A Single Systems Research Design to examine the effectiveness of osteopathic treatment for people with osteoarthritis of the hip

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DECLARATION

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This thesis entitled: A Single Systems Research Design to examine the effectiveness of osteopathic treatment for people with osteoarthritis of the hip is submitted in partial fulfilment for the requirements for the Unitec degree of Master of Osteopathy.

Candidate’s declaration

I confirm that:
This thesis represents my own work;

- The contribution of supervisors and others to this work was consistent with the Unitec Regulations and Policies.
- Research for this work has been conducted in accordance with the Unitec 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: 2011-1244

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Preface to Thesis

This thesis is arranged into seven chapters. The first chapter orients the reader to the relevant background knowledge regarding anatomy and physiology of synovial joints and in particular, the hip, and also provides information on osteoarthritis (OA), including epidemiology, risk factors, pathophysiology and source of pain. The second chapter focuses on the assessment, diagnosis and current treatment of osteoarthritis by providing information on common scales and questionnaires, medical imaging techniques, surgical procedures and manual therapy interventions. The third chapter critically reviews the current body of evidence for manual therapy interventions for osteoarthritis of the hip with regards to three studies in particular. The third chapter also presents a rationale for the research of osteopathic treatment of hip osteoarthritis. The fourth chapter explains the methods of research utilised in this study including information on study design, participants, the intervention and outcome measures. The fifth chapter presents the results of the study and an interpretation of the findings. The sixth chapter critically analyses and discusses the limitations of this study and provides suggestions for further research. The seventh chapter represents a departure from the typical format and contents of a Master of Osteopathy thesis and should be considered as a related, but separate, chapter to the main investigation reported in chapters 4-6. This chapter is a commentary in response to a number of points that became apparent during the planning and conduct of the study. The chapter outlines a broad, and evidence informed approach to the management of people with OA of the hip or knee. The chapter is not intended to be a fully formed package; instead it provides a clear direction for the development of clinical practice and associated research.
Thesis Abstract

Osteoarthritis (OA) is considered to be one of the leading causes of disability and the most frequent form of arthritis worldwide. There exists a growing body of evidence that manual therapy may be efficacious in reducing pain and improving function in individuals with hip OA. However, no studies have been conducted to study the effect of osteopathic treatment for hip osteoarthritis. The aim of this study was to quantitatively examine any functional effect osteopathic treatment might have on individuals with hip osteoarthritis. Participants (n=6) with previously diagnosed hip OA were recruited and followed during a 12-week study protocol. Participants completed 6 weekly osteopathic treatment sessions aimed at decreasing the pain experienced and increasing the participant’s overall functionality. Both pain and functionality were assessed using the WOMAC score and ICOAP score via an online survey. Clinically meaningful change was defined as effects larger than 14 points of change from mean baseline scores for both WOMAC and ICOAP. Outcome measures were taken weekly for 3-weeks prior to treatment, during the 6 weeks of treatment, and for 3-weeks following treatment. A number of participants were lost to follow up (n=4). All remaining participants showed no clinically meaningful change for both WOMAC and ICOAP at the end of the 12-week study protocol. The results of this study therefore fail to suggest any clinically meaningful effect to the pain and functionality of individuals affected by hip OA was caused by osteopathic treatment. Further research is required to determine the role of osteopathy in the management of people with hip OA.
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Chapter 1: Background Knowledge

Osteoarthritis (OA) is defined as a condition characterised by focal areas of loss of articular cartilage within synovial joints (Arden et al., 2006). It is associated with abnormal bone growth and deformation as well as thickening of the articular capsule (Pereira et al., 2011). Osteoarthritis is considered to be the leading cause of disability and the most common form of arthritis (Sun et al., 2007). The condition also accounts for a substantial financial burden in terms of health care costs and loss of productivity worldwide (Symmons et al., 2000). Recent data for New Zealand, show that OA accounted for 79% of all public inpatient costs, totalling $58 million for the year 2006–7, 40% of which was contributed by hip OA treatment cost alone (Borman et al., 2010).

To date, there exists no curative model for OA, instead it is typically managed by a multimodal health care approach consisting of conservative and/or surgical treatment (NHS, 2008). Conservative treatment consists of pharmacologic care (analgesics and anti-inflammatory), exercise therapy and manual therapy. Surgical treatment approaches vary depending on the severity of the condition and is considered to be the most invasive form of treatment (NHS, 2008).

Pharmacological treatment can provide short-term relief from pain and inflammation, but has no disease modifying effect (Tanna, 2004). A limitation of pharmacotherapy is that 15-30% of patients are unable to tolerate medication due to gastrointestinal and cardiovascular complications associated with the non-steroidal anti-inflammatory medication (Brantingham et al., 2012). Although surgery has a high success rate in the elimination of OA associated pain (Bachmeier et al., 2001) there are a number of mild to severe complications associated with the procedure including venous thromboembolism (Nutescu et al., 2013) and infection (Spiegl et al., 2013). Furthermore, the costs related to OA surgical procedures are high, for instance, a recent study estimated the annual cost of surgical treatment for hip OA in New Zealand as approximately $29 million for the financial year 2006-7 (Borman, et al., 2010).

Manual therapy is a non-invasive form of treatment for people with mild to moderate OA that is accessible to the general public and may offer a cost effective option (Abbott et al., 2012). This type of therapy has been shown to be an effective method of managing pain and functionality associated with OA (Abbott et al., 2013; Brantingham, et al., 2012; H. L. Hoeksma et al., 2004). Currently no published research has investigated the effectiveness of osteopathy in the management of OA, yet anecdotally this appears common practice. The osteopathic regulatory body in New Zealand (OCNZ) has extended gerontology as a scope of osteopathic practice (OCNZ, 2013).
The aims of this literature review are to:

1. Explore the relevant anatomy and physiology of synovial joints with special consideration to the hip.

2. Provide a basic review of osteoarthritis epidemiology, pathophysiology, and assessment and treatment options.

3. To critically discuss studies that investigate the effectiveness for manual therapy in people with OA of the hip.
1.1 Background

This section aims to inform the reader of the current relevant anatomy and physiology of synovial joints, paying particular attention to the hip joint.

1.1.1 Synovial Joints

Synovial joints are the most common type of joint in the body. These joints are distinguished by two articulating bony surfaces surrounded via a fluid filled capsule. This type of joint allows considerable freedom of movement and forms an integral part of the locomotor system (Standring, 2009).

1.1.1.1 Anatomy

A synovial joint is characterised by four distinct features.

1) An articular (hyaline) cartilage, made up of dense collagen fibres, covers the epiphyses of the articulating bones. The cartilage serves as a smooth cushion for shock absorption and joint gliding.

2) A two-layered articular capsule composed of an internal synovial membrane and a tough outer fibrous capsule. The fibrous capsule provides structural stability.

3) A synovial cavity filled with synovial fluid, a viscous substance that reduces friction and is secreted by the synovial membrane.

4) Reinforcing ligaments which are essentially thickened parts of the fibrous capsule and provide further strength and support. In comparison to the avascular, non-innervated hyaline cartilage, the capsule and ligaments are highly innervated and vascularised (Standring, 2009).

The hip is a synovial ball and socket joint. It is comprised of the ball shaped head of the femur that fits into the concave acetabulum formed by the innominate bones. The acetabulum is covered by a horse shoe shaped articular surface of hyaline cartilage. The concavity of the acetabulum is further increased by a fibrocartilagenous extension known as the acetabular labrum, which provides structural stability and contributes towards the negative pressure of the joint, holding the head in the acetabulum (Jacobs et al., 2003). The joint is supported by three strong extra-articular ligaments, the iliofemoral, ischiofemoral and pubofemoral ligaments. A fourth intra-articular ligament, the ligamentum teres, provides extra synovial housing for blood supply to the head of the femur (Byrne et al., 2010).

1.1.1.2 Physiology

The key function of a synovial joint is to reduce frictional resistance between bearing surfaces by keeping them apart. The synovial fluid forms a vital part in this. The clear fluid is composed primarily of hyaluronic acid which provides it with its lubricating and shock absorbing properties. It is secreted by fibroblast-like cells in the synovial membrane. It also acts as a transport medium that supplies the avascular joint surfaces with nutrition and removes metabolic waste material (Lipowitz, 1985).
Bone undergoes constant remodelling, which is a process of reabsorption and laying down of new bone. This is achieved through three major cell types.

1) Osteoblasts are bone forming cells that secrete osteoid, an organic matrix that subsequently undergoes mineralisation giving the bone its strength and rigidity.
2) Osteocytes are mature osteoblasts who have become trapped within their own secreted matrix. These cells control the concentration of calcium and phosphorous in bone and provide cell-to-cell interaction in response to the local environment.
3) Osteoclasts release hydrolytic enzymes that dissolve bone and calcified cartilage so it may be resorbed and subsequently remodelled (Kapandji, 2008).

Similarly to bone, cartilage contains chondroblasts, which are cartilage forming cells and chondrocytes, which are the mature chondroblasts. Remodelling of cartilage occurs as a response to tensile and compressive forces exhibited on the cartilage. However, remodelling in cartilage happens at a much slower rate than in bone (Standring, 2009).

1.2 Osteoarthritis
Osteoarthritis (OA) is a chronic degenerative condition of synovial joints characterised by the gradual development of joint pain, stiffness and limitation of movement (Finley, 2003). It is the most common form of arthritis and the fifth most treated disorder in general medical practice worldwide (Arden & Nevitt, 2006). It has significant economic impact, in terms of loss of productivity caused by days off work and also due to treatment costs (Schnitzer, 2000). The following section details the current epidemiology of OA in New Zealand.

1.2.1 Epidemiology
More than 80% of people older than 75 years have clinical signs of OA, and more than 80% older than 50 years have radiologic evidence of OA (Issa et al., 2006). Although osteoarthritis can affect any joint in the body, the hand has the highest prevalence (43%), followed by the knee (24%) and hip (11%) (Sun, et al., 2007).

1.2.1.1 Age & Gender
In the 2006/07 New Zealand Health Survey (MoH, 2008), data was collected regarding the prevalence of arthritis and, more specifically, OA in the New Zealand population. One of the aims of this survey was to assess the correlation between OA, age, gender and ethnicity. As shown in Fig. 1, the prevalence rate of OA in the general population rises significantly in individuals over 55 years of age, and especially in females.
FIG 1: Unadjusted prevalence of diagnosed osteoarthritis by gender and age groups (MoH, 2008)

FIG 2: Unadjusted prevalence of diagnosed osteoarthritis by gender and ethnic groups (MoH, 2008)
1.2.1.2 Ethnicity

Osteoarthritis prevalence varies according to ethnicity. In New Zealand, individuals of European descent are the ethnicity most commonly affected by OA, followed by Māori, Asian and Pacific Islanders respectively as shown in Fig. 2.

1.2.2 Risk factors

A number of factors can contribute to the development and progression of OA. Amongst the factors that are well understood are age, sex hormones, genetics, obesity, joint deformity, and history of trauma (Huether et al., 1996; Symmons, et al., 2000).

1.2.2.1 Age

As shown in Fig 1, the prevalence and incidence of OA increase sharply with age. Joint tissues become more vulnerable to the effects of biomechanical insults with age. This is mainly due to obesity, impaired neuromuscular joint protective mechanisms, and increased joint instability (Arden & Nevitt, 2006). A key factor that may contribute to this relationship is a degradation in the reparative capacity of cartilage due to a reduced anabolic response to growth factors, loss of chondrocytes, and thinning of the cartilage plate (Loeser et al., 2003).

1.2.2.2 Sex Hormones

Females demonstrate a higher incidence of OA than men after the age of 50 (MoH, 2008). This is believed to be partially associated with the change in sex hormones following menopause. Linn, Murtaugh et al. (2012) report that oestrogen has a protective effect on chondrocytes, thereby protecting the joint surface. Conversely, the effects of testosterone on joint health are unclear. One particular study of asymptomatic men (Hanna et al., 2005) reported a positive association between testosterone and tibial cartilage volume in the medial compartment of the leg, however, a separate longitudinal examination found a negative association between testosterone and tibial cartilage volume over two years (Ciicuttini et al., 2003). To date the effects of testosterone on OA progression remain unclear.

1.2.2.3 Genetics

Current evidence indicates that about half of the susceptibility to hand, hip and knee OA in women and hip OA in men can be attributed to genetic predisposition (Arden & Nevitt, 2006). Approximately 50% of heritability has been shown to be caused by European genetic variants (Hoaglund, 2013). Although heritability predisposes to hand, hip and knee OA, there is no evidence that suggests that genetic factors determine the occurrence of OA across all these skeletal sites (MacGregor et al., 2010).
1.2.2.4 Obesity

Obesity is one of the highest risk factor for OA in weight bearing joints, in particular the knee and hip joints. Furthermore, weight loss has been shown to reduce the risk of subsequent development of OA (Arden & Nevitt, 2006). The mechanism for the association between obesity and OA has previously been believed to be due to the breakdown of cartilage and damage to ligaments and other supporting structures due to the excess weight effectively overloading the weight bearing joints (Arden & Nevitt, 2006). However, not all individuals with a high Body Mass Index (BMI) develop OA, yet those with high fat mass as opposed to lean mass demonstrated a higher risk for acquiring OA. This insight provides a new avenue of study to explain the relationship between obesity and OA.

