Effectiveness of osteopathic manipulative treatment with home based exercises on progressed flexible pes planus

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Declaration

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This Thesis entitled “Effectiveness of osteopathic manipulative treatment with home based exercises on progressed flexible pes planus” 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;
- 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.

Researech Ethics Committee Approval Number: 2012-1085

Candidate Signature:……………………… Date:………………………

Student number: 1099744
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Preface

This 90-credit thesis is submitted in partial fulfilment of the requirements for the Masters of Osteopathy degree at Unitec Institute of Technology.

The following thesis contains three subsections:

1. Section one: The literature review, with emphasis on:
   • Anatomical structures about the condition
   • Ambiguity in the condition
   • Aetiology and its complications to musculoskeletal structures
   • Reviews of diagnostic methods for the condition
   • Different physical therapeutic approaches to the condition

2. Section two: A manuscript in the format specified for submission to the International Journal of Osteopathic Medicine, investigating the effectiveness of osteopathic manipulative treatment with home based exercises on progressed flexible pes planus.

3. Section three: Appendices including ethical approval, participant information sheets, consent forms, short form McGill’s pain questionnaire, editorials for participant recruitments, newspaper editorials, tables, a recruitment poster and the guidelines for authors to the International Journal of Osteopathic Medicine.
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# List of Abbreviations

<table>
<thead>
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<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>EMG</td>
<td>Electromyography</td>
</tr>
<tr>
<td>CT</td>
<td>Computed Tomography</td>
</tr>
<tr>
<td>2D</td>
<td>Two Dimensional</td>
</tr>
<tr>
<td>3D</td>
<td>Three Dimensional</td>
</tr>
<tr>
<td>ICC</td>
<td>Intraclass Correlation (Coefficient)</td>
</tr>
<tr>
<td>BMI</td>
<td>Body Mass Index</td>
</tr>
<tr>
<td>OMT</td>
<td>Osteopathic Manipulative Treatment</td>
</tr>
<tr>
<td>HVLA</td>
<td>High-Velocity Low-Amplitude thrust</td>
</tr>
<tr>
<td>MET</td>
<td>Muscle Energy Technique</td>
</tr>
<tr>
<td>BLT</td>
<td>Balanced Ligamentous Tension</td>
</tr>
<tr>
<td>SD</td>
<td>Standard Deviation</td>
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<tr>
<td>LED</td>
<td>Light Emitting Diode</td>
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<tr>
<td>IR</td>
<td>Infrared</td>
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<tr>
<td>MPQS</td>
<td>McGill’s Pain Questionnaire for Sensitivity</td>
</tr>
<tr>
<td>IQR</td>
<td>Inter Quartile Range</td>
</tr>
<tr>
<td>MPQA</td>
<td>McGill’s Pain Questionnaire for Affective</td>
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<tr>
<td>MPQPPPI</td>
<td>McGill’s Pain Questionnaire for Present Pain Intensity</td>
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SECTION 1: LITERATURE REVIEW
1. Introduction

Progressed flexible pes planus is a progressive condition of flexible pes planus found commonly in children and adults (Pfeiffer, Kotz, Ledl, Hauser, & Sluga, 2006). Flexible pes planus is a difficult entity to classify with no universally accepted aetiology as different types exist between children (naturally occurring) and adults (naturally occurring and acquired) (Harris et al., 2004). Progressed flexible pes planus is a progressed foot condition from flexible pes planus which developed under the age of 10 until adulthood (Nurzynska et al., 2012; Thomas & Harris, 2009). The most accepted aetiology for progressed flexible pes planus is laxity of ligamentous structures (Gardin, Middlemas, Williams, Leigh, & Horn, 2013) and dysfunction of muscular structures, in particular the prolonged tibialis posterior muscle insufficiency (Kulig, Lee, Reischl, & Noceti-DeWit, 2014). Progressed flexible pes planus results in alternations in the lower extremity kinetics such as an excessive calcaneal eversion and an internal rotation of the tibia (Shih, Chen, Chen, & Lin, 2012) causing anterior leg, foot insole, and navicular tuberosity pain from repetitive use of both tibialis anterior and posterior muscles in order to compensate for changes in the lower extremity kinetics (Moen et al., 2012; M. Wong & Griffith, 2009). Wearing foot orthoses or correction shoes and regular foot exercises are the core treatment suggested by physical therapy and medical experts (Langone, 2005).

Despite current treatments, individuals with progressed flexible pes planus often suffer from various musculoskeletal disorders in areas such as the lower back (Menz, Dufour, Riskowski, Hillstrom, & Hannan, 2013), pelvic (Abdel-Raoof, Kamel, & Tantawy, 2013), knee (Shih et al., 2012), ankle (Ellis, Williams, Yu, & Deland, 2010) and foot medial insole (Fabry, 2010). In addition, excessive pronation of forefoot and calcaneal eversion in progressed flexible pes planus carries increased possibility of surgical intervention (Zaw & Calder, 2010). The current exercise treatment regime, however, is becoming controversial (Cetin, Sevil, Karaoglu, & Yucekaya, 2011; Chu, Myerson, Nyska, & Parks, 2001; Emmerich, Wülker, & Hurschler, 2003) due to patient compliance issues (mostly difficulty in adherence to a program) observed in a prescribed exercise program (Sluijs & Kok, 1993). Consequently, there is still a need for passive manual therapy since combining active exercise with passive manual therapy are known to be effective in managing various musculoskeletal conditions such as lower back pain (Hough, Stephenson, & Swift, 2007), osteoarthritis of the hip (Brantingham et al., 2012), knee pain and arthritis (Deyle et al., 2005), shoulder impingement
(Kachingwe, Phillips, Sletten, & Plunkett, 2008) and ankle range of movement (Truyols-Domínguez, Salom-Moreno, Abian-Vicen, Cleland, & Fernández-De-Las-Peñas, 2013).

Osteopathy is a manual therapy which employs various manual techniques to treat musculoskeletal conditions and has been shown to be of clinical benefit for several musculoskeletal conditions such as lower back pain (Licciardon, Minotti, Gatchel, Kearns, & Singh, 2013) and ankle injury (Eisenhart, Gaeta, & Yens, 2003). Despite the benefits to musculoskeletal disorders, there are no studies exploring the effectiveness of osteopathic manipulative treatment or attempting to establish osteopathic clinical guidelines for the prescription of exercises for progressed flexible pes planus. There is a clear need for investigation into the effectiveness of osteopathic treatment for progressed flexible pes planus. This literature review, therefore, contains critical reviews of extended articles on flexible pes planus and even pes planus, in order to understand progressed flexible pes planus.

2. The condition: progressed flexible pes planus

2.1. Important anatomical structures in flexible pes planus

The foot consists of seven tarsal bones, four metatarsals and 14 phalanges. The articulation of a number of small bones provides flexibility to adapt to uneven ground surface and rigidity in propulsion during gait. Normal articulation and function of the foot bone is strengthened by various structures such as tendons, ligaments, and fascia.

