The effects of osteopathic treatment on non-specific chronic neck pain and disability

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Declaration

Name of candidate: Monique Gasson

This Research Project entitled “The effects of osteopathic treatment on non-specific chronic neck pain and disability” is submitted in partial fulfilment for the requirements for the Unitec degree of Master of Osteopathy.

Candidate's Declaration

I confirm that:

- This Research Project represents my own work;
- Research for this work has been conducted in accordance with the Unitec Research Ethics Committee Policy and Procedures, and has fulfilled any requirements set for this project by the Unitec Research Ethics Committee.

Research Ethics Committee Approval Number: 2011-1196

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Introduction

There are an abundance of studies that have been recently reviewed regarding the high prevalence of neck pain worldwide and the resulting disability and financial cost of pain arising from work absences and increased medical expenses (Feyer, Kyvik, & Hartvigse, 2006; Haldeman, Carroll, Cassidy, Schubert, & Nygren, 2008). Literature surrounding the treatment of neck pain is also abundant, especially studies investigating the effectiveness of different manual therapy techniques (Bronfort, Haas, Evans, & Bouter, 2004; Gross, Kay, Kennedy, et al., 2002). However literature is scarce when it comes to establishing the efficacy of osteopathic treatment for mechanical neck pain. Osteopathy is a physician-directed, non-invasive approach to patient care that incorporates diagnostic and therapeutic strategies to address body unity issues, enhance homeostatic mechanisms, and maximise structure-function interrelationships (Kuchera, 2007). In contemporary practice its multi-modal approach, inclusive of various treatment strategies or techniques, integrates each osteopathic principle with biopsychosocial and patient education models, as well as manual medicine and rehabilitation techniques proportionate to individual needs (Kuchera, 2007).

To date, there appears to be just one study that has investigated the effects of osteopathic manipulative treatment (OMT) on neck pain (Fryer, Alvizatos, & Lamaro, 2005), although the observed improvements in pain and disability cannot be attributed to the osteopathic treatment as the study lacked a control group. The aim of this thesis was to undertake an investigation of the effects of OMT in the relief of pain and disability for non-specific neck pain using a modified randomised controlled trial (RCT) design.
This thesis is arranged in 3 main sections: Section 1 is a literature review that outlines chronic pain and neck pain; explores its aetiology, prognosis, cost and potential for disability; and reviews treatment options. Section 2 of the thesis contains a manuscript formatted in the style for submission to the journal *International Journal of Osteopathic Medicine*. Section 3 (Appendices) contains other material supplementary to the thesis.
Section 1: Literature Review
Introduction

Neck pain is considered to be an unpleasant sensory and emotional experience in the region of the neck associated with actual or potential tissue damage, or described in terms of such damage (Merskey & Bogduk, 1994). Not only is neck pain one of the most frequent musculoskeletal complaints, it is second only to low back pain in terms of cost and prevalence (Childs et al., 2011; Fejer, Kyvik, & Hartvigsen, 2006). Neck pain is not just a personal health problem in terms of pain and the negative influence it can have on a person’s quality of life, but the high prevalence of the disorder also makes it a major public health problem in terms of overall well-being, cost of work absence and medical expenses (Feyer et al., 2006). There are many options for the management of neck pain including manual therapy, physical medicine methods, drug treatments, and education of patients (Aker, Gross, Goldsmith, & Peloso, 1996). Manual therapy is a common treatment choice with an increasing number of clinical trials emerging to provide an evidence base for the practice (Bronfort, Haas, Evans, Leininger, & Triano, 2010). These trials predominantly investigate the effectiveness of various manual techniques, and different types of manual therapy combined with other adjunct therapies including pain management, neck-specific strengthening exercises, and educational advice (Taimela, Takala, Asklof, Seppala, & Parviainen, 2000). The literature shows evidence of reduction of pain and disability, and improvement in overall quality of life with various manual therapies, including the use of specific techniques such as manipulation, mobilisation and massage (Bronfort et al., 2004; Gross et al., 2004). However, as there is no consensus on the best treatment, the aim of this literature review is to explore evidence regarding the effectiveness of manual therapy and neck pain management.
Chronic Pain

Pain is typically classified as either acute or chronic and is understood and managed differently depending on classification. Acute pain can be defined as short-term pain of less than 3-months duration which generally occurs in response to injury or tissue damage, and in simple terms is generally considered to act as a signal of actual or potential harm or damage (Conn, 2005). Chronic pain, which is the focus of this review, has been described as pain persisting for at least 12-weeks duration following onset (Merskey & Bogduk, 1994). The occurrence of chronic pain is not usually a result of new tissue damage, though it can be associated with an injury that has not resolved or healed within an expected time period (Conn, 2005; Turk & Melzack, 1992). The cause of chronic pain is often unknown, and as such is difficult to treat effectively (Conn, 2005). It can be associated with an underlying condition or disease process (e.g., rheumatoid arthritis), however in the majority of cases the aetiology of chronic pain is unknown. One possible explanation could be the role of psychological and social factors in the awareness of pain (Pool, Ostelo, Koke, Bouter, & de Vet, 2006). These factors are believed to play a role in the transition from acute to chronic pain and disability (Gatchel, 1996; Linton, 2000). What begins as a seemingly simple clinical problem can develop into a complex condition where a range of psychological and social factors interact with physical factors to cause disability and impact an individual’s ability to carry out normal daily activities (Côté, Cassidy, & Carroll, 2003). Pain has the ability to reduce a person’s quality of life due to the aggravation it can cause during daily activities (Ferrell, 1995). It can also result in fear-avoidance behaviours: that is the avoidance of activities or movements because of fear that they might cause pain (Vlaeyen & Linton, 2000).
The Neck and Cervical Spine

It is useful to define the anatomical boundaries of the neck and the following definition is perhaps the most authoritative: the neck is bounded superiorly by the superior nuchal line, inferiorly by the tip of the spinous process of the first thoracic vertebrae and laterally by the lateral borders of the neck (Merskey & Bogduk, 1994). Many significant structures are contained within this region including muscles, ligaments, a myriad of blood vessels and nerves, and the bony cervical spine. The cervical spine has been described as the most complicated articular system in the body (Bland & Boushey, 1990) and is comprised of 7 vertebrae and 37 separate joints that function to carry out the movement of the head and neck in relation to the trunk (Bland & Boushey, 1990). The neck subserves specialised sensory organs for hearing, vision, smell, taste, and lingual and labial sensations (Bogduk & Mercer, 2000). In order for these sensations to function optimally, it is important to be able to scan the environment and focus on objects of interest effectively, and the cervical spine permits this by moving and orientating the head in a 3-dimensional space (Bogduk & Mercer, 2000). For descriptive purposes, the cervical spine can be divided and perceived as consisting of four units, each of which has a unique morphology that determines its kinematics and overall contribution to the functioning of the cervical spine (Bogduk & Mercer, 2000). In anatomical terms, these units include the atlas, the axis, the C2-3 junction, and the remaining typical vertebrae.

Neck Pain

Neck pain, sometimes termed ‘cervicalgia’, is a common condition affecting as many as 70% of the general population at some time during their lives (Bovim,
Schrader, & Sand, 1994; Côté, Cassidy, & Carroll, 1998; Fejer et al., 2006; Mäkela et al., 1991). Of neck pain sufferers, 14-19% may develop chronic pain (Griffiths, Dziedzic, Waterfield, & Sim, 2009) and approximately 19% of the population may suffer from chronic neck pain at any given time (Bovim et al., 1994). Most neck pain is thought to result from irritation or injury to part of the neck, commonly caused by poor posture, mechanical stress, and changes to the normal condition of the joints and discs over time. Chronic neck pain, as with other chronic conditions, is generally considered to be of multicausal aetiology and does not lend itself to simple diagnosis (Mason, 2008). There are often several tissues implicated that contribute to the overall clinical picture, and it can be difficult to ascertain which tissue is injured or dysfunctional (Apkarian, Baliki, & Geha, 2009). Structures such as nerve and muscle tissue or processes such a joint degeneration have varying amounts of contribution to the overall dysfunction pattern, however in the majority of cases of chronic neck pain there is little evidence of specific pathology or cause, and neck pain is classed as non-specific (Hoving et al., 2002; Mayou & Farmer, 2002).

**Outcome Measures for Assessment of Neck Pain**

There are a variety of available tools to measure neck pain, especially self-report questionnaires which detect change in perceived pain and disability of individuals. The Neck Disability Index (NDI) and Patient Specific Functional Scale (PSFS) are commonly used to measure disability, and aspects of the McGill Pain Questionnaire (MPQ) and the Visual Analogue Scale (VAS) are commonly used to measure pain intensity.
Neck Disability Index (NDI)

The Neck Disability Index is a self-report questionnaire that consists of 10 items concerning daily living, pain and concentration (Vernon & Mior, 1991). Each item is scored from 0 – 5, 0 representing no disability and 5 signifying extreme disability. A minimum clinically important difference (MCID) of at least 5 points from a total of 50 is required to be clinically meaningful (Vernon & Mior, 1991). The NDI has been shown to demonstrate a high degree of test-retest reliability (ICC=0.91) and internal consistency (Vernon, 1996). In addition, NDI scores have been shown to correlate with visual analogue scores of pain and also with the McGill Pain Questionnaire scores (Pietroben, Coeytaux, & Carey, 2002). A number of studies related to the treatment of neck pain have also employed the NDI as an outcome measure (Fryer et al., 2005; Mandara et al., 2010; Ylinen et al., 2003).

Patient Specific Functional Scale (PSFS)

The Patient-Specific Functional Scale is designed to measure clinical progress and assess functional outcome. It requires respondents to self-nominate up to three activities that are affected by their pain, and rate each on an 11-point scale from 0 (unable to perform activity) to 10 (able to perform activity at pre-injury or pre-pain level). The PSFS measures change in individual participants over time, and helps to provide an in-depth representation of the activities associated with disability. Although this method has not been specifically validated in chronic neck pain, the scale has been shown to be a highly reliable (ICC=0.97) (Stratford, 1995) and responsive outcome measure (Pengel, Refshauge, & Maher, 2004).
McGill Pain Questionnaire (MPQ)

The McGill Pain Questionnaire is an elaborate, widely used method for pain evaluation by verbal description (Melzack & Katz, 1999). The MPQ requires respondents to identify self-perceived aspects of pain by selecting appropriate descriptors from a selection of 78 in order to assess the multidimensional nature of pain. The descriptors are given a numerical scale rating from ‘mildest’ to ‘worst’, and the sum of these scores represents the total Pain Rating Index (PRI). The questionnaire also investigates the pattern of pain (brief, intermittent, continuous), and includes a 5-point Present Pain Intensity (PPI) scale. This questionnaire has been shown to be a highly reliable (test-retest) and consistent measurement tool (Melzack & Katz, 1999) and correlates with the NDI (Vernon & Mior, 1991). The study most closely related to the investigation of this thesis has employed the MPQ as an outcome measure (Fryer et al., 2005).

Pain Intensity using Visual Analogue Scale (VAS)

The VAS is a simple measure of the intensity of pain which requires respondents to rate their present pain intensity by marking a point along a 100 mm straight horizontal line, the margins of the line labeled as ‘No pain’ on the left, and ‘Worst possible pain’ on the right. The scale has been reported to be one of the best methods available for estimating the intensity of clinical pain (Williamson & Hoggart, 2005), and is more robust than the PPI of the McGill Pain Questionnaire as it allows the participant greater choice when scoring pain intensity. A minimum clinically important difference of 14 mm is required to be clinically meaningful across the pain severity spectrum (Todd, Funk, Funk, & Bonacci, 1996). The VAS has been used in many other related studies (Allison, Nagy, & Hall, 2002; Fryer et
and is a standard assessment tool in clinical practice.

**Epidemiology and Prognosis of Neck Pain**

In comparison to other disorders, the current knowledge of neck pain epidemiology is limited (Hoy, Protani, De, & Buchbinder, 2010). Studies consistently report that the prevalence of neck pain increases with age (Bovim et al., 1994; Côté et al., 1998; Mäkela et al., 1991; Picavet & Schouten, 2003) and that it is higher in women than men (Bovim et al., 1994; Côté et al., 1998; Fejer et al., 2006; Lawrence, 1969; Mäkela et al., 1991; Picavet & Schouten, 2003; Van der Donk, Schouten, Passchier, Van Romunde, & Valkenburg, 1991). According to Fejer et al., (2006), women generally seem to report more musculoskeletal problems than men, and it has been suggested that this may be based on different physiological mechanisms for pain perception between the sexes (LeResche, 1999). Rekola, Keinänen-Kiukaanniemi, & Takala (1993) found that women visited healthcare services for neck pain more frequently than men. Little is known, however, about the age and gender-specific course of chronic neck pain in older individuals, which suggests that the prognosis of neck pain may vary with age and gender (Guez, Hildingsson, Nilsson, & Toolanen, 2002; Mäkela et al., 1991). A study by Croft et al. (2001) supported these findings, by concluding that the incidence of neck pain increased slightly with age and peaked between the ages of 30 and 45 years. These authors also found that females were shown to have a 30% increased risk of 12-month incidence of neck pain than males, though confidence limits show that this difference was of borderline statistical significance. Furthermore, neck pain is more common among lower
socioeconomic status groups, in people performing repetitive, static or physically demanding work, those with previous neck trauma, and among those suffering from conditions such as depression and headache (Côté, Cassidy, & Carroll, 2000; Côté et al., 2003).