Adipose tissue is now recognised as a metabolic endocrine organ with the ability to secrete three major adipocytokines: leptin, resistin and adiponectin. Adipocytokines are essentially adipose-derived hormones that play a role in the interaction between adipose tissue, inflammation and immunity (Tilg et al., 2006). It is now thought that these agents may play an integral role in cartilage homeostasis as their presence has been linked to local joint degradation effects (Sowers et al., 2010). Leptin is generally higher in obese individuals and its expression has been directly associated with the degree of cartilage damage, potentially due to its synergistic relationship with pro-inflammatory cytokines (Sowers & Karvonen-Gutierrez, 2010). Resistin levels also vary in obese individuals and have been shown to increase induction of the genes for pro-inflammatory cytokines, particularly in synovial fluid cells (Toussirot et al., 2007). Although less is known about the role of adiponectin and joint damage, a recent study showed that after synovial fibroblasts stimulated with adiponectin in joints with OA produced two key mediators of joint destruction; IL-6 and pro-metalloproteinase-1 (Toussirot, et al., 2007). The effect of adipocytokines on inflammatory mediation suggests involvement of these hormones in the progression of OA, yet further research is needed to substantiate this function.

1.2.2.5 Joint Deformity

The most common joint deformities associated with a higher risk of OA are acetabular dysplasia and slipped capital femoral epiphysis of the hip. These conditions affect the mechanical alignment of the hip/knee/ankle complex causing alterations in load distribution. Individual joint structures are subsequently subjected to increased loads, which leads to progressive loss of cartilage and subchondral bone (Arden & Nevitt, 2006).

1.2.2.6 History of Trauma

Acute or repetitive trauma like meniscal tears, fractures, carrying heavy loads or dislocations associated with certain occupations and sports confer a high risk of later development of OA in the affected joint (Arden & Nevitt, 2006). Post traumatic joints are marked by loss of articular cartilage leaving bone wearing against bone on bearing surfaces and eventually causing significant joint deformity (Buckwalte, 2003).
1.3 Pathophysiology of Osteoarthritis

The primary anatomical defect in OA is loss of articular cartilage (Huether and McCance, 1996). However, the initial onset and the full details of this process remain unclear (Cianflocco, 2011). It has been shown that a number of bony morphological pathologies may be the original stimulus for the process of OA, such as Perthe’s disease, slipped capitol femoral epiphysis or congenital hip dysplasia (Baird, 2001). These pathologies, along with others, set the scene for an unusual distribution of force through the joint, leading to high amounts of stress being placed through the cartilage and underlying bone (Weinans et al., 2012). However, it is not just the pathologies that can lead to the onset for OA, even mild alterations to the bony anatomy of the joint e.g. changes to the angle of femoral anteversion, retroversion or an overly deep acetabular socket can be associated with OA progression (Tönnis et al., 1999).

Regardless of the original stimulus, once mechanical overloading has occurred, a cascade of events leading to increased activation of osteoblast and osteoclast activity and therefore high bone turn over follows (Cianflocco, 2011). It is unclear which molecule, or molecules could be responsible for the initiation of this process. One potential candidate is vascular endothelial growth factor (VEGF). A study by Pickarski et al. (2011) showed that 2-weeks following an anterior cruciate ligament tear and partial meniscectomy in a rat model, the expression of VEGF on deep articular chondrocytes had occurred. As VEGF is known to cause formation of new blood vessels and osteoclasts, it may be responsible for the subchondral plate reabsorption and high bone turnover seen in OA (Pickarski, et al., 2011).

Once an increase in osteoclast and osteoblast activity begins, bony remodelling follows. This commonly occurs in the form of subchondral bone plate thickening, bone cysts and spurs. Alongside this bony remodelling are changes to the vascularity of the joint, in particular capillary penetration into the articular plate, which can weaken the articular plate and potentially lead to fractures and osteonecrosis (Baird, 2001).

Changes also occur in the synovium during the process of OA. As fragments of the damaged cartilage begin to break free, the synovium secretes a number of enzymes. The enzymes then initiate an inflammatory response (Pickarski, et al., 2011). The inflammatory mediators released include interleukin-1, nitric oxide, prostaglandin and tumour necrosis factor, all of which contribute to local oedema and vascular congestion. Over time, the joint capsule may become fibrotic in a response to the increase in intra articular pressure, effectively decreasing its ability to expand and altering fluid diffusion (Baird, 2001). As a result protein content changes in the synovial fluid. Immunoglobulins, immune complexes, and complement are produced by cells accumulating in the inflamed synovial membrane leading to sustained inflammation (de Lange-Brokaar et al., 2012).
The majority of the damage associated with OA can be attributed to breakdown of the cartilage matrix by enzymatic process, in particular, the destruction of proteoglycans. This interferes with the movement of water and synovial fluid out of the cartilage, thus reducing the joint’s ability to withstand the forces associated with weight bearing. As the cartilage is broken down, some areas become thin or absent, causing sclerosis of the underlying bone. Articular cartilage further erodes causing the formation of bone spurs, or osteophytes, changing the structure of the joint and its ability to move freely (Ganz et al., 2008).

1.4 The Source of Nociception in Osteoarthritis

As the deteriorated hyaline cartilage found in people with OA does not possess any nociceptors, the source of pain can be linked to the surrounding structures that are innervated such as the joint capsule, synovium, muscles, fat pads, ligaments and periostium (Kean et al., 2004). Inflammatory mediators released by the synovium in response to cartilage fragments are sufficient to activate A-delta mechanoreceptors and C-polymodal nerve endings leading to the production of a nociceptive stimulus (Kean, et al., 2004).

Due to the diffuse nature of the pain associated with OA some of the pain could also be attributed to sympathetic efferent nerve mediated pain (SENMP). SENMP involves the release of several chemical mediators from damaged cells which in turn sensitize the peripheral nerve endings resulting in a low pain threshold also known as primary hyperalgesia (Forrest, 1992). These nociceptive signals are transmitted to the spinal cord via the afferent nerves, forming junctions with other neurons in the spinal cord, and result in outgoing (efferent) nerve reflexes and secondary sensitization of tissues in and around the area of injury (Kean, et al., 2004). If the damaged tissue has been repaired, the tissue sensitization may return to a more normative state. In the case of OA this sensitization can become persistent. As the peripheral nerves are sensitized, substance P can be released from the interneurons in the spinal cord and travel to the nerve terminals. At the nerve endings substance P causes further sensitization, facilitates the release of more chemical mediators, and sensitizes the dorsal horn cells of the spinal cord. The sensitization of dorsal horn cells essentially facilitates the link with the sensitization in the injured tissues to form a closed loop pathway that becomes self-sustaining and is referred to as SENMP (Kean, et al., 2004).
Chapter 2: Assessment, Diagnosis and Current Treatment of Osteoarthritis

The assessment and diagnosis of OA combines both objective and subjective assessment and diagnostic tools. This chapter aims to explain the assessment and diagnosis of hip OA including various questionnaire based tools, manual clinical assessments, and imaging techniques. Furthermore, this chapter will provide information on the current conservative and surgical treatment approach for hip OA including manual therapy.

2.1 The Clinical Assessment of Osteoarthritis

The assessment of pain, its location, intensity, quality, and daily pattern is a fundamental component of the clinical evaluation of OA. However, pain is often poorly reported due to its individual interpretation and is affected by a large number of psychological factors (Peat et al., 2001). With this in mind it is important to explore other aspects of the condition. Common accompanying features include low grade synovial inflammation, ligament laxity and muscle inhibition and weakness (Peat, et al., 2001), hence palpation of the skin surrounding the joint, the range of motion, as well as assessments of strength and tonicity of muscles acting on the affected joint are required. Further clinical assurance of the diagnostician as well as methods of monitoring progression can be obtained by the use of disease specific questionnaires and imaging techniques.

2.2 Questionnaires and Scales

The most commonly used questionnaires that assess OA severity and progression are the Western Ontario and McMaster Universities Arthritis Index (WOMAC), the Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP), and the Harris Hip Score (HHS).

2.2.1 The Western Ontario and McMaster Universities Arthritis Index (WOMAC)

The Western Ontario and McMaster Universities Arthritis Index (WOMAC) was developed as an OA-specific measure of disability. It also contains a sub-scale for pain. The WOMAC is considered to be the primary measure of efficacy in OA management (Woolacott et al., 2012). The scale uses 24 parameters to measure pain, stiffness and physical function (see Appendix 1) and is the most commonly used disease-specific outcome measure for OA (Pollard et al., 2012). Generally the WOMAC is administered using a number of Visual Analogue Scales (VAS), although a Verbal Rating Scale (VRS) can be employed in its place to accommodate for date collection being made by telephone interview or online survey. The WOMAC has been demonstrated to be a reliable and valid measure of the outcome of individuals with OA of the hip or knee. (Abbott et al., 2009; Brantingham et al., 2010). Salaffi, et al (2003) investigated the internal consistency and test-retest reliability of the WOMAC scale for the three subscales pain, stiffness and physical function in 304 subjects affected by knee OA. All WOMAC subscales were internally consistent (Cronbach’s alpha = 0.91, 0.81 and 0.84
respectively) and demonstrated satisfactory test-retest reliability (ICC = 0.86, 0.68 and 0.89 respectively).

2.2.2 The Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP)

The Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP) was developed to assess intermittent and constant pain experienced by people with OA. The questionnaire contains 11 items that are subdivided into 2 subscales: pain intensity and effect of pain on quality of life (Moreton et al., 2012) The questionnaire has shown good test-retest reliability ($r = 0.57-0.67$) when compared with other measures such as the WOMAC (Moreton, et al., 2012). The ICOAP may be interviewer administered or self-completed by the participants. This scale can be found in Appendix 2.

2.2.3 The Harris Hip Score (HHS)

The Harris Hip Score (HHS) is a multidimensional approach to the assessment of hip function. It involves the subcategories pain, function, movement and deformity. The final score is composed of patient-reported and observer-assessed elements (Achten et al., 2010). The questionnaire has gained wide acceptance since its introduction in 1969 (Achten, et al., 2010). A validity study by Soderman and Malchau (2001) compared the results of 344 patients with total hip replacements as assessed by the HHS and the WOMAC, and demonstrated high validity and reliability (Cronbach's alpha coefficient of 0.83) (Roos et al., 1999) for both the HHS and the WOMAC (Soderman & Malchau, 2001).

2.3 Imaging Techniques

In recent years there has been an increase in the number of MRI-based studies dealing with epidemiological aspects of osteoarthritis with the conclusion that MRI may be more useful for ruling out OA suspected by other means, than it is in detecting new OA (sensitivity: 61% and specificity: 85%) (Roemer et al., 2012). Contrarily, ultrasound has been shown to be more specific than MRI, but less equipped to rule out osteoarthritis (Roemer & Guermazi, 2012). As a guideline, radiography is primarily useful in the assessment of the bony structures, ultrasound is primarily used for the evaluation of ligaments and the synovium, whereas MRI permits visualisation of intra-articular structures (Braun et al., 2012). Hence, a combination of imaging techniques may be the best approach to gain the most comprehensive view on the disease progress.

2.3.1 The Kellgren & Lawrence Score

The Kellgren and Lawrence Score is a radiographic rating scale for plain films used to assess the presence of osteoarthritis and to estimate its severity (Shamir et al., 2010). This scale is the most frequently used of all radiographic assessment tools and has been adopted by the World Health Organization (WHO) as the reference standard for cross-sectional and longitudinal epidemiologic studies (Park et al., 2013). Radiographs are assessed and graded on a 1 – 4 level of severity as follows:
Grade 1: ‘Doubtful narrowing of joint space and possible osteophytic lipping’
Grade 2: ‘Definite osteophytes, definite narrowing of joint space’
Grade 3: ‘Moderate multiple osteophytes, definite narrowing of joints space, some sclerosis and possible deformity of bone contour’

Grade 4: ‘Large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour.’ (Park, et al., 2013).

2.4 Diagnostic Guidelines of Osteoarthritis

There are a number of criteria involved with the diagnosis of OA, however, the most commonly used are those developed by the American College of Rheumatology (ACR) (Altman et al., 1991). These criteria were developed by comparing radiographically, clinically diagnosed OA patients to controls with similar joint pain due to other known pathologies or musculoskeletal diseases (Arden & Nevitt, 2006). The ACR criteria for OA of the hip joint are satisfied if the following items are present: 1, 2, 3 or 1, 2, 4 or 1, 3, 4 (Arden & Nevitt, 2006)

1) Hip pain for most days of the prior month;
2) Erythrocyte Sedimentation Rate ≤ 45 mm/h);
3) Radiograph femoral and/or acetabular osteophytes;
4) Radiograph hip joint-space narrowing;

2.5 Current treatment of Osteoarthritis

Presently, there exists no curative model for osteoarthritis; therefore treatment is aimed at reduction or management of symptoms. Treatment of people with hip OA consists of either conservative or surgical treatment, or a combination of the two (MoH, 2008).

2.5.1 Conservative treatment

As stated in the National Institute for Health and Clinical Excellence’s guidelines for The Care and Management of Osteoarthritis (2008), the key priorities for treatment consist of exercise, manual therapy and pharmacological therapy (NHS, 2008).