In normal feet, ligaments around the navicular bone, such as the superomedial and inferomedial calcaneonavicular, talocalcaneal interosseous, plantar naviculo-cuneiform, plantar first metatarso-cuneiform and anterior superficial deltoid ligaments are the main passive structures maintaining the medial longitudinal foot arch (Blackman, Blevins, Sangeorzan, & Ledoux, 2009). An anatomical area that is considered to be particularly relevant to progressed flexible pes planus is the navicular bone as it has been found to be a key stone in the medial longitudinal foot arch. The medial longitudinal foot arch is composed of the calcaneus, the talus, the navicular, the three cuneiforms, and the first, second, and third metatarsals (Chromey, 2008). A degree of stabilisation of the medial longitudinal arch is also provided by the tibialis posterior muscle and its tendon which is inserted into the navicular tuberosity.
The contribution of the abductor hallucis muscle in the maintenance of navicular height is a recent finding. The correlation of the abductor hallucis muscle with the navicular drop was determined in the study of Headlee, Leonar, Hart, Ingersoll and Hertel (2008), by measuring the navicular drop before and after muscle fatigued. Twenty one subjects with normal healthy feet showed the mean navicular drop increased by 1.8mm and decreased electromyography (EMG) measures of abductor hallucis muscle after the muscle fatigued (Headlee, Leonard, Hart, Ingersoll, & Hertel, 2008). The finding was novel but the study appeared to be biased because of two weaknesses: inability to isolate targeted muscles with a gross EMG technique and difficulty in separating flexion of big toe from extension of other toes at an in-vivo model while fatiguing foot intrinsic muscles. Consequently their data may have resulted in showing a poor correlation between fatigue and changes in the navicular drop. Chang, Kwon, Kim, Ahn and Park (2012) improved the methodological weaknesses seen in the previous study of Headlee, Leonar, Hart, Ingersoll and Hertel (2008) by employing isolating EMG techniques and various fatigue levels on the abductor hallucis muscle. The fatigued abductor hallucis muscle showed lower muscle activation with 2.58 EMG in pes planus groups whereas the tibialis anterior, gastrocnemius, vastus lateralis, and biceps femoris muscles showed increased activity in a pes planus group as fatigue levels increased (Chang, Kwon, Kim, Ahn, & Park, 2012). The findings of Chang, Kwon, Kim, Ahn and Park (2012) indicated that the abductor hallucis muscle fatigued earlier than other foot muscles in pes planus, signifying a correlation between fatigue of the abductor hallucis muscle and navicular drop changes.

Anatomically the Achilles muscle is attached to the calcaneus. Due to the relation between the Achilles muscle and the calcaneus, the lengths of the former have been the target of corrective management for patients with flexible pes planus requiring surgical treatment. Functional improvements were observed in 89% of 107 pes planus patients who had undergone Achilles muscle lengthening surgeries (Stauff, Kilgore, Joyner, & Juliano, 2011). In a meta-analysis study, Mosca (2010) also noted that the short Achilles muscle length is a primary pathological aetiology or a secondary developmental deformity of flexible pes planus. Mosca (2010) found that flexible pes planus with the short Achilles muscle length was highly associated with pain and functional disability such as difficulty in stair-up, stair-down movements or both (Mosca, 2010).
The rigidity of the medial longitudinal foot arch is maintained by plantar aponeurosis through the windlass mechanism. *In-vitro* (Murphy et al., 1998; Sharkey, Ferris, & Donahue, 1998) and *in-vivo* (Cheung, An, & Zhang, 2006; Gefen, 2002; Gefen, Megido-Ravid, & Itzchak, 2001) studies observed the dysfunction of the plantar aponeurosis resulting in an ample deviation from the normal foot mechanism. Such deviation included the diminishing of the medial longitudinal arch and increased plantar pressure under the metatarsal heads.

In conclusion, findings of flexible pes planus studies suggest ligament laxity and the tibialis posterior muscle dysfunction (mostly the muscle insufficiency) to be primary factors in the development of progressed flexible pes planus. Other foot structures such as the abductor hallucis muscle, the Achilles muscle, and the plantar aponeurosis, however, are important in understanding progressed flexible pes planus.

2.2. Ambiguity in flexible pes planus

Pes planus, also known as flatfeet, can be categorised as flexible or rigid in accordance with the characteristics of the foot arch. Most rigid pes planus is associated with either another isolated pathology or is part of several other pathologies. Thus, people with rigid pes planus often require medical and surgical treatment, whilst flexible pes planus is known to be mostly naturally occurring as opposed to traumatic and often considered a condition which does not require treatment. The main diagnostic characteristics of flexible pes planus are a flattened medial longitudinal arch on standing and reappearing a normal arch on sitting without weight bearing. Flexible pes planus is a very common condition in children and adults (Pfeiffer et al., 2006). A prevalence study on preschool-aged children reported 44% of 835 children had flexible pes planus (Pfeiffer et al., 2006). An epidemiological study of flexible pes planus conducted in recruits for compulsory military service aged ≥ 17 years, found 27.9% of 825 964 of the age group (9.3% of 467 412 males and 2.4% of 358 552 females) to be flexible pes planus sufferers (Tenenbaum et al., 2013). Despite its prevalence, flexible pes planus is not considered as a functional abnormality or limitation of the lower extremities, as pes planus itself rarely causes disability (Badlissi et al., 2005). There has been significantly less clinical and research attention carried out on flexible pes planus compared with that carried out on rigid pes planus. Less evidence and understanding of flexible pes planus has resulted in ambiguity.
Paediatric flexible pes planus is known to be a naturally occurred condition and caused by the presence of the midfoot plantar fat pad (Mickle, Steele, & Munro, 2008). Because the midfoot plantar fat pad is known to start to be resorbed naturally after the onset of independent walking, treatment is not suggested by medical professions (Mickle et al., 2008). There are few studies focusing investigation on as to exactly when the mid-foot plantar fat pad is resorbed in children (Mickle et al., 2008). The lack of a standard developmental time point in relation to plantar fat pad resorption may result in uncertainty for parents trying to ascertain whether the current foot state of their children is normal or requires treatment. Neglect, if the condition continues past the age 10, results in it becoming juvenile flexible pes planus which is considered as early progressed flexible pes planus. Studies in children and young adults with flexible pes planus have focused on the necessity of treatment. Most studies concluded that only if symptoms, such as calcaneal eversion and painful legs and feet, exist conservative treatment is necessary (Fabry, 2010). On the contrary, recent studies have proposed the necessity of preventative methods because several studies have demonstrated correlations of flexible pes planus with anterior knee pain (Shih et al., 2012) and lower back pain (Abdel-Raoof et al., 2013). The presence of a significant difference in pelvic inclination ($p = 0.012$), in lumbar ($p = 0.009$), and thoracic angles ($p = 0.028$) were also observed in 60 female participants aged between 13 and 18 years, with bilateral flexible pes planus (Abdel-Raoof et al., 2013). The study found that nearly double the rate of intermittent back pain was present in participants with flexible pes planus compared with those who had normal feet (Abdel-Raoof et al., 2013). Nevertheless, current studies have not precisely identified the link between lower back pain and flexible pes planus and there are limited results that show a correlation between pronated feet and lower back pain (Adams, Brantingham, Cooley, Globe, & Globe, 2007; Menz et al., 2013).

In adulthood, adult flexible pes planus is differentiated from paediatric flexible pes planus as the term, flexible pes planus in adulthood, includes both progressed, but naturally occurred, flexible pes planus and flexible adult acquired pes planus (Zaw & Calder, 2010). Naturally occurred flexible pes planus develops before the age of 10. Over time, the condition contributes to muscular and ligamentous laxity or physiological micro trauma as a result of prolonged flattened medial foot arches. On the contrary, adult acquired flexible pes planus results from injuries to the legs and feet and, in particular, the tibialis posterior tendon. The injured tendon becomes dysfunctional and is no longer able to support and sustain the arch
efficiently leading to a partial or complete collapse of the longitudinal medial foot arch at navicular bone level. Similarly, injured ligaments around feet and ankles result in increased demand of the tibialis posterior muscle in maintaining a medial longitudinal foot arch and, in particular, the spring ligament (Ellis et al., 2010), deltoid ligament (Crim, Beals, Nickisch, Schannen, & Saltzman, 2011), long and short plantar ligaments (Blackman et al., 2009), talocalcaneal intersosseous ligament (Nelson, Haycock, & Little, 2004), medial talocalcaneal ligament, and the tibionavicular portion of the superficial deltoid ligament (Blackman et al., 2009). Ambiguity occurs in the use of the term flexible pes planus when describing both flexible acquired pes planus and naturally occurred progressed flexible pes planus, causing a synonymous error present in the majority of previous flexible pes planus studies (Ferri, Scharfenberger, Goplen, Daniels, & Pearce, 2008).