Outside of New Zealand there is a high prevalence of neck pain, especially in Western countries (Côté et al., 1998; Fejer et al., 2006; Guez et al., 2002). Whilst no published literature exists for the epidemiology of neck pain in New Zealand, data obtained from the Accident Compensation Corporation (ACC) of New Zealand suggests that from July 2011 until July 2012 there were 87,093 new claims for pain relating to neck injuries ("Neck injury raw data: Accident Compensation Corporation (ACC) New Zealand," 2013). Of these claimants, the gender ratio was 5.0 female to 3.7 male, and most claims (84%) were made by people between 20-79 years of age ("Neck injury raw data: Accident Compensation Corporation (ACC) New Zealand," 2013). Costs incurred by ACC for neck injury claims for this period reached NZD$164,637,733. These figures grossly underestimate the prevalence of neck pain which is often, at least in part, attributable to the natural ageing process of joint degeneration and is not covered under the ACC insurance scheme.

**Disability and Cost of Neck Pain**

Neck pain can adversely affect a person's quality of life due to the disability associated with it. In cases of chronic neck pain, disability produces a high level of morbidity by affecting activities of daily living (Vernon & Humphreys, 2008) and can lead to functional limitations, lost work time, result in substantial healthcare
costs and a huge societal burden (Côté et al., 1998; Côté et al., 2003; Herd & Huijbregts, 2007). In some light manufacturing industries, neck-related disorders account for as many days work-absence as low back pain (Kvarnström, 1983). However, while the cumulative incidence of neck pain may be high, the incidence of disabling neck pain remains unknown (Côté, Cassidy, Carroll, & Kristman, 2004). A cross-sectional study by Côté et al, (1998) showed that neck pain had a high lifetime prevalence (66.7%) in the studied adult Saskatchewan population, and that 4.6% of the total population experienced significantly disabling neck pain. In a later study, Côté et al. (2004) attempted to quantify the burden of disability associated with neck pain in the general population. They found that each year in Saskatchewan, 600 out of 100,000 adults experienced a new episode of disabling neck pain, and only one-third of those with neck pain experienced complete resolution of their condition. A cross-sectional study (Picavet & Schouten, 2003) found that only 6.3% of individuals who suffered from neck pain in the previous year reported that their pain was non-recurrent. These findings suggest that neck pain is a chronic, episodic condition characterised by episodes of persistent or recurrent pain and disability, and emphasises that neck pain is likely to be related to significant activity limitations for a considerable proportion of the population. Several other studies suggest that neck pain may be similar to low back pain and follow an episodic course marked by periods of remissions and acute exacerbations (Hestbaek, Leboeuf-Yde, Engberg, et al., 2003; Hestbaek, Leboeuf-Yde, & Manniche, 2003; Picavet & Schouten, 2003).
Manual Therapy in the Treatment of Neck Pain

Pain is a powerful motivating force that guides patients to seek treatment (Bernard & Wright, 2004), and neck pain is no exception. As neck pain is a common occurrence, many people rely on conservative treatments such as manual therapy for symptomatic relief. Patient education, advice and exercise therapy are also commonly used in the management of neck pain (Haines et al., 2009) and, for non-specific neck pain, can be effective for relieving symptoms of pain and disability (Linton & van Tulder, 2001; Sarig-Bahat, 2003). Patient education can be defined as a learning experience intended to influence health knowledge and behaviour (Bartlett, 1985), and forms of advice regarding posture, stress, coping skills, self-management plans and exercises can be given (Haines et al., 2009). Prescription of exercise includes stretching, specific muscle strengthening, and active and passive relaxation exercises designed to meet demands of daily living (Tan & Horn, 1998).

Across clinical manual therapy the definition is varied, for example between osteopathy, physiotherapy and chiropractic professions, but can be defined as a hands-on clinical approach to treat health ailments of various aetiologies through passive movement techniques, including but not limited to manipulation, mobilisation and soft-tissue massage (Basmajian & Nyberg, 1993). The term manipulation describes manipulative therapies as used by chiropractors, physiotherapists, osteopaths and other manual therapists (McReynolds & Sheridan, 2005). Many researchers use the term manipulation to describe the localised high-velocity, low-amplitude (HVLA) thrust technique, which applies force to a joint that moves it beyond its active and passive range of movement,
often producing an audible click (McReynolds & Sheridan, 2005). In contrast to manipulation, *mobilisation* uses skilled low-grade passive movement with varying amplitudes (Pool et al., 2006). It is a non-thrust form of manipulation (Bronfort, 1999; Gross, Aker, & Quartly, 1996) in which manual force is applied to joints within its passive range of motion (Bronfort, 1999). Both manipulation and mobilisation of the cervical spine are common manual therapy techniques for the treatment of neck pain and have been shown to decrease pain and disability of the neck, and increase cervical range of motion (Cassidy, Quon, LaFrance, & Yong-Hing, 1992; Gross et al., 2004; Hains, Waalen, & Mior, 1998; Nordemar & Thörner, 1981).

Manual therapies are commonly used in the treatment of chronic neck pain, and there are numerous systematic reviews of the treatment of neck pain by manual therapy (Bronfort et al., 2004; Gross et al., 2004; Gross, Kay, Hondras, et al., 2002; Gross, Kay, Kennedy, et al., 2002; Haldeman et al., 2008; Hurwitz, Aker, Adams, Meeker, & Shekelle, 1996; Macaulay, Cameron, & Vaughn, 2007; Sarigiovannis & Hollins, 2005; Vernon & Humphreys, 2008). However, the methodological quality of trials included in many of these reviews has been poor. The majority of trials report comparisons of two or more interventions, with only one trial blinding subjects, assessors and therapists to the treatment type (Haas et al., 2003). In addition, only three of the reviewed trials included a placebo or sham group: two manipulation trials (Cleland, Childs, McRae, Palmer, & Stowell, 2005; Sloop, Smith, Goldenberg, & Doré, 1982) and the other a mobilisation trial (Sterling, Jull, & Wright, 2001), and none of these included blinding of both the subjects and assessors, only the therapists, to the experimental condition. Sterling et al., (2001) investigated the effects of spinal mobilisation on pain levels
and neck flexor muscle activity in subjects with chronic mid to lower cervical spine pain of insidious onset. This was compared to a placebo where there was manual contact but no movement, and also a control where there was no physical contact between the subject and researcher. No significant differences in pain were shown between groups.

Another difficulty in drawing conclusions about the effect of manual therapy on neck pain is the variability of inclusion criteria used for studies in the field. Definitions of chronic pain varied from one to three months depending on the trial (Cassidy, Lopes, & Yong-Hing, 1992; Hou, Tsai, Cheng, Chung, & Hong, 2002; Sloop et al., 1982; Yurkiw & Mior, 1996), which may have given an incorrect representation of change in pain scores. If one intervention group had more acute pain subjects than another, it is possible that they may have been more responsive to treatment. Furthermore, not all trials used pain intensity as measured on a 100 mm scale as the primary outcome: some used algometry or a combination of outcomes which makes calculating effect sizes and comparisons of manual therapies between studies more difficult (Hou et al., 2002; Vernon, Aker, Burns, Viljakaanen, & Short, 1990).

Sarigiovannis & Hollins (2005) reviewed 12 randomised controlled trials of manual therapy on non-specific neck pain. Inclusion criteria required that manual therapy was at least one of the study treatments, and that studies assessed at least one of the following outcome measures: pain, cervical mobility, global measurement of improvement, use of drugs or functional status. The authors concluded that despite the abundance of evidence supporting spinal manual therapy and exercise for neck pain, many of the studies demonstrate methodological
shortcomings in both design and reporting. Eight out of the 12 RCTs included in this review scored <50 points on a modified scale developed by Koes et al., (1991) (max score of 100), which indicated they were of low methodological quality. Only 4 studies scored >50 points: 2 of these reached a positive conclusion about the effectiveness of spinal manual therapy in the treatment of non-specific neck pain (Hoving et al., 2002; Hurwitz et al., 2002), and 2 trials a negative conclusion (Bronfort et al., 2001; Yurkiw & Mior, 1996). Possible reasons for these differing conclusions may include differences in the pain duration of the population groups. In both of the studies with positive conclusions (Hoving et al., 2002; Hurwitz et al., 2002) the population had relatively short pain durations (>2 weeks and <3 weeks respectively), and in both of the studies with negative conclusions where no significant differences were found (Bronfort et al., 2001; Yurkiw & Mior, 1996) subjects had longer pain durations (>12 weeks and >3 weeks respectively). Among the remaining 8 RCTs with <50 point scores, 6 reached a positive conclusion and 2 a negative conclusion (Sarigiovannis & Hollins, 2005).

It was noted that the findings of the Sarigiovannis & Hollins (2005) review should be interpreted cautiously as some of these papers demonstrate major methodological limitations and flaws. These included homogeneity of the study population (which limits the generalisability of conclusions drawn) and poor comparability of relevant baseline characteristics, as differences between groups could affect conclusions. Such flaws pose serious questions regarding both the internal and external validity of a study (Sim, 1995), and in relation to the treatment of neck pain, these results may not be generalisable to conventional group studies. On the other hand, since these results demonstrate that the RCTs with the highest methodological scores (Bronfort et al., 2001; Hoving et al., 2002;
Hurwitz et al., 2002) were published after the year 2000, this may indicate that RCT’s methodological quality is improving over time. Nevertheless, since the highest score for a study in the review was 67, there is still room for improved research designs in the field.

A similar, but more recent review executed by Macaulay, Cameron & Vaughn (2007) included five articles published between 1996 and 2006 that used manual therapy as their main intervention and one of the following outcome measures: pain, function, patient satisfaction, global perceived effect, overall improvement and adverse effects. This review differed from the previous review as it used different quality-grading criteria: Sarigiovannis & Hollins (2005) modified a scale developed by Koes et al. (1991) whereas the review by Macaulay et al., (2007) used the more accepted Jadad criteria (Jadad., 1996). Despite this however, two of the high-quality studies (Evans, Bronfort, Nelson, & Goldsmith, 2002; Hoving et al., 2006) in the present Macaulay et al., (2007) review were continuations of two of the high-quality methodologic studies reviewed by Sarigiovannis & Hollins (2005). Results of the Macaulay et al., (2007) review found that four of the trials were of high methodological quality (Evans et al., 2002; Hoving et al., 2006; Jull et al., 2002; Martínez-Segura, Fernández-de-las-Peñas, Ruiz-Sáez, López-Jiménez, & Rodríguez-Blanco, 2006) according to the validated Jadad criteria (Moher, David, & Lepage, 2001). However, due to the heterogeneity of the data from the included trials, the studies could not be pooled for meta-analysis, so a qualitative analysis was performed instead. Although strong evidence suggested that manual therapy was not significantly superior to other interventions (such as: exercise, physical therapy, analgesic medication) for the relief of neck pain, patients receiving manual therapy interventions were significantly more satisfied with their
care, and also demonstrated improvements in both the short- and long-term on a variety of occasions. These improvements included pain, disability and range of motion outcome measures, and were especially evident when combined with exercise. This result suggests that a multimodal approach including manual therapy and exercise may be a potentially useful intervention in the treatment of mechanical neck disorders (Macaulay et al., 2007).

**Cervical Spine Manipulation and Mobilisation**

Two reviews (Bronfort et al., 2004; Vernon & Humphreys, 2008) investigated the effectiveness of spinal manipulation and mobilisation directed at the cervical spine for both chronic and acute neck pain. Vernon & Humphreys (2008) concluded immediate benefit following a single session of cervical manipulation compared to mobilisation for patients with non-specific neck pain, and Bronfort et al., (2004) concluded that manipulation was superior to mobilisation for acute neck pain, but reported mixed results for chronic pain. Vernon & Humphreys (2008) identified and reviewed 9 trials of a single session of manual therapy on chronic, non-specific neck pain: 6 for spinal manipulation, 4 for spinal mobilisation or non-manipulative manual therapy (2 overlapping trials), and 1 using ‘ischemic compression’. Although all 9 studies scored at least 6 out of 10 on the PEDro methodological quality scale (de Morton, 2009), many of them lacked concealment of allocation, blinding of all subjects, and blinding of all therapists. Within the Vernon & Humphreys (2005) review, two important studies (Cassidy, Quon, LaFrance, & Yong-Hing, 1992; Vernon, Aker, Burns, Viljakaanen, & Short, 1990) specifically compared the effects of these two techniques.
Cassidy et al., (1992) compared a single cervical manipulation to cervical mobilisation via muscle energy technique in 100 subjects with unilateral neck pain, referral into the trapezius muscle, and with a wide range of causes of chronic of symptoms (<1 week to >6months). Vernon et al., (1990) compared a single cervical manipulation to rotational oscillatory mobilisation in 9 subjects with chronic neck pain, pre-evaluated using a pressure pain threshold meter. Both studies reported that the assessors were blinded to the subject complaint and treatment. The study by Cassidy et al., (1992) showed that both interventions increased cervical range of motion, but manipulation had a greater effect on pain, with 85% of manipulated patients reporting an immediate decrease in pain ($P = 0.05$) compared to 69% in the mobilisation group. There were no significant differences between the two intervention groups at baseline with respect to participant age, however there was no comparison of the different durations of pain between the groups. Therefore, it may be possible that more acute pain subjects were randomised to the manipulation group than the other and subsequently introduced an important systematic difference in the baseline clinical status between the groups. This is important because acute pain may be more responsive to treatment when compared to chronic pain. Vernon et al., (1990) showed mean increases in the pressure pain threshold in the manipulation group ranged from 40 – 56% and were greater than that observed following oscillatory mobilisation, for which changes were negligible. This suggests that a single session of manipulation can increase local paraspinal pain thresholds, which allows for such an effect in deeper tissues. Despite the reductions in pain shown in these comparative studies, the general conclusion appears to be that manipulation is superior to mobilisation for the relief of pain in subjects with both acute and chronic neck pain.
Bronfort et al., (2004) conducted a review examining the efficacy of spinal manipulation and mobilisation for neck pain in both the short- and long-term. Randomised trials that included ≥10 subjects per group who had received spinal manipulation or mobilisation, and who were measured using patient-oriented outcome measures were analysed. Twenty-three studies were identified for neck pain and of these 12 were included in the analysis: 7 for spinal manipulation, 4 for mobilisation, and 1 combining both manipulation and mobilisation. Two trials met inclusion criteria for acute pain (Howe, Newcombe, & Wade, 1983; Nordemar & Thörner, 1981), 5 for chronic pain (Bronfort et al., 2001; David, Modi, Aluko, Robertshaw, & Farebrother, 1998; Jordan et al., 1998; Koes et al., 1992; Sloop et al., 1982) and the remaining 5 were a mix of both acute and chronic neck pain.

