specific low back pain

The literature search revealed 102 studies into the efficacy of manual therapy interventions for cases of chronic NSLBP. A detailed investigation of all these studies identified 13 systematic reviews and 89 RCTs investigating spinal manipulation, massage, and physiotherapy interventions. Hand-searching of the references cited by these papers identified an additional 2 systematic reviews and four further RCTs that were not found in the original electronic database search. Four of those studies were osteopathic studies, which resulted in a grand total of 108 studies, 15 systematic reviews and 93 RCTs.

Identification of systematic reviews

In total there were three systematic reviews related specifically to massage (Furlan, Brosseau, Imamura, & Irvin, 2002; Furlan, Brosseau, Welch, & Wong, 2000; Furlan, Imamura, Dryden, & Irvin, 2008, 2009), and twelve systematic reviews that discussed physiotherapy interventions, spinal manipulations and osteopathic trials (Assendelft, et al., 2004; Bronfort, et al., 2004; Chou & Huffman, 2007; Ernst & Canter, 2006; Ferreira, et al., 2002; Keller, Hayden, Bombardier, & van Tulder, 2007; Lawrence, et al., 2008; Licciardone, et al., 2005; Maher, 2004; Mior, 2001; H. M. Pengel, Maher, & Refshauge, 2002; van Tulder, Furlan, & Gagnier, 2005). All fifteen systematic reviews are listed in Table 5 for clarity.
Identification of randomised controlled trials

Of the 93 RCTs identified on manual therapy interventions for non-specific low back pain, very few have been of high methodological quality based on the scoring criteria of the Cochrane low back pain group (Assendelft, et al., 2004). Of the RCTs identified since 1996, only three trials were of high quality (Aure, et al., 2003; Bronfort, et al., 1996; Niemisto, et al., 2003) – none of these were osteopathic based trials. A fourth, long term osteopathic based RCT, that has still to finish, may eventually prove to be of a high quality methodological standard (Licciardone, et al., 2008). In fact only three of the 93 RCTs were osteopathic based studies, but all of these used a pragmatic treatment approach (Andersson, et al., 1999; Licciardone, et al., 2008; Licciardone, et al., 2003). Only four non-osteopathic based manual therapy RCTs identified since 1998 used a pragmatic treatment design (Critchley, Ratcliffe, Noonan, Jones, & Hurley, 2007; Hough, Stephenson, & Swift, 2007; Torstensen, et al., 1998; Wilkey, Gregory, Byfield, & McCarthy, 2008). These RCTs are summarised in Table 6.
<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Massage Intervention</strong></td>
<td></td>
</tr>
<tr>
<td>Furlan, Brosseau, Imamura, &amp; Irvin, 2002</td>
<td>Massage and low back pain</td>
</tr>
<tr>
<td>Furlan, Brosseau, Welch, &amp; Wong, 2000</td>
<td>Massage for low back pain</td>
</tr>
<tr>
<td>Furlan, Inamura, Dryden, &amp; Irvin, 2008</td>
<td>Massage and low back pain</td>
</tr>
<tr>
<td><strong>Physiotherapy, Spinal Manipulative Therapy and Osteopathic Interventions</strong></td>
<td></td>
</tr>
<tr>
<td>Assendelft, et al., 2004</td>
<td>Spinal manipulative therapy for low back pain as part of the Cochrane low back pain group</td>
</tr>
<tr>
<td>Bronfort, et al., 2004</td>
<td>Spinal manipulation and mobilization for low back pain</td>
</tr>
<tr>
<td>Chou &amp; Huffman, 2007</td>
<td>Non-pharmacologic interventions for acute and chronic low back pain and neck pain</td>
</tr>
<tr>
<td>Ernst &amp; Canter, 2006</td>
<td>Review of spinal manipulation systematic reviews</td>
</tr>
<tr>
<td>Ferreira, et al., 2002</td>
<td>Spinal manipulative therapy and low back pain</td>
</tr>
<tr>
<td>Keller, Hayden, Bombardier, &amp; van Tulder, 2007</td>
<td>Non surgical treatments of non specific low back pain</td>
</tr>
<tr>
<td>Lawrence, et al., 2008</td>
<td>Chiropractic management of low back pain</td>
</tr>
<tr>
<td>Licciardone, et al., 2005</td>
<td>Review and meta analysis of osteopathic manipulative treatment randomized controlled trials</td>
</tr>
<tr>
<td>Maher, 2004</td>
<td>Physical treatments for low back pain</td>
</tr>
<tr>
<td>Mior, 2001</td>
<td>Exercise and the treatment of low back pain</td>
</tr>
<tr>
<td>Pengel, Maher, &amp; Refshauge, 2002</td>
<td>Conservative interventions for sub-acute low back pain</td>
</tr>
<tr>
<td>Van Tulder, Furlan, &amp; Gagnier, 2005</td>
<td>Complimentary and alternative therapies for low back pain</td>
</tr>
</tbody>
</table>
Table 6 - High quality and pragmatic manual therapy studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High Quality RCTs</strong></td>
<td></td>
</tr>
<tr>
<td>Aure, Nilsen, &amp; Vasseljen, 2003</td>
<td>Manual therapy and exercise therapy in chronic low back pain</td>
</tr>
<tr>
<td>Bronfort, et al., 2003</td>
<td>Spinal manipulation and mobilization of chronic low back pain</td>
</tr>
<tr>
<td>Niemisto et al., 2003</td>
<td>Combined manipulation, stabilising exercises and physical consultation</td>
</tr>
<tr>
<td><strong>Osteopathic Pragmatic RCTs</strong></td>
<td></td>
</tr>
<tr>
<td>Andersson, et al., 1999</td>
<td>Comparison of osteopathic spinal manipulative treatment with standard care for low back pain</td>
</tr>
<tr>
<td>Gibson, et al., 1985</td>
<td>Comparison of osteopathic manipulative treatment with shortwave diathermy in non-specific low back pain</td>
</tr>
<tr>
<td>Licciardone, et al., 2003</td>
<td>Osteopathic manipulative treatment for chronic low back pain</td>
</tr>
<tr>
<td>Licciardone, et al., 2008</td>
<td>Osteopathic health outcomes in chronic low back pain</td>
</tr>
</tbody>
</table>
Evidence for the efficacy of manual therapeutic interventions for chronic non-specific low back pain

Overview

Until recently the largest, and most influential, high quality systematic review of spinal manipulation was performed by Assendelft et al. (2004) as part of the Cochrane Collaboration low back pain group. This report found a moderate positive effect for spinal manipulation in the case of acute NSLBP, but no clear benefit in the case of chronic NSLBP. Without explanation an updated version of this study failed to include a number of more recent studies demonstrating a positive effect for the treatment of chronic NSLBP (Aure, et al., 2003; Bronfort, et al., 1996; Niemisto, et al., 2003) – a point also noted by Lawrence et al. (Lawrence, et al., 2008). In response, a high quality systematic review of non-pharmacologic treatments for chronic NSLBP was performed by Chou and Huffman (2007). The study by Chou and Huffman (2007) concluded that with the inclusion of these high quality studies since 2000 (Aure, et al., 2003; Bronfort, et al., 1996; Niemisto, et al., 2003), the literature may now demonstrate a moderate positive effect for the treatment of chronic NSLBP from spinal manipulation.

Methodological trials of high quality

An analysis of systematic reviews for the efficacy of manual therapy interventions of chronic NSLBP from 1996 to 2008 revealed only three high quality trials from a possible total of over fifty OMT Pragmatic RCTs (Aure, et al., 2003; Bronfort, et al., 1996; Niemisto, et al., 2003). Assendelft et al. (2004) has suggested that the best
approach to determine the efficacy of interventions for chronic NSLBP, would be to only include interventions from RCTs considered to be of very high quality. The earliest high quality RCT by Bronfort et al. (2004), found combined manual therapy to be ineffective compared to other forms of standard care, and is in agreement with conclusions from systematic reviews by Assendelft et al. (2004), and Ferreira et al. (2002). Two recent high quality RCTs found combined manual therapy had an equal to or greater effect than standard care (Aure, et al., 2003; Niemisto, et al., 2003), and agreed with the conclusions of the later systematic reviews by Chou and Huffman (2007) and Lawrence et al. (2008). These three RCTs will now be discussed in detail.

Bronfort et al. (1996) carried out a non-pragmatic, combined treatment RCT of SMT and exercises on a non-homogeneous study population of 174 participants with chronic NSLBP aged from 20 to 60 years of age, from a college outpatient clinic. The first group compared spinal manipulative therapy (SMT) and trunk strengthening exercises to SMT and trunk stretching exercises (TSE). The second group compared SMT and TSE to nonsteroidal anti-inflammatory drug (NSAID). Treatment consisted of five weeks of each therapy followed by an additional six weeks of supervised exercise alone. Outcome measures were recorded at five weeks, eleven weeks and one year. Results did not demonstrate any clinically important improvement in participants with chronic NSLBP, only a minor effect of an 8mm reduction in pain intensity on 100mm VAS was observed at eleven weeks. Similar results were observed for functional disability, and general health. The use of a mixed treatment design in each of the two groups may have hindered clear interpretation of the effect of the manual therapy intervention.
Aure, Nilsen, and Vasseljen (2003) performed a multicentre combined treatment RCT of SMT, mobilisation and stretches on a homogeneous population of 49 participants with chronic NSLBP who had been sick listed (i.e. off work), for a period of between eight weeks and six months. Participants, split into two groups, received 16 treatments twice per week, over an eight-week period. Treatment consisted of either manual therapy (spinal manipulation of thoracic and lumbar spine, combined with mobilisation and stretching techniques), or exercise therapy (exercise bicycle, supervised strengthening and stretching exercises). Outcome measures for pain intensity, functional disability and general health were recorded at four weeks, six months, and 12 months. A maximum improvement of 34mm reduction in pain intensity occurred at twelve months for the manual therapy group, compared to 19mm for the exercise therapy group. The reductions in both cases were statistically significant, but not clinically relevant when compared to the control group, despite the large reductions in pain intensities. The use of a control group with a potential treatment effect (i.e. exercise and stretching techniques) may well have made clear interpretation of the manual therapy intervention effect difficult. Although the results demonstrate the importance of control groups in order to determine the ‘true’ effect on any treatment intervention.

Niemisto et al. (2003) carried out a pragmatic, non SMT, manual therapy RCT on a homogeneous population of 204, 24 to 60 year olds from a rehabilitation clinic of an orthopaedic hospital in Finland. Participants were selected with both chronic NSLBP of at least three months duration, and a low Oswestry functional disability score (i.e. highly disabled). Participants were assigned to two groups. A manipulative treatment group received a single 60-minute session once a week for four weeks, where each
session was divided into three parts: evaluation, treatment and exercise. The manipulative treatment consisted of muscle energy technique rather than HVLA thrusts, and was applied only to the lumbar and pelvic regions. Specific muscle stretching and strengthening was performed of any muscles identified to be restricted or of a contracted state. The treatment for the participants of the consultation group was an information booklet on health and low back pain, followed by classes on how to use the book and exercise correctly. Outcome measures for pain intensity (100mm VAS), functional disability (Oswestry) and a general health questionnaire (HRQoL) were recorded at zero, five and twelve months. The reduction in pain intensity for the manual therapy group (34mm) was statistically significant, but not clinically relevant when compared to the consultation control group (21mm), despite the large reduction in pain intensity. This demonstrates the importance of a control group to show the ‘true’ effect of the intervention. The design of the control group in this study had attempted to minimise any unintended treatment effect. However, the use of exercises in the control group could potentially have produced a treatment effect, and thus confused the interpretation of the manual therapy effect intervention.