2.3. Aetiology
While the aetiology of progressed flexible pes planus is still controversial due to difficulty in identifying whether progressed flexible pes planus has naturally occurred or traumatic aetiology, the most accepted aetiology is the attenuation of the tibialis posterior muscle (Chromey, 2008). In contrast, a recent study investigated the existence of a relationship between the fatigued tibialis posterior muscle and navicular drop within healthy participants (Gardin et al., 2013). Gardin et al. (2013) found there to be no relationship. Although novel findings, Gardin et al. (2013)’s conclusion was nevertheless biased as the authors measured navicular drop from a mixture of samples of rigid and flexible pes planus. Navicular drop in flexible pes planus is usually larger than the navicular drop calculated from rigid pes planus since the main characteristics of flexible pes planus is reappearance of a normal arch during sitting while individuals with rigid pes planus lose the arch in both standing and sitting positions. Regardless its weakness the findings of Gardin et al. (2013) were consistent in view of the aetiological structure observed in previous cadaveric kinetic study on the roles of ligamentous structure in flexible pes planus (Emmerich et al., 2003). Emmerich et al. (2003) found that the ruptured tibialis posterior muscle did not produce significant changes in plantar pressure within eight cadaveric human feet. The authors suggested that the development of pes planus observed in degeneration of the tibialis posterior tendon occurred only after fatigue of the passive structures of the foot (Emmerich et al., 2003). Recent aetiological studies have moved research focus to the roles of various foot ligamentous structures in maintaining navicular drop and found a correlation with flexible pes
planus. The ligamentous structures include the spring ligament (Ellis et al., 2010), deltoid ligament (Crim et al., 2011), long and short plantar ligaments (Blackman et al., 2009), talocalcaneal intersosseous ligament (Nelson et al., 2004), medial talocalcaneal ligament, and the tibionavicular portion of the superficial deltoid ligament (Blackman et al., 2009). Because of several studies showing a number of correlations between various ligamentous structures and the condition, most researchers suspect a multifactorial aetiology as opposed to a single structure, the tibialis posterior muscle, causing the condition.

2.4. Complications of flexible pes planus

2.4.1. Changed mechanics of lower extremities

Progressed flexible pes planus is a condition which results in certain alterations in the lower extremity kinetics (Shih et al., 2012). As a progressive condition, the most common structural alterations in progressed flexible pes planus are an excessive calcaneal eversion and an internal rotation of the tibia (Shih et al., 2012). With normal gait, the subtalar joint pronates until the metatarsal head contacts the ground (Shih et al., 2012). In order for the foot to gain rigid structural propulsion through the windlass mechanism, the first toe extends whilst the subtalar joint supinates to allow the plantar aponeurosis to become taut. On the contrary, ligamentous laxity or muscular insufficiency in progressed flexible pes planus allow the foot to stay in a pronated position at the propulsion phase (Shih et al., 2012). As a result of prolonged pronation of the foot in gait, the tibia is rotated internally (Abdel-Raoof et al., 2013). Chronically accumulated kinematic changes and gait deviations may lead to various lower extremity pathologies later in life (Lin, Lai, Kuan, & Chou, 2001).

As part of compensation for diminished navicular height and tibial internal rotation, tibialis posterior, anterior muscles, and plantar aponeurosis have to overwork. In particular, the sitting to standing movement requires high activation of the tibialis anterior, posterior muscles, and plantar aponeurosis (Wiewiorski & Valderrabano, 2011). Flexible pes planus requires early activation of the tibialis anterior and posterior muscles in order to contribute both to stabilising the foot and rotating the shin forward at the ankle to assist in moving the body forward during sit to stand movements (Griffith & Wong, 2009; Moen et al., 2012). Prolonged precipitation of muscular stress on the low extremities results in frequent tibialis anterior muscle inflammation, foot insole, and medial navicular tuberosity pain (Lin et al., 2001).
2.4.2. Spinal change and lower back pain

Lower back pain is considered to be the most common musculoskeletal condition. Lower back pain refers to pain experienced between the lower margins of the 12th rib and the gluteal folds (Adegoke, Johnson, & Ogunlade, 2010). Lower back pain is the most prevalent of all musculoskeletal problems (Hoy, Brooks, Blyth, & Buchbinder, 2010). Aetiological studies for lower back pain generally consider back pain to be a multidimensional problem with a multi-causal aetiology (Dankaerts & O'Sullivan, 2011). Recent studies found pes planus could be a risk factor causing lower back pain (Abdel-Raoof et al., 2013).

An internal rotation of the tibia and femur is the key in understanding a relationship between spinal changes and pes planus. An internal rotation of femur caused by pes planus may shift the femoral head to posteriorly, which consequently shifts the pelvis anteriorly (Abdel-Raoof et al., 2013). Due to the changed pelvic position, the centre of body mass moves to anterior from its normal position (Abdel-Raoof et al., 2013). In order to achieve equilibrium of the postural balance, thoracic spine extends and the chest is fixed in an inhaled position (Abdel-Raoof et al., 2013; Parsons & Marcer, 2006). As a result of the endeavours to gain postural balance where pelvis is tilted anteriorly in the sagittal plane, the iliopsoas muscle becomes tensed. Due to the attachment of the iliopsoas muscle at the lumbar spine, the tension in the iliopsoas muscle lets the lumbar spine shift anteriorly. The iliopsoas muscles under chronic tension pull the lumbar spine inferioanteriorly continuously, and therefore contribute to lower back pain (Abdel-Raoof et al., 2013). Additionally, an antagonist muscle group such as gluteal and the hamstring muscles become tight and chronically dysfunctional (Abdel-Raoof et al., 2013; Parsons & Marcer, 2006). The piriformis muscle is attached at the anterior surface of the sacrum and inserted into the apex of the trochanter. Prolonged pelvic anterior tilt results in the sacrum being pulled to an antero-inferior position which leads to excessive tension of the piriformis muscle (Abdel-Raoof et al., 2013). The anteriorly tilted pelvis and increased lumbar lordosis, found in people with bilateral flexible pes planus, may lead to the presence of hyperlordosis of the cervical spine (Abdel-Raoof et al., 2013; Schafer, 2000).

Complications due to the pronation of the foot and eversion of the calcaneus caused by progressed flexible pes planus, are not limited to pelvis and lower back, but chronic effects of
biomechanical changes affecting the entire musculoskeletal system. The biomechanical effects of pronation of feet on occiput has also been witnessed (Schafer, 2000). Thus, flexible pes planus is a condition which may not cause acute disability (Badlissi et al., 2005), but chronically may produce severe biomechanical effects on the musculoskeletal system.