For acute pain, Howe, Newcombe, & Wade (1983) found manipulation was useful for pain relief and Nordemar & Thörner (1981) showed mobilisation was not. Howe et al. (1983) investigated the effects of high-velocity low-amplitude spinal manipulation to the cervical spine in acute neck pain patients, and found statistically significant improvements in pain ($P < 0.001$), neck stiffness ($P < 0.001$), and pain/paraesthesia in the shoulder ($P < 0.02$) immediately following the first manipulation. These improvements however did not last, and were non-significant compared to baseline, and at follow-up at weeks one and three after treatment. Nordemar & Thörner (1981) compared the effectiveness of a neck collar and analgesics to that of manual therapy consisting of soft-tissue therapy, gentle traction and mobilisation of the neck, in addition to the use of a neck collar and use of analgesics. Results showed non-significant trends for cervical range of motion between groups, though a high mean improvement in both cervical mobility and pain reduction was observed at one-week following the manual
therapy intervention. Despite Howe et al., (1983) demonstrating statistical significance and Nordemar & Thörner (1981) not, both were small trials (52 and 30 participants respectively).

There were mixed results reported in the Bronfort et al., (2004) review regarding the effectiveness of spinal manipulation and mobilisation for chronic neck pain with 4 of the 5 studies showing non-significant results (Bronfort et al., 2001; David et al., 1998; Jordan et al., 1998; Sloop et al., 1982), and 1 demonstrating a statistically significant effect (Koes et al., 1992). Each of the trials compared either spinal manipulation or mobilisation with a range of different therapies, and many of them used combination therapies, thus a direct comparison and evaluation is difficult. In addition, the reviewed trials had poorly defined subgroups of subjects, making it difficult to apply these findings to specific populations.

Bronfort et al., (2001) found that high-technology rehabilitation exercise (dynamic progressive resistance exercise) produced more long-term pain reduction than spinal manipulation. David et al., (1998) reported a non-significant trend of higher reduction in pain for mobilisation than acupuncture in the short- and long-term. Jordan et al., (1998) found small, non-significant trends between spinal manipulation, intensive exercise and physical therapy groups in the short- and long-term. Sloop et al., (1982) showed a non-significant trend of spinal manipulation over placebo in the short-term for pain reduction and improvement. Koes et al. (1992), however, found spinal manipulation and mobilisation after 6 weeks (short-term) to improve patients’ main spinal complaints 12% more than for general medical practice, though differences compared to placebo for did not attain statistical significance ($P < 0.1$). Similar advantages of manual therapy over
general practice care and placebo were reported for physical functioning in the short-term, and for perceived global improvement at 12 weeks (long-term). As a result of findings from the analysis of these 12 studies concerned with manual therapy for both acute and chronic neck pain, Bronfort et al., (2004) suggested that the use of manipulation and/or mobilisation was a viable option for the management of neck pain, but that future trials should determine well defined subgroups of patients.

**Thoracic Spine Manipulation and Mobilisation**

Manipulation of the thoracic spine has been used in patients presenting with neck pain (Di Fabio, 1999; Hurwitz et al., 1996). Although the effectiveness of manipulation and mobilisation of the cervical spine is reasonably well documented, increased attention has been given to the risk of rare but serious complications such as vertebrobasilar insufficiency (VBI) for manual therapy interventions directed at the cervical spine (Cleland et al., 2005). Nonetheless, the risk of VBI has been estimated to be very low at approximately 6 in 10 million manipulations (Hurwitz et al., 1996). As a result of the biomechanical relationship between the cervical and thoracic spines, disorders of thoracic joint mobility or tissues may contribute to the development of neck pain. It has been suggested that reductions in neck pain from thoracic spine manipulation interventions may be attributable to a restoration of more normal biomechanics to this region, potentially lowering mechanical stresses and improving the distribution of joint forces in the cervical spine (Norlander, Gustavsson, Lindell, & Nordgren, 1997). Clinician authors of clinical manual therapy textbooks have suggested that a
thoracic spine examination should be included in the assessment of patients with neck pain complaints (Greenman, 1996).

Despite the rationale for involving thoracic spine treatment in those with neck pain, only one study known to the author compared the effects of cervical manipulation to thoracic manipulation for the relief of neck pain and disability (Puentedura et al., 2011). Twenty-four patients were randomly assigned to one of two treatment groups: the thoracic group received thoracic spine thrust joint manipulation (TJM) and a cervical range-of-motion (ROM) exercise for the first 2-sessions, followed by a standardised exercise programme for an additional 3-sessions, and the cervical group received cervical TJM and the same exercise protocol. Patients who received cervical TJM demonstrated greater improvements in Neck Disability Index ($P \leq .001$) and Numeric Pain Rating Scale ($P \leq .003$) scores at all follow-up times.

Similar to comparative studies of cervical manipulation and mobilisation, one randomised trial compared the effects of thoracic manipulation to a sham (Cleland et al., 2005), and another compared the effects of thoracic manipulation versus mobilisation on neck pain (Cleland et al., 2007). Both studies found statistically significant differences in change between groups. Cleland et al., (2005) found manipulation was effective compared to sham for pain intensity with change scores of 15.5 mm for manipulation and 4.2 mm for the placebo group, whilst Cleland et al. (2007) found manipulation superior to mobilisation for pain (change score of 2 points) and disability (10 percentage points) between-groups respectively. The manipulation intervention group in the study by Cleland et al. (2005) received high-velocity low-amplitude (HVLA) thoracic spine manipulation
directed at specific segmental mobility restrictions with the therapist using a “pistol grip”; and the sham-manipulation group received no HVLA, but patients were placed in an identical set-up position and the therapist used an “open hand”. Both applicator-hand positions in spinal manipulation manoeuvres are effective, and it is generally the thrust velocity and direction that causes the audible cavitation (Conway, Herzog, Zhang, Hasler, & Ladly, 1993). Given that the included participants had not had previous exposure to spinal manipulation, it is unlikely that they were aware that a HVLA thrust manoeuver is usually performed during this manipulation intervention, and could reasonably be considered blinded to the treatment. The non-thrust (mobilisation) intervention group in the study by Cleland et al., (2007) consisted of segmental mobilisation from T1-T6, and the thrust (manipulation) group consisted of two HVLA thrusts: one to the upper thoracic spine (T1-4) and one to the mid-thoracic spine (T5-8). Both groups were instructed on general cervical mobility exercise to improve rotation of the neck.

No differences in key demographic variables (age, gender, medical history, location and nature of pain) or baseline levels of pain and disability were detected in either study. In the Cleland et al., (2007) study however, more participants who were assigned to the manipulation group were receiving workers’ compensation which may mean that their complaints of neck pain were more likely to be related to a specific traumatic event and perhaps thus a specific acute injury. Additionally, those receiving workers compensation may have had a reduced desire to get better or improve. A different chronicity of neck pain or differences in motivation to improve might have contributed to the observed differences between the two treatment groups. A further limitation of both studies was the limited timeframe for follow-up. Cleland et al., (2005) performed post-treatment measures immediately
following the intervention, and Cleland et al., (2007) 48 hours following the initial examination. In addition, the Cleland et al., (2007) study also lacked a control group, so it was not possible to attribute clinical change to either treatment with certainty. Cleland et al., (2005) suggested that future studies should investigate the long-term effects in outcomes of pain, patient satisfaction and costs, and also suggested that more comparative clinical trials are necessary to determine whether spinal manipulation is most beneficial in isolation, or if it should supplement manual therapy interventions directed to the cervical spine. The authors also discussed the benefit of examining changes in cervical range of motion in order to provide further insight into the biomechanical implications associated with thoracic spine manipulation in patients with neck pain.

**Multimodal Care in Manual Therapy and Osteopathy**

A combination of several treatment techniques or modalities can be referred to as multi-modal care. In osteopathy, multi-modal care includes the integration of each osteopathic principle with biopsychosocial and patient education models, as well as manual medicine, and rehabilitation techniques proportionate to individual needs (Kuchera, 2007). There is evidence to suggest that manual therapy, in addition to patient education and exercise therapy, produces better results compared to either modality used alone.

Three systematic reviews, including a Cochrane review addressing the effects of manipulation and mobilisation for sub-acute and chronic non-specific neck disorders (Gross et al., 2004), concluded there is strong evidence that mobilisation and/or manipulation plus exercise reduces pain and improved
function in the short-term compared to a wait-list control (Gross et al., 2004; Gross, Kay, Hondras, et al., 2002). Similarly, a review by Miller et al., (2010) concluded that high-quality evidence suggests that the combination of manual therapy and exercise produces greater improvement in all outcome measures (pain, function/disability, quality of life, and patient satisfaction) when compared to manipulation or mobilisation alone for chronic neck pain.

Additionally, several important trials exploring multi-modal care including a combination of spinal manipulation, exercise, education and advice were identified. These were included in the aforementioned reviews. Bronfort et al., (2001) compared the benefit of spinal HVLA manipulation combined with rehabilitative exercise, to rehabilitative neck exercise alone, and to spinal manipulation alone for patients with chronic neck pain. They found significant pre/post improvements in all groups, however there were no significant differences between groups in the Visual Analogue Scale or Neck Disability Index scores, only differences which existed for satisfaction ratings and measures of strength, which were the highest in patients receiving the multi-modal combination of manipulation and exercise. The multi-modal care group showed greater average gains in all measures of strength, endurance and range of motion compared to either uni-modal group, however none of these were statistically significant, and patient satisfaction was the only outcome measure that achieved statistical significance compared to spinal manipulation alone after 11 weeks of treatment.

Another randomised controlled trial by Scholten-Peeters et al., (2006), similar in approach to the Bronfort et al., (2004) study, aimed to compare the effectiveness
of education and advice given by general practitioners (GPs) with education, advice, and active exercise therapy given by physiotherapists for patients with whiplash associated disorders. GP care consisted of reassurance that there was no serious injury, indication of expected positive prognosis, and the importance of staying active and resuming activities as soon as possible. They also encouraged patients to take responsibility for their health problem and de-emphasised the focus on pain. The exercise therapy consisted of the physiotherapist demonstrating a range of progressive loading exercises for cervical and shoulder muscle functions for participants to undertake in their own homes (which included stabilisation, coordination, muscle strength, endurance and length, posture and balance). Although no significant differences were identified between the enhanced general practitioner and physiotherapist care, the physiotherapist seemed to have a larger effect of cervical range of motion at short-term follow-up (12-weeks), and general practitioner care was more effective in the long-term (12-months) in terms of functional recovery, coping and physical functioning. The authors’ suggested that the lack of improvement in physiotherapist reduction in pain could be associated with poor understanding by participants when performing exercises in their own homes, and the encouragement of self-responsibility by GPs may have been a factor in the long-term improvements of the studies population. An alternative explanation might be that the physiotherapy treatment was not effective.

**Osteopathy as a Multi-modal Care**

There appears to be very limited research regarding the efficacy of osteopathic treatment for chronic neck pain, with only two sources identified in the indexed
literature: a single-cohort pilot study reported by Fryer et al., (2005), and a published abstract describing a randomised placebo controlled trial which compared 6 sessions of osteopathic manipulative treatment OMT and standard treatment with standard treatment alone (Mandara et al., 2010). The study by Fryer et al., (2005) employed multi-modal care within their treatment intervention. The ‘standard care’ aspect of treatment in the abstract by Mandara et al., (2010) was unspecified and it is thus unknown whether the treatment was multi-modal. Both studies found that self-rated pain and disability significantly reduced following 6 osteopathic treatments.

Fryer et al., (2005) explored relief of both chronic and sub-chronic pain in 17 subjects, and Mandara et al., (2010) investigated the treatment effects with 28 chronic neck pain subjects. The intervention in the study by Fryer et al., (2005) was clear, and consisted of various techniques including soft-tissue, muscle energy, counterstrain, and high-velocity low-amplitude thrust (HVLA) applied to the cervical and thoracic spines, as well as the inclusion of postural advice and exercise prescription (neck mobility and stretching) at the discretion of the practitioner. Being only a published abstract, the intervention in the study by Mandara et al., (2010) was less clear and precludes further analysis here. The study by Fryer et al., (2005) demonstrated mean (±SD) reduction in pain intensity over time on a 10 cm visual analogue scale, from pre-treatment (6.5 ± 3.1 cm), to 2 weeks (2.4 ± 2 cm), and 4 weeks (1.4 ± 2 cm) in both groups combined. Both the chronic and sub-chronic pain groups showed similar trends.