In summary, one reason for the lack of recovery in chronic NSLBP cases may be due to the complex, multi-factorial nature of chronic NSLBP (Dagenais, Caro, et al., 2008; Hall, McIntosh, & Boyle, 2009). Conditions that have multiple aetiologies like chronic NSLBP may therefore respond better to multiple treatment techniques, and may explain why the combined treatment approach of trials from Aure, Nilsen, and Vasseljen (2003) and Niemisto et al. (2003) produced a larger reduction in low back pain intensity than single treatment interventions. Both Assendelft et al. (2004) and
Licciardone et al. (2004) suggest acute NSLBP responds better to manual therapy due to its more simplistic nature in comparison to chronic NSLBP.

**Pragmatic Osteopathic Trials**

There have been very few osteopathic orientated interventions into the efficacy of OMT for chronic NSLBP. However all of the studies since 1996 did use a pragmatic approach but failed to identify a benefit for OMT in the treatment of chronic NSLBP compared to sham treatment or compared to standard care (Andersson, et al., 1999; Licciardone, et al., 2008; Licciardone, et al., 2003). Each of these three studies is discussed in more detail below.

Licciardone et al. (2003) conducted an osteopathic based pragmatic RCT to compare the efficacy of OMT with either a sham treatment or a no intervention control group for the treatment of chronic NSLBP. Participants aged in a range from 21-69 years were recruited using advertisements, GP referral and word of mouth. They were screened intensively for pre-existing back pain conditions and were only included in the trial if they did not have any serious spinal pathology. To identify areas of somatic dysfunction that may be associated with low back pain, eligible participants all received an osteopathic structural evaluation, that guided the choice of treatment. The OMT intervention included seven visits over five months lasting 15-30 minutes each. Treatment was administered by 3rd and 4th year osteopathic students – a potential limitation of the study. The techniques included one or a combination of the following techniques: myofascial release, strain-counterstrain, muscle energy, soft tissue, high-velocity-low-amplitude (HVLA) thrusts, cranial-sacral. All treatment was restricted to the low back and adjacent areas, which is another limiting factor of the study. Sham
control treatment was applied to the same area as the treatment intervention, using light touch, and simulated OMT techniques. All of these techniques purposely avoided treatable areas of dysfunction. Results show that both the sham and intervention group demonstrated statistically and clinically relevant improvements compared to the no-intervention control group only at the three-month stage. Participants receiving OMT treatment reported using less co-treatments (e.g. pain medication) than those in the sham or the no-treatment control groups. The study suggests that OMT is no better than sham treatment in the treatment of chronic NSLBP.

A second randomized controlled trial was conducted in the USA by Andersson et al. (1999) on 178 participants with sub-acute and chronic low back pain. Participants ranged in age from 20 to 59 years and were recruited from a health maintenance organization. Eligible patients were then invited into the trial and excluded if there were any signs of spinal pathologies, or if their spinal conditions would be difficult to treat, which limited the applicability of this trial to the general population. Participants were randomized to either an OMT or a standard care group, and were treated by an experienced physician, where treatment could be applied on any part of the body that the physician deemed appropriate. Eight treatments were given in total over a period of 12 weeks. The treatments that were allowed were HVLA, muscle energy, strain-counterstrain, articulation, and myofascial release. Results of the trial showed a clinically important change in chronic NSLBP pre to post intervention for both of the groups, with no meaningful difference between the intervention and the control group at follow up. However the OMT group did report less medication use
than the control group over the period of the trial, which may suggest that OMT is no better than standard care in resolving chronic NSLBP.

A third pragmatic OMT based RCT was conducted by Gibson et al. (1985) on 109 participants with low back pain of two-twelve months duration. The trial firstly compared OMT against placebo control treatments of short-wave diathermy and secondly OMT against detuned short-wave diathermy. Four treatments using a variety of techniques were applied over the course of four weeks, and changes in pain intensity were measured via a 100mm horizontal VAS. Results at four weeks post follow up were very similar for both groups with a minor reduction of 6 to 7mm on the VAS pain intensity scale.
Literature review of subjective measures for chronic non-specific low back pain

There has been little research into self-reported pain measures and manual therapy treatment of chronic NSLBP in New Zealand. The majority of research for self reported pain intensity in chronic NSLBP has been performed in Europe and North America (Carlsson, 1983; Hudak & Wright, 2000; Kovacs, et al., 2007; Ostelo, et al., 2008; Sriwatanakul, et al., 1983; van der Roer, Ostelo, Bekkering, van Tulder, & de Vet, 2006).

Importance of minimum clinically important change

Previous studies have reported changes in pain intensity and functional disability in terms of statistical significance rather than minimal clinically important change (MCIC) (Aure, et al., 2003; Bronfort, et al., 1996; Niemisto, et al., 2003). Future studies that wish to provide strong evidence for reductions in pain intensity and improvements in functional disability in chronic NSLBP, should report not just a statistical effect of the intervention, but also the clinically relevant change. To date no manual therapy RCT intervention for chronic NSLBP has demonstrated an MCIC for pain intensity or functional disability when compared against a control group (Assendelft, et al., 2004; Chou & Huffman, 2007).

Visual Analogue Scale

The use of a 100mm scale is a sensitive, and a highly reliable pain intensity measure that produces an integer in the range of 0mm to 100mm (Bijur, Silver, & Gallagher,
2001; Hagg, Fritzell, & Nordwall, 2003; Jensen, Karoly, & Braver, 1986; Ostelo, et al., 2008; Williamson & Hoggart, 2005). Minimally clinically important change values for 100mm VAS have been reported as 15mm for chronic, and 20mm for acute NSLBP respectively (Ostelo & de Vet, 2005). Hagg et al (2003) is in broad agreement for acute NSLBP and reports 18mm-19mm for the VAS outcome measure.

Quebec Low Back Pain Disability Questionnaire
Functional disability can be measured using the Quebec Back Pain Disability Scale (QBPDS), which consists of 20 questions on a five-point Likert scale that produces an integer score from 0 to 100 points. The QBPDS has been found to be reliable and concise for the measurement of NSLBP with an MCIC of 15 points (Davidson & Keating, 2002; Fritz & Irrgang, 2001; Kopec, et al., 1995, 1996; Muller, Roder, & Greenough, 2006; Ostelo, et al., 2008; van der Roer, et al., 2006). Van der Roer et al. (2006) is in agreement and reports QBPDS as 8.5 to 24.6 points for chronic NSLBP.

Short Form 12 General Health Questionnaire
The short form 12 (SF-12) general health questionnaire (QualityMetric Incorporated, Lincoln, RI, 02865 USA), comprises of two subscales: one aggregate value for physical status and another aggregate for mental health status. Each aggregate is adjusted to a 100-point scale based on the USA general population, and the SF-12 form has been shown to be of high validity and less cumbersome to use than other
general health questionnaires (Haywood, Garratt, Dziedzic, & Dawes, 2002; Singh, Gnanalingham, Casey, & Crockard, 2006; Wee, Davis, & Hamel, 2008).

**Global rating change scale**

The global rating change seven-point scale has been used by several RCTs on NSLBP to determine SEM and MCIC values for other outcome measures. The global rating change seven-point scale has been used to provide a direct measure of the benefit of the treatment intervention in the opinion of the participant at the end of the trial. The seven-point scale is easy to use, and has been considered to be sensitive and of high reliability (Kovacs, et al., 2007; Kovacs, et al., 2008; Muller, et al., 2006; Wyrwich, Tierney, & Wolinsky, 1999).
Literature review pertaining to data analysis

Reliability - Intraclass correlation coefficient (ICC), statistical detectable difference (SDD), and standard error of measurement (SEM)

Intra-class correlation coefficients (ICC) are used to assess inter-rater and intra-rater reliability of quantitative measurements, and as a measure of reproducibility. According to Shrout & Fleiss (1979), the ICC is the correlation between one measurement (single rating or mean of ratings) on a target and another measurement obtained on that target. Reliability refers to the reproducibility of values of a test, assay or other measurement in repeated trials on the same individuals (W. Hopkins, 2000).

Correlation coefficient values calculated via the methods of Griffin & Gonzalez (1995), or Shrout & Fleiss (1979) demonstrate high reliability when greater than 0.80 (Littlewood & May, 2007). Values between 0.60 to 0.79 are considered moderately reliable, and values below 0.60 are considered of questionable reliability. According to the criteria of Hopkins (2000). ICC’s from 0.0 to 0.1 are considered ‘trivial’, from 0.1 to 0.3 are considered ‘small’, from 0.3 to 0.5 are considered ‘moderate’, from 0.5 to 0.7 are considered ‘large’, from 0.7 to 0.9 are considered ‘very large’, and ICC’s from 0.9 to 1.0 ‘almost perfect’. Summaries of previous ICC test re-test reliability values from similar studies on NSLBP are listed in Table 7.

Calculations of ICC’s were required for the calculation of the standard error of measurement (SEM) and the smallest detectable difference (SDD). The SEM reflects the variability of measurements due to repetition and random error, and gives an indication of the absolute reliability of the measures used (Kropmans, Dijkstra,
Stegenga, Stewart, & de Bont, 1999). The SEM was calculated as the square root of the absolute error variance \( SE = SD \cdot \sqrt{\frac{1}{1-ICC}} \), where SD was the standard deviation of the grand mean (Kropmans, et al., 1999). The SDD for the measurements reflects the smallest valid change between the two independent measurements that can be detected in a subject. If the variances between the two observations are approximately the same, the SDD was calculated using the formula \( SDD = 1.96 \cdot \sqrt{SE} \). If the variances between the 2 observations were different, the SDD was calculated using the formula \( SDD = 1.96 \cdot \sqrt{SE_{1-ICC} + SE_{2-ICC}} \) (Kropmans, et al., 1999). The SDD is a clinically relevant measure that represents the change that might be expected because of an intervention rather than sampling error at the 0.05 level of statistical significance.

Table 7 - Test-retest reliability ICC values

<table>
<thead>
<tr>
<th>outcome measure</th>
<th>study</th>
<th>ICC</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS</td>
<td>Lenert (2000)</td>
<td>0.82</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Bijur et al. (2001)</td>
<td>0.99</td>
<td>0.989 – 0.992</td>
</tr>
<tr>
<td></td>
<td>Gallagher, Bijur, Latimer, Silver (2002)</td>
<td>0.97</td>
<td>0.97 - 0.98</td>
</tr>
<tr>
<td></td>
<td>Yip, Tse &amp; Wu (2007)</td>
<td>0.98</td>
<td>na</td>
</tr>
<tr>
<td>QBPDS</td>
<td>Davidson &amp; Keating (2002)</td>
<td>0.84</td>
<td>0.73 – 0.91</td>
</tr>
<tr>
<td>SF-12 PCS</td>
<td>Ware, Kosinski, &amp; Keller (1996)</td>
<td>0.89</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Resnick &amp; Parker (2001)</td>
<td>0.73</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Haywood, et al. (2002)</td>
<td>0.90</td>
<td>0.86 – 0.92</td>
</tr>
<tr>
<td></td>
<td>Bohannon et al. (2004)</td>
<td>&gt;0.80</td>
<td></td>
</tr>
<tr>
<td>SF-12 MCS</td>
<td>Ware, Kosinski, &amp; Keller (1996)</td>
<td>0.76</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Resnick &amp; Parker (2001)</td>
<td>0.86</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Haywood, et al. (2002)</td>
<td>0.79</td>
<td>0.73 – 0.84</td>
</tr>
<tr>
<td></td>
<td>Bohannon et al. (2004)</td>
<td>&gt;0.80</td>
<td></td>
</tr>
</tbody>
</table>

Notes:

1 – ICC from SPSS as outlined by Griffin & Gonzalez (1995), and Shrout & Fleiss (1979).
**Effect Sizes**

The effect size is a measure of the strength of the relationship between two variables. Effect size according to Hopkins (2009), are as follows: an effect size less than 0.2 is considered ‘trivial’; from 0.2 to 0.6 is considered ‘small’; from 0.6 to 1.2 is considered ‘moderate’; from 1.2 to 2.0 is considered ‘large’; from 2.0 to 4.0 is considered ‘very large’; from 4.0 – infinite is considered ‘nearly perfect’. Cohen’s $d$ is a standardized measure of effect, defined as the difference between two means divided by a standard deviation for the data. Effect sizes are defined as <0.2 as trivial; 0.2 to 0.5 as small; 0.5 to 0.8 as medium; 0.8 to infinity as large (Field, 2005).