2.5. Different diagnostic methods

2.5.1. Contemporary methods and related issues
Clinically, the extent of surgical and orthotic therapeutic effects on pes planus has been measured by a computed tomography (CT) and radiography (Harris et al., 2004). Schreiner (2008) however noted that repetitive, unnecessary exposure to radiation is a major ethical issue, which may have an influence on both the recruitment of participants for studies and participants’ health. Likewise, the alternatively introduced method to avoid such ethical issues, the use of an inclinometer, in the study of Burn and Crosbie (2005), failed to show reliability in measuring the range of ankle dorsiflexion. This could be largely due to therapeutic effects on the measuring variables obtained with repetitive lunging against the wall during experimental procedure. Due to the weaknesses in using a CT, radiography, and an inclinometer, the most commonly and routinely used method in private practices are footprints (Harris et al., 2004). However, Pfeiffer et al. (2006) observed that this method failed to measure foot deformities due to low inter-rater reliability, as measurements were highly influenced by body composition and activities. Pfeiffer et al. (2006) found that a two dimensional (2D) foot scanner, introduced to replace footprints, also failed in terms of reliability when measuring foot deformities, because it usually scans the sole of both feet as opposed to the whole foot. Consistent findings were observed by Papuga and Burke (2011), who claim that a 2D foot scanner uses the same protocol as that of standard footprints. Pfeiffer et al (2006) introduced a three dimensional (3D) scanner when taking measurements of feet, where a 3D scanner analyses an object using collected data on its shape and appearances. A 3D scanner can construct digital 3D images on a computer screen using collected data. A pilot study conducted prior to their study showed very high inter- and intra-rater reliability compared to the aforementioned measuring methods (Pfeiffer et al., 2006). Despite its high reliability and reproducibility, the availability and accessibility of this instrument is limited to only certain countries. Alternatively, a photographic method can be used to measure treatment effectiveness on foot deformities at post treatment. Cobb, James, Hjertstedt, and Kruk (2011) found the inter-rater
reliability of a photographic method in measuring pes planus to be higher than footprints, thus a photographic method is applicable in measuring treatment effectiveness in progressed flexible pes planus. However, as this photographic method is reliant on the visual estimation of the researcher, it has potential weakness in interpreting photographic data. Cobb, James, Hjertstedt, and Kruk (2011) in this regard, suggest that further studies should improve their protocol so as to minimise the bias potentially present in their study.

2.5.2. Measuring navicular height
A photographic method combined with the navicular drop test has been used to measure clinical changes of foot conditions as an alternative to a CT, radiographic and foot scanning method. In contrast, Vinicombe, Raspovic and Menz (2001) found the intraclass correlation coefficients (ICC) of the navicular drop test to exist within the range of 0.33 and 0.76 (Vinicombe, Raspovic, & Menz, 2001). Evans, Scutter and Iasiello (2003) observed consistently low reliability and consequently proposed the inclusion of navicular height when measuring clinical changes. Morrison, Durward, Watt and Donaldson (2004) suggested the use of navicular height should be limited to individuals over the age of 16 years (ICC=0.84) due to the occurrence of low intra-tester reliability of navicular height in children aged 4~6 (ICC = 0.55) and 8~15 year old adolescents (ICC=0.74) (Morrison, Durward, Watt, & Donaldson, 2004).

2.6. Management and Treatment of progressed flexible pes planus
Notwithstanding the possible complications of progressed flexible pes planus, there are conflicting options on treatment of progressed flexible pes planus whether treatment is necessary or not (Evans, Nicholson, & Zakarias, 2009; Evans & Rome, 2011; Rome, Ashford, & Evans, 2010). In an early study by Harris and Beath (1947) who first described the concept of flexible pes planus, flexible pes planus was regarded as of little consequence since flexible pes planus rarely causes disability and consequently no obvious treatment was necessary in particular paediatric flexible pes planus. However, as various complications such as low extremities and spinal biomechanical alterations have been observed in correlation studies, much controversy has been generated against the main suggestions of Harris and Beath (1947) in deciding on treatment necessity for flexible pes planus. Currently, most authors believe that consequences of progressed flexible pes planus may be preventable and recommend symptomatic relief of complications with physical treatment or treatment combining
correction shoes, or orthoses with regular exercises (Adegoke et al., 2010; Headlee et al., 2008).

Wearing correction shoes or orthoses and regular exercise is beneficial to all ages (Y. S. Wong, 2007). Treatment options of progressed flexible pes planus in children, however, are different from those of progressed adult flexible pes planus since treatment in children does not guarantee the same results from the same interventions used in adults. This is because growth and biomechanical adaptation in children is much faster. By wearing correction shoes during this critical time of body growth in children, intrinsic foot muscles are weakened and the medial arch improves unequally (Pfeiffer et al., 2006). Pfeiffer et al. (2006) noted that children who wore shoes in early childhood showed a higher prevalence of flexible pes planus than those who were unshod before 6 years of age (Pfeiffer et al., 2006). Stronger statistical significance were observed in children with correlations of progressed flexible pes planus in particular males, higher BMI, more severe arthritis if they have, and presence of other foot deformities such as bunion, hammertoe, and calluses (Shibuya, Jupiter, Ciliberti, VanBuren, & La Fontaine, 2010; Shih et al., 2012). Thus, current flexible pes planus intervention studies suggested life style modification, reducing body mass, finding appropriate activity level, and improving individual’s health through appropriate exercises in managing the condition without the need of treatment (Fabry, 2010; Yagerman, Cross, Positano, & Doyle, 2011).

2.7. Physical therapy in treating progressed flexible pes planus

The review of literature on flexible pes planus and progressed flexible pes planus indicated that rigid pes planus and its post-operative care after reconstruction, arthrodesis, or arthroereisis of soft tissues or bones has generated much physiotherapy research interest. Only a few studies were conducted in relation to flexible pes planus. No studies have investigated manual therapy aspects of physiotherapy treatment effectiveness on flexible pes planus. Instead, physiotherapy studies have focused on the effectiveness of combining therapy of exercises with foot orthoses. Lee, Kim and Cho (2012) investigated effectiveness in using foot orthoses and short-foot exercise of the abductor hallucis muscle on pes planus. Regardless the type of pes planus, flexible or rigid, the group received a combination therapy of foot orthoses and short-foot exercise of the abductor hallucis muscle resulting in a largely (mean difference between a control and an intervention group = 13.61 mm²; p = 0.008)
increased diameter of the abductor hallucis muscle seen on ultrasonography (Lee, Kim, & Cho, 2012).

According to the New Zealand Society of Physiotherapists, flexible pes planus in relation to one of musculoskeletal issues is managed through stretches for areas which are too tight; strengthening for core areas which are weak and affecting the alignment of the body; soft tissue therapy to release the tight muscles; taping and orthotics to unload painful structures and assist in correcting muscle and biomechanical imbalances; assisting in foot wear and further referral (NZ Society of Physiotherapists, 2010). Only two chiropractic studies investigated effectiveness of orthotic intervention on flexible pes planus (Kuhn, Shibley, Austin, & Yochum, 1999; Michaud & Stude, 2001), whilst no studies have investigated chiropractic treatment for pes planus using physical therapy. Similarly, there are no osteopathic studies investigating effectiveness of osteopathic manipulative treatment on the condition.

3. Osteopathy

3.1. Brief historical background of osteopathy

‘Osteopathy’ was founded by Doctor Andrew Taylor Still, born 1828 in Lee County, Virginia. Still later became a medical doctor (Parsons & Marcer, 2006). During the Civil War, Still was a captain in the Union Army and used his medical skills to develop comprehensive anatomical knowledge (Parsons & Marcer, 2006). He continued studying anatomy and physiology with the importance of anatomy and its relationship to the ‘flow of natural forces’ in the body (Parsons & Marcer, 2006). In 1874, Still proposed concepts which form the basic principle of osteopathy (Parsons & Marcer, 2006):

- The body is a unit
- Structure governs function
- The rule of the artery is supreme
- The body possesses self-regulatory and self-healing mechanisms

By 1892, the American School of Osteopathy (ASO) was established in Kirksville where Still was a lecturer (Parsons & Marcer, 2006). Since the early 1970s, osteopathy in the United States has evolved into osteopathic medicine and surgery which functions as a paralleled medical system to regular medicine or biomedicine with full practice rights in all fifty states
and the District of Columbia (Baer, 2009). Conversely, osteopathy in the United Kingdom, which was introduced by Littlejohn in 1898, continues to function primarily as a system of manual medicine (Baer, 2009). This health system of osteopathy was introduced to Canada, Australia, and New Zealand in the early 1900s. Statutory registration of New Zealand osteopathy was achieved in 2003 with the passage of the Health Practitioners Competence Act which came into force 18 September 2004 (Ministry of Health, 2013). Osteopathy is a form of manual therapy and has been shown to produce clinical improvements in health condition and quality of life of patients who suffer from musculoskeletal disorders along with systemic disorders (Eisenhart et al., 2003; Jäkel & von Hauenschild, 2011; Jardine, Gillis, & Rutherford, 2012). As primary health care providers in New Zealand since 2003, osteopaths have effectively managed various musculoskeletal disorders.