Various forms of exercise are effective in decreasing pain and increasing functionality in individuals with OA, however, few studies relate specifically to OA of the hip (Abbott, et al., 2009). Evidence shows that when exercise is undertaken, it should be conducted regularly irrespective of age group, pain severity or level of disability, with a focus on local muscle stretching and general aerobic fitness (NHS, 2008).

Another form of conservative treatment is the prescription of paracetamol for pain relief or Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) to counter inflammatory processes, either as required or as a regular dosage (NHS, 2008). Although pharmacological therapy may provide symptomatic relief, there is no evidence to show that it alters the progression of the disease (Kennedy et al., 2010).
2.5.2 Surgical Treatment

As OA progresses and the anatomical changes become more severe, surgical intervention is considered the most suitable treatment (NHS, 2008). Currently surgical intervention consists of 4 main procedures: arthroscopy, osteotomy, arthrodesis, or arthroplasty.

2.5.2.1 Arthroscopy

Arthroscopy is a form of minimally invasive surgery (MIS) where a small incision is made to allow entrance of an arthroscope to permit small operations to be performed. In OA of the hip, arthroscopy is aimed at the removal of loose cartilage or bone in order to decrease pain and improve functionality. Arthroscopy is suggested for individuals with mild to moderate OA of the hip who have evidence of bone and cartilage fragments in the joint, or patients whose joints lock or catch with movement (Onuora, 2012). However, the 2012 evidence based treatment guideline by the American Association of Orthopaedic Surgeons strongly recommends against arthroscopy with lavage and/or debridement in patients with a primary diagnosis of symptomatic osteoarthritis (AAOS, 2013).

2.5.2.2 Arthroplasty

Arthroplasty, more commonly known as ‘joint replacement’, has become the most common surgical intervention for severe OA, especially in the hip (Bachmeier, et al., 2001). In the US alone, the combined number of knee and hip joint replacements performed is in excess of 350,000 annually (Arden & Nevitt, 2006). In New Zealand, the intervention rate for total hip and knee replacement surgery was 33.0 per 10,000 in 2011 (Gwynne-Jones, 2013b). This procedure involves replacing both the head of the femur and the acetabulum with synthetic materials such as titanium alloys or ceramics. Although pain and functionality are significantly improved after the one year recovery phase, the procedure is commonly avoided in younger individuals as artificial joints tend to wear down over time, becoming more prevalent at 5 years postoperatively and increasing subsequently (Crowther et al., 2002). Arthroplasty also bears the possibility of serious complications such as blood loss during surgery, postoperative infection and postoperative deep vein thrombosis (Onuora, 2012), although these complications are shared with all major surgery. Arthroplasty is considered the most effective from of surgical procedure and hence exhibits both a growing demand by patients and a growing confidence of surgeons to perform the procedure (NHS, 2008).

2.5.2.3 Osteotomy

A slightly less invasive surgical approach is osteotomy where a slice of bone is taken out of the shaft of the femur or the pelvis in an attempt to re-align the damaged bone structure. This procedure often provides only mid-term relief of pain and is also associated with serious complications similar to those associated with arthroplasty (Onuora, 2012). The procedure has been shown to be effective in delaying hip replacement in younger patients. Good prognosis with delay of THR of more than
ten years can be expected to exceed 40% of cases, even when indications are less than optimum (Zweifel et al., 2011).

2.5.2.4 Arthrodesis

The last resort for severe OA hips is a complete fusion of the affected joint. Although this method almost entirely reduces the patient’s pain, it also completely reduces the movement of the joint (Onuora, 2012). Arthrodesis is a viable technique especially for younger patients with a recent history of local infection and/or trauma. Current internal fixation techniques provide a fusion rate of 80% or greater with maximal preservation of bone stock. However, the procedure can be technically challenging and has a high risk of postoperative complications. Hence the procedure is not viewed as a favourable alternative to THR by most orthopaedic surgeons (Beaulé et al., 2002).

2.6 Manual Therapy Techniques

Non-pharmacological and non-surgical approaches such as manual therapy are considered the first line of treatment for osteoarthritis (Abbott, et al., 2009). Unlike surgical procedures, they offer a non-invasive approach to managing OA and may be combined with other forms of intervention such as exercise and pharmacological therapy (NHS, 2008).

The majority of manual therapy techniques for treating OA are aimed at two main approaches. One such treatment approach is aimed at increasing the patient’s range of motion (ROM). Recent research by Cramer, Fournier et al. (2004) in a rat model found that when causing hypomobile joint dysfunctions, early treatment of these dysfunctions can decrease the onset of OA (2004). Each manual therapy utilises different techniques aimed at mobilization of the joint, often intended specifically to stretch the joint capsule and increase the ROM (Abbott, et al., 2009). The other key approach of many manual therapies is increasing the fluid movement in and around the inflicted joint, thus allowing adequate nutrition to reach the articular cartilage (Sims, 1999). Many techniques of manual therapy cause a loading and unloading movement on the targeted joint, and this is thought to result in a ‘pump like’ action to facilitate the movement of fluids (Sims, 1999).

Currently there is only a limited amount of research investigating the effectiveness of manual therapy on OA. Some relevant studies are discussed later in chapter 3.

2.7 Osteopathic Treatment for Osteoarthritis

Although osteopathic promotional materials and websites often imply, if not claim, to be able to treat OA, to date no research on the use of osteopathic techniques to treat OA exists. Osteopathy utilises a similar style of manual therapy techniques to those employed by physical therapists and other manual therapists to treat OA. These techniques are used in an attempt to increase joint range of motion (including both gross range and accessory movements) and increasing “fluid dynamics”, aiding the flow of blood to an area and increasing drainage of inflamed areas (Ward, 2003).
Osteopathic treatment is not considered a primary treatment method for OA, but an additional mode of therapy to be incorporated alongside another forms of management (physical exercise, pharmacological intervention).

The aims of an osteopathic treatment for OA vary for each individual depending on risk factors, predisposing and maintaining factors and severity. However, overall the practitioner of osteopathy may choose to focus on increasing the ROM of the affected joint and joints surrounding it, increasing venous and lymphatic drainage from the affected area whilst promoting arterial supply, decreasing the tonicity of muscles surrounding the affected joint and also assessing and treating the entirety of the body for altered biomechanics caused by the affected joint (Nicholas et al., 2008; Ward, 2003).
Chapter 3: Critical Review of Manual Therapy Intervention for Hip Osteoarthritis

Currently little research exists in relation to the efficacy of manual therapy (delivered by any practitioner group) in the treatment of hip OA. The following chapter aims to summarise and critique the three most comprehensive studies to date regarding manual therapy intervention for hip osteoarthritis (Hoeksma, Dekker et al., 2004; Abbott, et al., 2013; Brantingham, et al., 2010). Article reviews were based on criteria for critical appraisal described by Verhagen, et al (1998). These criteria were developed to assess the quality of clinical trials of physical therapy interventions and are utilised as the basis of the commonly used PEDro scale (Sherrington et al., 2000). The PEDro scale commonly utilizes a numerical rating scale, however this approach was not used in this study because there is disagreement on the appropriateness of weighting of scores for different items (Colle et al., 2002; Jüni et al., 1999) and so each appraisal item was considered separately. This section will give a brief explanation of each study reviewed, the main findings of each; and includes a summary table comparing each study against the PEDro criteria.

3.1 Review of Hoeksma, Dekker et al. (2004)

A study by Hoeksma, Dekker et al. (2004) compared the effectiveness of a manual therapy program with an exercise program in people with OA of the hip. The study was a single blind, randomized clinical trial of 109 participants with hip OA in the Netherlands. The manual therapy program focused on specific manipulations and mobilization of the hip joint, whereas the exercise therapy program focused on active exercises to improve muscle function and joint motion. Outcome measures were:

1) A 6 point Likert scale (ranging from ‘much worse’ to ‘complete recovery’)

2) The short form 36 questionnaire (scaling bodily pain, physical function, and role physical function)

3) Harrison Hip Score

4) Walking speed over distance of 80m.

‘Success’ was defined as a 30% increase on a 6 point Likert scale. After 5-weeks, 81% of the manual therapy group showed improvement in comparison to 50% of the exercise group (OR = 1.92; 95%CI =1.30, 2.60) (Hoeksma et al, 2004). Participants in the manual therapy group showed marginally better outcomes on pain, function, and role function compared to the exercise group (Effect Sizes = 0.1, 0.2, 0.1 respectively) (H. L. Hoeksma, et al., 2004). For the group allocated to manual therapy, the effect size for Harris Hip Score and the walking speed were 0.5 and 0.6 respectively at 29-week follow-up. Table 1 shows the appraisal of Hoeksma, Dekker et al. (2004) using the PEDro criteria.
Summary

Although this study could now be considered somewhat dated, it was the first clinical trial to investigate manual therapy as an intervention for osteoarthritis. This study is of sound quality as it used a number of valid and reliable outcome measures and showed adequate control of bias. The results of this study indicate that manual therapy is moderately superior to exercise therapy alone in increasing hip functionality and decreasing pain in people with OA of the hip.
### Table 1: Comparison of Hoeksma et al. (2004) to PEDro scale criteria

<table>
<thead>
<tr>
<th>PEDro Scale Criteria</th>
<th>Hoeksma et al.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Eligibility criteria were specified</td>
<td>Eligibility criteria were specified based on ACR criteria and decreased ROM, showing no threat to external validity.</td>
</tr>
<tr>
<td>2. Subjects were randomly allocated to groups (in a crossover study, subjects were</td>
<td>Subjects were randomly allocated to groups using random number blocks and sealed, non-translucent envelopes providing evidence that both groups are in fact comparable.</td>
</tr>
<tr>
<td>randomly allocated an order in which treatments were received)</td>
<td></td>
</tr>
<tr>
<td>3. Allocation was concealed</td>
<td>Allocation was performed by the referring physician and was concealed as to avoid systematic biases in otherwise random allocation.</td>
</tr>
<tr>
<td>4. The groups were similar at baseline regarding the most important prognostic</td>
<td>The two groups were similar at baseline in regards to the main prognostic indicators including age, gender, Kellgren/Lawrence score and HHS showing no bias was created via random allocation.</td>
</tr>
<tr>
<td>indicators</td>
<td></td>
</tr>
<tr>
<td>5. There was blinding of all subjects</td>
<td>The subjects were not blinded (NA to this study due to the obvious nature of the intervention ie it is challenging given the absence of accepted sham procedures to blind participants to the fact they are receiving “real” manual therapy.</td>
</tr>
<tr>
<td>6. There was blinding of all therapists who administered the therapy</td>
<td>The therapists were not blinded (NA to this study due to the obvious nature of the intervention ie it is not possible to blind therapists when delivering manual therapy)</td>
</tr>
<tr>
<td>7. There was blinding of all assessors who measured at least one key outcome</td>
<td>One assessor who carried out all assessments was blinded to the allocation of intervention group as not to introduce a preconceived bias.</td>
</tr>
<tr>
<td>8. Measures of at least one key outcome were obtained from more than 85% of the</td>
<td>The author does not state what percent of the initial participants are used in the follow up data. The subjects who were not followed up may have differed dramatically from those included, potentially introducing a bias. The size of this bias can increase with the number of subjects not included in the follow up data.</td>
</tr>
<tr>
<td>subjects initially allocated to groups</td>
<td></td>
</tr>
<tr>
<td>9. All subjects for whom outcome measures were available received the treatment or</td>
<td>Analysis was performed following “intention to treat” and “per-protocol” principles yet data was only presented for the “intention to treat” analysis. Analysis of data according to how subjects were treated as opposed to how subjects should have been treated may produce biases.</td>
</tr>
<tr>
<td>control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”</td>
<td></td>
</tr>
<tr>
<td>10. The results of between-group statistical comparisons are reported for at least one key outcome</td>
<td>Between-group statistical comparisons are reported for SF-36, HHS and walking speed.</td>
</tr>
<tr>
<td>11. The study provides both point measures and measures of variability for at least one key outcome</td>
<td>Effect sizes were calculated for SF-36, HHS and walking speed.</td>
</tr>
</tbody>
</table>
3.2 Review of Abbott, Robertson et al. (2013)

Recently, a large scale study by Abbott, et al. (2013) also examined the effects of manual therapy and exercise therapy on OA progression. This study utilized a 2 x 2 factorial randomized controlled trial protocol to treat 224 participants with either hip or knee OA over a 12-month period. The primary outcome measure was the WOMAC scale. The study also used a number of physical performance tests as secondary outcomes. Outcome assessors were blind to group allocation, and were not involved in providing the interventions. The participants were divided into four groups:

1) Usual care group
2) Usual care + manual therapy group
3) Usual care + exercise therapy group
4) Usual care + combination therapy group (manual and exercise therapy)

Usual care consisted of the routine care offered by the participants’ GPs and other healthcare providers. Manual therapy involved a semi standardised protocol where practitioners used standardised techniques to modify the quality and range of motion of the target joint and associated soft tissue structures. The practitioners used further interventions for individual participants based on their own physical findings according to a provided protocol. The exercise therapy consisted of a supervised programme of warm-up/aerobic, muscle strengthening, muscle stretching, and neuromuscular control exercises.