**Power analysis**

The power of a statistical test is the probability that the test will reject a false null hypothesis (that it will not make a Type II error) (Field, 2005; W. Hopkins, 2000). As power increases, the chances of a Type II error decrease. The probability of a Type II error is referred to as the false negative rate ($\beta$). Therefore power is equal to $1 - \beta$. Power analysis can either be done before (a priori) or after (post hoc) data is collected. A priori power analysis is conducted prior to the research study, and is typically used to determine an appropriate sample size to achieve adequate power. Post-hoc power analysis is conducted after a study has been completed, and uses the obtained sample size and effect size to determine what the power was in the study. The power of a study determines the smallest detectable difference (SDD) of a sample population.
Conclusions

The review of the literature suggests a moderate positive effect for manual therapy, particularly spinal manipulative therapy, in the case of acute NSLBP. The evidence for the efficacy of manual therapy in chronic NSLBP has until recently been inconclusive, partly due to the lack of high quality randomised clinical trials. High quality studies since 2003 have provided evidence for clinically relevant improvements in chronic NSLBP with the application of manual therapy with no control group. When manual therapy treatments have been compared to control groups there was no clinically relevant improvement, but still a moderate improvement. The design of these studies has included a potential treatment effect within the control group, through the use of stretches and exercises. The use of better-designed controls and sham treatment groups in future studies needs to be addressed, if MCIC effects for manual therapy are to be confirmed.

The manual therapy studies that produced the most clinically important improvements were from studies that used a combined treatment approach, similar to a pragmatic design. Studies that employed a single treatment technique intervention design produced a smaller treatment effect compared to combined treatment studies. The disadvantage of the combined treatment or pragmatic approach from a research perspective is that one can not know which of the various treatment techniques was the most efficacious in the reduction of a participant’s chronic NSLBP. However, as this study proposes, the use of a pragmatic design, or combined techniques is analogous to the situation found in clinical practice.
References


SECTION II – MANUSCRIPT
Abstract

Background: Chronic Non specific Low Back Pain (NSLBP) is a large economic burden to the healthcare systems of western industrialized countries. Although studies have demonstrated the efficacy of spinal manipulative therapy for NSLBP, few studies have adopted a pragmatic approach using a wide range of techniques that would typically be employed in a clinical setting.

Design: A homogenous sample of twenty, predominantly Maori and Pacific Islands factory workers gave informed consent. The participants took part in a single cohort pre/post repeated measures intervention over nine weeks.

Outcome Measures: Visual Analogue Scale (VAS), Quebec Back Pain Functional Disability Score (QBPDS), and short form 12 (SF12), completed at baseline, pre and post treatment, and one week follow up.

Methods: Baseline subjective measures were recorded over five weeks. Three pragmatic-based osteopathic treatments, tailored to each participant, were administered once per week.

Results: Intention to treat analysis of fifteen participants (67% male and 33% female, mean age 43.6 years), with a mean duration of chronic NSLBP of 6.6 years, showed a clinically relevant 20.1mm reduction in LBP intensity on VAS (95% CI = 8.5 to 18.1; p<0.0001). A 15.1 points fall in physical disability on QBPDS (95% CI = 6.29 to 16.1; p<0.001), and a 6 point increase in SF12 physical ability (95% CI = 45.3 to 52.5; p<0.004) were also clinically relevant. No substantial changes were found in mental health scores as measured by SF12 (p=0.323).

Conclusion: Application of manual therapy techniques using a pragmatic osteopathic approach demonstrated a clinically relevant reduction in LBP intensity and physical disability in a population of Maori and Pacific Islands factory workers with chronic NSLBP.

(Keywords: chronic, low back pain, spinal manipulation, osteopathy, manual therapy)
Introduction

Chronic non-specific low back pain (NSLBP) is a major cause of lost work hours in the western world. 1-5 Studies show that the high incidence of chronic NSLBP is not restricted to the western world; for example, it is also common throughout Africa. 6 In New Zealand in 2001, chronic NSLBP accounted for 70% of all NSLBP, and in 1999 it was the fourth most costly worker complaint for large corporations in the United States (USA). 7 Reported lifetime prevalence rates in the western world for chronic NSLBP in adults ranges from 50% to 84%, with no difference in prevalence between males and females in the adult population. 8-10

Acute NSLBP has been defined as pain of less than three months duration,11 and chronic NSLBP as low back pain of greater than three months duration. 2, 11 Acute NSLBP with its more recent onset is more likely to respond rapidly to treatment than chronic NSLBP. Chronic NSLBP is routinely treated by various healthcare disciplines using a variety of techniques, including manual therapy. Previous research investigating the efficacy of manual therapy for chronic NSLBP has included spinal manipulative therapy (SMT), physiotherapy interventions, massage and osteopathic manipulative treatment (OMT).1-18 The most widely used of these manual therapy techniques has been SMT. It is important at this juncture to define spinal manipulation, since there have been different interpretations in previous trials of the techniques classed as ‘manipulation’. In this study SMT refers to spinal manipulative thrust techniques, such as High Velocity Low Amplitude (HVLA) thrusts applied to joints of the body with a restricted range of motion (e.g. vertebrae of the spine). In the study by Harvey19 Muscle Energy Technique (MET), which is not categorised as a
manipulative thrust, had been misleadingly included as one of the manipulative techniques used.

The majority of high quality manual therapy interventions for chronic NSLBP have used SMT techniques.\textsuperscript{20-22} The high quality randomised controlled trials (RCTs) that were the most effective in the reduction of low back pain intensity were those that adopted a combined treatment approach rather than SMT alone.\textsuperscript{20, 22} The use of a combined treatment approach closely reflects the use of osteopathic treatment in clinical practice. Therefore chronic NSLBP studies that assess the effectiveness of single treatment interventions, may not be representative of the treatment that occurs in clinical practice. To investigate the efficacy of a clinical osteopathic approach to the treatment of chronic NSLBP, a more pragmatic approach would be required. In this scenario the application of several techniques, tailored to the individual patient, would comprise the treatment intervention. In the research of chronic NSLBP one argument from osteopathic practitioners is that it would be unlikely that a single treatment could resolve a condition that has been acknowledged to be complex and multi-factorial.\textsuperscript{6} This argument from osteopaths has been partly in response to the low to medium effects observed in previous single treatment manual therapy studies.\textsuperscript{4, 17} Unfortunately the majority of the research that has been conducted using this approach has consisted of poor design and low quality trials, which has resulted in vague interpretations and conclusions that are of limited value.

The aim of the study was to investigate the effect of a pragmatic, participant-focused OMT intervention on low back pain intensity, functional disability, and general
health. Previously in New Zealand there have been epidemiological,10,23 and exercise therapy studies for chronic NSLBP.24,25 But at the time of submission this study may be the first pragmatic OMT intervention for chronic NSLBP performed on a New Zealand study population. This study represents a first step into a pragmatic, participant focused study of chronic NSLBP in a population that is highly relevant in the context of New Zealand.
METHODS

Design

The study was a single cohort, pre-test post-test repeated measures design with each participant acting as his or her own control. The study was conducted at a West Auckland poultry factory in New Zealand, to study the efficacy of pragmatic OMT for chronic NSLBP. Subjects were recruited by poster advertisement at the factory premises. Subjects with constant or intermittent NSLBP for at least three months comprised the target study population. The research protocol was approved by the Unitec Ethics Committee, Unitec, Mt Albert, New Zealand.

Subjects were excluded from participation if they were younger than 20 years of age or older than 60 years of age, or had any of the following underlying causes of low back symptoms in their history: (1) had a possibility of serious spinal disorder (malignancy, osteoporosis, ankylosing spondylitis, cauda equina compression or infection), (2) had any back pain that radiated below the knee, (3) reported previous spinal surgery, or a history of vertebral fracture (in the last 10 years), (4) reported another musculoskeletal disorder more troublesome than back pain, (5) were using any medication with known side-effects of myalgia, (6) reported an underlying systemic or visceral disease (such as cardiovascular or inflammatory disease) that could interfere with therapy, (7) reported moderate/severe hypertension (blood pressure greater than or equal to 150/90), (8) were on anticoagulant treatment, or had been diagnosed with a clotting disorder, (9) were taking long-term steroids (e.g. for osteoporosis), (10) were pregnant, (11) had back pain intensity greater than 90mm on the VAS pain intensity scale, (12) were currently receiving other manual or physical
therapy based treatment for their NSLBP, and (13) could not read and write English fluently.

Eligible participants were interviewed by the study organizer who explained the research protocol to the participants, and obtained verbal and written informed consent. The baseline assessment included a focused medical history, which was supplemented by a thorough clinical assessment by the osteopathic practitioner prior to each treatment session.

At baseline assessment data were collected on each subject’s age, gender, ethnicity, weight, height, and outcome measures. Outcome measures were collected once per week for a three-week period. Each participant’s perception of their low back pain intensity was assessed using a 100mm visual analogue scale (VAS). Findings have shown that the data derived from VAS scales amongst patients with chronic NSLBP are normally distributed. The two extremes of the VAS pain scale were labeled as “0” and “100” for the left and right margins respectively. Rather than report the values of these outcome measures as ‘statistically meaningful’, recent RCTs have started to describe the relevance of such measures as a Minimum Clinically Important Change (MCIC). This term implies that the value of the reported outcome measure is a clinically relevant change when measured at a 95% confidence level. The 100mm VAS is considered to be more sensitive than the verbal numerical scale, and is a highly reliable measure that produces an integer in the range of 0 to 100. Values considered to be MCIC have been reported at 15mm for chronic, and 20mm for acute NSLBP respectively. Hagg et al. have reported MCIC values of 18mm to 19mm on VAS for chronic NSLBP.
Functional status and disability resulting from back pain were measured with the Quebec Low Back Pain Disability Score Questionnaire (QBPDS); a 20 question survey on a five-point Likert scale. This questionnaire is short and simple to complete, and appears to be suitable for studies involving participants with mild to moderate disability. The QBPDS has been found to be valid and reliable for the measurement of NSLBP, with an MCIC of 15 points. Van der Roer et al. has measured confidence intervals for chronic NSLBP at 8.5 points to 24.6 points for chronic NSLBP, and this range is in agreement with the suggested MCIC for this outcome measure.