### 3.2. Osteopathic manipulative treatment

#### 3.2.1. Osteopathic manipulative treatment in the research field

In order to understand osteopathic studies, the clarification of osteopathic manipulative treatment (OMT) should be made as Patterson (2002) proposed that there exist essentially two different types of osteopathic manipulation studies: osteopathic manipulative technique and osteopathic manipulative treatment. Research studies on the efficacy of osteopathic manipulative technique enables osteopaths to illustrate and determine the specific effects of a well-defined technique on a target problem (Patterson, 2002). Osteopathic manipulative treatment studies, in contrast, investigate the effectiveness of osteopathic treatment by retrieving response to treatment (Patterson, 2002).

Osteopathic manipulative treatment consists of three basic components: passive treatment, active treatment, and advices for life style modifications (Parsons & Marcer, 2006). As osteopathic principles include holistic care for a patient as an individual person not just a presented condition, osteopathic manipulative treatments include various advice and possible multidisciplinary approaches to treat a person as a whole. Such advice includes exercises, identification of predisposing, contributing and precipitating factors and, if necessary, referral to other professions. Thus, studies on osteopathic manipulative treatment usually contain osteopathic intervention with various exercises which have proven its effectiveness, whereas osteopathic manipulative technique studies investigate individual and isolated efficacy or effectiveness of an individual technique.
3.3. Feasibility of osteopathic treatment to the condition

In the literature review of published osteopathic studies for treating foot conditions, no osteopathic studies on progressed flexible pes planus were found. A different search was done with widened search terms in order to see effectiveness of osteopathic manipulative treatment in managing musculoskeletal conditions. Within the large range of treatment techniques, certain types of osteopathic treatment techniques are preferably used in treating musculoskeletal conditions by contemporary osteopathic practitioners. These techniques include soft tissue, high-velocity low-amplitude thrust (HVLA), muscle energy technique (MET), counter-strain, myofascial and integrated neuromuscular release, articulatory, lymphatic, functional, fascial ligamentous release, facilitated positional release, and cranial (Johnson & Kurtz, 2003). In a hospital based retrospective study on 1509 osteopathic manipulative treatment consultations, treated patients with myofascial release, balanced ligamentous tension (BLT), MET, soft tissue and inhibition, had a shorter mean of patients’ hospital length of stay (Snider et al., 2013). The mean (standard deviation SD) of a control group without OMT was 5.7 (3.3) days, while the mean (SD) number of days the patient received OMT was 3.1 (2.2) days (Snider et al., 2013). The common reasons for osteopathic manipulative treatment were chest pain, rib pain, spinal pain, lower respiratory infection, cranial asymmetry, and an infant feeding disorder (Snider et al., 2013).

A randomised controlled trial examined osteopathic treatment effectiveness on acute lower back pain (Cruse et al., 2012). Crust et al. (2012) found that the use of soft tissue, myofascial release, counter-strain, MET, articulation, and HVLA were more effective in comparison to the usual care group administered with naproxen, ibuprofen, acetaminophen, cyclobenzaprine, and the combination of acetaminophen with codeine. The results indicated that both groups, n=60, showed a significant improvement but greater in the osteopathic intervention group, 76.7% of the osteopathic manipulative treatment group after four treatments and 43.3% of the usual care group (Cruse et al., 2012). Similar results were observed in a randomised controlled trial of osteopathic manipulative treatment effectiveness on 488 chronic lower back pain sufferers (Licciardon et al., 2013). Licciardon et al. (2013) examined an osteopathic manipulative treatment, consisting of soft tissue stretching, kneading, myofascial stretching and release, positional treatment of myofascial tender points, MET, and HVLA. The results indicated the osteopathic manipulative treatments effects to be statistically and clinically
significant since the outcome measures met or exceeded the Cochrane Back Review Group criteria (Licciardon et al., 2013) for the effect sizes, response rates of 95% confidence interval. In contrast, the sham group which was applied with an ultrasound therapy in the study did not meet the same criteria (Licciardon et al., 2013).

A randomised controlled clinical trial of acute ankle injuries found that the use of soft tissue, fascial release, MET, strain and counter-strain, and lymphatic drainage techniques resulted in statistically significant improvement in range of motion, + 3.5 degree dorsiflexion, compared to the current standard of care for acute ankle sprains: rest, ice, compression, and elevation (Eisenhart et al., 2003). Despite the successful improvement of decreased circumference for oedema, increased range of motion, and decreased pain scale presented in the study, the conclusion may also contain potential errors. Initially a total of 55 patients were enrolled and lost 15 participants at follow up. The conclusion was drawn from analysis which was made based on data consisting of 55 participants at baseline and 40 participants at follow-up without discarding data of the 15 participants who had withdrawn.

Based on literature reviews on effectiveness of osteopathic manipulative treatment on musculoskeletal conditions and considering the characteristics of flexible pes planus, namely ligament and muscular structural impairments, osteopathic manipulative treatment (soft tissue, MET, strain counter-strain, and BLT) (DiGiovanna, Schiowitz, & Dowling, 2005; Greenman, 2003; Parsons & Marcer, 2006) may be effective in managing progressed flexible pes planus, a musculoskeletal condition. There is a need for studies to be conducted to determine the effectiveness of osteopathy on the treatment of progressed flexible pes planus.

4. Exercise prescription

4.1. Current research state in combining exercise with physical therapy

Exercise has been used as a single therapy or part of a non-operative treatment program combined with manual therapy. Due to patients’ compliance bias observed when a prescribed exercise program used alone (mostly difficulty in adherence to a program) (Sluijs & Kok, 1993), combining active exercise with passive manual therapy became common practice and effective treatment when treating musculoskeletal conditions such as lower back pain (Hough et al., 2007), osteoarthritis of the hip (Brantingham et al., 2012), knee (Deyle et al., 2005), shoulder (Kachingwe et al., 2008), and ankle (Truyols-Domínguez et al., 2013). In managing
progressed flexible pes planus, combining orthoses or wearing customised corrective shoes with exercises is the core treatment (Langone, 2005). This is supported by studies, undertaken to investigate efficacy and effectiveness of these treatment regimens (Rome et al., 2010; Yagerman et al., 2011). However, no studies have investigated the effectiveness of combining active exercise with passive manual therapy on the condition.