The major limitation of the study by Fryer et al., (2005) is that as a single-cohort design it lacked a control group, and that as a pilot study it only measured the
short-term effects (a 4-week programme) of treatment on pain. A key drawback with osteopathic research in the past has been the lack of a control group with which to compare and contrast results (Andersson, 1999; Fryer, 2005). Lack of resources, ethical issues and adverse psychological effects on participants that do not receive treatment are all reasons why this methodology is not more frequently applied. As it is impossible to blind this type of research some studies have applied sham treatments, which has been shown to be effective in certain situations (Licciardone, 2003), however this approach still lacks the robustness of a control group. Fryer et al., (2005) recommended that future investigators conduct research with a longer period to monitor longer-term improvements. The long-term effects of OMT for chronic neck pain are unknown, thus controlled studies with clearly described interventions with longer follow-up periods are required to address the near complete absence of literature reporting OMT investigations.

Conclusion

Neck pain is a common problem affecting a large percentage of the general population. Chronic pain and disability in particular lay a heavy burden on the individual and society as a whole. While current evidence of many manual techniques have been well explored, research regarding the effects of osteopathic treatment is limited both in quality and volume. Only one study was found that investigated the effects of osteopathy for chronic neck pain, though the sample size was small, there was no control group, and changes were only examined over a short 4-week period. Multimodal treatment, including exercise, sometimes lifestyle modification and postural advice has been suggested to provide greater
benefits than studies addressing the effects of a single technique. For these reasons, a study to investigate both the short- and long-term effects of a course of osteopathic treatment, incorporating multimodal strategies, on chronic neck pain and disability is necessary.

Section 2 of this thesis reports on such an investigation.
References


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Section 2: Manuscript

**Note:** This manuscript has been prepared in accordance with the instructions for authors for the journal *International Journal of Osteopathic Medicine (IJOM)* [See Appendix K for Guide for Authors]. For the purposes of completion of this thesis some guidelines from *IJOM* have not been followed. The instructions suggest tables, illustrations and figures should not be placed within the manuscript, however in this manuscript they are positioned where they are most readable.
The effects of osteopathic treatment on non-specific chronic neck pain and disability
The effects of osteopathic treatment on non-specific chronic neck pain and disability

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1. ABSTRACT

**Background:** Neck pain is common among the general population and can be disabling and costly. **Aim:** The aim of this quasi-randomised controlled trial was to investigate whether osteopathic treatment would reduce perceived disability and pain in people with chronic neck pain. **Methods:** Twenty-one participants (mean age 52.1 ± 10.8 years; 6 males, 15 females) with chronic, non-specific neck pain (median duration of symptoms of 313 weeks [range = 17-1565]) were recruited and enrolled in this study. Participants were randomised either to begin immediately or after 3 weeks, a 3-week course of osteopathic. **Results:** An ANOVA model revealed greater improvements after 3 weeks in Neck Disability Index (NDI) ($P = 0.03$) for the Immediate-Start group (from 23 ± 12 to 17 ± 11 points) compared to a negligible change for those who had a delayed start (25 ± 10 to 26 ± 10 points). Analysed as a single cohort, improvements over time were observed for all outcome measures ($P$ values all <0.01). Post hoc analyses showed a mean reduction of 9 percentage points (95% CI: 5 – 13) for NDI, 2 points reduction (95% CI: 1 – 3) for PSFS, and 9-point reduction (95% CI: 3 – 14) for MPQ from before to immediately following the last treatment session as well as similar reductions from before treatment to the 6-week follow-up measure (at $P < 0.05$ level). A similar analysis for pain intensity (VAS) showed changes from pre-intervention 3.3 ± 2 cm to all follow-up treatment measurements, the final measurement at 6-weeks being 1.5 ± 1.5 cm. **Conclusion:** Self-reported pain and disability were reduced following a course of osteopathic treatment. This quasi-randomised controlled trial suggests that osteopathic treatment may be effective for the management of chronic neck pain.

**Keywords:** Clinical trial; Pain management; Osteopathic medicine; Spinal manipulation
2. INTRODUCTION

Neck pain is common, disabling to various degrees, and a major problem in modern society.\textsuperscript{1,2} It has a lifetime prevalence of approximately 70\% in the general population\textsuperscript{3,4} and is higher for women than men.\textsuperscript{1,3-8} Prevalence has been shown to increase with age.\textsuperscript{1-5} Although neck complaints are often self-limiting within a few weeks of onset, approximately 19\% of the population suffer from chronic neck pain at any given time,\textsuperscript{3,9} and approximately 50\% of people who experience neck pain at some point will report recurrences or persistent complaints 1-5 years after the index complaint.\textsuperscript{10} This chronic neck pain has been associated with functional limitation, lost work time, and also results in substantial healthcare costs and a significant societal burden.\textsuperscript{1,11,12}

‘Chronic pain’ has been described as pain persisting for at least 12-weeks duration following onset, or when a person experiences essentially continuous, low level exacerbations of pain (each of which may be referred to as an ‘acute’ episode) for a period greater than 12-months.\textsuperscript{13} The occurrence of chronic neck pain is not usually a result of new tissue damage, though it can be associated with an unresolved injury.\textsuperscript{14,15}

Aetiological studies indicate that the majority of traumatic neck injuries occur in automotive collisions, with vertebral fracture and whiplash the most commonly reported injuries.\textsuperscript{16,17} However, in the majority of cases, the aetiology of chronic neck pain is non-traumatic and is not associated with tissue pathology.\textsuperscript{18} Clinically, the concept of neck dysfunction is widespread, and may be associated with poor posture and stress. It has also been suggested that in
various occupations such as office jobs, neck pain may be associated with the adoption of sustained non-neutral spinal postures, causing increased activation of the neck and shoulder muscles resulting in higher levels of cervical spine mechanical loading.\textsuperscript{19}

Neck pain is a common occurrence, and as such many people seek conservative treatment such as manual therapy for symptomatic relief.\textsuperscript{20} Many studies and systematic reviews have examined the efficacy of manual therapies on neck pain,\textsuperscript{21-28} and have demonstrated positive outcomes for patients with neck pain, with reports of reductions in pain,\textsuperscript{29-31} and in pain and disability.\textsuperscript{32-34}

Osteopathy is a multi-modal approach that integrates manual therapy and other management approaches including patient education, movement and exercise advice. Treatment depends on the aetiology of pain, predisposing and maintaining factors and the patient’s treatment goals, and manual techniques can be directed at regions remote from the site of pain in an attempt to address dysfunction.\textsuperscript{35}

Osteopathic treatment of the cervical spine has been claimed to assist healing of injury or dysfunction of the cervical region,\textsuperscript{36} although there is limited research regarding the effectiveness of osteopathic treatment for chronic neck pain with only one single-cohort pilot study reported by Fryer et al\textsuperscript{33} and a published abstract describing a randomised placebo-controlled trial.\textsuperscript{34}

Fryer et al.\textsuperscript{33} explored the effects of a semi-standardised osteopathic treatment
programme in 17 participants with either chronic or sub-chronic non-specific neck pain. Despite the findings that self-rated pain and disability were significantly reduced after treatment, compared to before, changes cannot be unquestionably attributed to the osteopathic treatment as the study lacked a control group. Additionally, it only explored the short-term effects, after the 4-weeks of treatment, and the authors recommended monitoring longer-term outcomes in future studies.

Although there is an abundance of research which has examined the effects of specific manual therapeutic techniques on neck pain, quality studies examining the effects of an all-encompassing osteopathic management treatment programme are lacking. The aim of this quasi-randomised controlled trial is to examine the effects of osteopathic management for people with neck pain in both the short-term and a longer-term period of 6-weeks.
3. METHODS

The study was designed as a quasi-randomised controlled trial in which participants were randomised to begin treatment immediately (Immediate-Start group) or after 3 weeks (Delayed-Start group). It was therefore possible to compare the effect of the 3-week intervention with a control condition. Because all participants eventually received treatment, an additional analysis, including the entire cohort, of changes from before to after treatment and after an additional 3-week follow-up was also possible.

3.1. Study Sample

Participants were recruited from the local community using published newspaper editorials, advertising posters and through an online service that offers strategic online and social marketing assistance for study promotion and recruitment (http://www.getparticipants.com). For inclusion, all participants were required to be aged between 25 and 65 years with current neck pain of at least 12-weeks duration; to experience at least 3/10 pain intensity at some point on most days; to be able to read and understand English; and to have a primary complaint perceived as arising from the neck region, as defined by Merskey & Bogduk.\textsuperscript{13} Participants were ineligible to participate if they demonstrated any signs of spinal pathology (e.g. tumor, infection, fracture); signs of nerve root compression; recent (within previous 6-months) history of spinal surgery or whiplash; or history of symptoms related to significant trauma. Osteopathy students or anyone who had substantial experience of osteopathic treatment were also ineligible. Interested applicants received a phone call or email to determine their eligibility [See Appendix B], and prospective participants were
invited to attend a consultation where they were informed of the study procedures and gave written informed consent [See Appendices C and D]. The study was approved by the institutional research ethics committee (UREC Approval 2011-1196) [See Appendix A].

3.2. **Outcome Measures**

Neck disability outcomes were assessed using the Neck Disability Index (NDI)\(^{37}\) and Patient Specific Functional Scale (PSFS)\(^{38}\) and pain outcomes using the McGill Pain Questionnaire (MPQ)\(^{39}\) and pain intensity using a 100 mm Visual Analogue Scale (VAS).\(^{40}\)

### 3.2.1. **Neck Disability Index**

The NDI consists of 10-item questionnaire which requires respondents to self-report the degree to which pain affects their specific ability to manage activities of daily living, and rate them on a 0 to 5 point scale: 0=no disability, 5=extreme disability. The scale has been shown to achieve a high degree of reliability, validity and internal consistency.\(^{37}\)

### 3.2.2. **Patient Specific Functional Scale**

The PSFS requires respondents to self-nominate up to three activities that are affected by their neck pain, and rate each on an 11-point scale from 0 (unable to perform activity) to 10 (able to perform activity at pre-injury or pre-pain level). The scale has been shown to be a highly reliable (ICC=0.97)\(^{41}\) and responsive\(^{42}\) outcome measure.
3.2.3. *McGill Pain Questionnaire*

The MPQ requires respondents to identify self-perceived aspects of pain by selecting appropriate descriptors from a selection of 78 in order to assess the multidimensional nature of pain. The descriptors are given a numerical scale rating from ‘mildest’ to ‘worst’, and the sum of these scores represents the total Pain Rating Index (PRI). The questionnaire also investigates the pattern of pain (brief, intermittent, continuous), and includes a 5-point Present Pain-Intensity (PPI) scale. This questionnaire has been shown to be a highly reliable, valid and consistent measurement tool\(^\text{39}\) and correlates with the NDI.\(^\text{37}\)

3.2.4. *Pain Intensity using the Visual Analogue Scale*

The VAS is a simple measure of the intensity of pain, which requires respondents to rate their present pain intensity by marking a point along a 100 mm horizontal line, the margins representing ‘No pain’ to ‘Worst possible pain’. The scale has been reported to be one of the best methods available for estimating the intensity of clinical pain,\(^\text{43}\) more robust than the PPI of the McGill Pain Questionnaire as it allows the participant greater choice when scoring pain intensity.

Three measures (NDI, PSFS, MPQ) were taken prior to any scheduled treatment every 3 weeks, until 3 weeks after the intervention had concluded (at weeks 0, 3, and 6 for the Immediate-Start group, and at Weeks 0, 3, 6 and 9 for the Delayed-Start group) [See Figure 1 for CONSORT Diagram]. Pain intensity was measured prior to each treatment session.
3.3. **Intervention**

Participants were physically examined by one of two supervised final-year student osteopathy practitioners prior to each treatment session. Examination included observation, active and passive motion testing of the axial skeleton, palpation of tissue texture of the cervical and thoracic spinal regions and any related pain responses. All findings were recorded in the clinical notes.

The intervention consisted of a selection of osteopathic manual techniques applied to the neck and upper-to-mid back and every session included at least one of the following components: (1) soft tissue technique (cross-fibre kneading, longitudinal stretch and inhibition) to upper trapezius, scalene, sternocleidomastoid, cervical, thoracic erector spinae, levator scapulae and sub-occipital muscles; (2) articulation (passive joint mobilisation) to the cervical and thoracic spine; (3) muscle energy technique (isometric facilitated stretching) to the scalenes, levator scapulae, trapezius and sternocleidomastoid muscles; (4) counterstrain technique (positional release); (5) and high-velocity low-amplitude thrust to intervertebral joints of the cervical or thoracic vertebrae, performed at the discretion of the practitioner. Treatment of other regions was permissible if it was in clinical judgment of the practitioner. Each participant received two 30-minute treatment sessions per week for 3 weeks. In an attempt to represent typical osteopathic practice, practitioners were permitted to include postural advice and exercise prescription (neck mobility and stretching) if they judged it to be appropriate to the case.
3.4. **Data Analysis**

Data were analysed using SPSS version 19 (SPSS and IBM Co., Chicago IL). Variables were explored for assumptions of normality by analysing the values for skewness and kurtosis with their standard errors and completing a Shapiro-Wilk test. ANOVA models were used both to compare differences in change of outcome measures between those who had and who had not yet received treatment, and to analyse change from pre- to immediately post-intervention and to 3-week follow-up. Tests for equality of variance and sphericity assumptions were also applied for t-tests and ANOVAs, and Levene’s and Mauchley’s corrections applied when these were violated. Effect sizes were calculated using Cohen’s formula, with the standard deviation of the difference used as the common denominator. These effect sizes were evaluated using Hopkins descriptors of magnitudes of effect and the level of statistical significance set at $P = 0.05$. 