Results were considered using two sub-groups: ‘No hip or knee replacement’ and ‘all participants’. The results are summarised in the following table (Table 2)

Table 2: Mean (SD) WOMAC scores at 1-year follow-up and change in score from baseline redrawn from (Abbott, et al., 2013).

<table>
<thead>
<tr>
<th>Change in WOMAC score from baseline</th>
<th>Usual care Group</th>
<th>Usual care Group + manual therapy group</th>
<th>Usual care Group + exercise therapy group</th>
<th>Usual care Group + combination therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>No hip or knee replacement</td>
<td>3.7 (33.4)</td>
<td>-28.2 (46.0)</td>
<td>-12.6 (31.0)</td>
<td>-15.3 (34.4)</td>
</tr>
<tr>
<td>All participants</td>
<td>-12.9 (51.8)</td>
<td>-41.4 (55.5)</td>
<td>-29.3 (50.4)</td>
<td>-27.4 (41.1)</td>
</tr>
</tbody>
</table>

Note: Data are shown as mean (SD). A negative number represents a decrease in pain and disability.

These results indicate that the group receiving manual therapy demonstrated the highest improvement compared to the usual care (control) group, followed by the exercise therapy group and the combination care group. The usual care group demonstrated the least improvement, where there were in fact increases in pain scores recorded in the no hip or knee replacement group. In terms of
physical performance outcomes, the exercise therapy group demonstrated the most improvement (Abbott, et al., 2013). Table 3 shows the appraisal of Abbott, et al. (2013) using the PEDro criteria.

The long duration of the study is well matched to the chronic nature and progression of OA. This study design is therefore superior to other studies with a shorter follow up period. The lack of control over the usual care group due to the potential influences of other interventions (eg use of analgesics) may have confounding effects on the results of the study. However, given the large sample size and ethical considerations, a more stringent approach is not practical. Interestingly, the combination of manual and exercise therapy yielded less improvement than when undertaken in isolation. This may be, as the authors suggest, due to an antagonistic interaction between the two interventions. This has an important real-life application as it indicates that the two interventions show less benefit when being used in combination. The utilisation of a high sample size in conjunction with a long follow up period and a strong study design means this study has set a high benchmark for further research in this field.
Table 3: Comparison of Abbott, et al. (2013) to PEDro scale criteria

<table>
<thead>
<tr>
<th>PEDro Scale Criteria</th>
<th>Abbott, et al.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Eligibility criteria were specified</td>
<td>To be eligible, participants were required to meet clinical criteria for diagnosis of OA of the hip or knee established by the American College of Rheumatology. Also, a number of strict exclusion criteria were enforced.</td>
</tr>
<tr>
<td>2. Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)</td>
<td>After baseline assessment, participants were randomised using TENALEA, an online randomisation service.</td>
</tr>
<tr>
<td>3. Allocation was concealed</td>
<td>The TENALEA service generated and held the randomisation schedule, ensuring allocation concealment.</td>
</tr>
<tr>
<td>4. The groups were similar at baseline regarding the most important prognostic indicators</td>
<td>The two groups were similar at baseline in regards to both the primary and secondary outcomes, yet the Manual therapy + usual treatment group did exhibit a slightly higher WOMAC score and pain intensity VAS score.</td>
</tr>
<tr>
<td>5. There was blinding of all subjects</td>
<td>The subjects were not blinded (NA to this study due to the obvious nature of the intervention ie it is challenging given the absence of accepted sham procedures to blind participants to the fact they are receiving “real” manual therapy.</td>
</tr>
<tr>
<td>6. There was blinding of all therapists who administered the therapy</td>
<td>The orthopaedic surgeons and GPs managing the participants’ care were blind to group allocation. The therapists were not blinded (NA to this study due to the obvious nature of the intervention ie it is not possible to blind therapists when delivering manual therapy)</td>
</tr>
<tr>
<td>7. There was blinding of all assessors who measured at least one key outcome</td>
<td>Outcome assessors were blind to group allocation, and were not involved in providing the interventions. Also, the statisticians conducting the statistical analyses were blind to group allocation until after the analyses were completed.</td>
</tr>
<tr>
<td>8. Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups</td>
<td>Measures of all outcomes were obtained from 193 participants, 93.2% of the subjects initially allocated to groups.</td>
</tr>
<tr>
<td>9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”</td>
<td>The initial analysis used the intention-to-treat principle, however as joint replacement surgery is a major confounding intervention a per-protocol analysis was also performed and data was presented for each analysis.</td>
</tr>
<tr>
<td>10. The results of between-group statistical comparisons are reported for at least one key outcome</td>
<td>Between-group statistical comparisons are reported for all primary and secondary outcome measures</td>
</tr>
<tr>
<td>11. The study provides both point measures and measures of variability for at least one key outcome</td>
<td>Effect sizes were calculated for all primary and secondary outcome measures</td>
</tr>
</tbody>
</table>
3.3 Review of Brantingham, Globe et al. (2010)

Another notable study was a single-group pre-test post-test design by Brantingham, et al. (2010) to examine the effectiveness of chiropractic manipulative treatment on osteoarthritic hips. In this study 18 individuals with a low level of OA of the hip (WOMAC < 960 mm) were treated two times a week for a period of 5 weeks (total treatment n=9) following a full kinetic chain manipulative therapeutic approach (mobilisation through manipulation to the lumbosacral, knee, ankle and foot joints as tolerated and indicated per patient) (Brantingham, et al., 2010). The primary outcome measure was the Overall Therapeutic Effectiveness (OTE) tool, a 7 point Likert scale of self-reported patient satisfaction and improvement. Secondary outcome measures consisted of the WOMAC scale, the HHS, and range of motion (ROM) as measured by a goniometer. Results showed that 83% of patients exhibited an improvement of at least +30% on the OTE after the ninth visit, p = .005, and 78% showed the same +30% improvement after a 3 month follow up, p = .018. At the ninth visit, the WOMAC demonstrated an overall change (-175.58 mm) of 64% (p = .000; 95%CI, 190.9-430.9), and an overall WOMAC change of 47% (-257.83 mm) at the 3-month follow-up (p = .011; 95%CI, 60.2-397.3). The HHS at the ninth visit increased from a baseline by +12.2 points (p = .001; 95% CI, −18.7 to −5.7) and by +11.8 points (p = .007; 95% CI, −19.9 to −3.7) at the 3-month follow-up. The total increase in the global ROM was +11.9°. ROM increased in flexion, extension, and internal rotation significantly at the 3-month follow-up (Brantingham, et al., 2012). Table 4 shows the appraisal of Brantingham, et al. (2010) using the PEDro criteria.

Contrary to Hoeksma et al. (2004) and Abbott, et al. (2013), the results of this study are compromised by the poor control of bias inherent in the design. For one, the study design did not incorporate a control group, which negated the possibility of blinding. Hence, there is no way to determine whether the observed effects were caused by the intervention or may be attributable to other unknown factors such as placebo. Another concern is the lack of reporting of participant drop outs over the duration of the study. The lack of this information makes result interpretation difficult as it is unknown whether the results of potential drop outs varied from those included in analysis. Lastly, the sample size of the presented study was relatively small and all participants exhibited low WOMAC baseline scores. This effectively limits the generalizability of the sample to the population it was drawn from. Although the use of a pre-test/post-test design as opposed to a RCT render this study less credible than Hoeksma et el. (2004) and Abbott, et al. (2013), the results of this study are suggestive of the potential benefit of short and long term effects of manual therapy on the progression of OA, but should be interpreted cautiously given the limitations of the design.
Table 4: Comparison of Brantingham et al. (2010) to PEDro scale criteria

<table>
<thead>
<tr>
<th>PEDro Scale Criteria</th>
<th>Brantingham et al.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Eligibility criteria were specified</td>
<td>Inclusion criteria was specified yet only 18 subjects were used, all of which did not reach inclusion criteria for another study</td>
</tr>
<tr>
<td>2. Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)</td>
<td>NA to this study due to the single-group pre-test post-test design</td>
</tr>
<tr>
<td>3. Allocation was concealed</td>
<td>NA to this study due to the single-group pre-test post-test design</td>
</tr>
<tr>
<td>4. The groups were similar at baseline regarding the most important prognostic indicators</td>
<td>NA to this study due to the single-group pre-test post-test design</td>
</tr>
<tr>
<td>5. There was blinding of all subjects</td>
<td>The subjects were not blinded (NA to this study due to the obvious nature of the intervention ie it is challenging given the absence of accepted sham procedures to blind participants to the fact they are receiving “real” manual therapy.</td>
</tr>
<tr>
<td>6. There was blinding of all therapists who administered the therapy</td>
<td>The therapists were not blinded (NA to this study due to the obvious nature of the intervention ie it is not possible to blind therapists when delivering manual therapy)</td>
</tr>
<tr>
<td>7. There was blinding of all assessors who measured at least one key outcome</td>
<td>Blind assessors were trained to perform assessment over multiple instructional sessions with the principal investigator.</td>
</tr>
<tr>
<td>8. Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups</td>
<td>The author does not state what percent of the initial participants are used in the follow up data. As mention in Hoeskma et el’s study, the subjects who were not followed up may have differed dramatically from those included, potentially introducing a bias</td>
</tr>
<tr>
<td>9. All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”</td>
<td>As no dropout rate was mentioned, it is unknown whether analysis was performed according to “intention to treat” or by “per protocol” means.</td>
</tr>
<tr>
<td>10. The results of between-group statistical comparisons are reported for at least one key outcome</td>
<td>NA to this study due to the single-group pre-test post-test design</td>
</tr>
<tr>
<td>11. The study provides both point measures and measures of variability for at least one key outcome</td>
<td>A number of point measures and measures of variability were utilized including Kolmogorov-Smirnov (K-S) Z test and, Friedman test</td>
</tr>
</tbody>
</table>
3.4 Rationale for Research

Osteoarthritis has been described as a complex disease whose cause is not completely understood (Pereira, et al., 2011). At present there is no cure for the condition. With a growing increase in life expectancy comes the challenge of maintaining quality of life in the face of chronic debilitating conditions such as OA. The current management of the condition focuses on surgical, pharmacological and manual therapy approaches. Surgical intervention is generally reserved for failed conservative management where functional disability severely compromises a person’s quality of life. In the case of OA, pharmacological therapy includes control of pain and inflammation with the aim of improving physical function and quality of life. Manual therapy has been shown to have beneficial impacts on functionality and pain levels for mild to moderate OA severity (Abbott, et al., 2013; Brantingham, et al., 2012; H. L. Hoeksma, et al., 2004). Total annual health care costs in New Zealand directly attributable to OA are estimated to be $555 million with a further $2.1 billion of lost productivity and other indirect financial costs (Abbott, et al., 2012). On the basis of recent trial outcomes, Abbott et al. (2013) have argued that manual therapy has been found to be cost saving relative to usual care from the societal perspective. As one of the professions characterised by the use of manual therapy, osteopathy may have a role to play in the provision of care to address disability, suffering and economic costs associated with OA in New Zealand. Although claims have been made in practice promotional material such as websites that osteopathy can help relieve pain and improve functionality in people with OA, there appears to be no peer reviewed studies investigating osteopathic treatment for OA to support such claims. Further research into the effectiveness of osteopathic treatment of OA would be useful in considering the role of osteopathy in the manual therapy approach for OA.

Therefore, the research question of this study is: What effect does osteopathic treatment have on people with osteoarthritis of the hip?

The Aim of this study is: To investigate the effect of osteopathic treatment on people with osteoarthritis of the hip.

The objectives of this study are:

1. To compare pre and post measures of WOMAC scores following an intervention of semi-standardized osteopathic treatment.

2. To compare pre and post measures of ICOAP scores following an intervention of semi-standardized osteopathic treatment.
Chapter 4: Methods of Research

This is the first study conducted specifically to test the effectiveness of osteopathic treatment on individuals with OA of the hip joint, however, three previously mentioned studies have shown manual therapy to be effective in treating people with hip OA. This study was intended to investigate the effect of osteopathic treatment on osteoarthritis of the hip using a Single Systems Research Design (SSRD).

4.1 Study Design

Randomized Controlled Trials (RCTs) are regarded as the ‘gold standard’ for investigating the effectiveness of a clinical intervention. However, RCTs can also provide logistical constraints for the under-resourced researcher such as time, funding and need for large samples (Sanders, 2003).

Not to be confused with a case report or retrospective case study, Single System Research Designs (SSRD) are a prospective design, intended to focus on the individual whilst still allowing control of variables (Sanders, 2003). As defined by Bloom et al. (2009), an SSRD involves studying a single individual or system by taking repeated measurements of one or more dependent variables and systematically applying, and sometimes withdrawing, or varying the independent variable. It is important to note that the unit of interest in a SSRD is not that of a group but of an individual and the name “single system” refers to the individual and their related circumstances.

A typical SSRD commonly utilise an A-B-A withdrawal approach where participants are first observed (A), then treated (B), and then treatment is ceased to measure the effect of the intervention (A) (Miller et al., 2003). This approach was utilised in this study and will be described further in the “Intervention” section of this thesis.