The medical outcomes study, Short Form-12 Health Survey (SF-12), was used to measure the self-reported health status of the subjects. The SF-12 is a twelve-question general health questionnaire (QualityMetric Incorporated, Lincoln, RI, 02865 USA). It comprises of two subscales: one aggregate value for physical health status, and another aggregate for mental health status. Each of these subscales is adjusted to a 100-point scale based on the USA general population. The SF-12 is valid, reliable and a widely used measure for generic health status.

The global rating change seven-point scale, was used to measure the perceived benefit of the treatment intervention in the opinion of the participant after completion of the trial. The global rating change scale has been used by several previous RCTs in the area of NSLBP, and has been easy to use and considered to be sensitive with high reliability. The global rating change seven-point scale can be used to determine the standard error of measurement (SEM) and validate MCIC values for VAS and QBPDS as explained by Ostelo et al.
Additional data were specifically collected on the number of co-treatments received by participants from a list of: over-the-counter medications, physical therapy, massage therapy, chiropractic treatment, osteopathic treatment, and herbal therapies.

During a five-week period, participants were treated by a registered, experienced osteopathic practitioner once per week for a total of three treatments. Follow-up data for VAS, QBPD, and SF-12 measures were collected one week after the final treatment. The following protocol was used for OMT treatments. The OMT session consisted of a timed five-minute pre-treatment consultation that included a thorough medical history, and physical examination. The pre-treatment consultation was followed by a timed treatment session that lasted fifteen minutes exactly. The OMT treatments could be performed in any order, to any area of the body, any number of times as deemed appropriate by the osteopathic practitioner. Manual therapy techniques approved for use in this study were selected from a number of publications that categorize and explain osteopathic techniques: Foundations of Osteopathic Medicine, Osteopathy, Handbook of Osteopathic Technique, and a selection of the most commonly used osteopathic clinical techniques by American osteopaths. The techniques applied by the practitioner were one or more of those listed in Table 1. Because the trial was intended to assess the efficacy of a pragmatic course of OMT, as practiced in ‘real-world’ clinical encounters, the research protocol allowed for discretion on the part of the practitioner in the selection and application of the techniques.

[Insert Table 1]
**DATA ANALYSIS**

**Sample size**

The *a priori* sample size for a two-tailed dependent t-test for the difference between two means was calculated using G*Power software (v3.0.10). Based on an alpha error probability of 0.05, minimum power ($1 - \beta$ error probability) of 0.80 and a medium effect size of 0.5, the minimum required sample size was determined to be 34 subjects. Given the limited number of participants recruited, it was accepted that the study would only be able to detect a treatment that produced a large effect size.

**Initial statistical data analysis**

Raw data were checked for errors and assessed for normality. Non-normally distributed data were log transformed. Analyses described by Mee (see Figure 1) were conducted to determine the extent of regression towards the mean, which is a potential source of error in single cohort designs. Baseline outcome measures were analysed using a repeated measures ANOVA to assess the stability of the baseline data, and to investigate if there was any treatment effect present (see Appendix A).

[Insert Figure 1]

The treatment phase was analysed using a two-tailed paired students’ t-test, comparing the mean baseline and follow up VAS pain intensities for each participant. The same analysis was repeated for QBPDS and SF-12 outcome measures. Effect
sizes and confidence intervals were calculated for each outcome measure to determine the magnitude of any detected treatment effect. All statistical analyses were performed using SPSS version 16 for Microsoft Windows® (SPSS Inc. Chicago, IL, USA); effect sizes and observed power calculations were performed using G*Power version 3.0.10 for Mac OSX®.  

**Intra-class Correlation Coefficients**

Intra-class Correlation Coefficients (ICC) were derived from the three recorded baseline measurements using methods documented from Hopkins, and using the reliability function from SPSS version 16 for Microsoft Windows® (SPSS Inc. Chicago, IL, USA), and are listed in Table 2. In the case of the SPSS reliability function a one-way random effects model with average measures was used to calculate the ICC. The method provided by Hopkins uses a formula based on the statistical F ratio (e.g. ICC = (F - 1) / (F + k - 1), where k = (number observations – number of tests) / (number of subjects - 1)).

[Insert table 2]
RESULTS

The flow of participants through the study is shown in Figure 2. Altogether fifteen persons (75%) were eligible for entry into the study from a total of twenty people who responded to the poster advertisements. The study population characteristics were homogeneous for years duration of NSLB, age, body mass index (BMI), and ethnicity (see Table 3). At study entry eleven (73%) participants had suffered from NSLB for over one year, seven (47%) had experienced NSLB for greater than three years, and six (40%) for greater than ten years. The mean duration of chronic NSLB in the study population was relatively high at 6.6 years, with a mean age of 43.6 years, and a relatively high mean BMI of 34. Possibly due to the location of the trial in the West Auckland region of New Zealand, there were a high proportion of South Pacific Islanders in the study population (eleven of the fifteen (73%) participants). Although not intentionally targeted in the recruitment phase of the study, there were a total of five (33%) Maori participants.

Seventeen participants (85%) out of the twenty who responded to the poster advertisements, entered the baseline period of the study. Of the three participants who did not enter the study: one declined to take part after explanation of the trial procedure, and two failed the exclusion criteria due to spinal pathologies. Of the fifteen eligible participants entered into the treatment phase of the study, thirteen
(87%) completed the eight-week study and follow-up assessment. The two participant withdrawals before the end of the treatment phase were because: one took herbal supplements that negated their low back pain, and the other preferred not to receive any OMT, which left a total of fifteen entrants eligible for the treatment phase of the study. During the treatment phase, two participants withdrew before completion of the study: one had a treatment reaction and preferred not to receive any further treatment, and the second no longer had any low back pain after their first treatment. Both of the withdrawals agreed to take part in the follow-up assessment, and entered the intention to treat analysis.

In general there were no negative responders for the VAS measure during the study, there were six non-responders (40%) and nine positive responders (60%) to the treatment intervention (see Table 4 and Table 5). Of the six non-responders there was an average of 6.5mm reduction in pain intensity, as measured by VAS by the end of the treatment intervention compared to the baseline period. The treatment effect appeared to be cumulative as the largest reduction in low back pain intensity occurred after the third treatment intervention (see Figure 3). The degree of pain intensity reduction was over four times greater in the positive responders than the non-responders, with a 20.5mm (60%) mean reduction on VAS; $p < 0.0001$ (95% CI: 8.5, 18.1) (see Table 6). There was a very large effect size of ($Cohen \, d = 1.45$) (see Table 6). There were notably different trends in the participant’s reactions to treatment between the baseline and treatment phases for low back pain intensity on VAS. The baseline scores on VAS illustrated a consistent increase in the mean low back pain intensity score, followed by a large reduction in mean low back pain intensity after treatment (see Table 5). The results of the linear regression analysis demonstrated an
upward trend in low back pain intensity in the baseline period, compared to a steeper downward trend in the treatment period (see Table 5).

[Insert Table 4]

[Insert Table 5]

[Insert Table 6]

[Insert Figure 3]

Results for functional disability showed no negative responders to treatment, nine non-responders (60%) and six positive responders (40%). The effect of the treatment intervention appeared to be cumulative with the largest reduction of 15.1 points (57%) on QBPDS occurring at the end of the third treatment; $p < 0.001$ (95% CI: 6.3, 16.1). This clinically relevant change had a very large effect size ($Cohen \ d = 1.08$), and demonstrated an observed power for the study of 0.97 as calculated using G*Power$^{51}$ (mean of difference 15.133, standard deviation of difference of 14.081). The scores on QBPDS illustrated relatively similar values for mean functional disability score during the baseline period, followed by a large reduction after treatment (see Figure 3). Physical health status as recorded by the SF12-PCS measure also demonstrated a clinically relevant improvement in physical health with an increase of 6.0 points (14%) from baseline; $p$ value $< 0.004$ (95% CI: 45.3, 52.5) (see Table 6). This improvement has a large effect size ($Cohen \ d = 0.85$) with a moderate observed power of 0.86 as calculated using G*Power$^{51}$ (mean of difference 6.0, standard deviation of difference of 7.1). The clinically relevant improvement in SF-12 Physical Health
Status was illustrated in the moderate rise in mean scores after treatment intervention, compared to the relatively constant values during the baseline period (see Figure 4).

There was no meaningful result in the case of the SF-12 Mental Health score, with a small increase of 3.7 points from the baseline mean of 47.1 points; \( p = 0.323 \) (95% CI: 45.4, 56.1) (see Table 6).

[Insert Table 6]

[Insert Figure 4]
DISCUSSION

The aim of this study was to investigate the efficacy of pragmatic OMT for chronic NSLBP in a population of poultry factory workers. There was a clinically relevant improvement in the low back pain intensity and functional disability of the study population. The effect sizes for both of these measures were very high and according to Hopkins\textsuperscript{53, 54} have a very high likelihood to have a beneficial clinical treatment effect. This beneficial treatment effect was in agreement with the lack of any overall negative treatment effect in the study population, and the majority of participants who had demonstrated a positive treatment response (60%). Trend analysis indicated that prior to treatment participants had demonstrated a small consistent increase in their low back pain intensity, which changed after treatment to a steep decrease in their low back pain intensity (see Table 5). These clinically relevant improvements in low back pain intensity are unlikely to have been a natural product of regression towards the mean. The suggested improvement in low back pain intensity was likely due to the treatment received, despite the lack of a control group in the study, as participants had suffered from NSLBP for an average of 6.6 years. To calculate the degree of any regression towards the mean effect, or the natural tendency of an individual to return towards their state of health over time, this study used a statistical analysis by Mee\textsuperscript{49}. The results of the analysis failed to show any effect of regression towards the mean in this study population.

The potential clinically relevant improvements in pain intensity and functional disability of participants in the study after manual therapy treatment, are in agreement with similar high quality, pragmatic based studies by Aure\textsuperscript{20} and Niemisto et al.,\textsuperscript{22}
and the reviews of moderate quality from Licciardone et al.,55 Andersson et al.,56 and Gibson et al.57. The proposed finding of this study that large reductions in low back pain intensity are linked to a pragmatic treatment approach, is in agreement with similar findings from Aure,20 and Niemisto et al.22 A single treatment intervention may be insufficient to produce a large reduction in the low back pain intensity of participants with chronic NSLBP. Trials by Licciardone et al.,55 Andersson et al.,56 and Gibson et al.,57 that used a single treatment intervention strategy for chronic NSLBP, demonstrated a smaller treatment effect than trials using a pragmatic treatment approach like those of Aure,20 and Niemisto et al.22 The effectiveness of a pragmatic treatment approach may be due to the multi-factorial nature of chronic NSLBP where the participants may suffer from one or more conditions.20-22, 55-57 In this scenario it may be unreasonable to expect a single treatment technique to resolve all of their low back pain.

There were six participants who did not respond, either negatively or positively to the treatment intervention, one possible explanation may be the higher initial low back pain intensities observed in the baseline VAS scores of the positive responders (mean VAS = 28.1mm). In comparison the baseline VAS scores of the non-responders to treatment were considerably lower (mean VAS = 6.5mm) (see Table 5). It has been argued by Ostelo et al.,30 and Kovacs et al.,42 that one would be less likely to observe reductions in mean low back pain intensities in those participants whose low back pain intensity is already relatively low. Rather larger falls in low back pain are to be expected in a population with levels of low back pain intensity that are already relatively high. Another possible explanation for the reduced treatment response in the non-responders may be the rate at which participant’s low back pain intensity reduced
over time. The rate of reduction in low back pain intensity on VAS in the non-
responders, was more than half of the rate of participants who were positive
responders (see Table 5). In other words, the positive responders at baseline had
already shown a trend for larger reductions in low back pain intensity on VAS, which
may suggest the participants were stratified in their response to treatment for chronic
NSLBP; a future analysis of covariance with a larger study population may find a
reason for the difference between the participants.