4.2. Tibialis posterior muscle strengthening exercise
The primary exercise in treating flexible pes planus targets the tibialis posterior muscle due to its anatomical characteristics: one of the largest cross-sectional areas in the flexor muscles of the lower extremity with the gastrocnemius and the soleus muscles; tendon inserted into the navicular tuberosity (Bloome, Marymont, & Varner, 2003). In a randomised clinical trial study Kulig et al. (2009) compared the effectiveness of different exercise regimens in combination with orthoses. 36 participants were randomly placed into three different groups: 1) orthoses and stretching; 2) orthoses, stretching, and concentric exercise; 3) orthoses, stretching, and eccentric exercise (Kulig et al., 2009). Three outcome measures were compared between pre and post intervention: foot functional index; 5-minute walk test; visual analogue scale. As a three-month exercise intervention, a standing wall exercise was used for stretching calf muscle and individuals performed tibialis posterior muscle resistive concentric or eccentric exercise, respectively. Results of analysis of covariance indicated that significant foot function improvement was observed in the group that received a combination of orthoses, stretch, and eccentric exercise ($p = 0.042$). Results of the 5-minute walk test showed that individuals who received orthoses, calf stretch, and eccentric exercise intervention walked 445.1m in comparison to 433.7m before the intervention ($p = 0.075$) and 91% pain reduction ($p = 0.042$) was observed at post intervention. On the basis of the study results, the combination of orthoses, calf muscle stretch, and tibialis posterior muscle eccentric exercise was reasonably effective in improving foot function and highly effective to increase a walking distance without pain. Despite the study having showed effectiveness of exercise the use of the 5-minute walk test might not be the suitable method to measure the effectiveness of their intervention because the test and retest reliability of the 5-minute walk test has not been established for foot conditions. The reliability studies were conducted for only lower back pain (ICC = 0.87) and the healthy individuals (ICC=0.60) (Simmonds et al., 1998).

4.3. Abductor hallucis muscle involvement
Exercise prescription for flexible pes planus commonly includes the medial fibre of
gastrocneumius muscle and soleus muscle (Lee et al., 2012). A recent randomised controlled trial indicated possibly advanced exercise prescription for individuals with pes planus exercise targeting the abductor hallucis muscle. Lee et al. (2012) examined the effectiveness of combining the abductor hallucis muscle exercise (one leg standing exercise) with foot orthoses in comparison to a control group worn only foot orthoses for eight weeks. The study originated from the findings of the correlation between increased cross sectional area of the abduct hallucis muscle and inclined strength of the flexor hallucis muscle, and between the increased cross sectional area of the muscle and decreased pain in individuals with symptomatic pes planus (Lee et al., 2012). The results of a post hoc test showed that the cross sectional area of abductor hallucis muscle was significantly greater in an exercise and orthoses group (mean difference between groups = 13.61 mm$^2$; $p = 0.008$) since intervention started. The strength of the flexor hallucis muscle in the group with exercise and orthoses also improved greatly (mean difference = 0.90 kilogram-force; $p = 0.008$). Both increased cross sectional area and strength of the abductor hallucis muscle rated less pain scale ($p = 0.008$) at post intervention. The authors suggested that inclusion of the abductor hallucis muscle in an exercise prescription is important to treat pes planus.

5. Conclusion

Even though the exact aetiology of progressed flexible pes planus is unknown, chronic laxity of ligamentous structure and tibialis posterior muscle dysfunction are the most accepted causes of the condition. Progressed flexible pes planus is prone to the development of musculoskeletal compensation and subsequently various complications of the condition may arise in later life. Using orthoses or correction shoes and having exercise are the core in treating dysfunctions in muscular and ligamentous components presented in progressed flexible pes planus. There is emerging evidence that effectiveness of foot orthoses only lasts when individuals wear the device.

The use of an osteopathic manipulative treatment protocol has previously been employed and its effectiveness examined on various musculoskeletal conditions. Nevertheless little is known about the effectiveness of manual treatment for progressed flexible pes planus. No study has reported the use of osteopathic manipulative treatment for flexible pes planus or progressed flexible pes planus. Therefore, the aim of the study reported in the manuscript of this thesis is to explore the effectiveness of osteopathic manipulative treatment with known
exercises in individuals with progressed flexible pes planus.
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Note: This manuscript has been prepared in accordance with the instructions for authors for the *International Journal of Osteopathic Medicine* (IJOM). For the purposes of examination, illustrations and figures are positioned where they are most readable. Tables for mean data were placed in the appendices of this thesis in order to provide additional information.
Effectiveness of osteopathic manipulative treatment with home based exercises on progressed flexible pes planus

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ABSTRACT

Background: Flexible pes planus presents under the age of 10 years and may progress leading to various lower-limb symptoms later in life. To date, there is little evidence for non-orthotic rehabilitative strategies. Objectives: The objectives of this study were to determine the impact of an osteopathic and exercise intervention on objective measures of navicular heights and positions, navicular drop, and self-report measures of pain using a short-form McGill’s pain questionnaire in participants with progressed flexible pes planus. Methods: Fourteen participants with pre-diagnosed or examined progressed flexible pes planus were randomly allocated into either the immediate start group (one week of baseline, three weeks of intervention, four weeks follow-up) or the delayed start group (four weeks baseline, three weeks intervention, one week follow-up). Navicular heights, positions, and drop were recorded weekly using sagittal photographs taken with an infrared-filter and analysed using AutoCAD 2010. Pain change was monitored by a short-form McGill’s pain questionnaire. Results: Welch’s t-test indicated a statistically significant (left feet p = 0.05) improvement of sitting navicular heights at the follow-up between the two groups. Pain sensitivity (p < 0.01) and present pain intensity (p < 0.01) exhibited a significant difference between baseline and follow-up with both measures improving by at least 30%. Conclusion: The results of this mixed research study (a randomised controlled trial and a single cohort) found the osteopathic manipulative treatment with home based exercise to be beneficial in reducing the pain sensitivity and intensity experienced in individuals with progressed flexible pes planus.

Keywords
Flexible flatfeet; flexible pes planus; foot disorder; New Zealand; osteopathic medicine; osteopathy; physical therapy; progressed flexible pes planus; progressed flexible flatfeet
INTRODUCTION

Pes planus, also known as flatfeet, is a very common condition in children and adults.\textsuperscript{1, 2} Pes planus can be categorised as either flexible or rigid, in accordance with the characteristics of the foot arch. In general, most rigid pes planus is associated with either another isolated pathology, or is part of an array of accompanied large pathological entities. Subsequently, people with rigid pes planus often require medical and surgical consideration. When comparing flexible and rigid pes planus, there has been significantly less clinical attention put on the former.

When flexible pes planus is ignored after the age of 10 years, the condition progresses and predisposes individuals to develop calcaneal eversion, various foot dysfunctions including metatarsal stress fracture,\textsuperscript{3} plantar fasciitis,\textsuperscript{3} Achilles tendinitis,\textsuperscript{3} tibialis anterior inflammation\textsuperscript{4} and patello-femoral joint pain,\textsuperscript{3} low back\textsuperscript{5} and pelvis anteriorisation.\textsuperscript{5} Wearing correction shoes and performing exercises with orthotics is beneficial for individuals with the condition,\textsuperscript{6} but the contemporary exercise treatment regime is becoming controversial due to patients' compliance issues observed in a prescribed exercise program.\textsuperscript{1, 7-14} Moreover, therapeutic effectiveness of orthoses or correction shoes may only last when individuals are wearing the devices. Consequently, passive manual therapy could be beneficial to progressed flexible pes planus since combining active exercise with passive manual therapy are known to be effective in managing various musculoskeletal conditions such as low back pain,\textsuperscript{15} osteoarthritis of the hip,\textsuperscript{16} knee pain and arthritis,\textsuperscript{17} shoulder impingement,\textsuperscript{18} and ankle range of movement.\textsuperscript{19}

Osteopathy is a manual therapy which employs various manual techniques to treat musculoskeletal conditions and has been shown to be of clinical benefit for several musculoskeletal conditions such as low back pain\textsuperscript{20} and ankle injury\textsuperscript{21}. Despite its benefit to musculoskeletal disorders, there are no studies exploring effectiveness of osteopathic manipulative treatment on progressed flexible pes planus. There is a clear need for investigation into the effectiveness of osteopathic treatment for progressed flexible pes planus. The aim of this study is therefore to explore the osteopathic manipulative treatment with home-based exercises on the condition, progressed flexible pes planus.
MATERIALS AND METHODS