4.2 Participants

A small sample was chosen for this study as it is the first of its kind in the field of osteopathy and could therefore be considered to be a preliminary or pilot study. The decision to limit the number of individuals was based on time and physical constraints. The study was approved by the Unitec Research Ethics Committee (Approval number: 2012-1244) [Appendix 1, 2, 3].

Participants matched the inclusion/exclusion criteria below. Practitioners were recruited for this study from an osteopathic teaching clinic (Clinic 41, Unitec, Auckland) based on the premise that they would attend an hour-long seminar regarding the use of a semi-standardised treatment protocol. All practitioners were osteopathic students in their final year of the Master of Osteopathy program at Unitec, Mt Albert and were assigned as a dyad to each participant such that each participant consulted exclusively with one practitioner.
4.2.1 Inclusion Criteria

All recruited participants matched the following ACR criteria for OA of the hip:

1. Hip pain for most days of the prior month
2. Erythrocyte Sedimentation Rate ≤ 20 mm/h
3. Radiograph femoral and/or acetabular osteophytes
4. Radiograph hip joint-space narrowing

Participants were included if the following items are present: 1, 2, 3 or 1, 2, 4 or 1, 3, 4 (Altman, et al., 1991).

Furthermore participants were required to be aged between 30 and 80 yrs and provide pre-existing, recent plain film images (within 6-months) and/or blood tests as to avoid unnecessary testing procedures.

4.2.2 Exclusion Criteria

Exclusion criteria were:

1. Presence of major neurological signs or symptoms of motor or sensory impairment.
2. Diseases that could propose a major constraint to their physical, psychological or social functioning.
3. Additional pain in the lower back, pelvis, knee or ankle which outweighed the pain perceived in their hip.
4. Currently undergoing any other forms of manual therapy throughout the course of this study.

No medications were considered in the exclusion criteria yet all medication use was recorded throughout the duration of the study.

4.2 Study Setting

The study took place at an osteopathic teaching clinic; Clinic 41, Unitec, Mt Albert, Auckland, New Zealand. Auckland city has a population of 1 377 000 and has a hip osteoarthritis prevalence of 8.45% (Yoshida et al., 2011).

4.3 Intervention

The data collection process took place over a period of 12-weeks in spring 2012. Practitioners attended two 1-hour sessions during which they were briefed about the treatment protocol. Furthermore, practitioners received a written copy of the treatment protocol as well as a documentation template for clinical notes. The treatment protocol involved the techniques shown in Table 5.
Currently there appears to be an absence of osteopathic treatment protocols for the treatment of people with OA. Given the apparent absence of standard treatment approaches there was a risk when using multiple practitioners that a diverse range of treatment techniques would be delivered. In order to at least partially minimise this diversity, a semi-standardized protocol was devised for use in this study based on informal interviews with osteopathy clinical educators (n=6) in the Unitec Osteopathic Teaching Clinic (Table 5). Practitioners were required to use techniques 1) and 2) on the hip joint and could use techniques 3) to 6) on the hip at their own discretion. Furthermore, practitioners assessed secondary joints including the lumbar spine, knee and ankle and treated at least one of these secondary joints accordingly, including at least one mobilisation and one soft tissue technique, but also any of the other predetermined techniques they felt necessary. Practitioners maintained clinical notes for each consultation throughout the duration of the study.

The process of data collection is summarized in the following 3 phases:

4.3.1 Phase A – Baseline – 3 weeks

In phase A of this study, all participants were observed for 3-weeks in order to establish a baseline via repeated measure of the outcome variables, in this case the WOMAC scale and ICOAP scale. This phase helped to establish the level of usual care the participants were receiving before the commencement of OMT. This phase aimed to establish 6 time points per participant.
4.3.2 Phase B – Treatment – 3 weeks

In the second phase, all participants underwent the intervention, a semi-standardised osteopathic treatment, once per week for 6 consecutive weeks, whilst continuing to repeat measurement of the outcome variables. This phase aimed to establish 12 time points per participant.

4.3.3 Phase C – Withdrawal – 3 weeks

In the final phase of the study, all participants ceased treatment yet continued undergoing measurement of the outcome variables for a further 3-week period. This phase aimed to establish 6 time points per participant.

4.4 Outcome Measures

Participants completed two primary outcome measures for this study: 1) WOMAC; and 2) ICOAP questionnaires that were presented to participants online using a web-based form. Measures were administered once per week for the data collection duration of 12-weeks. The WOMAC scale utilises a number of Visual Analogue Scales (VAS). This study utilized a modified version of the VAS comprising of 10 check boxes anchored on the left as “no pain/stiffness/difficulty” and on the right as “extreme pain/stiffness/difficulty”. Questionnaires were recorded by item and not just by final outcome score as to further assess the possibility of changes in separate domains.

In addition to the WOMAC and ICOAP measures, specific diary questions were also asked throughout the duration of the study as a secondary outcome measure [see appendix 3a, 3b, 3c]. These diary questions were aimed at determining and recording factors that may compliment or negate the effect of OMT, such as the patients experiences throughout the past week in regards to the OMT, exercise, medication use, activities of daily living (ADL), pain and general health. This method of specific diary questions was selected over a standard diary as poor participant adherence would be expected over a 12-week period, especially if daily recordings were required.

4.5 Methods of Analysis

Outcome values for WOMAC and ICOAP were displayed graphically on time series plots to enable visual inspection. This is the traditional method for the analysis of continuous data in single case studies, such as in SSRD methods (Ottenbacher, 1986), and despite limitation (Riddoch et al., 1994) has been commonly employed in a number of recent studies (Boersma et al., 2004; Christenson, 2007; Roy et al., 2009). The outcome values obtained in phase B and C were compared to the pre-intervention values using a two standard deviation band spanning above and below the pre-intervention mean. Two consecutive scores outside the pre-intervention mean were necessary to conclude to a significant statistical change in the corresponding B and C phases.
Clinically relevant change for WOMAC is considered to be a change of at least 14 points in each subscale (Roos, et al., 1999). In the absence of normative data for ICOAP, a decrease of 14 points from pre-test to follow-up was operationally defined as representing a clinically relevant change as this utilises a similar magnitude to WOMAC.
Chapter 5: Results and Case Discussion

A total of 6 people responded to advertisements in the form of posters placed in local community organizations including rest homes, churches, GP practices and a local branch of the Returned Services Association. An advertisement was also placed on the website of Arthritis New Zealand (http://www.arthritis.org.nz). All 6 respondents met eligibility criteria and were enrolled in the study. The flow of participants over the course of the study is illustrated in Figure 3. Over the duration of the study 4 participants were withdrawn from the study: 1 due to hip replacement surgery; 1 due to failure to comply with surveys; 1 due to change in diagnosis of OA after a pre-scheduled consultation with a rheumatologist that was not declared to the researcher at the time of initial enrolment; and 1 due to personal reasons (sickness within the family). The remaining 2 participants completed the full treatment and data collection phase. No changes were made to the study design or to outcome measures once the study had commenced.

Figure 3 – Participant flow
5.1 Participant 1 Clinical Presentation

Participant 1 was a 66-year old, 52 kg (BMI = 24.5 kg/m\(^2\)) European/Pākehā female who worked full-time in financial services. She had a two year history of hip pain and a 30 year history of running 4 times weekly. She was diagnosed with right hip OA 1 month prior to the commencement of the study by her GP. Initial symptoms included right groin pain, dull in nature, aggravated by rising to standing after being seated for long periods of sitting. Her pain was relieved by regular aerobic exercise (3 x weekly) and the use of paracetamol (1000mg b.i.d). She described herself as being of good general health, no history of smoking, and no systemic health conditions reported. Physical examination revealed mildly decreased ROM of her right hip, especially in flexion and internal rotation in comparison to her left hip.

5.2 Participant 1 Interpretation of Findings

The WOMAC and ICOAP scores for Participant 1 remained similar for the initial baseline period of 3 weeks (fig. 4 and fig. 5). Examination of her completed questionnaires revealed that she answered all three surveys on the intended due dates yet with the same answers which strongly suggests the possibility of recall bias. There was a large decrease in all three categories of the WOMAC score and also her intermittent pain in the ICOAP score during the treatment of week 7. This substantial symptomatic relief coincided with the application of a HVLA thrust technique to the affected hip and ipsilateral sacroiliac joint. As this was the only HVLA performed during participant 1’s treatment phase, this could be considered a contributing factor to symptomatic relief. The participant concurred that the symptomatic relief was attributable to the application of the HVLA technique in an ad hoc phone conversation following the conclusion of the data collection phase. Participant 1’s sudden changes in WOMAC and ICOAP scores over such a short period are not typical for a person with OA (Bachmeier, et al., 2001; Moreton, et al., 2012), and may be suggestive of stronger affective contributions to pain, rather than changes in nociception around the hip.

Also noteworthy is the fact that although the pain and disability categories of her WOMAC scale increased at week 10, her stiffness did not come back following week 8. This further questions the source of her pain as OA pain is often accompanied by stiffness yet hers did not return. The large decrease in symptoms could be attributed to false reporting or recruitment of a participant that does not exhibit a normal OA presentation despite satisfying the ACR criteria. The increase in symptom score above baseline levels at week 10 coincided with the participant’s participation in unaccustomed physical activity (line dancing at a social event) following her last treatment. As this also coincided with the cessation of her treatment phase, it is impossible to deduce whether this substantial shift was related to treatment cessation, or some other factors.
Fig 4: Participant 1 WOMAC Scores. Grey shaded bands represent ±2SD from the mean of the baseline (Note: Week 8 coincides with a manipulation to the participant’s right sacroiliac joint. Week 10 coincides with the participant dancing at a social event . See text “5.2 Participant 1 Interpretation of Findings” for full description)
Fig 5: Participant 1 ICOAP Scores. Grey shaded bands represent ±2SD from the mean of the baseline. (Note: Week 8 coincides with a manipulation to the participant’s right sacroiliac joint. Week 10 coincides with the participant dancing at a social event. See text “5.2 Participant 1 Interpretation of Findings” for full description)
5.3 Participant 2 Clinical Presentation

Participant 2 was a 54-year old, 95 kg (BMI = 29.3 kg/m$^2$) European/Pākehā female teacher aid/librarian with a 2-year history of left sided hip and groin pain. She was diagnosed with OA of her left hip 3-months prior to commencing this study by her GP. She initially presented with left sided groin pain which was aggravated by sitting in a low chair, rolling over in bed and walking up and down stairs. She found her pain was worse near the end of the day and was relieved by paracetamol. Upon examination, her left hip ROM was found to be decreased in flexion, extension, and external rotation, but her internal rotation was found to be significantly more compared to her right hip.

5.4 Participant 2 Interpretation of Findings

Participant 2 demonstrated clinical improvements for WOMAC (‘total’, ‘disability’ components) and ICOAP (‘total’, ‘intermittent’, ‘constant’ components) scores in the post-intervention period that exceeded the 2SD band. This level of change exceeded the minimum clinically meaningful change of 14-points. However, during the course of this study Participant 2 was preparing to move house, which required a considerable amount of bending and lifting especially in week 7. In her diary entry for week 7 she states she had a particularly bad week with her hip due to “double the normal amount of bending and lifting”. The increase in WOMAC and ICOAP score between week 10 and 11 may be explained by the fact that participant 2 ceased the intake of anti-inflammatories during week 10 and resumed medication at week 11. She had been taking over-the-counter anti-inflammatories regularly prior to the commencement of this study.
Fig 6: Participant 2 WOMAC Scores. Grey shaded bands represent ±2SD from the mean of the baseline. (Note: Week 7 coincides with the participant moving house. Week 8 to 10 coincides with an increased intake of NSAID's. See "5.4 Participant 2 Interpretation of Findings" for full description)
Fig 7: Participant 2 ICOAP Scores. Grey shaded bands represent ±2SD from the mean of the baseline. (Note: Week 7 coincides with the participant moving house. Week 8 to 10 coincides with an increased intake of NSAID’s. See “5.4 Participant 2 Interpretation of Findings” for full description)
Chapter 6: Limitations and Suggestions for Further Research

This section serves as an analysis of the limitations of the study design. Furthermore, suggestions and guidelines are provided regarding further investigations in this field of study.

6.1 Recruitment

Although 6 participants were recruited and enrolled in this study, 4 failed to complete the protocol as planned. An attempt to recruit additional participants in a reasonable time frame was not successful. Researchers commonly expect and plan for a certain rate of dropouts over the duration of a study, however, this rate may not always be estimated correctly. In this study, we observed a 66% drop out rate, which, when compared to other clinical trials for OA and could be considered atypical of research in this field. For instance, Abbott, et al. reported a 6.8% drop out rate (Abbott, et al., 2013), and Hoeksma et al. reported at 23% drop out rate (Hoeksma et al., 2004). When deciding upon the sample size for this study, many factors were considered including the prevalence of hip OA in the local area, accessibility of the study setting and willingness to participate. Notwithstanding these considerations, the sample size was insufficient to withstand substantial non-completion of the protocol.