4. RESULTS

Assessed for eligibility (n=63)

Excluded (n=35)
  • Not meeting inclusion criteria (n=35)

Randomised (n=28)

Immediate-Start Group (n=14)

Initial/Pre-Intervention measures (NDI, PSFS, MPQ, VAS)

Intervention (3 weeks)
  • Provided advice and completed full osteopathic intervention programme twice per week for 3 weeks (n=11)
  • Failed to complete the full osteopathic intervention and advice programme twice per week for 3 weeks (n=3)

Post-Intervention measures
  • Outcome measures taken after final osteopathic intervention (n=11)

Follow-Up
  • Further outcome measures taken after 6-week follow up (n=11)

Allocation

Delayed-Start Group (n=14)

Initial measures (NDI, PSFS, MPQ)

Pre-Intervention measures
  • Scheduled for delayed treatment twice per week for 3 weeks (n=14)

Intervention (3 weeks)
  • Provided advice and completed full osteopathic intervention programme twice per week for 3 weeks (n=10)

Post-Intervention measures
  • Outcome measures taken after final osteopathic intervention (n=10)

Follow-Up
  • Further outcome measures taken after 6-week follow up (n=9)
  • Lost to follow up (n=0)

Analysis

Figure 1. CONSORT diagram of the trial design
All 28 participants enrolled in the study completed the initial assessments; 7 withdrew due to time constraints (4 prior to starting the treatment intervention and 3 during the intervention). Thus, 21 participants, 75% of the original sample, completed the intervention (with a minimum of 5 treatments) and both post-intervention assessments. The majority of the participants (n=15/21) were older than 45 years, and the median duration of symptoms was 313 weeks (range 17 – 1565) (Table 1). A small proportion of the participants (n=6/21) received prescriptive stretches, mobilisation exercises and/or advice in addition to the osteopathic manipulative therapy (Table 2).

Z-scores for skewness and kurtosis of pre- to immediately post-intervention change for NDI, PSFS and MPQ were within 95% confidence interval for normal distribution, using a procedure recommended by Field et al. (pg 139). Similarly, the Shapiro-Wilk test showed no evidence that the distribution varied from normal for changes in NDI or MPQ. The Shapiro-Wilk test indicated that PSFS was non-normally distributed, however an analysis using both parametric and non-parametric approaches showed similar findings therefore parametric results are reported. The pre-treatment to final treatment change in VAS indicated possible skewness but did not violate the assumption of normality according to Shapiro-Wilk test. Additionally, distribution of the changes to follow-up indicated possible skewness for NDI and MPQ and possible kurtosis for NDI but the Shapiro-Wilk test was not significant for either.
4.1. **Analysis as a Randomised Controlled Trial**

Whilst the Neck Disability Index did not change appreciably between Visit 1 and Visit 2 for the Delayed-Start group, there was an improvement in the Immediate-Start group (reduction of 6 percentage points), who had intervening treatment during this time period (Figure 2; $P = 0.03$ for interaction between group and time). There was also an improvement in the Immediate-Start compared to the Delayed-Start group for the Present Pain Intensity (MPQ) (Figure 5; $P = 0.02$). Similar trends were shown for both the Patient Specific Functional Scale and Pain Rating Scale (MPQ), though they did not achieve statistical significance (Figures 3 & 4; $P = 0.2-0.3$).
Figure 2. Randomised controlled trial of the Neck Disability Index (/50) in patient’s with non-specific chronic neck pain for the Immediate-Start group (Two-way ANOVA, $P = 0.03$) Error bars show 95% CI.

Figure 3. Randomised controlled trial of the Patient Specific Functional Scale (/10) in patient’s with non-specific chronic neck pain for the Immediate-Start group (Two-way ANOVA, $P = 0.3$) Error bars show 95% CI.

Figure 4. Randomised controlled trial of the McGill Pain Questionnaire Pain Rating Index (/78) in patient’s with non-specific chronic neck pain for the Immediate-Start group (Two-way ANOVA, $P = 0.2$) Error bars show 95% CI.

Figure 5. Randomised controlled trial of the McGill Pain Questionnaire Present Pain Intensity (/5) in patient’s with non-specific chronic neck pain for the Immediate-Start group (Two-way ANOVA, $P = 0.02$) Error bars show 95% CI.
4.2. **Analysis as a Single Cohort**

Data were also analysed as a single cohort to ascertain the degree of change in outcome variables following treatment using multilevel linear ANOVA models which use all available data when some data-points are missing.\(^{47}\) Changes from pre- to immediately post-intervention to 6-week follow-up were analysed for NDI, PSFS and MPQ (PRI and PPI), as were changes in VAS from pre-intervention to the final measurement made prior to the final treatment. Differences over time were significant for all variables (See Table 3).

The effect sizes of exercise and advice were tabulated, and differences in outcomes between compliance versus non-compliance were observed. Overall, there were negligible differences in outcome for NDI, PSFS or MPQ between those who were compliant with exercise prescription (n = 4) and those who were not (n = 2) (Table 2). All participants who were compliant with prescribed exercise or advice (n = 4/21) displayed ‘moderate’ to ‘very large’ improvements for pain, and 3 of the 4 participants showed ‘moderate’ to ‘large’ improvements for disability. Both non-compliant (n = 2/21) participants showed ‘moderate’ improvements in disability, ‘small’ to ‘nearly perfect’ differences for pain as measured by VAS, and ‘trivial’ to ‘large’ differences for the PPI.
5. DISCUSSION

The aim of this study was to build on the work outlined in Fryer et al\textsuperscript{33} by documenting the outcomes of a semi-standardised osteopathic treatment approach combined with postural advice and exercise prescription (neck mobility and stretching) for those with non-specific, chronic neck pain. By improving on the trial design of Fryer et al\textsuperscript{33} this study demonstrates that osteopathic treatment can be effective in the treatment of chronic neck pain.

In conducting their trial, Fryer et al\textsuperscript{33} examined a single cohort which by design, lacks a control group. As a result, the possibility exists that the improvement in outcomes was as a result of an effect other than osteopathic treatment. In an effort to improve on the single cohort design employed by Fryer et al\textsuperscript{33} this research examines the study sample both as a single cohort (to determine the degree of change following treatment) and a randomised controlled trial (RCT) with a control group. According to Altman\textsuperscript{48} RCTs are the best way to compare the effectiveness of different interventions, allowing valid inferences of cause and effect. The control group, achieved by staggering treatments for the Immediate-Start and Delayed-Start groups, was a useful addition in comparing the effects of the natural course of the condition, and the approach may also offer ethical advantages as both the Immediate and Delayed-Start groups received treatment. This delayed-start approach provides a useful template that efficiently and ethically uses limited resources, which is particularly appropriate in the context of osteopathy, due to the newly developing research environment within the profession.
Although there are limited data available, combining osteopathic manual therapy, advice and exercise prescription appears to be reasonably common practice in New Zealand. As a result, these treatment strategies were included in this study to improve the external validity of the trial findings. In addition, a semi-standardised intervention was used to promote a degree of consistency between treating practitioners whilst allowing sufficient flexibility to address individual clinical requirements. This approach to clinical studies has been effectively demonstrated in other manual therapy studies, and reduces the restrictions upon the practitioner’s ability to treat compared to fully standardised approaches. Despite the limited availability of clinical trials employing semi-standardised osteopathy interventions, there is precedent for successful use in clinical trials of acupuncture.

Although there is little reference to practice style in the literature, it appears that osteopaths employ a variety of techniques in their practice. In a survey of New Zealand osteopathic practitioners, Wittwer-Blaser showed those who used a more ‘structural’ style were less likely to use ‘non-structural’ techniques, and vice versa. Techniques such as muscle energy technique, high-velocity low-amplitude thrust, and joint articulation were shown to strongly cluster together to form this ‘structural’ approach, which could suggest that multiple techniques are commonly used in everyday practice. In addition, Mistry showed that exercise prescription and advice to be common practice within the osteopathic profession in New Zealand. The nature of the approach used in this study was intended to be broadly representative of contemporary osteopathic clinical practice in New Zealand.
Addressing the outcomes of this study, results demonstrated that osteopathic treatment, when used in combination with appropriate exercise and advice, significantly reduced neck pain and disability. RCT analysis showed participant improvement in self-rated pain intensity (PPI), pain quality (PRI) and disability (NDI and PSFS) for the Immediate-Start group compared to the Delayed-Start group (control) from pre- to post-treatment and from pre-treatment to follow-up 6 weeks later. The single cohort analysis reinforced findings from the RCT, since differences were found over time for all outcome measures, including pain intensity. The single cohort study by Fryer et al.,\textsuperscript{33} showed similar results, with differences found between all times points (at 2-weeks and 4-weeks) for NDI and PRI, and between pre-treatment and 2-weeks and pre-treatment and 4-weeks for VAS.

‘Moderate’ effect sizes were demonstrated in this study for all outcome measures from pre- to post-treatment, and between pre-treatment to follow-up. Of the four self-report measures employed in this research, variances between the pre- and post-measures for the VAS and PSFS pain and disability questionnaires were greater than the reported minimum clinically important difference (MCID), which, as described by Kvien et al\textsuperscript{53} indicates an improvement of relevance in a clinical trial. Conversely, variances between the pre- and post-measures for NDI were less than the MCID, although it appears that no MCID value has been identified for MPQ, PPI nor PRI.

Exploring perceived pain intensity in detail, both the VAS and the PPI demonstrated improvements over time. At the end of the trial, the mean VAS score had decreased by 18 mm, above the MCID of 14 mm on a 100 mm
This compares with results published by Todd et al who found that despite being statistically significant, studies reporting less than a 13 mm change in pain severity may have no clinical importance.

Focusing on improvements in disability in detail, the pre- to post-NDI score was 9 percentage points, which was less than the MCID range of 15 to 21 percentage points determined by Carreon and Young. Pre- to post-intervention change for the PSFS was 2 points, the same as the MCID as reported by Cleland et al who examined test-retest reliability, construct validity and minimum levels of detectable and clinically important change for the NDI and PSFS in a cohort of patients with cervical radiculopathy.

With regard to exercise prescription and advice, the changes in pain and disability do not appear to have been associated with the participants’ compliance although the limited sample precludes formal statistical analysis. As there were only 2 non-compliant participants it is not possible to generalise the findings regarding the effect of compliance with exercise and advice to a wider population.

Clinically meaningful reductions in neck pain and disability were observed in participants following a semi-standardised course of osteopathic treatment. Despite this relationship between treatment and clinical improvement, a definitive causal relationship cannot be concluded due to several limitations of the study design. These data (NDI, PSFS, MPQ) were collected immediately after their final treatment session which may have resulted in a bias towards evaluating the effect of the last treatment rather than overall treatment.
would possibly have been better to have obtained data several days after the final session to provide separation between the outcome of the final session and the overall outcome. In addition, the VAS was only completed prior to each treatment rather than also at the primary measurement points. This resulted in missing data points, and limited the ability to correlate VAS and the PPI.

This study was intended to be consistent with the characteristics of a pragmatic approach to trial design\textsuperscript{46} in which the use of non-blinded assessors is common, especially in non-pharmacologic trials.\textsuperscript{56} Therefore, an independent blinded assessor was not employed. The lead researcher assisted in the assessment of participant eligibility, collection of data, and the administration of osteopathic treatment and advice, and it is possible that they unintentionally transferred their attitudes for or against the intervention (or lack thereof), or they subtly and unconsciously encouraged or discouraged continuation of the trial on the basis of knowledge of the intervention group assignment.

Future studies should include a larger sample size in order to improve generalisability, or to include a sub-group analysis to determine those more likely to benefit from osteopathy.\textsuperscript{57} Studies should also have a longer-term follow-up period as literature for low back or neck pain trials typically report 1-2 year follow-up periods, and they should include an independent blinded assessor to avoid bias.
6. CONCLUSION

Osteopathic treatment, when used in combination with appropriate exercise and advice, was found to significantly decrease the quality and intensity of neck pain and disability over a 3-week treatment period when compared to a control group receiving no treatment. When analysed as a single cohort, these effects were demonstrated both immediately post-intervention, and at a follow-up period 3-weeks after cessation of treatment. Results showed that scores for VAS and PSFS were greater than the MCID whilst the NDI scored lower and no MCID score was found for MPQ. This study indicates that osteopathic treatment, as structured in this study, may be effective for the management of chronic neck pain. Future research using a larger sample size and a longer follow-up period is recommended.
7. REFERENCES


8. **TABLES**

**Table 1.** Participant characteristics at baseline

<table>
<thead>
<tr>
<th></th>
<th>Female</th>
<th>Male</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>15</td>
<td>6</td>
<td>21</td>
</tr>
<tr>
<td>Age (years)</td>
<td>51 ± 11</td>
<td>55 ± 10</td>
<td>52 ± 11</td>
</tr>
<tr>
<td>Duration of pain (weeks)</td>
<td>495 ± 545</td>
<td>141 ± 170</td>
<td>412 ± 502</td>
</tr>
</tbody>
</table>

Data are mean (±SD)
Table 2. Scores of all outcome measures for participants who received exercise prescription or advice