Research design
A cross-over study (a mixed study of a randomised controlled trial and a single cohort) design was used to assess the effectiveness of osteopathic treatment with home-based exercises. Participants were randomly allocated into two groups: immediate start group (group A), and delayed start group (group B) (Figure 1). Randomisation of participants into group A and B relied on the simple randomisation. A random number was assigned to each participant and group allocation was based on whether the number was even or odd. Even numbers represented the immediate start group whilst the odd number referred to the delayed start group. Participants in both groups started with one week of baseline measures (BL_A1 and BL_B1) (Figure 1). The immediate start group commenced the intervention at week 2 (Tx_A1, 2, 3) while the delayed start group continued with baseline measures for three more weeks (BL_B2, 3, and 4) prior to beginning the intervention. The duration of intervention for both groups was three weeks (Tx_A1, 2, 3 and Tx_B1, 2, 3). Group A completed four weeks of follow-up measures (FU_A1, 2, 3 and 4) after the intervention period while group B completed one week of follow-up (FU_B1).
Figure 1. CONSORT diagram showing the flow of participants and procedure through each stage

Note: The study design enabled analysis as both a randomised controlled trial and a single cohort, repeated measures study. A randomised controlled component: comparison of the intervention (Δ BL_A1 to Tx_A3) with a control group (Δ BL_1 to BL_4); a single cohort component: baseline = BL_A1 & BL_B4; intervention = Tx_A1-3 & Tx_B1-3; follow up = FU_A1 & FU_B1.
This study was designed as a mixed study with two sub parts: a randomised controlled trial and a single cohort study. For the randomised controlled trial, BL_A1, Tx_A1, 3, 4, and FU_A1 of group A became measures for an intervention group while group B formed the control group in the period of BL_B1, 2, 3, and 4 (Figure 1). The single cohort part of this study was obtained by summation of all variables of BL_A1 and BL_B4 for a baseline, measures of Tx_A1, 2, 3 and Tx_B1, 2, 3 for interventions, and variables of FU_A1 and FU_B1 for follow-up (Figure 1).

**Participants**

Participants were recruited using an editorial published in 13 local newspapers in New Zealand, online news (www.stuff.co.nz), a recruitment website (www.researchstudies.co.nz), and poster advertising. People who responded to the advertisements and met demographic criteria were invited to attend a clinical eligibility assessment.

The eligibility assessment involved a 10-minute session which included basic case history and a physical examination as previously described. Briefly, the physical examination consisted of inspection, palpation, and articulation of bones of the foot to confirm the presentation of the condition to be assigned for the study. The eligibility assessment also included a navicular drop test. The navicular height difference between sitting and standing should be greater than 10mm. This study was approved by the Unitec Research Ethics Committee, file number 2012-1085 (Approval: 24.10.12 to 24.10.13).

**eligibility criteria**

Participants were eligible for this study if they: 1) were between 18 and 60 years of age; 2) presented with an arch with no pressure on the foot that is lost upon standing, or had been diagnosed with bilateral flexible pes planus prior; 3) have pain and discomfort/tiredness of extrinsic foot muscles after standing, walking and running or combination. Exclusion was considered if participants: 1) had structural or systemic pathologies including fracture, gout, neuropathies due to diabetes or others which might affect foot function; 2) had an abnormally shaped calcaneus; 3) had been taking medication which influenced muscular function; 4) had been receiving physical therapy for the foot, ankle or knee; 5) had been diagnosed as having rigid pes planus; 5) had flexible pes planus which is a part or consequence of other underlying pathologies such as tibialis posterior tendon rupture or foot ligament damage or
rupture; 6) had severe pain in the lower extremities due to progressed flexible pes planus.

**Procedures**

*preparation*

Four medial foot landmarks from front to back of the medial side of the right foot shown in Figure 2: the first metatarsal bone, navicular tuberosity, the medial malleolus, and the point where the horizontal line from the medial malleolus and the Achilles tendon meet, were marked using a steel ruler and a goniometer. A medi trace self-adhesive pad attached the light emitting diode (LED) circuit to the landmarks on the medial foot. The landmarks on the medial foot were re-marked with a pen skin marker at each session.

![Figure 2. A participant standing on a wooden plate with a vertical supporter, where the first toe and knee are in contact with the supporter](image)

The camera (Canon digital model EOS 20D), was placed at a distance of 40cm from the edge of a wooden plate with a vertical supporter (Figure 2). A Hoya 720nm 58mm infrared (IR) filter was inserted into the camera to detect the wavelength above 720nm, generated from the
white LEDs on the landmarks of the foot. The filtered results produced an image void of any content other than four red points for each LED marker (Figure 3).

![Figure 3](image_url)

**Figure 3. Measurements of the right foot using AutoCAD 2010**

Note: Markers were identified and positions measured using AutoCAD 2010. Distances were measured in mm and angles were indicated in degrees. Four red dots from the right, represent the metatarsophalangeal joint, the navicular bone, the medial malleolus and the point where the horizontal line from the medial malleolus and the Achilles tendon intersect respectively; a = medial malleolus; b = navicular bone; c = the horizontal line to Achilles tendon

**data collection**

Photographs were taken in seated and then standing positions. Each participant was seated on a treatment table with feet flat against the floor. The angle of the hip, the knee, and the ankle were maintained at 90 degrees as confirmed with a hand-held goniometer. A steel ruler was used to ensure the 40cm distance between the camera and the medial aspect of the first metatarsophalangeal joint. Participants were then asked to stand in an upright position with toes pointing forward, with the tested foot behind the non-tested foot. The first toe and the knee of the tested foot were in the same coronal plane with contact to the vertical support (Figure 2). The files containing foot images were saved under participant numbers. All values for the navicular height, drop, and positions. The measurement of navicular positions were taken by gauging the acute angles, \( \angle abc \) measured (Figure 3). All values were measured by processing images with Adobe Photoshop CS6 to ensure that each marker was presented as a perfect circle (approx. diameter 20 pixels). Angles and distances between markers were calculated with AutoCAD 2010 by rendering linear lines from the centre of each circular
Participants were required to complete a short form McGill’s pain questionnaire at the non-intervention visit while two short form McGill’s pain questionnaires (pre- and post-intervention) were completed during the intervention period. Participants used their participant number when completing the short form McGill’s pain questionnaire ensuring that the participant identities were blinded to the researchers while analysing data.

**intervention**

All participants received three 20-minute intervention sessions. The intervention used in this study consisted of osteopathic manual techniques including mobilisation of joints, cross fibre, fascial release, strain and counter-strain, Muscle Energy Technique, and balanced ligamentous tension. The participants received the same amount of six osteopathic manipulative techniques at each session. Each session started with articulation of bilateral tibiofemoral joints, superior/inferior tibiofibular joints, talocural joints, and subtalar joints. Cross fibre manual technique included the bilateral hamstrings, gastrocnemius, soleus, flexor hallucis longus and brevis, tibialis posterior, tibialis anterior, and abductor hallucis muscles. Bilateral plantar fascia was then released in the side-lying position of participants. Pain on tibialis anterior and fibularis longus/brevis was monitored with verbal analogue scale between 0 and 10 (0= no pain and 10= worst pain imaginable) and treated with the strain counter-strain technique. Muscle Energy Technique was performed on the tibialis posterior muscle. Ligamentous structures around the navicular bones were treated with the balanced ligamentous tension technique. All treatment was performed by the primary researcher.

**home based exercise**

All participants were introduced with home based stretches for the soleus, medial fibres of gastrocnemius muscle, abductor hallucis, and strengthening exercises for the tibialis posterior muscle using a mid-resistance Thera-band. Each participant was individually instructed by the primary researcher and provided with a compact disc containing verbal and visual explanations about the exercises. Participants were then asked to continue all regular activities as per the study. In order to encourage and monitor adherence to home exercise, an eight-week exercise calendar was given to participants to keep track of their exercises. Additionally, participants were asked to report leg and foot pain on their personal journal with a visual analogue scale during normal daily activity. All participants received automated
emails and SMS text reminders for the exercises twice a day since commencing intervention.