Advertising posters were placed at a number of community based centres located near the osteopathic clinic, such as retirement villages, churches, and a local Returned Services Association club. Although approximately 20 posters were deployed over a 6-week period, only 6 enquires were received in response to this advertising and this respondent was enrolled. The advantage of posters is that they are inexpensive to produce and position although there effectiveness appears to be limited. Poster advertising is passive, and it may be that more active recruitment strategies would result in more effective recruitment rates. One method of active recruitment would be direct recruitment from radiography or GP clinics. This would have allowed participants with already diagnosed OA an opportunity to try an alternative approach of treatment before surgical intervention but would also have the advantage of a person being able to directly raise awareness of the study and invite them to consider reading the information material and consider participating.

The majority of the participants were recruited using an online advertisement on arthritis.org.nz. The participants recruited were mainly in their 50’s and had only recently been diagnosed with OA. Individuals in this age group who are diagnosed with OA are often informed that medical care available to them is limited to medication until the condition has progressed to a stage where surgical joint replacement is warranted. Affected individuals consequently visit arthritis.org.nz to find other means of managing their condition. Securing a longer duration for the advertisement on this website or a location on the website with more traffic may also have helped to find more participants.
Another potential reason for the reluctance of participants to engage in the study could be a poor understanding by the general public of what osteopathy actually involves. Osteopathy as a profession has struggled to define itself in New Zealand for years now which may contribute towards this poor understanding by the general public (Peachey, 2012). Perhaps this issue could have been resolved by providing a brief explanation of what osteopathy is on the posters.

6.2 Outcome Measures and Diagnostic Criteria

The weekly use of the WOMAC and ICOAP scales provides specific temporal data which is important for accurate visual analysis. However the short time periods between measures could be considered laborious for some participants. A more appropriate use of these scales could be on a fortnightly basis instead of weekly, which would decrease the dependency on participant cooperation with minimal detrimental effect to data accuracy. Furthermore, the increased time frame could extend the duration of the baseline and long term effects phases. Another option could be to allow time before each treatment for the participant to fill out their survey, ensuring that it is done on a regular basis.

Individual response items of the two questionnaires used were not randomly ordered between data collection events as suggested by the developers of the outcome measures (Moreton, et al., 2012; Roos, et al., 1999). Yet this may have increased the potential for recall bias as respondents may have been able to reproduce similar answers to previous surveys.

The symptom presentation of OA may potentially be mimicked by various other conditions or sources of pain such as crystalline arthropathies or inflammatory arthritis (Huether & McCance, 1996). Hence it can be difficult to determine if the source of a patient’s pain is linked to OA. This poses certain difficulties in a research setting as the outcome measures may not be reflecting treatment effects on OA progression but rather effects on underlying conditions. Hence, even with strict inclusion criteria, such as the ACR criteria, there is still a chance of a pain source other than OA (clinical utility of ACR criteria). In their study Kean and Buchannan (2004) discuss a case of a patient with L4 nerve impingement. The patient met the ACR criteria for hip OA, yet the actual source for the pain was most likely the nerve impingement (Kean, et al., 2004). The variety of conditions causing similar pain presentation needs to be considered when selecting participants for OA clinical outcome trials.

6.3 Design

The Single System Research design (SSRD) was selected over a group design such as a Cohort study or Randomised Controlled Trial (RCT) due to resource and time constraints. An SSRD involves measuring a low number of participants, each in isolation, which makes this study design vulnerable to failure, as even a modest rate of participant non-completion is sufficient to strongly impact on the completion of the study.
Bildt et al., (2001) analysed data from longitudinal musculoskeletal studies from 1969 to 1993. The authors found that there was a wide range of dropout rate (7-53%). Furthermore, results demonstrated that participants dropped out of studies primarily due to factors unrelated to the study. Considering this no precautions could be taken to mitigate against dropouts in this study short of using good communication and creating a pleasant research environment for all participants.

Outcome measures can be subjective and objective (Harcourt et al., 2003; Jette, 1989). Subjective outcome measures reflect entities that are only perceivable by the participant such as feelings or sensations (Harcourt, et al., 2003). Objective measurements are quantifiable data that are not influenced by personal feelings or opinions (Jette, 1989). Combinations of subjective and objective measures are valuable in capturing a broader range as subjective evaluation can document patient satisfaction and health-related quality of life, whereas objective measures provide quantifiable data for statistical evaluation (Jette, 1989). Hence, the combination of the two different types of measures could present the most complete picture of an individual’s response to intervention. The outcome measures utilized in this study were restricted to subjective self-reported measures only. A more comprehensible approach would be to use a form of objective measure in addition to subjective measures. The use of goniometry (range of motion) and functional scales like pain-free walking distance or the sit-to-stand test could have provided a broader perspective.

In studies concerned with pain as an outcome measure, external factors that could affect pain levels need to be considered to be certain that changes in pain levels are attributable to the intervention. This study recorded usage of pain medication. However, results could not be evaluated due to low participant compliance in reporting medication usage.

6.4 Chapter 6 Conclusion

In conclusion, SSRDs demonstrate limited leniency for participant dropouts. A more effective way of conducting research in this form would be to minimize factors that require participant cooperation and increase sample recruitment size as dropouts should be expected. In order to reduce the need for participant cooperation, a decreased frequency of measurement events could be implemented.
Chapter 7: A Post Diagnosis Package

Preamble

This chapter is a commentary that addresses a number of points that became apparent during the planning and conduct of the study. These points include:

1. The apparent lack of a standardised osteopathic treatment protocol for people with hip OA.
2. The existence of a ‘gap’ in patient management and guidance, between the time of initial diagnosis and often much later surgical intervention (Jacobson, 2012; Parsons, et al., 2009).
3. A range of treatment modalities for hip and knee OA that when considered in isolation, have good supportive evidence (AAOS, 2013), but have not been practised or investigated in combination.
4. An emerging climate of health governance in New Zealand that appears to be moving towards a more integrative, or interdisciplinary provision of healthcare. For example, a 2012 review of the Health Practitioners Competence Assurance Act 2003 (MOH, 2013) includes encouragement for healthcare disciplines to engage in greater inter-professional communication and collaboration.

In response to these points, this chapter is a commentary that outlines a comprehensive approach to the management of people with OA in the form of a novel management approach for people with OA of the hip or knee to these problems.

7.1 Rationale for development of a post-dx treatment package

Hip and knee OA are progressive conditions for which few, if any, disease modifying treatments have been developed (Abadie et al., 2004). Conventionally, orthopaedic surgery, usually in the form of joint replacement, has been used as invasive, but definitive treatment when conservative measures have been exhausted. The term ‘conservative measure’ is descriptive of any therapy option other than surgery (Bachmeier, et al., 2001). Surgery can, in some cases, provide a substantial increase in functional status and improved quality of life in OA patients (Ritter et al., 1995). However, in New Zealand, a District Health Board may not offer surgery to a patient if they are not certain the surgery can be performed within 6-months, which has led to an increase in the number of individuals with OA not qualifying for surgery in the public sector (Gwynne-Jones, 2013a). There does not appear to be any clear management strategy for the time period leading up to surgery; a period during which individuals with OA are left with a poor understanding of what OA is, and what they can do to alter its progression (Parsons et al., 2009). This was also noted by a number of qualitative studies reflecting on the lived experience of individuals with OA (Jacobson, 2012; Parsons, et al., 2009) as well as during interaction with the participants involved in the current study. This apparent “gap” in patient management and guidance, between the time of initial diagnosis and later surgical intervention, may
be bridged by the proper delivery and implementation of a standardised pre-surgical management strategy.

Several administrative agencies including public health agencies and orthopaedic organizations have undertaken comprehensive systematic reviews of current OA management and treatment approaches resulting in the production of best quality evidence based guidelines (AAOS, 2013; NHS, 2008; Zhang et al., 2007). However, at least on an anecdotal basis it appears that these guidelines are perhaps not being delivered effectively to the patient to bridge the aforementioned gap between diagnosis and surgery. Recent systematic reviews have focussed on the effectiveness of a number of different therapies for management of OA, typically in isolation to other management approaches. A logical step would be to consider combinations of these aspects to provide a standardised, user-friendly management “package” for the purpose of filling the aforementioned “gap” in OA management.

The management components considered by the majority of the systematic reviews have included:

- Education on:
  - OA and its progression and risk factors
  - Diet and nutraceuticals
  - Sleep Quality
- Exercise Therapy
- Manual Therapy
- Cognitive Behavioural Therapy

The next section of this chapter aims to elaborate on these main factors by explaining their role in the management of hip and knee OA and the current body of evidence that supports their use.

### 7.2 Education

Education can play a major role on pain management (Augarten et al., 2006), especially when combined with other management strategies (Moseley et al., 2004). Education should also play an important role in the management of OA as it encourages individuals to make informed choices about lifestyle modifications that could potentially influence disease progression. Education encourages joint responsibility of the management of OA in the form of a cooperative provider/patient approach (Stewart, 2005). This cooperative approach in responsibility fits into the person centred care model (Ferguson et al., 2013), encouraging the person to take control of their own health and increase their adherence to active measures that can be taken to limit OA disease progression (Stewart, 2005).

Having an understanding of a basic anatomy and physiology especially regarding what happens to a joint when it is affected by OA may help a person understand the modifiable risk factors involved in OA (Allen et al., 2010). Subsequently further information should be dedicated to modifiable risk
factors, especially those such as obesity and physical activity. Education has been shown to play an important role in changing beliefs and attitudes as well as the perception that a patient has of their condition (Falvo, 2004). A meta-analysis by Superio-Cabuslay et al. (1996) to compare the effects of education interventions and non-steroidal anti-inflammatory drug (NSAID) treatment on pain and functional disability in patients with osteoarthritis showed that patient education interventions provide additional benefits that are 20–30% as great as the effects of NSAID treatment for pain relief in OA. These findings are included by the American Association of Orthopaedic Surgeons in their recent guideline recommendations for osteoarthritis of the knee which strongly recommends the participation in self-management programs and neuromuscular education (AAOS, 2013). The utilisation of a disease specific educational program for osteoarthritis could help in reducing common misconceptions regarding the condition such as the view that OA is a “wear and tear” type disease and that further exercise will only worsen the condition.

Other aspects of OA management that the patient can control such as diet, exercise and sleep quality are included in the education part of this model and are discussed below.

### 7.3 Diet and Nutraceuticals

Diet and supplementation may play a role in the management of OA through two main mechanisms: 1) change in body composition especially with regards to minimizing levels of fatty body mass (Arden & Nevitt, 2006; Sowers & Karvonen-Gutierrez, 2010); and 2) the pro- and anti-inflammatory effects of certain foods (Lopez, 2012).

Currently there is an absence of evidence that weight loss can slow OA progression or alter pain associated with OA. However, data does provide evidence that reduction of excess joint load, such as through control of non-lean body mass (excessive adipocytes), leads to improvement in physical function (NHS, 2008) and has been shown to reduce the risk of subsequent development of OA in other joints (Arden & Nevitt, 2006). Furthermore, the pro-inflammatory environment created by adipocytes is reduced as a result of a reduction in adipose tissue (Sowers & Karvonen-Gutierrez, 2010). This in turn provides a systemic anti-inflammatory environment. In line with potential beneficial effects on OA management, weight loss will also incur other health benefits associated with sustained weight loss such as improved risk profiles in cardiovascular health and reduced risk of diabetes and metabolic syndrome (Gallagher et al., 2013).

The topic of essential fatty acid (FA) balance is central to recent nutritional debate. The metabolism of the two FA groups (omega-3 and omega-6) produces several derivatives necessary for normal physiological processes. The current diet typical of developed countries has raised the dietary intake of omega 6 FA, effectively causing a shift in balance between the two FAs. Most studies that have been undertaken on the topic have demonstrated that this shift in balance is detrimental to health as it increases the risk of disease such as cardiovascular and Inflammatory bowel disease due to the pro-
inflammatory effect of an increase omega-6 FA intake (Candela et al., 2011). However, further research is needed to confirm these data. The efficacy of nutrition in the management of OA remains uncertain; hence no specific nutritional guidelines have been created for the disease. However, numerous studies have been conducted on the topic and have provided evidence for the effectiveness of specific nutritional interventions (Ameye et al., 2006). A systematic review by Ameye and Chee (2006) of 53 randomised controlled trials demonstrates that nutrition can improve OA associated symptoms, yet there is limited data on the effect of nutrition on disease progression. Nutritional elements that have demonstrated good evidence for efficacy were foods rich in omega-3 components such as Avocado-soybean unsaponifiables (ASU) and methylsulfonylmethane and SKI306X containing foods (Ameye & Chee, 2006). Given the beneficial effects of nutrition on symptomatic relief as well as the low risk of negative outcomes associated with it, there is no reason why these nutritional elements should not be included in the management plan of osteoarthritis in the form of dietary modification.

Contrary to the common perception that the supplementation with glucosamine and chondroitin improves the outcomes of OA, recent studies have shown that evidence in support of the beneficial effects of these supplements is poor with regard to symptom modification and structural changes (AAOS, 2013). Consequently, supplementation with glucosamine and chondroitin for OA is not recommended by current evidence-based treatment guidelines (AAOS, 2013; NHS, 2008; Zhang, et al., 2007).

For the purpose of this package, information should be provided involving dietary advice specific to weight loss and regulation of foods that have a pro-inflammatory effect. This information could be delivered during a consultation or in the form of written material.