Correlation coefficients greater than 0.8 are necessary in order to be considered
reliable, although Chinn\textsuperscript{38} suggests that for reliability in a clinical context, a
correlation coefficient value greater than 0.6 would be adequate. Apart from the SF-
12 Physical Health Status aggregate measure, test-retest reliability measures for VAS,
QBPDS and SF-12 measures were found to be reliable (see Table 4).

The observed powers for VAS and QBPDS outcome measures were found to be very
high (0.999 and 0.971 respectively), and suggest that the study was adequately
powered to observe the measured treatment effects (see Table 6). The lower observed
power for the SF-12 measure would suggest that it is slightly less sensitive than VAS
and QBPDS, and may require a larger sample size.

The majority of research for pain intensity in chronic NSLBP has been performed in
Europe and North America, involving mostly heterogeneous study populations.\textsuperscript{27, 30, 38,
At the time of submission, this may be the first OMT based study to report clinical MCICs for VAS, QBPDS and SF-12 scores in a homogeneous sample of Maori and Pacific Islands factory workers with chronic NSLBP. In this context, the findings of this study may be more relevant to the New Zealand population than previous studies on chronic NSLBP.

The test re-test measurement error between questionnaires has been cited as a possible reason for the reduced significance of reported outcome measures in subjective studies. Any increase in measurement error of VAS, QBPDS and SF-12 measures decreases the minimum detectable change, and therefore decreases the sensitivity of the study. In an attempt to minimise measurement error the following three approaches were taken: (1) a within subjects design to eliminate the between subject variance (e.g. paired Student t-test), (2) a separate study to assess the error variance of the outcome measures prior to the treatment intervention, and (3) participants were given clear instructions and assistance on how to complete the questionnaires. The high correlation coefficients recorded in the separate reliability studies suggest that measurement error variance in all outcome measures was minimal, and acceptable (see Table 2).

The decision to recruit participants with a narrow set of inclusion criteria was taken to increase the homogeneity of the study population, and increase the potential of the study to detect a treatment effect. The study population included participants with criteria such as: age (44 years, sd = 9.0), BMI (34, sd = 4.9), and workplace (poultry factory population). A possible drawback of this approach may be the limitation of
any findings to a subset of the general population (i.e. Maori and Pacific Islands factory workers).

Despite the large reductions in pain intensity, and decrease in functional disability suggested by this study, the single cohort design prevents a direct correlation between any such improvements and the treatment intervention. In single cohort designs due to the lack of treatment control groups, any observed treatment effect might be due to other factors (e.g. the tendency for participants low lack pain to naturally reduce over time). Results from RCTs by Aure,20 Bronfort et al.,13 Licciardone et al.,55 and Niemisto at al.22 suggest the importance of control groups to control for bias. These studies reported meaningful improvements in pain intensity and functional disability in the treatment group, but no meaningful effect when compared to the control groups. Despite the apparent clinically relevant findings observed in this study, the lack of a treatment control group for bias is the one of biggest limitations of this study. Given the difficulty of adequate sham control groups in manual therapy studies,65, 66 the inclusion of a no treatment or ‘wait-list’ group may be worthy of consideration in any future follow on study.
Limitations of the study

One limitation of this study was the selection of a small sample size from a local population, which is unlikely to represent a diverse population. Whilst this homogeneous sample may have aided in the observation of a treatment effect, it is unlikely that these results could be generalised to a larger population, and therefore the findings of this study are of limited applicability.

This study suggests that three, short duration tailored OMT sessions can achieve clinically relevant improvements in participant’s health. The one-week follow-up period is a limitation that permits only short-term conclusions to be drawn from the results. A follow-up period of six months, as used in other studies in this area, would allow deductions about the long-term duration of any potential treatment effect to be determined.

This study was unable to recruit sufficient participants to perform a randomised controlled trial design with at least two groups: treatment group and control group. One limitation of current manual therapy research has been the lack of a clinically relevant treatment effect, once results were compared against a control group. The potentially relevant treatment effect observed by this study can not be ascribed to the osteopathic treatment intervention without an adequate treatment control group. Any larger future studies should address this limitation.
No analysis of covariance was performed to assess for potential effects of external variables such as: job role, ethnicity, age, years duration of NSLBP, and BMI. In order to perform adequate analysis of covariance in any future study, a much larger sample size would be necessary, as the size of the sub analysis categories in this study were too small at two to five participants.
CONCLUSION

Application of osteopathic techniques, specifically selected for the individual, appear to have demonstrated an effect greater than the MCIC for VAS and QBPDS in a population of Maori and Pacific Islands poultry factory workers. A follow up investigation to assess whether this potential beneficial effect can be maintained long term is recommended.
REFERENCES


SECTION III - APPENDICES
Appendix A – Reliability analysis of baseline outcome measures

Introduction

This reliability study was undertaken to establish the reliability of the proposed outcome measures for the pilot study into the efficacy of a pragmatic OMT intervention for chronic non-specific low back pain. Previous studies have reported the validity of such outcome measures in the treatment of low back pain. This study assessed the reliability of the proposed outcome measures in the homogeneous study population of poultry factory workers. The five-week baseline period prior to the onset of the treatment intervention was used to determine if the outcome measures were of satisfactory reliability. A moderate to high ICC score for each outcome measure in this study population would suggest high reliability of the proposed outcome measures in the target population. Poor reliability ICC scores from the baseline data would suggest that modification of the study design might be necessary prior to the onset of the intervention phase.

The secondary aim of this study was to determine if there was any treatment effect during the baseline period. The absence of any such effect would suggest that the pain intensity and functional disability scores of the study population was ‘stable’. A stable baseline period would add ‘weight’ to any treatment effect that might be detected in the future intervention phase.
**Intrareliability coefficients (ICC)**

Intra-class Correlation Coefficients (ICC) have been widely used to demonstrate the reliability of outcome measure questionnaires in manual therapy interventions. These ICC scores provide a concise method of reporting the degree of reliability of such tools. Intra-class Correlation Coefficients were calculated from the three recorded baseline measurements using commonly approved methods.\(^{53, 63, 68, 69}\) Values were reported in Table 2, and these were compared against previously reported values.\(^{33, 39, 70-76}\)

[Insert table 2]

**Methods**

Participants were recruited from a poultry factory workforce located in Auckland, New Zealand, using poster advertisement. Eligible participants were interviewed by the study organizer who explained the research protocol to the participants, and obtained verbal and written informed consent. Over the course of five weeks, three baseline measurements were recorded for VAS, QBPDS and SF-12 measures, at one, three and week intervals. The proposed outcome measurements to be investigated were chosen for high validity and reliability in the area of chronic non-specific low back pain with manual therapy interventions.
**Data Analysis**

Raw data were checked for errors and assessed for normality. Non-normally distributed data were log transformed. Participant’s baseline VAS, QBPDS and SF-12 scores were analysed using a repeated measures ANOVA to assess the stability of the baseline data, and assess if there was any evidence of a treatment effect in the baseline data. All statistical analyses were performed using SPSS version 16 for Microsoft Windows® (SPSS Inc. Chicago, IL, USA); effect sizes and observed power calculations were performed using G*Power version 3.0.10 for Mac OSX®.

**Results**

The scores recorded from VAS, QBPDS and SF-12 measures during the baseline demonstrated a consistent, repeatable mean score trend. The results for VAS illustrated a consistent increase in the mean low back pain intensity score (see Figure 2). Intra-class Correlation Coefficients (ICC) were derived from the three recorded baseline measurements using methods documented from Hopkins,52 and using the reliability function from SPSS version 16 for Microsoft Windows®, and these values were reported in Table 2. Results for the ICCs were in agreement with previous reliability studies as reported in Table 7. Compared against previously reported reliability values, all baseline outcome measures, except the SF-12 Physical Health Status, were found to be reliable. The reliability value for the SF-12 Physical Health Status was found to be moderately reliable. Results from the repeated measures ANOVA of the baseline scores on VAS did not show any evidence of a treatment effect. Pairwise comparisons between each of the three baselines were not significant; $p$ values > 0.356 (see Table 8).
Discussion

Previous studies have demonstrated a high validity and reliability for each of the three outcome measures to be used in the treatment phase of this study. Values from this reliability investigation reported ICC values of similar reliability to previous studies for chronic NSLBPP. Whilst the number of measurements performed could have been greater and ideally over a longer time period, the results suggest the reliability of the VAS, QBPDS and SF-12 measures were acceptable.

Conclusion

The baseline VAS, QBPDS, and SF-12 outcome measures recorded from the poultry factory study population were valid, and demonstrated moderate to high reliability. Each of these outcome measures has demonstrated sufficient reliability for use in the treatment phase of this study, and no change to this study design appears to be necessary.
Appendix B – Figures

Figure 1 - Equation for calculation of regression to the mean

Equation for the calculation of the degree of regression towards to the mean present in a sample of baseline data from an analysis performed by Mee. The equation uses values from the baseline study population and recorded outcome measures to produce a value that can be used to determine if, and to what extent a regression towards the mean effect has occurred.
After discussion of the exclusion criteria with all the subjects, 3 were excluded from the study before onset, and 17 participants entered the baseline data collection. Two participants were excluded before the first treatment because of (a) personal reasons and (b) due to consumption of an herbal supplement that masked pain (both were included in the baseline data). In total 15 participants entered the treatment phase. During the treatment phase, two further participants declined to take any further part in the intervention phase, (a) due to a painful reaction to the second treatment, and (b) because they no longer had any NSLBP after their first treatment. Both agreed to complete a follow up questionnaire, and entered intention to treat analysis on that basis.
Figure 3 - Graph of the change in VAS from baseline to follow-up

Plot of overall mean VAS score (y axis; low back pain intensity in mm) against treatment intervention (x axis; baseline and treatment interventions in weeks). Data points plotted at baseline (weeks 0, 3 and 5), and treatment (weeks 6, 7 and 8). Each data point includes a 95% confidence interval bar. The final follow up score on VAS is clinically relevant as the confidence interval lies outside of the mean baseline confidence interval.
Figure 4 - Graph of change of all outcome measures from baseline to follow-up

Plot of overall mean of QBPDS, SF-12 Physical Health Status, and SF-12 Mental Health Status score (y axis; pain scale in points from 0 to 100) against treatment intervention (x axis; baseline and treatment interventions in weeks). Data points plotted at baseline (weeks 0, 3 and 5), and treatment (weeks 6, 7 and 8).
Table 1 - List of permitted manual therapy techniques