<table>
<thead>
<tr>
<th>ID</th>
<th>Gender</th>
<th>Advice/exercises given</th>
<th>NDI pre</th>
<th>NDI post</th>
<th>NDI ES</th>
<th>VAS pre</th>
<th>VAS post</th>
<th>VAS ES</th>
<th>PSFS pre</th>
<th>PSFS post</th>
<th>PSFS ES</th>
<th>MPQ pre</th>
<th>MPQ post</th>
<th>MPQ ES</th>
<th>PPI pre</th>
<th>PPI post</th>
<th>PPI ES</th>
</tr>
</thead>
<tbody>
<tr>
<td>3*</td>
<td>M</td>
<td>5x bilateral daily shoulder rolls</td>
<td>10</td>
<td>0</td>
<td>1.1</td>
<td>1.5</td>
<td>0.0</td>
<td>1.5</td>
<td>5</td>
<td>8</td>
<td>1.6</td>
<td>6</td>
<td>0</td>
<td>0.5</td>
<td>1</td>
<td>0</td>
<td>1.3</td>
</tr>
<tr>
<td>6*</td>
<td>F</td>
<td>3x bilateral daily shoulder rolls</td>
<td>34</td>
<td>22</td>
<td>1.4</td>
<td>6.4</td>
<td>-</td>
<td>-</td>
<td>4.8</td>
<td>7.7</td>
<td>1.5</td>
<td>39</td>
<td>6</td>
<td>2.6</td>
<td>4</td>
<td>1</td>
<td>3.8</td>
</tr>
<tr>
<td>7*</td>
<td>F</td>
<td>3x bilateral daily shoulder rolls + neck side bending stretches</td>
<td>16</td>
<td>12</td>
<td>0.5</td>
<td>2.0</td>
<td>0.2</td>
<td>1.9</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>25</td>
<td>7</td>
<td>1.4</td>
<td>2</td>
<td>1</td>
<td>1.3</td>
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<tr>
<td>21*</td>
<td>F</td>
<td>Thoracic and cervical mobility alphabet</td>
<td>26</td>
<td>16</td>
<td>1.1</td>
<td>2.0</td>
<td>0.1</td>
<td>2.0</td>
<td>4.5</td>
<td>5.5</td>
<td>0.5</td>
<td>9</td>
<td>7</td>
<td>0.2</td>
<td>1.5</td>
<td>1</td>
<td>0.6</td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>Chin tucks</td>
<td>26</td>
<td>18</td>
<td>0.9</td>
<td>6.8</td>
<td>5.4</td>
<td>4.1</td>
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<td>-</td>
<td>-</td>
<td>14</td>
<td>17</td>
<td>0.2</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>18</td>
<td>M</td>
<td>Use heat pack on rhomboids</td>
<td>6</td>
<td>0</td>
<td>0.7</td>
<td>0.7</td>
<td>0.9</td>
<td>0.3</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>4</td>
<td>0</td>
<td>0.3</td>
<td>1</td>
<td>0</td>
<td>1.3</td>
</tr>
</tbody>
</table>

a. Effect sizes for parametric data were calculated using Cohen statistic.

b. Abbreviations as follows: Neck Disability Index (NDI), Visual Analogue Scale (VAS), Patient Specific Functional Scale (PSFS), McGill Pain Questionnaire (MPQ), Pain Rating Index (PRI), Present Pain Intensity (PPI). Pre = pre-intervention measure, post = immediately post-intervention measure, ES = effect size.

c. * Compliant participants (defined as those who undertook the exercises-prescribed)
<table>
<thead>
<tr>
<th></th>
<th>Baseline Mean (±SD)</th>
<th>Change to Immediately Post-Intervention Mean (95% CI)</th>
<th>Effect size (d)</th>
<th>P</th>
<th>Change to Follow-up Mean (95% CI)</th>
<th>Effect size (d)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDI score</td>
<td>24.3 ± 10.5</td>
<td>8.7 (4.7 – 12.7)</td>
<td>0.99</td>
<td>P &lt; 0.001</td>
<td>9.7 (6.4 – 13.0)</td>
<td>1.36</td>
<td>P &lt; 0.001</td>
</tr>
<tr>
<td>VAS (mm)</td>
<td>3.3 ± 1.9</td>
<td>1.8 (1.0 – 2.6)</td>
<td>1.03</td>
<td>P &lt; 0.001</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>PSFS score</td>
<td>5.1 ± 1.4</td>
<td>2.0 (3.2 – 0.7)</td>
<td>1.01</td>
<td>P = 0.005</td>
<td>2.1 (3.6 – 0.6)</td>
<td>0.88</td>
<td>P = 0.01</td>
</tr>
<tr>
<td>MPQ (PRI score)</td>
<td>19.4 ± 9.8</td>
<td>8.5 (2.6 – 14.3)</td>
<td>0.66</td>
<td>P = 0.007</td>
<td>12.1 (7.0 – 17.1)</td>
<td>1.11</td>
<td>P &lt; 0.001</td>
</tr>
<tr>
<td>MPQ (PPI score)</td>
<td>2.0 ± 0.8</td>
<td>0.9 (0.6 – 1.3)</td>
<td>1.17</td>
<td>P &lt; 0.001</td>
<td>0.7 (0.2 – 1.2)</td>
<td>1.17</td>
<td>P = 0.008</td>
</tr>
</tbody>
</table>

Effect sizes for parametric data were calculated using Cohen’s formula,44 with the standard deviation of the difference used as the common denominator. Abbreviations as follows: Neck Disability Index (NDI), Visual Analogue Scale (VAS), Patient Specific Functional Scale (PSFS), McGill Pain Questionnaire (MPQ), Pain Rating Index (PRI), Present Pain Intensity (PPI).
Section 3: Appendices
Appendix A: Ethics Approval Letter
25 August 2011

Re: Request for changes

Dear Catherine,

Your file number for this application: 2011-1196

Project Title: The effect of osteopathic therapy on chronic neck pain and disability: associations with neck posture and mobility.

Your request for changes to the above application have been reviewed by the Unitec Research Ethics Committee (UREC) and have been approved for the following period:

**Start date: 28.7.2011**
**Finish date: 28.7.2012**

Please note that:

1. The above dates must be referred to on the information AND consent forms given to all participants

2. You must inform UREC, in advance, of any ethically-relevant deviation in the project. This may require additional approval.

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

Yours sincerely,

Scott Wilson
Deputy Chair, UREC

cc: Kathryn Marr
Monique Gasson
Appendix B: Telephone Screen
Hi, Who am I speaking with? Name: ...........................................  Age: .......

Blurb about research: Thank you for your interest in our research project. The study is looking at evaluating the effectiveness of osteopathic treatment on neck pain. It involves treatment by Unitec Master of Osteopathy students. Still interested? Great, can I ask you a few questions to make sure that you can take part in the study?

1. Do you currently have neck pain?
2. Has your neck pain been present for 12 weeks or more? No - exclude
3. Do you experience pain at least 3/10 at some point on most days? No - exclude
4. Is your neck pain due to a motor vehicle accident or significant trauma? Yes - exclude
5. Have you been diagnosed with whiplash in the past 6 months? Yes - exclude
6. Have you undergone any surgery involving your neck? Exclude if the surgery occurred in the past 6 months
7. Do you experience any symptoms in your arms – like pain, weakness or numbness? If yes, please explain: .......................................................... May require physical examination – exclude if stenosis, nerve root compression, rheumatologic
8. Would you be willing to commit to attending 2x 30-minute treatment sessions per week for 3 consecutive weeks (total of 6 treatments) at Unitec Osteopathic Clinic in Mount Albert?
9. Would you be willing to attend a pre-intervention and a follow-up session (30-minutes each)?
Appendix C: Participant Information
You are invited to participate in our research investigation. Please read carefully through this information sheet before you make a decision about volunteering.

**Researchers**
Kathryn Marr and Monique Gasson, Bachelor of Applied Science (Human Biology). Kathryn is in her final year of the Master of Osteopathy Programme at Unitec New Zealand, and Monique is in her first year.

**Our Purpose**
This study aims to determine whether osteopathic treatment of the neck and upper-mid thoracic spine is effective in the management of non-specific chronic neck pain when it is provided in addition to standard advice and exercises which are commonly prescribed. Measures of pain, disability, posture and neck mobility will be examined and their relationships with each other, and with pain reduction following treatment, will also be investigated.

Chronic neck pain is defined as pain which has been present for at least 12 weeks since onset (Merskey & Bogduk, 1994). It is often associated with varying degrees of disability which can affect a person’s quality of life and may also be associated with specific conditions such as fracture, disc compression or neurological compromise. However, a specific cause cannot be identified for the majority of cases in neck pain, and as such pain is classed as *non-specific*.

There are a wide range of treatments for chronic neck disorders ranging from pain management and manual therapy, to neck-specific strengthening exercises and educational advice. Manual therapy and exercise have become common choices in the management of chronic neck pain. By participating in this study you will help us to determine whether osteopathic treatment is effective at reducing pain or disability and the factors that might affect treatment success.

**Who may participate?**
We are looking for adults aged 25 to 65 years who suffer from chronic neck pain that has lasted at least 12 weeks. You must experience regular pain of mild-moderate severity (at least 3 out of 10 on a numeric pain scale most days).
Unfortunately, you will be ineligible to take part in the study if:

- Your symptoms are related to a motor vehicle accident or significant trauma that has occurred in the last 6 months
- You have been diagnosed with whiplash disorder
- You have undergone neck surgery in the past 6 months
- You have any diagnosis or signs of serious pathology such as fracture, inflammatory disorders or infection
- There are any signs of neurological symptoms determined by the presence of sensory abnormalities, weakness, or altered reflexes
- You have recently had regular osteopathy treatment for your neck

Please feel free to contact the principal researcher if you have any questions regarding your eligibility.

**What will happen in the study?**

If you meet the inclusion criteria of the study and are willing to participate you will be asked at your first appointment to complete a medical questionnaire that provides information about your neck pain, and will be examined to identify whether there are any specific pathological causes of your pain. These examinations will determine your eligibility to take part in the study. Once eligibility is confirmed, you will be asked to complete a series of four questionnaires, a posture evaluation and range of motion assessment. This initial session will take approximately 90 minutes and every participant will receive standard advice and exercises to perform at home. For effective osteopathic diagnosis you will be required to undress to your underwear (shorts and sports bra are appropriate). If you are ineligible to take part in the study, your treatment options will be discussed with you.

You will then be randomly assigned to one of two groups, an **immediate start** or a **delayed start group**. If you are randomised to the immediate start group, an appointment will be made for you for the following week to begin the osteopathic treatment intervention. Osteopathic treatments will occur twice per week for 3 weeks (a total of 6 treatments) and take approximately 30-45 minutes. At the end of the 3 weeks you will be required to complete the same questionnaires and measurements that were carried out during the first treatment consultation. There will also be a follow up 3 weeks after your last treatment, where you will be required to complete the same measures once more. This is to provide us with some longer-term information.

If you are randomised to the delayed-start group, an appointment will be made for you in 3 weeks time, when you’ll be asked to complete the questionnaires and neck assessments again. You will then begin the osteopathic interventions the following week. At the end of the 3 weeks of the
osteopathic intervention, and again 3 weeks following the end of treatment the
same measures will be completed once more.

The osteopathic treatment
The selection of osteopathic techniques used will include those that are
regularly used in the Unitec Student Osteopathic Clinic. The treatment will be
carried out by a student osteopath currently undertaking a Masters of
Osteopathy at Unitec New Zealand, and will be supervised by a registered
osteopath with substantial clinical experience.

What we do with the data and results, and how we protect your privacy
Personal information is collected and stored under the guidelines provided by
the Privacy Act 1993 and the Health Information Privacy Code 1994. Your
name will be recorded on the written consent form, your health questionnaire
and on the VAS, NDI, MPQ and PSFS questionnaires. In all other instances of
information collection your identity will remain confidential and you will be
allocated an identification number. If the information you provide is reported or
published, this will be done in a way that does not identify you as its source.
All the data recorded and collected will be stored in a secure manner and
access to it will be limited to the principal researcher, the research
supervisors, and yourself.

Discomforts/risks and benefits
While there is a small risk associated with manipulation of the neck, the
medical questionnaire and the physical examination which are both completed
before any technique is applied, are designed to ensure your safety by
identifying and excluding any individual that may be put at risk by any
subsequent techniques.

Any aggravation you may experience from treatment should last no more than
24 hours. However, should the discomfort persist assistance will be given to
help relieve it.

Your voluntary participation
The decision to participate in this study is totally voluntary. During the
treatment process, consent will be obtained prior to any technique being used.
If at any time you feel uncomfortable with any technique/s during the course of
the osteopathic treatment intervention, you may inform the osteopath and the
technique will be stopped immediately. Data collected from your involvement
in the study may be withdrawn up until 1 week following your final
assessment.

Your participation in this study will help to provide further research into neck
pain and its relationship with body posture. It will provide a valuable addition
to the ongoing research surrounding the effectiveness of osteopathic technique.

Please contact us if you require further information about this study.

Contact Details:

Monique Gasson or Kathryn Marr
Phone: +64 2102928011
Email: neckpainstudy2011@gmail.com

Catherine Bacon or Rob Moran
Phone: (09) 849 4180 ext 5043
Email: cbacon@unitec.ac.nz
rmoran@unitec.ac.nz

UREC REGISTRATION NUMBER: 2011-1196
This study has been approved by the UNITEC Research Ethics Committee from 28th July, 2011 to 27th July, 2012. If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (ph: 09 815-4321 ext 6162). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.
Appendix D: Consent Form
Osteopathic Treatment for Chronic Neck Pain

This research project examines the effectiveness of a 6-week osteopathic treatment intervention on chronic neck pain. The research is being conducted by Monique Gasson and Kathryn Marr, Master of Osteopathy students at Unitec, and will be supervised by clinical tutors, as well as chief supervisors Catherine Bacon and Rob Moran.

Name of Participant ………………………………………………………..

This form is to ensure that you understand the requirements of your participation and that you aware of your rights. Please read carefully through the points below. If you are happy and agree with the points then please sign at the bottom of the page. If you have any questions at all please ask the researcher before signing this form.