### 7.4 Physical Exercise

Appropriate levels of physical activity and exercise are well known to have strong beneficial health effects in a wide range of disorders (Linonis et al., 2012). Further, exercise is known to have health promoting effects. The majority of models of health include physical activity as one of their key aspects, including Te Whare Tapa Whā, the Māori model of health and wellbeing. In this model, physical health, or ‘taha tinana’, is considered one of the four cornerstones required for overall health (MOH, 2013).

Obesity is the largest modifiable risk factor for OA, yet a rapid increase in incidence of obesity is being recorded in most developed countries (NHS, 2008). One of the primary outcomes of regular physical activity is weight loss. Research has shown that a decrease of body mass index of 2 kg/m² or more decreases the risk of developing OA by more than 50% over 10-years following weight loss (Felson et al., 1988). A more practical standard may be expressing goals of weight reduction in percentage of loss of total fatty body mass. A recent study by Messier et al. (2011) suggests that a 10% weight loss
in an overweight and obese OA population elicits positive changes in the mechanical pathway to knee OA by having lower knee joint compressive loads during walking compared with low weight loss and no weight loss groups (Messier, et al., 2011).

Another important effect of physical activity is that of improving joint health. Immobilisation of joints causes a number of negative physiological consequences. This is reflected in a seminal study by Palmoski, Perricone et al. (1979) who measured the effects of immobilisation on proteoglycan count in canine joints. The authors found that after 6 days of immobilisation the proteoglycan synthesis was reduced by 41%. After 3 weeks proteoglycan aggregation was no longer demonstrable. However, the full synthesis rate was recovered following 2 weeks of mobilisation (Palmoski, et al., 1979). A systematic review by Urquhart et al. (2011) on studies examining the effects of physical activity on OA knee joint structures found that there was no related increase in joint space narrowing, increases in cartilage volume and decreases in cartilage defects on magnetic resonance imaging. Given that optimizing cartilage health is important in preventing osteoarthritis, these findings indicate that physical activity is beneficial, rather than detrimental, to joint health (Urquhart, et al., 2011).

In line with direct benefits on joint health, physical activity also promotes physical and psychological health. Potential co-morbidities of OA such as cardiovascular disease (Currie, 2013) and depression (Song et al., 2012) have been shown to be positively affected by physical activity. Improvements in general and joint health, associated with physical exercise, could provide a better mental state for an individual in the management of OA.

There is a large body of evidence, including a number of systematic reviews, that supports the utilisation of physical exercise as a pre-operative measure to decrease pain and increase functionality in OA patients (Wallis et al., 2011). Due to the heterogeneity of study designs there is a wide range of study results, yet the overall conclusion is that the benefits of physical exercise outweigh the risks involved even though the magnitude of efficacy is still under scientific scrutiny (Wallis & Taylor, 2011).

### 7.4.1 Aerobic Exercise

Aerobic exercise types can include exercises such as aerobic walking, Tai Chi and hydrotherapy (Escalante et al., 2011). Specific information regarding these exercises are beyond the scope of this chapter, however, a pre-surgical OA management package should include considerations for exercise prescription with regard to OA severity, body mass, exercise intensity and functional capacity and needs to be made on an individual basis (National Collaborating Centre For Chronic Conditions, 2008; Escalante, et al., 2011).

### 7.4.2 Resistance Exercise

There is no convincing evidence that favours one type of strength training over another for the management of OA (American Geriatrics Society, 2012). However, one recent study by Escalante et
al. (2011) found that compared to other types of resistance training, concentric and eccentric work programs appear to generate a more substantial effect (Escalante, et al., 2011). Regardless of the type of strength training, it is widely accepted that focus should be placed on increasing strength in muscles associated with the affected joint in order to improve joint stability (Society, 2001).

7.5 Sleep Quality

Sleep dysfunction has been recognized as a contributing factor to a poorer quality of life, and an increase in morbidity or mortality (Gallicchio et al., 2009). Sleep has been shown to be a strong determinant of health and wellbeing, with poor sleep quality effecting a number of health outcomes including immune function, metabolic state, inflammation and even arterial calcification (Williams et al., 2013).

Taylor-Gjevre et al. (2011) have observed a high prevalence of abnormal sleep quality in both RA and OA patient populations, showing 67% of OA patients exhibited scores indicative of poor sleep quality. Moldofsky (2010) has recently described how disturbances of sleep and sleep restriction may result in increased sensitivity and increased musculoskeletal pain. Furthermore, a review by Ranjbaran et al. (2007) found a substantial body of published evidence that sleep disturbances can worsen the course of chronic inflammatory conditions, aggravate disease symptoms such as pain and fatigue, and increase disease activity and lower the quality of life.

The impact of sleep deprivation on chronic inflammatory conditions is evident from existing research and studies have shown that a sleep intervention program improves the sleep quality of people affected by insomnia (Kaku et al., 2012). However, no research has been conducted on sleep hygiene education on OA symptoms or progression, hence, it is not clear whether poor sleep quality can affect OA symptoms. Regarding the body of evidence vindicating detrimental effects of sleep disturbance it is a possibility that interventions aimed at increasing the quality of sleep may improve OA related symptoms.

7.6 Manual Therapy

In general terms, manual therapies (the application of ‘hands on’ therapeutic technique) have been employed to affect changes in motor control, changes in symptom perception, improvement of body function and changes in soft-tissue. (Macedo et al., 2009; Petty et al., 2004; Ward, 2003)

Notwithstanding any specific effects that manual therapy may have, even just basic human touch has been shown to provide health benefits (Howe-Colt, 1998). Consedine (2008) examined the patient’s experience of touch during an osteopathic consultation and found that for the participants touch plays a critical role in the therapeutic relationship by supporting and validating their experiences and by
communicating practitioner humanism and professionalism. Furthermore, the experience of touch was identified as a critical component of the therapeutic interaction.

As previously mentioned, a moderate body of reasonable quality evidence exists for the use of manual therapy as an intervention for people with OA of the hip or knee (Abbott, et al., 2013; Hugo L. Hoeksma et al., 2004). On the basis of this evidence, a pre-surgical OA package should include a manual therapy based treatment protocol consisting of a range of different approaches and techniques focussing on mobilisation and decrease of muscle tonicity. The manual therapy protocol would perhaps be best implemented as a semi-standardised treatment protocol that includes treatment of body regions that are functionally related to the hip affected by OA. These regions could include the lumbar spine, contralateral hip, thigh, and knee, ankle and foot joints. Furthermore, treatment approaches can employ a specific range of techniques such as utilized in this study.

### 7.7 Cognitive Behavioural Management

Pain producing mechanisms associated with OA are currently not fully understood. The extent of pain is not always consistent with the extent of radiological changes in a joint. Recent reviews emphasize the presence of central processing mechanisms that produce a diffuse hyperalgesic state (Girbés et al., 2013). The contemporary views emphasise a more modern biopsychosocial model in OA management approach where a patient's psychological aspects of disease have influence on pain and disability (Girbés, et al., 2013).

Cognitive Behavioural Therapy aims to directly affect psychological aspects of a patient's condition such as catastrophising and cognition of pain in an attempt to decrease their effect on OA pain and disability (Girbés, et al., 2013). CBT is based on creating a change in the relationship to maladaptive thinking regarding a patient's OA pain in the form of fear avoidance and anxiety (Bradley et al., 2003).

The American Association of Orthopaedic Surgeons strongly recommends the utilisation of self-management programs and neuromuscular education in their recent document of evidence based guidelines in the management of OA (AAOS, 2013). A pilot study by Hunt et al. (2013) on physiotherapist-delivered, combined exercise and pain coping skills training intervention for individuals with knee osteoarthritis, showed statistically significant improvements in isometric knee strength, self-reported knee pain and physical function, self-efficacy for control of pain management, pain control coping and rational thinking. This evidence suggests that the combination of physical exercise and pain coping skills may contribute an important role toward the management of OA.

### 7.8 Package Implementation and Rationale

As with any form of health intervention, this package should be developed and linked to an associated program of research in order to investigate if the package is effective and acceptable in the
management of OA. Evidence based medicine utilises a hierarchy based evidence model to establish causality from a hypothesis (Petrisor et al., 2007). Evidence produced by methods at the top of this hierarchy such as systematic reviews and meta analyses are considered to identify causal relationships and to minimize bias (Borgerson, 2009). This chapter has provided the first tier of the hierarchy in that it provides a rationale to undertake research in this direction. The next step would be to implement the proposed package on a single patient basis in line with case reports or case studies. Results from such a case series would indicate either the continuation or cessation of research of this package. Should further research be warranted, an SSRD will provide a higher quality of evidence as variables are controlled. Finally, research would require the implementation of more rigorous designs including assessor blinded outcomes and randomisation as well as large sample sizes and longer study durations, either in the form of a cohort study or RCT.

The procedure of researching and developing this package should be developed as a two-stranded approach. As the package is developed, it will require further research. Information gained from this research will then feed back into the package allowing its advancement to a new stage. (Figure 8)

![Figure 8: Proposed research routine comprised of two tracks, the clinical process (blue squares) and the research process (green ovals). Neither track may be developed in isolation as each path requires the other before it may be further developed.](image)

### 7.8.1 Package Delivery

The following is a summary of considerations suggested for the implementation of the package. A detailed description of these aspects does not fall within the scope of this chapter. Future development of the package requires each aspect to be based on best practice in line with evidence based principles.

#### 7.8.1.1 Client Profile

A clear definition of who would qualify to receive the package and on what basis would need to be determined. Considerations should include severity of disease, symptom state and functional status.

#### 7.8.1.2 Setting

The health care provider of this package would need to decide in what level of health care delivery this service would be located, for example primary, secondary or tertiary. The most likely scenario...
would be placing the service into the primary level of healthcare given its growing role in the New Zealand healthcare system (King, 2000).

7.8.1.3 Funding

The health care provider of this package would need to explore funding mechanisms for including access to public or private funding (e.g. District Health Board support), privately or by a 3rd party provider such as ACC or medical insurance agencies.

7.8.1.4 Dose / Frequency / Duration / Volume

The health care provider of this package would need to decide how often treatments occur and for what time duration. A potential for this could be one treatment session a week of 60 minute duration.

7.8.1.5 Physical resources / Materials / Equipment

The type of physical space required for the implementation of this package needs to be identified. Consideration should be given towards a location containing individual consultation rooms, a classroom setting and an open studio style space in which exercise could be performed. Consideration should also be given towards materials such as exercise equipment, treatment tables and educational materials.

7.8.1.6 Clinical Governance

A clinical governance structure needs to be developed to oversee this package. The use of a clinical director or Medical Advisory Board should be considered. An interdisciplinary approach including physiotherapists, exercise therapists, podiatrists, occupational therapists, pain medication specialists, clinical psychologists, osteopaths etc would provide the most holistic approach to the development of this package. This would be in line with the 2012 review of the HPCA act that encourages team work between different health professionals (MoH, 2012).

7.8.1.7 Measures of clinical success

A package of outcome measures would need to be utilized (for both research and clinical practice and monitoring). Specific measures should be used for each aspect of the package and, where available, both objective and subjective measure should be used. Questionnaires that are valid, reliable and currently used include (but are not limited to): WOMAC (Pollard, et al., 2012), ICOAP (Moreton, et al., 2012), and the HHS (Achten, et al., 2010).
7.8.2 Personnel

7.8.2.1 Researcher

Case series and SSRD type studies are suitable for a Masters level research project and could as such be undertaken by students enrolled in a Masters programme such as the Master of Osteopathy. Furthermore, due to the small sample size and duration of study minimal funding would be required to undertake research. As RCT and cohort study designs require more funding and place higher demands on the researcher, these higher levels of study designs would be more suited for PhD or full time research facilities.

7.8.2.2 Practitioners

Initially there may be a single practitioner who is specifically trained to deliver all aspects of the proposed package. Ideally the practitioner would be a manual therapist with the ability to provide the manual therapy and exercise prescription components of the package. The educational aspects of this package could be predefined and supplied to the practitioner to enable them to deliver information regarding OA, sleep, diet and CBT.

Studies that place higher in the evidence hierarchy could benefit from the participation of expert level practitioners in the educational field of this package e.g. dieticians and CBT therapists in order to ensure a high level of education is provided.

7.8.3 Suggested Pathway for Case Series and SSRDs

Participants of the case series and SSRD design would initially take part in one-on-one consultations with a protocol trained practitioner. During these sessions the individual’s baseline data would be collected in various outcome measures in the form of questionnaires and functional tests e.g. the WOMAC scale and ROM tests respectively. The participants would be provided with the educational aspect associated with this package including information on OA pathology as well as dietary and sleep advice. Aspects of pain psychology would be evaluated separately and CBT would be tailored to the individual’s needs. Exercise prescription and advice would be administered according to the participant’s physical abilities and severity of OA. Finally manual therapy would be provided following a semi standardised treatment protocol. Outcome measures need to be at regular yet practical intervals i.e. on a monthly basis. A summary of this process is supplied in Fig. 9.
Fig. 9: Flow chart of study procedure

7.8.4 Suggested Pathway for Cohort studies and RCTs

Baselines for participants taking part in cohort studies and RCTs would be recorded in a similar fashion as described above, yet the involvement of the data collector would be limited to measuring baseline data and outcome measures to ensure successful blinding of practitioners. Due to increased sample sizes the educational and exercise prescription aspects of this package could be delivered in a group setting. Classes have been shown to be cost effective. Furthermore, a class-based exercise programme has been shown to be superior to a home exercise programme at 12 months for pain, disability and walking speed in knee osteoarthritis (NHS, 2008). However, the manual therapy and CBT aspects of this package would be required to be delivered on an individual basis.
8. References


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Appendix 1

RESEARCH INFORMATION FOR PARTICIPANTS

A Study to Examine the Effectiveness of Osteopathic Treatment for People with Osteoarthritis of the Hip

You are invited to participate in a research investigation of osteopathic treatment of osteoarthritic hips. Please read carefully through this information sheet and ask as many questions as you like before you make a decision about participating.