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft Tissue Technique</td>
<td>Passive technique applied by the hands, similar to massage, to areas of the body with muscle or tissue tightness. Rhythmic or inhibitory technique. Treatment duration may be several minutes.</td>
</tr>
<tr>
<td>High Velocity Low Amplitude Thrust</td>
<td>Passive technique involving a small thrust force to restricted joints of the body by use of the hands. No cervical manipulation will be undertaken. Treatment duration is approx. 10 seconds.</td>
</tr>
<tr>
<td>Muscle Energy Technique</td>
<td>Active technique applied by the hands to any joint of the body. Treatment duration may be from 30-60 seconds.</td>
</tr>
<tr>
<td>Strain Counter Strain</td>
<td>Passive technique applied by the hands to any joint of the body. Treatment duration of at least 90 seconds, or even longer.</td>
</tr>
<tr>
<td>Myofascial Release</td>
<td>Passive technique applied by the hands to any tissue tightness, or restriction of the body. Treatment duration of 30-90 seconds.</td>
</tr>
<tr>
<td>Articulation</td>
<td>Passive technique applied by the hands to any joint of the body. Treatment duration of approx. 30-60 seconds.</td>
</tr>
<tr>
<td>Functional Technique</td>
<td>Passive technique applied by the hands to any joint of the body. Treatment duration of 1-3 minutes.</td>
</tr>
<tr>
<td>Visceral Technique</td>
<td>Passive technique applied by the hands to any visceral structure (e.g. liver) of the body. Treatment duration of 1-3 minutes.</td>
</tr>
<tr>
<td>Balanced Ligamentous Tension</td>
<td>Passive technique applied by the hands to any tissue restriction of the body. Treatment duration of 30-90 seconds.</td>
</tr>
<tr>
<td>Facilitated Positional Release</td>
<td>Passive technique applied by the hands to any restricted joint of the body. Treatment duration of 30-90 seconds.</td>
</tr>
<tr>
<td>Fascial-Ligamentous Release</td>
<td>Passive technique applied by the hands to any tissue restriction of the body. Treatment duration of 30-90 seconds.</td>
</tr>
</tbody>
</table>
Table 2 - Outcome measures test re-test reliability measures

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Internal Validity (Cronbach α)</th>
<th>ICC$^1$</th>
<th>ICC$^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS</td>
<td>0.82</td>
<td>0.71</td>
<td>0.80</td>
</tr>
<tr>
<td>QBPDS</td>
<td>0.85</td>
<td>0.77</td>
<td>0.85</td>
</tr>
<tr>
<td>SF12-PCS</td>
<td>0.70</td>
<td>0.61</td>
<td>0.70</td>
</tr>
<tr>
<td>SF12-MCS</td>
<td>0.90</td>
<td>0.84</td>
<td>0.90</td>
</tr>
</tbody>
</table>

$^1$ - ICC from method outlined by Hopkins.64
$^2$ - ICC from SPSS as outlined by Griffin & Gonzalez.77 and Shrout & Fleiss.69

ICC = Intraclass Correlation Coefficient; Values calculated from methods described by.
Table 3 - Characteristics of sample population

<table>
<thead>
<tr>
<th>Subject demographics</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years</td>
<td>Mean (SD)</td>
<td>44 (9.0)</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>45</td>
</tr>
<tr>
<td>Gender</td>
<td>Number Males</td>
<td>6 (40%)</td>
</tr>
<tr>
<td></td>
<td>Number Females</td>
<td>9 (60%)</td>
</tr>
<tr>
<td>Ethnicity (%)</td>
<td>Maori</td>
<td>33%</td>
</tr>
<tr>
<td></td>
<td>NZ/Euro</td>
<td>27%</td>
</tr>
<tr>
<td></td>
<td>Samoan</td>
<td>20%</td>
</tr>
<tr>
<td></td>
<td>Cook</td>
<td>13%</td>
</tr>
<tr>
<td></td>
<td>Fijian/Indian</td>
<td>7%</td>
</tr>
<tr>
<td>Mean BMI (SD)</td>
<td>34 (4.9)</td>
<td></td>
</tr>
<tr>
<td>Years NSLBP (SD)</td>
<td>6.8 (9.0)</td>
<td></td>
</tr>
<tr>
<td>Job Role (%)</td>
<td>Factory</td>
<td>73%</td>
</tr>
<tr>
<td></td>
<td>Factory/Admin</td>
<td>27%</td>
</tr>
</tbody>
</table>

Demographics of the sample population of poultry factory workers in West Auckland, New Zealand. Mean values with standard deviation, and percentages are given with normally distributed data.
Table 4 - Minimum clinically important change

<table>
<thead>
<tr>
<th></th>
<th>n ≤ -MCIC n subjects (%)</th>
<th>No MCIC n subjects (%)</th>
<th>n ≥ +MCIC n subjects (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS</td>
<td>0 (0)</td>
<td>6 (40)</td>
<td>9 (60)</td>
</tr>
<tr>
<td>QBPDS</td>
<td>0 (0)</td>
<td>9 (60)</td>
<td>6 (40)</td>
</tr>
<tr>
<td>SF12-PCS</td>
<td>1 (7)</td>
<td>5 (33)</td>
<td>9 (60)</td>
</tr>
<tr>
<td>SF12-MCS</td>
<td>5 (33)</td>
<td>3 (20)</td>
<td>7 (47)</td>
</tr>
</tbody>
</table>

VAS = Visual Analogue Scale; QBPDS = Quebec Back Pain Disability Scale; SF12-PCS = Short Form 12 General Health Questionnaire for Physical Health (PCS) and Mental Health (MCS); MCIC = Minimum Clinically Important Change.

Total number of participants = 15; MCIC values for VAS, QBPDS, SF-12 are 15mm, 15points, and 5points respectively in the case of chronic NSLBP.
Table 5 - Regression analysis of the primary outcome measure (VAS)

<table>
<thead>
<tr>
<th>Type</th>
<th>Numbe</th>
<th>Mean baseline VAS</th>
<th>Mean VAS change</th>
<th>Mean baseline slope</th>
<th>Mean treatment slope</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Responders (-MCIC)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Non Responders (no MCIC)</td>
<td>6</td>
<td>25 (11.4)</td>
<td>6.5 (5.3)</td>
<td>8.2 (13.9)</td>
<td>-1.3 (7.3)</td>
</tr>
<tr>
<td>Responders (+MCIC)</td>
<td>9</td>
<td>39 (17.2)</td>
<td>28.1 (7.8)</td>
<td>3.4 (11.8)</td>
<td>-10.5 (5.6)</td>
</tr>
</tbody>
</table>

VAS = Visual Analogue Scale; MCIC = Minimum Clinically Important Change.

Fifteen participants were classed as negative responders if their pain intensity increase was greater than or equal to the VAS MCIC, or responders if their pain intensity decreased by greater or equal to the VAS MCIC. If participant’s change in pain intensity was outside of the VAS MCIC then they were classed as non-responders.

Mean baseline slopes values are derived from the slopes of the linear regression lines for the baseline and treatment phases.
Table 6 - Outcome measures across interventions with paired t-tests

<table>
<thead>
<tr>
<th></th>
<th>Mean (SD)</th>
<th>95% CI</th>
<th>P value</th>
<th>Effect size (Cohen d)</th>
<th>Effect size descriptor</th>
<th>Observed power</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>VAS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>33.8 (16.9)</td>
<td>25.3 – 42.4</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment 1</td>
<td>31.5 (17.2)</td>
<td>22.8 – 40.2</td>
<td>( p = 0.686 )</td>
<td>0.13</td>
<td>trivial</td>
<td>0.08</td>
</tr>
<tr>
<td>Treatment 2</td>
<td>20.3 (14.7)</td>
<td>12.9 – 27.4</td>
<td>( p &lt; 0.002 )</td>
<td>0.92</td>
<td>large</td>
<td>0.91</td>
</tr>
<tr>
<td>Treatment 3</td>
<td>13.3 (9.5 )</td>
<td>8.5 – 18.1</td>
<td>( p &lt; 0.0001 )</td>
<td>1.50</td>
<td>very large</td>
<td>0.999</td>
</tr>
<tr>
<td><strong>QBPDS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>26.3 (15.6)</td>
<td>18.4 – 34.2</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment 1</td>
<td>18.5 (13.1)</td>
<td>18.4 – 34.2</td>
<td>( p &lt; 0.017 )</td>
<td>0.70</td>
<td>medium</td>
<td>0.71</td>
</tr>
<tr>
<td>Treatment 2</td>
<td>14.1 (10.8)</td>
<td>8.63 – 19.6</td>
<td>( p &lt; 0.002 )</td>
<td>0.91</td>
<td>large</td>
<td>0.91</td>
</tr>
<tr>
<td>Treatment 3</td>
<td>11.2 (9.7 )</td>
<td>6.29 – 16.1</td>
<td>( p &lt; 0.001 )</td>
<td>1.08</td>
<td>large</td>
<td>0.97</td>
</tr>
<tr>
<td><strong>SF12-PCS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>42.9 (6.0 )</td>
<td>39.9 – 46.0</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment 1</td>
<td>45.5 (7.6 )</td>
<td>41.7 – 49.4</td>
<td>( p = 0.146 )</td>
<td>0.40</td>
<td>small</td>
<td>0.30</td>
</tr>
<tr>
<td>Treatment 2</td>
<td>45.2 (6.2 )</td>
<td>42.1 – 48.3</td>
<td>( p = 0.167 )</td>
<td>0.38</td>
<td>small</td>
<td>0.27</td>
</tr>
<tr>
<td>Treatment 3</td>
<td>48.9 (7.1 )</td>
<td>45.3 – 52.5</td>
<td>( p \leq 0.004 )</td>
<td>0.85</td>
<td>large</td>
<td>0.86</td>
</tr>
<tr>
<td><strong>SF12-MCS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>47.1 (10.3)</td>
<td>41.9 – 52.3</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment 1</td>
<td>49.0 (13.7)</td>
<td>42.1 – 55.9</td>
<td>( p = 0.401 )</td>
<td>0.22</td>
<td>small</td>
<td>0.13</td>
</tr>
<tr>
<td>Treatment 2</td>
<td>51.1 (9.8 )</td>
<td>46.1 – 56.0</td>
<td>( p = 0.154 )</td>
<td>0.38</td>
<td>small</td>
<td>0.28</td>
</tr>
<tr>
<td>Treatment 3</td>
<td>50.8 (10.6)</td>
<td>45.4 – 56.1</td>
<td>( p = 0.323 )</td>
<td>0.26</td>
<td>small</td>
<td>0.16</td>
</tr>
</tbody>
</table>

VAS = Visual Analogue Scale; QBPDS = Quebec Back Pain Disability Scale; SF12-PCS = Short Form 12 General Health Questionnaire for Physical Health (PCS) and Mental Health (MCS).
Values are expressed as mean (Standard Deviation) and 95% Confidence Intervals, recorded one-week post intervention at 1, 2 and 3 weeks; except baseline values that were recorded pre treatment, over 5 weeks at 1, 3 and 5 week intervals.
<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Study</th>
<th>ICC(^1)</th>
<th>CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS</td>
<td><em>Lenert</em> 2000</td>
<td>0.82</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td><em>Bijur et al.</em> 2001</td>
<td>0.99</td>
<td>(0.989 - 0.992)</td>
</tr>
<tr>
<td></td>
<td><em>Gallagher, Bijur, Latimer, Silver</em> 2002</td>
<td>0.97</td>
<td>(0.97 - 0.98)</td>
</tr>
<tr>
<td></td>
<td><em>Yip, Tse &amp; Wu</em> 2007</td>
<td>0.98</td>
<td>na</td>
</tr>
<tr>
<td>QBPDS</td>
<td><em>Davidson &amp; Keating</em> 2002</td>
<td>0.84</td>
<td>(0.73 – 0.91)</td>
</tr>
<tr>
<td>SF12-PCS</td>
<td><em>Ware, Kosinski, &amp; Keller, 1996</em></td>
<td>0.89</td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Resnick &amp; Parker</em> 2001</td>
<td>0.73</td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Haywood, et al.</em> 2002</td>
<td>0.90</td>
<td>(0.86 – 0.92)</td>
</tr>
<tr>
<td></td>
<td><em>Bohannon et al.</em> 2004</td>
<td>&gt;0.80</td>
<td></td>
</tr>
<tr>
<td>SF12-MCS</td>
<td><em>Ware, Kosinski, &amp; Keller, 1996</em></td>
<td>0.76</td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Resnick &amp; Parker</em> 2001</td>
<td>0.86</td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Haywood, et al.</em> 2002</td>
<td>0.79</td>
<td>(0.73 – 0.84)</td>
</tr>
<tr>
<td></td>
<td><em>Bohannon et al.</em> 2004</td>
<td>&gt;0.80</td>
<td></td>
</tr>
</tbody>
</table>

VAS = Visual Analogue Scale; QBPDS = Quebec Back Pain Disability Scale; SF12-PCS = Short Form 12 General Health Questionnaire for Physical Health (PCS) and Mental Health (MCS); CI = 95% Confidence Interval.