- I have had the research project explained to me and I have read and understood the information sheet given to me.

- I understand that I don't have to be part of this if I don't want to, and may withdraw at any time.

- I understand that everything I say and the information I provide will be collected in accordance with the Health Information Privacy Code 1994 and be kept confidential and in accordance with the Privacy Act 1993. I understand that the only persons who will have access to my information will be the researchers and relevant clinical staff.

- I understand that all the information I give will be stored securely at Unitec for a period of 5 years.

- I understand that I can see the finished research document.

- I understand that data collected may be used for further publication.

- I have had time to consider the information provided, to ask questions, and to seek any guidance.

I give my consent to be a part of this project.
Participant Signature .................................................. (date)

Project explained by ..................................................
Researcher Signature .................................................. (date)

UREC REGISTRATION NUMBER: 2011-1196
This study has been approved by the UNITEC Research Ethics Committee from 28 July 2011 to 27 July 2012. If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (ph: 09 815-4321 ext 6162). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.
Appendix E: Medical Questionnaire
Absolute contraindications to HVLA manipulative techniques (Gibbons & Tehan, 2000): Have you ever experienced any of the following conditions or pathologies? (Please tick)

Bone - Any pathology that has lead to significant bone weakening:
- tumour, e.g. metastatic deposits
- infection, e.g. tuberculosis
- metabolic, e.g. osteomalacia
- congenital, e.g. dysplasia
- iatrogenic, e.g. long-term corticosteroid medication
- inflammation, e.g. rheumatoid arthritis
- traumatic, e.g. fracture

Neurological
- cervical myelopathy
- cord compression
- cauda equina compression
- nerve root compression with increasing neurological deficit

Vascular
- diagnosed vertebrobasilar insufficiency
- aortic aneurysm
- bleeding
- diastheses, e.g. haemophilia

Instability
- incompetence of the odontoid process
- incompetence of the transverse atlantal ligament

Relative contraindications to HVLA manipulative techniques (Gibbons & Tehan, 2000):
- adverse reactions to previous manual therapy
- disc herniation or proplase
- inflammatory arthritides
- pregnancy
- women post-partum
- spondylolysis
- spondylolisthesis
- osteoporosis advanced
- degenerative joint disease and spondylosis
- arterial calcification
- non active Schurmann’s disease
- abdominal hernia
- psychological dependence on HVLA technique

The signs and symptoms of vertebrobasilar insufficiency (VBI) and upper cervical instability: Have you ever experienced any of the following? (please tick)

**Signs of VBI (Gibbons & Tehan, 2000)**
- nystagmus (abnormal eye movements consisting of repetitive jerks)
- gait disturbances
- Horner’s syndrome (consists of drooping upper eyelid, constricted pupil and endopthalmus-impression that eye is sunk in compared to opposite eye)
- dizziness/vertigo
- diplopia (double vision)
- tinnitus (ringing in the ears)
- nausea
- drop attacks
- dysarthria or disruption in speech
- dysphagia or difficulty swallowing
- occipital headaches
- facial paraesthesia
- tingling in upper limbs
- blurred vision
- fainting/blackouts

**Signs and symptoms of upper cervical instability (Gibbons & Tehan, 2000):**
- Overt loss of balance in relation to head movements
- Facial lip paraesthesia, reproduced by passive and active neck movements
- Bilateral or quadrilateral limb paraesthesia, either constant or reproduced by neck movements
- Nystagmus produced by active and passive neck movements

Participant Signature: .................................................................
Appendix F: Neck Disability Index Questionnaire
NDI QUESTIONNAIRE

Participant Name: ............................ Date: ....... Score: ........ [50]

This questionnaire has been designed to give your healthcare professional information as to how your neck pain has affected your ability to manage everyday life activities. Please mark in each section ONE box that applies to you. We realise that you may consider that two of the statements in any one section relate to you, but please just mark the box that most closely describes your present day situation.

Pain Intensity
- I have no pain at the moment
- The pain is very mild at the moment
- The pain is moderate at the moment
- The pain is fairly severe at the moment
- The pain is very severe at the moment
- The pain is the worst imaginable at the moment

Lifting
- I can lift heavy weights without extra pain
- I can lift heavy weights but it gives extra pain
- Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, for example on a table
- Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- I can lift very light weights
- I cannot lift or carry anything at all

Headaches
- I have no headaches at all
- I have slight headaches which come infrequently
- I have moderate headaches which come infrequently
- I have moderate headaches which come frequently
- I have severe headaches which come frequently
- I have headaches almost all the time

Personal Care
- I can look after myself without causing extra pain
- I can look after myself normally but it causes extra pain
- It is painful to look after myself, I am slow and careful
- I need some help but manage most of my personal care
- I need help everyday in most aspects of self-care
I do not get dressed, I wash with difficulty and stay in bed

Reading
- I can read as much as I want to with no pain in my neck
- I can read as much as I want to with slight pain in my neck
- I can read as much as I want with moderate pain in my neck
- I can’t read as much as I want, because of moderate neck pain
- I can hardly read at all because of severe pain in my neck
- I cannot read at all

Concentration
- I can concentrate fully when I want to with no difficulty
- I can concentrate fully when I want to with slight difficulty
- I have a fair degree of difficulty concentrating when I want to
- I have a lot of difficulty concentrating when I want to
- I have a great deal of difficulty concentrating when I want to
- I cannot concentrate at all

Work
- I can do as much work as I want to
- I can do my usual work
- I can do my usual work, but no more
- I can do most of my usual work, but no more
- I can hardly do any work at all
- I can’t do any work at all

Sleeping
- I have no trouble sleeping
- My sleep is slightly disturbed (< 1 hr sleepless)
- My sleep is mildly disturbed (1-2 hrs sleepless)
- My sleep is moderately disturbed (2-3 hrs sleepless)
- My sleep is greatly disturbed (3-5 hrs sleepless)
- My sleep is completely disturbed (5-7 hrs sleepless)

Driving
- I can drive my car without any neck pain
- I can drive my car as long as I want with slight pain in my neck
- I can drive my car as long as I want with moderate pain in my neck
- I can’t drive my car as long as I want because of moderate pain in my neck
- I can hardly drive at all because of severe pain in my neck
- I can’t drive my car at all
Recreation

- I am able to engage in all my recreation activities with no neck pain at all
- I am able to engage in all my recreation activities, with some pain in my neck
- I am able to engage in most, but not all my usual recreation activities, because of some pain in my neck
- I am able to engage in a few of my usual recreation activities because of pain in my neck
- I can hardly do any recreation activities because of pain in my neck
- I can’t do any recreation activities at all

Appendix G: Patient Specific Functional Scale
PATIENT SPECIFIC FUNCTIONAL SCALE

This useful questionnaire can be used to quantify activity limitation and measure functional outcome for patients with any orthopaedic condition.

Clinician to read and fill in below: Complete at the end of the history and prior to physical examination.

Initial Assessment:
I am going to ask you to identify up to three important activities that you are unable to do or are having difficulty with as a result of your neck pain. Today, are there any activities that you are unable to do or having difficulty with because of your neck pain? (Clinician: show scale to patient and have the patient rate each activity).

Follow-up Assessments:
When I assessed you on (state previous assessment date), you told me that you had difficulty with (read all activities from list at a time). Today, do you still have difficulty with: (read and have patient score each item in the list)?

Patient-specific activity scoring scheme (Point to one number):

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unable to perform activity</td>
<td>Able to perform activity at the same level as before injury or problem</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Participant Name: ......................... .................(date)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Initial</th>
<th>3 week Follow-up</th>
<th>6 week Follow-up</th>
<th>9-week Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Appendix H: McGill Pain Questionnaire
**MCGILL PAIN QUESTIONNAIRE**

**What does your pain feel like?**

Some of the following words below describe your present pain. Circle ONLY those words that best describe it. Leave out any category that is not suitable. Use only a single word in each appropriate category – the one that applies best.

<table>
<thead>
<tr>
<th>Temporal</th>
<th>Spatial</th>
<th>Punctate Pressure</th>
<th>Incisive Pressure</th>
<th>Constrictive Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flickering</td>
<td>Jumping</td>
<td>Pricking</td>
<td>Sharp</td>
<td>Pinching</td>
</tr>
<tr>
<td>Quivering</td>
<td>Flashing</td>
<td>Boring</td>
<td>Cutting</td>
<td>Pressing</td>
</tr>
<tr>
<td>Pulsing</td>
<td>Shooting</td>
<td>Drilling</td>
<td>Gnawing</td>
<td>Gnawing</td>
</tr>
<tr>
<td>Throbbing</td>
<td></td>
<td>Stabbing</td>
<td>Cramping</td>
<td>Cramping</td>
</tr>
<tr>
<td>Beating</td>
<td></td>
<td>Lancinating</td>
<td>Crushing</td>
<td>Crushing</td>
</tr>
<tr>
<td>Pounding</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Traction</strong></td>
<td><strong>Pressure</strong></td>
<td><strong>Brightness</strong></td>
<td><strong>Dullness</strong></td>
<td><strong>Sensory</strong></td>
</tr>
<tr>
<td><strong>Pressure</strong></td>
<td><strong>Thermal</strong></td>
<td><strong>Brightness</strong></td>
<td><strong>Dullness</strong></td>
<td><strong>Sensory</strong></td>
</tr>
<tr>
<td>Tugging</td>
<td>Hot</td>
<td>Tingling</td>
<td>Dull</td>
<td>Tender</td>
</tr>
<tr>
<td>Pulling</td>
<td>Boring</td>
<td>Itchy</td>
<td>Sore</td>
<td>Taut</td>
</tr>
<tr>
<td>Wrenching</td>
<td>Scalding</td>
<td>Smarting</td>
<td>Hurting</td>
<td>Rasping</td>
</tr>
<tr>
<td></td>
<td>searing</td>
<td>Stinging</td>
<td>Aching</td>
<td>Splitting</td>
</tr>
<tr>
<td><strong>Tension</strong></td>
<td><strong>Autonomic</strong></td>
<td><strong>Fear</strong></td>
<td><strong>Punishment</strong></td>
<td><strong>Affective</strong></td>
</tr>
<tr>
<td><strong>Autonomic</strong></td>
<td></td>
<td></td>
<td></td>
<td>evaluative-sensory:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>miscellaneous</td>
</tr>
<tr>
<td><strong>Tiring</strong></td>
<td><strong>Exhausting</strong></td>
<td><strong>Fearful</strong></td>
<td><strong>Punishing</strong></td>
<td><strong>Wretched</strong></td>
</tr>
<tr>
<td><strong>Exhausting</strong></td>
<td><strong>Sickening</strong></td>
<td><strong>Frightful</strong></td>
<td><strong>Gruelling</strong></td>
<td><strong>Blinding</strong></td>
</tr>
<tr>
<td><strong>Suffocating</strong></td>
<td></td>
<td><strong>Terrifying</strong></td>
<td><strong>Cruel</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Evaluative</strong></td>
<td><strong>Sensory:</strong></td>
<td><strong>Sensory:</strong></td>
<td><strong>Sensory</strong></td>
<td><strong>Affective</strong></td>
</tr>
<tr>
<td><strong>miscellaneous</strong></td>
<td><strong>miscellaneous</strong></td>
<td><strong>miscellaneous</strong></td>
<td></td>
<td>evaluative:</td>
</tr>
<tr>
<td><strong>Annoying</strong></td>
<td><strong>Spreading</strong></td>
<td><strong>Right</strong></td>
<td><strong>Cool</strong></td>
<td><strong>Nagging</strong></td>
</tr>
<tr>
<td><strong>Troublesome</strong></td>
<td><strong>Radiating</strong></td>
<td><strong>Numb</strong></td>
<td><strong>Cold</strong></td>
<td><strong>Nauseating</strong></td>
</tr>
<tr>
<td><strong>Miserable</strong></td>
<td><strong>Penetrating</strong></td>
<td><strong>Drawing</strong></td>
<td><strong>Freezing</strong></td>
<td><strong>Agonizing</strong></td>
</tr>
<tr>
<td><strong>Intense</strong></td>
<td><strong>Piercing</strong></td>
<td><strong>Squeezing</strong></td>
<td></td>
<td><strong>Dreadful</strong></td>
</tr>
<tr>
<td><strong>Unbearable</strong></td>
<td></td>
<td><strong>Tearing</strong></td>
<td></td>
<td><strong>Torturing</strong></td>
</tr>
</tbody>
</table>

**How does your pain change with time?**
1. Which word or words would you use to describe the pattern of your pain?
   a. continuous, stead, constant
   b. rhythmic, periodic, intermittent
   c. brief, momentary, transient

2. Do the following items increase or decrease your pain?
   (Use ↑ and ↓ arrows to indicate an increase/decrease. Leave blank if there is no effect).
   - Liquor
   - Stimulants such as coffee
   - Eating
   - Heat
   - Cold
   - Damp
   - Weather changes
   - Massage or use of a vibrator
   - Pressure
   - No movement
   - Movement
   - Sleep or rest
   - Lying down
   - Distraction (TV, reading, etc)
   - Urination or defecation
   - Tension
   - Bright lights
   - Loud noises
   - Going to work
   - Intercourse
   - Mild exercise
   - Fatigue
How strong is your pain?

Statement: People agree that the following 5 words (mild, discomforting, distressing, horrible, excruciating) represent pain of increasing intensity. To answer each question below, write the most appropriate word in the space beside the question.