Who are the researchers?
Tony Howat is a Masters Student in Osteopathy at Unitec New Zealand (Mt Albert Campus). He is supervised by Dr Craig Hilton (Health Researcher) and Rob Moran (Osteopath) within the Faculty of Health and Social Sciences at Unitec New Zealand (Mt Albert campus).

What is this study all about?
We are examining what effect osteopathic treatment may have in improving function, pain and disability in individuals with osteoarthritis of the hip. By participating in this study you will help us to determine whether osteopathy is useful in treating this common condition and whether a further, large study may be justified.

Who may participate?
We are seeking people between the age of 30 and 80 with already diagnosed osteoarthritis of at least one hip. Participants will need to meet the American College of Rheumatology (ACR) criteria for hip osteoarthritis which will be discussed with you by the researcher. Essentially this means that you will have already had an x-ray that confirms the presence of osteoarthritis in at least one hip. If osteoarthritis has not been confirmed we are not able to include you in the study. Unfortunately, you will not be eligible to participate if you:

- Are experiencing any major neurological signs or symptoms eg numbness, tingling
- Have any other major health conditions that limit physical, psychological or social functioning
- Have pain in the lower back, pelvis, knee or ankle which is more severe than your hip condition
- Are currently undergoing any other forms of manual therapy, exercise therapy or physical therapy.
- Are taking any medication that makes it unsuitable for you to receive hands on manual therapy treatment including blood thinners (eg warfarin)

Please feel free to contact the Tony Howat if you are unsure about any of these points and we can discuss your situation.
**What will happen in the study?**
If you are interested in participating you will be asked to attend a free 6-week treatment program for your hip, whilst occasionally filling out forms regarding your hip pain.

Participation requires you to attend 6 to 8 treatment sessions, once a week, at Unitec, Mt Albert Campus. During these sessions, a 5th year osteopathic student will use a number of manual therapy ("osteopathic") techniques to treat your hip. These techniques will be aimed at increasing the range of motion in your hip, loosening off surrounding muscles and increasing the fluid flow to your hip. The osteopath may also choose to treat other parts of your body, such as your ankle, knee or low back as these areas may be affecting the way your hip feels.

The first treatment session will take approximately 90 minutes. At this first appointment, Tony (Researcher and osteopathy student) will ask you some questions regarding your hip pain and your general health, followed by physical assessment and treatment. The remaining 5 treatments will take approximately 60 minutes and will be scheduled at times that suit you. **All treatment is free of charge.**

Also, for 3 weeks prior to and following your treatment, Tony will contact you once a week by telephone to ask some questions about your hip pain and how it has affected you throughout your week. This phone call should take 20 to 30-minutes and can be arranged to be at a time suitable for you. During the 6-weeks you are undergoing treatment, someone from the clinic will call you the day before your treatment to ask these same questions, again, at a time that suits you. **Your participation in this study will not affect your ongoing medical care in any way.** You will continue taking any medication or pain relief drugs that you have been taking before the study. Treatment may sometimes require you to remove your outer clothing so we can properly treat you (women can wear a bra or close fitting top). Treatment appointments will be at Clinic 41, Gate 3 on Carrington Rd, Mt Albert.

**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 and details will be recorded on the written consent form and the clinic notes which will be stored confidentially. All data recorded from the study will be stored securely at Clinic 41 and access to it will be limited to the osteopaths and researchers. You will receive a summary of your own data. Other than this personal summary, all data from the study will be presented anonymously in a way that will not identify any individual as their source.

**Participation is completely voluntary**
The decision to participate in this study is completely voluntary. If at any time you feel uncomfortable you may inform the osteopath or researcher and the treatment will be stopped immediately.

Your participation in this study will help to evaluate the effect osteopathic treatment has on individuals with osteoarthritic hips and will provide a valuable addition to the ongoing research into osteoarthritis of the hip.

If you would like to receive further information or have any other queries about the project please feel free to contact us directly:
Tony Howat  
Phone: 027 255 7563  
Email: tony.howat@gmail.com

Rob Moran  
Phone: 815 4321 x8197 or 021 073 9984  
Email: rmoran@unitec.ac.nz

UREC REGISTRATION NUMBER: (2011-1244)  
This study has been approved by the UNITEC Research Ethics Committee from (7 December 2011) to (24 December 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 2

Participant Consent Form

A Study to Examine the Effectiveness of Osteopathic Treatment for People with Osteoarthritis of the Hip

This form is to ensure that you understand the requirements of your participation and that you are 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 given to me.

- I understand that I don’t have to be part of this if I don’t want to and I 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 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.

- I understand that all the information I give will be stored securely on a computer at Unitec according to Unitec privacy regulations.

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

- 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: ……………………………

Principal Researcher: ………………………….. Date: ……………………………

UREC REGISTRATION NUMBER: (2011-1244)
This study has been approved by the UNITEC Research Ethics Committee from (7 December 2011) to (24 December 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.
Do you suffer from osteoarthritis of the hip?

If so, then you are invited to participate in a research investigation of osteopathic treatment of osteoarthritic hips.

The study involves 6 free sessions of osteopathic treatment once a week and one phone call a week to ask some questions regarding your hip pain and the activities you have been doing throughout the week.

Treatment will be safe and pain free and delivered by 5th year, post grad, osteopathy students at Clinic 41 Osteopathic clinic located at Unitec Mt Albert.

Participants must be between the age of 30 and 80 and have x-rays to show osteoarthritis of the hip.

If you have any queries regarding the study or are interested in participating, please call the number listed below.

Tony Howat: 027 255 7563
Appendix 4  Breakdown of techniques

- **Mobilization** – Can be further subdivided into
  - **Articulation** – The practitioner gently guides a joint through its complete range of motion and challenges a restrictive barrier, generally maintained by taut muscles or connective tissue (Patriquin et al., 2003).
  - **Harmonic technique** – The practitioner induces a cyclic motion of the patient's joint to use a state of resonance to effect tissues (Waugh et al., 2007).

- **Muscle Energy Technique (MET)** – The patient contracts a muscle as the practitioner opposes the patient movement, and then stretches the muscle avoiding strong myotatic reflex opposition (Ehrenfeuchter & Sandhouse, 2003).

- **Soft tissue techniques** – Practitioner uses a number of direct techniques to address the muscular and facial structures and the neural and vascular elements associated with them (Ehrenfeuchter, Heilig, et al., 2003).

- **Manipulation** – The practitioner uses a high velocity/low amplitude thrust (HVLA) to push a joint through a restrictive barrier (Kappler et al., 2003).

- **Strain/counterstrain** – Practitioner finds a "position of ease" of the joint of the patient and holds them in this position for a short time in order to neurologically reset the targeted area (Glover et al., 2003).

- **Facilitated positional release (FPR)** – Practitioner places the patient's joint in neutral position and applies an activating force directed at facilitate immediate release of tissue tension or joint motion restriction (Schiowitz et al., 2003).

References:


Appendix 5  

Technique Demonstrations

**Longitudinal traction to the hip.** Support is provided to the knee and ankle via hand and arm contact. Force is applied distally along the direction of the femur.

**Articulation of the hip with accessory movement.** Lateral traction is applied to the hip via a belt. Flexion or internal rotation can then be applied.

**Soft tissue to gluteal muscles.** Force is applied with palm of the hand in a perpendicular direction to the muscle fibre direction of the gluteal muscles.

**Lumbar spine HVLA manipulation.** The lumbar spine is rotated in opposite directions to create a “bind” at a restricted segment. A small rotational thrust is then applied causing a cavitation of the joint.

**Stretch to hamstring muscles.** Support is given to the knee whilst the leg is lifted into a flexed position creating a sustained stretch to the hamstring muscles.

**Stretch to hip flexors.** Support is given to the pelvis whilst the knee is brought back to the practitioner creating a sustained stretch to the hip flexor muscles.
Appendix 6

Western Ontario and McMaster Universities Arthritis Index (WOMAC)

NOTE: All answers are placed on a 10 point scale ranging from 0 = no pain/stiffness/difficulty to 10 = extreme pain/stiffness/difficulty

Pain

Think about the pain you felt in you hip due to your arthritis in the last 48 hours.

How much pain do you have?
1. Walking on a flat surface?
2. Going up or down stairs?
3. At night while in bed i.e. pain that disturbs your sleep?
4. Sitting or lying?
5. Standing upright?

Stiffness

Think about the stiffness (not pain) you felt in your hip due to your arthritis during the last 48 hours. Stiffness is a sensation of restriction or slowness in the ease with which you move your hip.

6. How severe is your stiffness after first awakening in the morning?
7. How severe is your stiffness after sitting, lying or resting later in the day?

Difficulty performing daily activities

Think about the difficulty you had in doing the following daily physical activities due to arthritis in your hip during the last 48 hours. By this we mean your ability to move around and look after yourself.

What degree of difficulty do you have?

8. Descending stairs?
9. Ascending stairs?
10. Rising from sitting?
11. Standing?
12. Bending to the floor?
13. Walking on a flat surface?
14. Getting in or out of a car, or getting on or off a bus?
15. Going shopping?
16. Putting on your socks or stockings?
17. Rising from bed?
18. Taking off your socks or stockings?
19. Lying in bed?
20. Getting in or out of the bath or shower?
21. Sitting?
22. Getting on or off the toilet?
23. Performing heavy domestic duties?
24. Performing light domestic duties?
Appendix 7

A Measure of Intermittent and Constant Osteoarthritis Pain, ICOAP: HIP Version

People have told us that they experience different kinds of pain (including aching or discomfort) in their hip. To get a better sense of the different types of hip pain you may experience, we would like to ask you about any "constant pain" (pain you have all the time) separately from any pain that you may experience less often, that is, "pain that comes and goes". The following questions will ask you about the pain that you have experienced in your hip in the PAST WEEK. Please answer ALL questions.

A) CONSTANT PAIN

For each of the following questions, please select the response that best describes, on average, your constant hip pain in the PAST WEEK.

1. In the past week, how intense has your constant hip pain been?
   - 1  2  3  4  5
     Not at all/ Mildly Moderately Severely Extremely
     No constant hip pain

2. In the past week, how much has your constant hip pain affected your sleep?
   - 1  2  3  4  5
     Not at all/ Mildly Moderately Severely Extremely
     No constant hip pain

3. In the past week, how much has your constant hip pain affected your overall quality of life?
   - 1  2  3  4  5
     Not at all/ Mildly Moderately Severely Extremely
     No constant hip pain

4. In the past week, how frustrated or annoyed have you been by your constant hip pain?
   - 1  2  3  4  5
     Not at all/ Mildly Moderately Severely Extremely
     No constant hip pain

5. In the past week, how upset or worried have you been by your constant hip pain?
   - 1  2  3  4  5
     Not at all/ Mildly Moderately Severely Extremely
     No constant hip pain
B) PAIN THAT COMES AND GOES

For each of the following questions, please select the response that best describes your hip pain that comes and goes, on average, in the PAST WEEK.

6. In the past week, how intense has your most severe hip pain that comes and goes been?
   | 1 | 2 | 3 | 4 | 5 |
   | Not at all/No hip pain that comes and goes |

7. In the past week, how frequently has this hip pain that comes and goes occurred?
   | 1 | 2 | 3 | 4 | 5 |
   | Never/No hip pain that comes and goes |

8. In the past week, how much has your hip pain that comes and goes affected your sleep?
   | 1 | 2 | 3 | 4 | 5 |
   | Not at all/No hip pain that comes and goes |

9. In the past week, how much has your hip pain that comes and goes affected your overall quality of life?
   | 1 | 2 | 3 | 4 | 5 |
   | Not at all/No hip pain that comes and goes |

10. In the past week, how frustrated or annoyed have you been by your hip pain that comes and goes?
    | 1 | 2 | 3 | 4 | 5 |
    | Not at all/No hip pain that comes and goes |

11. In the past week, how upset or worried have you been by your hip pain that comes and goes?
    | 1 | 2 | 3 | 4 | 5 |
    | Not at all/No hip pain that comes and goes |
Appendix 8

Diary Questions

Below are some basic questions regarding your activities over the past week.

1. In the 2 days after the last treatment did you experience soreness or pain that you think was caused by the last treatment?

2. Over the last week have you undertaken any unaccustomed exercise or physical activity or prolonged sitting or standing?
3. If so, what activity, how long, how often ect.
4. Have your medications changed in any way over the last week?

5. Have you been unwell in the past week? (eg common cold)

6. Have you noticed anything that particularly aggravated your hip/thigh/groin pain?

7. Do you have any other comments you would like to add?