\(^1\) -- ICC from SPSS as outlined by Griffin & Gonzalez, \(^68\) and Shrout & Fleiss. \(^69\)
Table 8 – Repeated measures ANOVA of baseline period VAS

<table>
<thead>
<tr>
<th>Baseline Week 1</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline 2</td>
<td>0.705</td>
<td>14.7 – 33.9</td>
</tr>
<tr>
<td>Baseline 3</td>
<td>0.356</td>
<td>0.6 – 35.5</td>
</tr>
<tr>
<td>Baseline Week 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>baseline 1</td>
<td>0.705</td>
<td>27.9 – 47.1</td>
</tr>
<tr>
<td>baseline 3</td>
<td>0.618</td>
<td>14.0 – 39.7</td>
</tr>
<tr>
<td>Baseline Week 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>baseline 1</td>
<td>0.356</td>
<td>32.6 – 67.5</td>
</tr>
<tr>
<td>baseline 2</td>
<td>0.618</td>
<td>32.8 – 58.5</td>
</tr>
</tbody>
</table>

Results from repeated measures ANOVA statistical analysis of pairwise comparisons between each of the baseline scores on VAS. Values shown as p-values and 95% confidence intervals.
Appendix D – Raw Data

The following pages show the raw data recorded from the outcome measure questionnaires during the baseline and treatment intervention phases. The data has been output from a ‘screen capture’ from a Microsoft® Excel spreadsheet that contained the validated data collected from the study.
Appendix E – Information and consent forms

An Investigation into the Efficacy of Osteopathic Manipulative Treatment (OMT) on Chronic Low Back Pain in Factory Workers

Consent Form

This research project is to investigate the change in low back pain and general health outcome measures by a clinical based osteopathic treatment approach, using a combination of agreed OMT techniques. The research is being undertaken by Simon Yardley from Unitec New Zealand, and will be supervised by Dr Andy Stewart and Dr Graham Fordy.

Name of Participant: ........................................................................................................

I have seen the Information Sheet dated March 2009 for people wishing to participate in the project investigating the change in low back pain intensity and general health outcome measures by clinical based OMT.

I have had the opportunity to read the contents of the information sheet, and to discuss the project with the researcher or a support person, and I am satisfied with the explanations that I have been given.

I understand that taking part in this project is voluntary (my choice), and that I may withdraw from this study for any reason, at any time up until the last assessment (treatment) session. Any such withdrawal will in no way affect my access to the services provided by Unitec New Zealand, or any other support service.

I understand I may need to remove any outer clothing covering the upper body (shirts/blouses etc), from the waist up [NOT underwear].

I understand all data will be kept for a maximum of five years, during which time it may be used for further research purposes. After five years all data related to me from this study, will be destroyed.

I understand that I can withdraw from this study for any reason if I want to, up until after the last assessment (treatment) session.

I have had sufficient time to consider whether I want to take part or not.

I know whom to contact if I have any questions or concerns about this study.

The principal researcher and first contact for this project is:

Simon Yardley
021 152 1774
mailto: nzosteopath@gmail.com

Signature...................................................................................................................(Date)

Project explained by:.................................................................................................

Signature...................................................................................................................(Date)

The participant should retain a copy of this consent form.

This study has been approved by UREC Ethics Committee from March 2009 to December 2009. If you have concerns about the way in which the research is being conducted you can contact the following: Health Advocates: Advocates Network Services Trust, Phone (09) 623 5799, 0800 205 555, Fax (09) 623 5798, PO Box 9983, Newmarket, Auckland. Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.
An Investigation into the Efficacy of Osteopathic Manipulative Treatment (OMT) on Chronic Low Back Pain in Factory Workers

Information Sheet

About the Research
You are invited to take part in a research project being undertaken by Simon Yardley as part of the Masters of Osteopathy Degree at Unitec, New Zealand. Simon Yardley is the principal researcher and not a qualified or registered osteopath. This information sheet is designed to inform you as to the nature of the research project and what will happen should you choose to take part.

The purpose of this research is to investigate the change in low back pain intensity after osteopathic treatment. We are recruiting individuals who currently (at this time) have low back pain.

It is hoped that the information gained from this research will help osteopaths when making treatment decisions in the management of patients, and assist in the design of future osteopathic research.

The treatment approach will be decided and performed by a qualified, New Zealand registered osteopath. The treatment techniques performed will be chosen from an allowed list of techniques that commonly occur in osteopathic treatment (these techniques are summarized in a table at the end of this information sheet). The treatment may involve hands placed on the participant’s back, hips, arms or legs – potentially applied several times, and in any order that the osteopath deems appropriate. It is hoped that this approach will mimic the style of treatment received by a patient when they see an osteopath in an osteopathic clinic.

The practitioner may ask you questions about your low back pain, and/or your life in general. This is to better understand the most likely cause of your low back pain – you will be instructed that you may decline to answer any or all of these questions. None of these answers will be formally recorded by the practitioner or researcher, but may be used to better tailor the treatment you receive. In general each technique consists of hand contact and gentle pressure to various areas of your body – you will be instructed that you can stop the treatment at any time.

You have the right not to participate in this study, or to withdraw from it at any time up until the last assessment (treatment) session. To do so you may contact either Simon Yardley or Dr Andy Stewart (see contact details below), and inform them that you no longer wish to participate in this study.

A summary of the results of the study will be made available for all workers to view, even those who did not take part in the study, and without the need for a request to your employer. This will be achieved by placement of a copy on the workers noticeboard. A copy of the final report will also be available from the Unitec library, and from the health and safety officer at Tegel Foods Inc. Summaries and recommendations may be published in research journals, but your name will be kept anonymous (not printed).

The Research Team
The principal researcher is Simon Yardley. The registered osteopathic practitioner, who will apply the treatments, will be Philip Rowe. Dr Andy Stewart and Dr Graham Fordy will be supervising the research project, but may not be present during the study.
What will participation involve?

- Reading of this document and completion of a screening questionnaire on General Health and Musculoskeletal Injuries, that may prevent you from participating in the project. This should take no more than 15 minutes to complete.

- Be available during work hours, without loss of pay, for three assessments (paper based survey questions), three treatments, and one follow up assessment (paper based survey questions). Each assessment or treatment session should last no more than 20 minutes.

- Your participation in this study should require approx. two hours of your time over the next six weeks.

- The osteopathic treatment will be performed by Philip Rowe, a New Zealand registered Osteopath, in a private room that cannot be observed by other workers or Tegel Foods management.

- The principal researcher, Simon Yardley, will collect data from you via questionnaires regarding your general health, and your current (at this time) low back pain intensity.

- As this is an experimental design study, you will expected to complete several research questionnaires and receive three osteopathic treatments.

- In order to participate you are required to sign the consent form.

- This research prefers a participant (you) to remove any outer clothing covering the upper body (shirts/blouses etc), from the waist up, but not your underwear. If you prefer not to remove ANY clothing then you do not have to do so, and may withdraw from the study.

- All treatment will be applied by a male osteopath, if you prefer not to be treated by a male osteopath you may withdraw from this study now.

- You are free to withdraw from this study at any point, and you do not need to state a reason why you chose to do so.

- Consent to the research team’s use of your data in preparation of both a research project dissertation, and an article for publication. Note that all data will be anonymous and will not be shared with your employer.

- Consent to the storage of your anonymous research data for a maximum of five years after completion of this study. After five years this data will be destroyed.

Getting help

Please contact either one of us should you require help with this research project.

Simon Yardley     Email: nzosteopath@gmail.com     Phone: 021 152 1774
Dr Andy Stewart   Email: astewart@unitec.ac.nz     Phone: (09) 815 4321 ext 8384
Dr Graham Fordy  Email: gfordy@unitec.ac.nz     Phone: (09) 815 4321 ext 7908
Potential risks to research participants

There may be a treatment reaction, increase in your pain, from this osteopathic treatment. For example this could involve a muscle ache the day after the treatment was applied – similar to muscle stiffness after performing exercise for the first time in many weeks (e.g. in the garden). The research team and registered osteopath have attempted to minimize all potential risk, however it is possible there may be some undetermined risks involved in this research process. In the event that any potential risk of harm or increase in pain should arise for any participant (you), it will be treated on an individual and confidential basis. This may involve medical care, a nurse or doctor, to be contacted if requested by you, or may be suggested to you by the osteopath or Simon Yardley. In any such case the research process will be halted immediately.

Confidentiality

Confidentiality and your anonymity will be protected in the following ways:

- Your employer will not see, or have knowledge of your results or participation in this research.
- Only the researchers will see completed questionnaires and consent forms.
- All forms will be stored in a locked file. Only the researchers will have access to this file.
- Any data derived from this research will be made anonymous, and your identity not made public.

Information and concerns

If you want further information about the project, you can call or email the above addresses. At anytime if you are concerned or confused about the research project you may contact Simon Yardley, the primary researcher at the details above.

If you have concerns about the way in which the research is being conducted you can contact the following:

Health Advocates: Advocates Network Services Trust, Phone (09) 623 5799, 0800 205 555, Fax (09) 623 5798, PO Box 9983, Newmarket, Auckland. Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.
Permitted Osteopathic Techniques

This is a summary of the osteopathic techniques that may be applied by the practitioner as part of the treatment sessions.

In each summary technique below, the use of hands refers to the practitioners hands. The treatment term ‘passive’ means that there is no requirement of any actions (e.g. body movement) from the participant. The term ‘active’ requires the participant to use their muscles when requested by the practitioner.

Each of the technique summaries below has been compiled from details listed in ‘well regarded’ osteopathic treatment publications (Hartman, 1996; Parsons & Marcer, 2006; Ward, 2003).