<table>
<thead>
<tr>
<th>1. Which word best describes your pain right now?</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Which word describes it at its worst?</td>
</tr>
<tr>
<td>3. Which word describes it when it is least?</td>
</tr>
<tr>
<td>4. Which word describes the worst toothache you ever had?</td>
</tr>
<tr>
<td>5. Which word describes the worst headache you ever had?</td>
</tr>
<tr>
<td>6. Which word describes the worst stomach-ache you ever had?</td>
</tr>
</tbody>
</table>

Appendix I: Visual Analogue Scale
VISUAL ANALOGUE SCALE

<table>
<thead>
<tr>
<th>No pain</th>
<th>Worst possible pain</th>
</tr>
</thead>
</table>

---

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Appendix J: Case History & Physical Examination Form
## Case History & Physical Examination

### History of Neck Pain

<table>
<thead>
<tr>
<th>Presenting complaint</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Where is the pain exactly?</td>
<td></td>
</tr>
<tr>
<td>Quality of pain?</td>
<td></td>
</tr>
<tr>
<td>Associated symptoms</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mode of Onset</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>When did it start? How?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Frequency</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>How has it progressed?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duration of symptoms</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Daily Pattern</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Aggravating Factors</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Relieving Factors</th>
<th></th>
</tr>
</thead>
</table>

### Physical Examination

<table>
<thead>
<tr>
<th>Active tests:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Passive tests:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Special tests/other findings:</th>
<th></th>
</tr>
</thead>
</table>

| Working Diagnosis: |  |

| Treatment: |  |

<table>
<thead>
<tr>
<th>No pain</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Worst possible pain</th>
<th></th>
</tr>
</thead>
</table>
Appendix K: IJOM Guidelines
Submission

Submission to this journal proceeds totally online at (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.

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.

Contributions

Reviews and Original Articles (2,000 - 5,000 words)
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; or (ii) a critical or systematic review that seeks to summarise or draw conclusions from the established literature on a topic relevant to osteopathic medicine. Word limits exclude tables, figures and references.

The editors are looking for studies that will appeal to a wide general readership. The question being addressed and the planned design and analysis will need to be as original as possible, topical, and valid. All protocols will be subject to the journal's usual peer review process.

Submission Declaration

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 copyright-holder.

Ethical considerations

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

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

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

Even where consent has been given, identifying details should be omitted if they are not essential. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance that alterations do not distort scientific meaning and editors should so note. Authors submitting manuscripts as Case Reports, Case Problems, and Evidence in Practice should ensure that they have received consent from patients who are the subject of such reports. A statement to this effect should
be included in the manuscript. If such consent has not been obtained, personal details of patients included in any part of the paper and in any supplementary materials (including all illustrations and videos) must be removed before submission.

**Role of the funding source**

You are requested to identify who provided financial support for the conduct of the research and/or preparation of the article and to briefly describe the role of the sponsor(s), if any, in study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the paper for publication. If the funding source(s) had no such involvement then this should be stated. Please see [http://www.elsevier.com/funding](http://www.elsevier.com/funding).

**Conflict of interest**

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

**Acknowledgments**

In the appendix one or more statements should specify (a) contributions that need acknowledging, but do not justify authorship (b) acknowledgments of technical support (c) acknowledgments of financial and material support, specifying the nature of the support. Persons named in this section must have given their permission to be named. Authors are responsible for obtaining written permission from those acknowledged by name since readers may infer their endorsement of the data and conclusions.

**Review Process**

The decision to publish a paper is based on an editorial assessment and peer review. Initially all papers are assessed by an editor of the journal. The prime purpose is to decide whether to send a paper for peer review and to give a rapid decision on those that are not. Manuscripts going forward to the review process are reviewed by members of an international expert panel. All such papers will undergo a double blind peer review by two or more reviewers. All papers are subject to peer review and the Journal takes every reasonable step to ensure author identity is concealed during the review process. The Editors reserve the right to the final decision regarding acceptance.
Author Enquiries

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PREPARATION OF THE MANUSCRIPT

Submitted papers should be relevant to an international audience and authors should not assume knowledge of national practices, policies, law, etc. Authors should consult a recent issue of the journal for style if possible. Since the journal is distributed all over the world, and as English is a second language for many readers, authors are requested to write in plain English and use terminology which is internationally acceptable.

Abbreviations - Avoid the use of abbreviations unless they are likely to be widely recognised. In particular you should avoid abbreviating key concepts in your paper where readers might not already be familiar with the abbreviation. Any abbreviations which the authors intend to use should be written out in full and followed by the letters in brackets the first time they appear, thereafter only the letters without brackets should be used.

Statistics - Standard methods of presenting statistical material should be used. Where methods used are not widely recognised explanation and full reference to widely accessible sources must be given.

Manuscript Layout

The manuscript with a font size of 12 or 10 pt double-spaced with wide margins (2.5 cm at least) and number pages consecutively beginning with the Title Page. Depending on the paper type (see above) this should include the title, abstract, key words, text, references, tables, figure legends, figures, appendix. Microsoft Word or similar programme should be used. 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 blinded 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 four to ten keywords in alphabetical order, which accurately identify the paper's subject, purpose, method and focus. 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. Use the Medical Subject Headings (MeSH®) thesaurus or Cumulative Index to Nursing and Allied Health (CINAHL) headings where possible (see http://www.nlm.nih.gov/mesh/meshhome.html).

Abstract
Both qualitative and quantitative research approaches should be accompanied by a structured abstract of no more than 250 words. 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, Participants, 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 headings should be typed in capital letter in the centre of the page and underlined (i.e. INTRODUCTION)
• secondary ones should be typed in lower case (with an initial capital letter) in the left hand margin and underlined (i.e. Participants).
• minor ones typed in lower case and italicised (i.e. questionnaire).

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

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

References

Responsibility for the accuracy of bibliographic citations lies entirely with the authors.

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

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

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

Reference to a journal publication:

Reference to a book:

Reference to a chapter in an edited book:

For journal articles, the abbreviated title of the journal should be used. Authors should refer to the National Library of Medicine database for journal abbreviations ([http://www.ncbi.nlm.nih.gov/nlmcatalog/journals](http://www.ncbi.nlm.nih.gov/nlmcatalog/journals)).

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

Web references - As a minimum, the full URL and access date should be given. Any further information, if known (DOI, author names, dates, reference to a source publication, etc.), should also be provided. Web references should be included in the reference list.

**Tables, Illustrations and Figures**

Tables, illustrations and figures should be placed on separate pages as separate electronic files and not placed within the manuscript. Each table, illustration or figure should be accompanied by a number (e.g. Table 1) and a brief description of the content of the table, figure or illustration, below the table, illustration or figure. All tables, illustrations or figures should be referred to in the manuscript.

**File Formatting for Artwork & Illustrations** - General points
- Make sure you use uniform lettering and sizing of your original artwork.
- Save text in illustrations as "graphics" or enclose the font.
• Only use the following fonts in your illustrations: Arial, Courier, Times, Symbol.
• Number the illustrations according to their sequence in the text.
• Use a logical naming convention for your artwork files.
• Provide captions to illustrations separately.
• Produce images near to the desired size of the printed version.
• Submit each figure as a separate file.

A detailed guide on electronic artwork is available on our website: http://www.elsevier.com/artworkinstructions

Appendices

Ordinarily there should be no appendices although in the case of papers reporting tool development or the use of novel questionnaires authors must include a copy of the tool as an appendix unless all items appear in a table in the text. Appendices may be published as online supplementary files to which a reference should be made in the printed article.

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Identifiable clinical photographs must be accompanied by written permission from the patient.

SPECIFIC GUIDANCE FOR ORIGINAL RESEARCH ARTICLES

The text of original research for a quantitative or qualitative study is typically subdivided into the following sections:

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

Materials and Methods
Describe your selection of observational or experimental participants (including controls). Identify the methods, apparatus (manufacturer's name and address in parenthesis) and procedures in sufficient detail to allow
workers to reproduce the results. Give references and brief descriptions for methods that have been published but are not well known; describe new methods and evaluate limitations. Indicate whether procedures followed were in accordance with the ethical standards of the institution or regional committee responsible for ethical standards. Do not use patient names or initials. Take care to mask the identity of any participants in illustrative material.

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

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

**Conclusion**
A summary of the pertinent findings and, relevance of the study and implications of the study for future research.

**IJOM Author Contribution Statement**
All manuscripts submitted to the journal should be accompanied by an Author Contribution Statement. The purpose of the Statement is to give appropriate credit to each author for their role in the study. All persons listed as authors should have made substantive intellectual contributions to the research. To qualify for authorship each person listed should have made contributions in each of the following; 1) Contributions to conception and design; data acquisition; data analysis and interpretation; 2) Drafting of manuscript, or critical revision for important intellectual content; 3) All authors must have given approval to the final version of the manuscript submitted for consideration to publish. Acquisition of funding; provision of resources; data collection; or general supervision, alone, is not sufficient justification for authorship. Contributors who do not meet the criteria for authorship as outlined above should be listed in the Acknowledgements section. Acknowledgements may include contributions of technical assistance, proof reading and editing, or assistance with resources and funding. The statement
may be published in the paper as appropriate. Example of suggested format (note the use of author initials). AB conceived the idea for the study. AB and CD contributed to the design and planning of the research. All authors were involved in data collection. AB and EF analysed the data. AB and CD wrote the first draft of the manuscript. EF coordinated funding for the project. All authors edited and approved the final version of the manuscript.

SPECIFIC GUIDANCE FOR PROTOCOLS

**Organisation of a Protocol** - the following need to be adequately addressed.

- **Title**
- **Abstract/Summary** - this should provide a concise description of the purpose of the Protocol and should not exceed 200 words.
- **Background**, including rationale and any previous systematic review(s).
- **Keywords** - provide 4-10 keywords.
- **Principal investigator(s); contact details**.
- **Aim(s)**.
- **Design** (randomised, double-blind) - including inclusion and exclusion criteria; intervention(s)/method; primary and secondary endpoint(s); side-effects reporting and quantification • **Statistical analysis** - including sample size and power calculations; type of analysis; statistical testing.
- **Ethical issues** - including ethics committee approval; informed consent form and information sheet.
- **Publication plan**.
- **Time required** - an estimation of the time required to run the protocol should be given per separate step and for the whole protocol, including reporting.
- **Funding source(s)**.
Appendix L: Editorials
Pain in the neck? Unitec wants you

People who suffer from neck pain are being sought to undertake a research project examining osteopathy as a treatment option.

Student researchers at Unitec’s Osteopathy Clinic are investigating the effectiveness of osteopathic treatments and techniques for individuals with neck pain.

“Osteopathy is a form of manual therapy, which takes a holistic, whole body approach to health,” student researcher Monique Gasson says. “We are looking for individuals with neck pain to volunteer for this research.”

Neck pain sufferers who enrol in the study will receive six osteopathic treatments free and will be asked to attend three to four sessions where questionnaires and other measures will be carried out.

The study will take place at the Unitec Osteopathic Clinic in Mt Albert.

Visit www.getparticipants.com/neckpain or email Monique or Kathryn at neckpainstudy2011@gmail.com for more details.

Participants needed: Unitec student researchers Kathryn Frith and Monique Gasson are looking for participants for their study into neck pain.
Neck pain research

Student researchers at Unitec’s Osteopathy Clinic are urging people with neck pain to come forward.

They are investigating the effectiveness of osteopathic treatments and techniques and would like people to volunteer to be a part of the research programme.

The cause of chronic neck pain is often unknown and there are very few treatment options available to people who experience ongoing neck pain.

Student Monique Gasson says osteopathy is well recognised as a treatment for back pain, sciatica, headaches or pain in joints, although its effectiveness on neck pain is not yet known.

“Osteopathy is a form of manual therapy which takes an holistic whole body approach to health,” she says.

Volunteers will undergo six free osteopathic treatments and will be asked to attend three to four sessions where questionnaires and other measures will be carried out.

The study will take place at the Unitec Osteopathic Clinic in Mt Albert.

Go to www.getparticipants.com/neckpain for more information or contact Monique or Kathryn at neckpainstudy2011@gmail.com.
Appendix M: Recruitment Poster
Do you suffer from neck pain?

We (Monique and Kathryn) are two Master of Osteopathy students at Unitec investigating the effects that osteopathic treatment has on chronic neck pain. The techniques we’re studying are regularly used on the neck in everyday practice. We are looking for participants for our study who are aged between 25-65 years and have had neck pain for at least 12 weeks.

Participants will receive a fuel voucher as a token of appreciation for their time and contribution to this study

Contact Monique at 021 0292 8011 or neckpainstudy2011@gmail.com
Appendix N: Analysis of assumptions of normality
Analysis of assumptions of normality.

<table>
<thead>
<tr>
<th></th>
<th>Z-Skewness</th>
<th>Z-Kurtosis</th>
<th>Shapiro-Wilk Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Change to</td>
<td>Change to</td>
<td>Change to</td>
</tr>
<tr>
<td></td>
<td>Immediately</td>
<td>Follow-Up</td>
<td>Immediately</td>
</tr>
<tr>
<td>NDI</td>
<td>-0.07</td>
<td>-2.23</td>
<td>-0.04</td>
</tr>
<tr>
<td>PSFS</td>
<td>1.51</td>
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<td>0.01</td>
</tr>
<tr>
<td>MPQ (PRI)</td>
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</tr>
<tr>
<td>VAS</td>
<td>-2.15</td>
<td>-</td>
<td>0.67</td>
</tr>
</tbody>
</table>

Highlighted areas indicate violations of normality.

Abbreviations as follows: Neck Disability Index (NDI), Visual Analogue Scale (VAS), Patient Specific Functional Scale (PSFS), McGill Pain Questionnaire (MPQ), Pain Rating Index (PRI).