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft Tissue Technique</td>
<td>Passive technique applied by the hands, similar to massage, to areas of the body with muscle or tissue tightness.</td>
</tr>
<tr>
<td></td>
<td>Rhythmlical or inhibitory technique. Treatment duration may be several minutes.</td>
</tr>
<tr>
<td>High Velocity Low Amplitude Thrust</td>
<td>Passive technique involving a small thrust force to restricted joints of the body by use of the hands.</td>
</tr>
<tr>
<td></td>
<td>No cervical manipulation will be undertaken. Treatment duration is approx. 10 seconds.</td>
</tr>
<tr>
<td>Muscle Energy Technique</td>
<td>Active technique applied by the hands to any joint of the body. Treatment duration may be from 30-60 seconds.</td>
</tr>
<tr>
<td>Strain Counter Strain</td>
<td>Passive technique applied by the hands to any joint of the body. Treatment duration of at least 90 seconds, or even longer.</td>
</tr>
<tr>
<td>Myofascial Release</td>
<td>Passive technique applied by the hands to any tissue tightness, or restriction of the body. Treatment duration of 30-90 seconds.</td>
</tr>
<tr>
<td>Articulation</td>
<td>Passive technique applied by the hands to any joint of the body. Treatment duration of approx. 30-60 seconds.</td>
</tr>
<tr>
<td>Functional Technique</td>
<td>Passive technique applied by the hands to any joint of the body. Treatment duration of 1-3 minutes.</td>
</tr>
<tr>
<td>Visceral Technique</td>
<td>Passive technique applied by the hands to any visceral structure (e.g. hwe) of the body. Treatment duration of 1-3 minutes.</td>
</tr>
<tr>
<td>Balanced Ligamentous Tension</td>
<td>Passive technique applied by the hands to any tissue restriction of the body. Treatment duration of 30-90 seconds.</td>
</tr>
<tr>
<td>Facilitated Positional Release</td>
<td>Passive technique applied by the hands to any restricted joint of the body. Treatment duration of 30-90 seconds.</td>
</tr>
<tr>
<td>Fascial-Ligamentous Release</td>
<td>Passive technique applied by the hands to any tissue restriction of the body. Treatment duration of 30-90 seconds.</td>
</tr>
</tbody>
</table>

Note no spinal techniques will be permitted due to head contact and lack of time in intervention.

Appendix F – Questionnaires

Questionnaire on General Health and Musculoskeletal Injuries

<table>
<thead>
<tr>
<th>Participant number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>My gender is:</td>
</tr>
<tr>
<td>O Male</td>
</tr>
<tr>
<td>O Female</td>
</tr>
<tr>
<td>My age is:</td>
</tr>
<tr>
<td>My ethnicity is:</td>
</tr>
</tbody>
</table>

1. Have you recently received, or are you presently receiving treatment for any muscle, bone, or joint disorder? If yes, please explain.

2. Do you experience any low back pain now, or have you experienced low back pain in the last year?

3. Have you received any treatment for low back pain in the last week?

   If you experience pain in ANY of the above situations, please fill out the body map/pain scale and the short form McGill pain questionnaire on the following page.

4. Are you currently taking any prescription pain medication? Do you regularly use any other prescription or over-the-counter medication? If so, please explain.

5. Have you been diagnosed, treated and/or medicated for any circulatory, blood or heart conditions in the last 10 years (including any of the following)?

   - Arteriosclerosis/Artherosclerosis
   - Coronary Artery Disease / Angina
   - High Blood Pressure (Hypertension)
   - Aneurysm
   - Rheumatic fever
   - Pericarditis
   - Blood Clots / Deep Vein Thrombosis
   - Other (please explain)

6. Have you been diagnosed, treated and/or medicated for any digestive conditions in the last 10 years? If yes, please explain:

7. Have you been diagnosed, treated and/or medicated for any medical conditions in the last 10 years?

8. Have you recently been taking any steroid medications?

9. Are you currently receiving treatment, or have received treatment, within the last month for any muscle, skeletal or skin condition, including any of the following?

   - Arthritis (e.g. rheumatoid arthritis, Ankylosing Spondylitis, Degenerative Disk Disease, and Psorsatic Arthritis)
   - Bone Disorders (e.g. Osteoporosis, breaks or fractures)

10. Have you been diagnosed, treated and/or medicated for osteoporosis?

11. Have you been diagnosed, treated, and/or medicated for arthritis, either on the spine, hip, or anywhere else?
Body Map / Pain scale

Indicate on this line how intensive your pain is—at the left end of line means no pain at all, at right end means worst pain possible.

Also, please draw on the body map where you feel the pain.

<table>
<thead>
<tr>
<th>No</th>
<th>Pain</th>
<th>Worst</th>
<th>Pain</th>
<th>Possible</th>
</tr>
</thead>
</table>

SHORT FORM McGILL PAIN QUESTIONNAIRE and PAIN DIAGRAM
(Reproduced with permission of author & Dr. Ron Melzack, for publication and distribution)

Check the column to indicate the level of your pain for each word, or leave blank if it does not apply to you.

<table>
<thead>
<tr>
<th></th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Throbbing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Shooting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Stabbing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Sharp</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Cramming</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Gnawing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Hot-burning</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Aching</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Heavy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Tender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Splitting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Tiring-Exhausting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Sickening</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Fearful</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Cruel-Punishing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
An Investigation into the Efficacy of Osteopathic Manipulative Treatment (OMT) on Chronic Low Back Pain in Factory Workers

VAS Pre-Intervention Form

About This Form
This form records how much pain you feel in your low back now, prior to treatment. Another form will record your pain after treatment.

This form is completed by you – your ID number should already be marked at the bottom of the form along with the date and time.

The horizontal line below represents pain on a scale from 0 to 100, where no pain is recorded as 0 at the far left, and the worst pain imaginable as 100 to the far right.

To record your low back pain, place a small vertical mark through the line below, to indicate your pain level in relation to the scale e.g.

```
0          100
```

PLEASE INDICATE YOUR PAIN LEVEL BY VERTICAL MARK THROUGH THE LINE BELOW:

```
0          100
```

Participant ID: 
Date: 
Time: 
An Investigation into the Efficacy of Osteopathic Manipulative Treatment (OMT) on Chronic Low Back Pain in Factory Workers

VAS Post-Intervention Form

About This Form
This form records how much pain you feel in your low back now, after treatment.
This form is completed by you – your ID number should already be marked at the bottom of the form along with the date and time.
The horizontal line below represents pain on a scale from 0 to 100, where no pain is recorded as 0 at the far left, and the worst pain imaginable as 100 to the far right.
To record your low back pain, place a small vertical mark through the line below, to indicate your pain level in relation to the scale e.g.

0

100

PLEASE INDICATE YOUR PAIN LEVEL BY VERTICAL MARK THROUGH THE LINE BELOW:

0

100

Participant ID: 
Date: 
Time: 

Page 104
The Quebec Back Pain Disability Scale

This questionnaire is about the way your back pain is affecting your daily life. People with back problems may find it difficult to perform some of their daily activities. We would like to know if you find it difficult to perform any of the activities listed below, because of your back. For each activity there is a scale of 0 to 5. Please choose one response option for each activity (do not skip any activities) and circle the corresponding number.

Today, do you find it difficult to perform the following activities because of your back?

<table>
<thead>
<tr>
<th>Activity</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Get out of bed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Sleep through the night</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Turn over in bed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Ride in a car</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Stand up for 20-30 minutes</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Sit in a chair for several hours</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Climb one flight of stairs</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Walk a few blocks (300-400 m)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Walk several kilometres</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Reach up to high shelves</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Throw a ball</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Run one block (about 100m)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Take food out of the refrigerator</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Make your bed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Put on socks (pants/hose)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Bend over to clean the bathtub</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Move a chair</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Pull or push heavy doors</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Carry two bags of groceries</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Lift and carry a heavy suitcase</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Add the numbers for a total score: __________

Minimum detectable change (90% confidence) 15 points

The SF-12™ Health Survey

Instructions for Completing the Questionnaire

Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble that best represents your response.

EXAMPLE

This is for your review. Do not answer this question. The questionnaire begins with the section Your Health in General below.

For each question you will be asked to fill in a bubble in each line.

1. How strongly do you agree or disagree with each of the following statements?

   a) I enjoy listening to music.  
      Strongly agree  Agree  Uncertain  Disagree  Strongly disagree
   b) I enjoy reading magazines.
      \[\text{\bullet} \quad \text{\bullet} \quad \text{\bullet} \quad \text{\bullet} \quad \text{\bullet} \quad \text{\bullet} \]

   Please begin answering the questions now.

Your Health in General

1. In general, would you say your health is:

   Excellent  Very good  Good  Fair  Poor
   \[\text{\bullet} \quad \text{\bullet} \quad \text{\bullet} \quad \text{\bullet} \quad \text{\bullet} \quad \text{\bullet} \]

2. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

   a. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
   b. Climbing several flights of stairs

   \begin{matrix}
   \text{Yes, Limited A Lot} & \text{Yes, Limited A Little} & \text{No, Not Limited At All}
   \end{matrix}

   \[\text{\bullet} \quad \text{\bullet} \quad \text{\bullet} \quad \text{\bullet} \quad \text{\bullet} \quad \text{\bullet} \]

   Please turn the page to continue.
3. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Accomplished less than you would like</td>
<td>O</td>
</tr>
<tr>
<td>b. Were limited in the kind of work or other activities</td>
<td>O</td>
</tr>
</tbody>
</table>

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Accomplished less than you would like</td>
<td>O</td>
</tr>
<tr>
<td>b. Didn't do work or other activities as carefully as usual</td>
<td>O</td>
</tr>
</tbody>
</table>

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>A little bit</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks . . .

<table>
<thead>
<tr>
<th>All of the Time</th>
<th>Most of the Time</th>
<th>A Good Bit of the Time</th>
<th>Some of the Time</th>
<th>A Little of the Time</th>
<th>None of the Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>a. Have you felt calm and peaceful?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>b. Did you have a lot of energy?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>c. Have you felt downhearted and blue?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE!
Appendix G – Ethics Approval Confirmation Letter

27th March 2009

To Whom it may concern
School of Health Science (Osteopathic studies)
Unitec NZ

Dear Sir / Madam

STUDY INTO OSTEOPATHIC TREATMENT.

Tegel Foods Ltd has agreed to give their permission for Simon Yardley (principal researcher) and Unitec, to perform a randomized controlled study into the efficacy of osteopathic treatment upon Tegel Foods Ltd workers with existing low back pain – subject to subsequent approval by the Unitec ethics committee.

It is understood that the study will be performed from April 2009 on Tegel Foods Ltd premises, under the supervision of Dianne Emmerson of Tegel Foods Ltd, and a small number of Unitec researchers required to administer the study.

Yours sincerely
TEGEL FOODS LTD

David Taylor
OPERATIONS MANAGER - VALUE ADDED / HENDERSON PROCESSING

Enc
Appendix I – Instructions for manuscript submission

Online Submission

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

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

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

Types of contributions

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

**Reviews and Original Articles** These should be either i) reports of new findings related to osteopathic medicine that are supported by research evidence. These should be original, previously unpublished works. The report will normally be divided into the following sections: abstract, introduction, materials and methods, results, discussion, conclusion, references. Or ii) critical or systematic review that seeks to summarise or draw conclusions from the established literature on a topic relevant to osteopathic medicine.

**Short review** The drawing together of present knowledge in a subject area, in order to provide a background for the reader not currently versed in the literature of a particular topic. Shorter in length than and not intended to be as comprehensive as that of the literature review paper. With more emphasis on outlining areas of deficit in the current literature that warrant further investigation.

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

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

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

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

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

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

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

**Presentation of Typoscripts**

Your article should be typed on A4 paper, double-spaced with margins of at least 3cm. Number all pages consecutively beginning with the title page.
To facilitate anonymity, the author's names and any reference to their addresses should only appear on the title page. Please check your typescript carefully before you send it off, both for correct content and typographic errors. It is not possible to change the content of accepted typescripts during production.

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

**Title page**

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

**Keywords**

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

**Abstract**

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

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

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

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

**Statement of Competing Interests**
When submitting a Research report you will need to consider if you, or any of your co-authors, are an Editor or Editorial Board member of the International Journal of Osteopathic Medicine. If this is the case you will need to include a section, at the end of your manuscript immediately before the reference section, called "Statement of Competing Interests". Example statement, which may require editing, is as follows: 78 is an Editor of the Int J Osteopath Med; 78 is a member of the Editorial Board of the Int J Osteopath Med but was not involved in review or editorial decisions regarding this manuscript.

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

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

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

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