Data analysis

analysis as a randomised controlled trial

Participants’ data were analysed anonymously in random order for blinding purposes. Analysis and statistical tests were conducted using Microsoft Excel (2013) and SPSS version 22 (SPSS and IBM Co., Chicago IL). Data from the first five weeks, BL_A1 to FUA1 of group A (an intervention group) and BL_B1 to BL_B4 of group B (a control group), were selected for analysis of the randomised controlled trial component (Figure 1). The Shapiro-Wilk test was used to assess normality of measures. Parametric means were analysed with Welch’s t-test due to the small and unequal sample size of both groups. Non-parametric means were analysed with Mann-Whitney U test. Measure changes at each week were calculated from their baseline in order to see if differences from baseline are significant between the two groups. Measure changes were then analysed again with Welch’s t-test for parametric and Mann-Whitney U test for non-parametric variables. Parametric measure changes were plotted into graphs with 0 as origin to illustrate a positive change (increase) and a negative change (decrease). Non-parametric measure changes were plotted in box and whiskers plots based on median and interquartile ranges using SPSS version 22.

analysis as a single cohort

Data were set for single cohort analysis: baseline, interventions, and follow up (Figure 1). The Shapiro-Wilk test was conducted for normality of measures. Measure changes at baseline to interventions and follow up were calculated and plotted with the same methods used to produce data for randomised controlled trial components. A paired t test was used for analysing parametric variables while non-parametric measures were analysed with Wilcoxon signed rank test. All probability levels for statistical significance were set at $p < 0.05$.

RESULTS

Demographic reports

Of the 123 applicants who responded to the advertisement, 32 were enrolled in this study. Eight participants withdrew after three weeks of intervention from group A due to time constraints whilst ten participants from the group B withdrew due to time constraints and personal health issues that were unrelated to the condition being studied. 14 participants
completed the study (Table 1). Welch’s t-test indicated that mean height, weight, and gender were not significantly different between the two groups.

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<td>Mean weight (SD) kg</td>
</tr>
<tr>
<td>Mean BMI (SD) kg/m²</td>
</tr>
<tr>
<td>n(male)</td>
</tr>
</tbody>
</table>

Note: SD=Standard deviation. BMI = Body mass index, n=number of participants.

*p-value are from Welch’s t-test, difference between immediate and delayed start groups

patients’ self-reporting of changes
Upon completion of the study, nine of 14 participants reported as having “a noticeable difference in symptoms”. Seven participants experienced no leg or sole pain during the same standing activity at work after completion of the intervention. The most significant change reported among the seven participants was participants’ feeling after the intervention - pressure of feet to sand while walking on beaches was made mainly by metatarsophalangeal joints and heels rather than from insole. Five participants responded that changes were experienced but that they were not meaningful.

adherence to home based exercises
Six participants reported difficulty in continuing exercises during the intervention period in spite of 100% adherence to the daily home-based exercises. This was due to the time compliance and frequent cramping in the medial aspect of the leg where the tibialis posterior muscle passes.

Analysis as a Randomised Controlled Trial
parametric variables
Mean sitting navicular height of the left foot for the intervention group at week 1 ($p = 0.04$), week 2 ($p = 0.05$) and week 5 ($p = 0.05$) were statistically different from the control group. Larger improvements of the left foot were observed in the intervention group than in the control group during the 3-week intervention period. Difference in improvements of the left
foot between the two groups became the largest with a mean of 2.80mm and 95% confidence interval -2.09 mm to 7.69mm at week 3 (the second treatment for the intervention group) although this difference failed in establishing statistical significance [Welch’s t (11.95) = 1.247, p = 0.22].
Figure 4: Changes in sitting and standing navicular height, and navicular drop for the randomised controlled trial component

<table>
<thead>
<tr>
<th></th>
<th>Left feet</th>
<th>Right feet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sitting navicular height (mm)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 1</td>
<td>Week 2</td>
<td>Week 3</td>
</tr>
<tr>
<td>Immediate start group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delayed start group</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Standing navicular height (mm)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 1</td>
<td>Week 2</td>
<td>Week 3</td>
</tr>
<tr>
<td>Immediate start group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delayed start group</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Navicular drop (mm)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 1</td>
<td>Week 2</td>
<td>Week 3</td>
</tr>
<tr>
<td>Immediate start group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delayed start group</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Error bars = Standard deviation

Week 1 - week 5 = the immediate start group started treatments from week 2 to week 4 while the delayed start group was a control group. i.e. no treatment was given.

Tx = the commencement of treatment. Three treatments were completed immediately following the measures taken on weeks 2, 3, and 4.

No significant differences were found.
Right feet showed significant difference in mean standing navicular heights between the two groups at week 3 [Welch’s t (10.05) = -3.11, \( p = 0.01 \)], week 4 [Welch’s t (9.42) = -2.33, \( p = 0.04 \)], and week 5 [Welch’s t (11.82) = -3.25, \( p<0.01 \)]. Changes in standing navicular height of both feet for the intervention group at week 4 and week 5 were lower than changes recorded in the control group (Figure 4). These changes were, however, not recognised as statistically significant (\( p > 0.14 \)).

Mean navicular drop of both feet in the two groups at week 1 was not significantly different whereas the drop measure of the right foot in the intervention group was significantly greater than the measure of the control group at week 5 [Welch’s t (9.97) = 2.83, \( p = 0.01 \)], where a mean ± SD was 17.67 ± 4.61 mm for the intervention and 11.20 ± 3.76 mm for the control group. Navicular drop changes of the right foot for the intervention group reported from the week 1 to week 5 were, however, statistically insignificant (\( p = 0.17 \)).

Mean sitting navicular position angles of both feet were not significantly different between the two groups for five weeks (\( p > 0.28 \)). Similarly, changes in both feet from week 1 through to weeks 2, 3, 4 and 5 were not statistically different between the two groups even though changes in mean values were observed for five weeks.
Figure 5: Changes in sitting and standing navicular position for the randomised controlled trial component

<table>
<thead>
<tr>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Week 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitting navicular position (degree)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediate start group</td>
<td>Delayed start group</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Week 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standing navicular position (degree)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediate start group</td>
<td>Delayed start group</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Error bars = Standard deviation
Week 1 - week 5 = the immediate start group started treatments from week 2 to week 4 while the delayed start group was a control group. i.e. no treatment was given.
Tx = the commencement of treatment. Three treatments were completed immediately following the measures taken on weeks 2, 3, and 4.
No significant differences were found.

Changes in standing navicular position angles of the right foot from week 1 to week 5 showed that navicular angles increased in the intervention group 4.11 ± 6.95° (mean ± SD) whereas in the control group, -10.79 ± 9.38° (Figure 5), showed a decline in navicular angles. The difference in the changes from week 1 to week 5 between the two groups was noted to be statistically significant [Welch’s t (6.51) = 3.10, p = 0.01].

**non-parametric variables**
Statistical significance of McGill’s Pain Questionnaire for sensitivity (MPQS) between the two groups was noted at week 3 (U = 50.00, p = 0.04), week 4 (U = 38.00, p = 0.01), and
week 5 ($U = 18.00, p < 0.01$). Reduction of MPQS was greater in the intervention group at week 5 [median = -2.00, interquartile range (IQR = -2.25 to -1.00)] than the control group (median = 1.00, IQR = 0.25 to 1.25). The Mann-Whitney U test indicated that the reduction of MPQS reported in the intervention group at week 5 was significantly larger than the control group ($U = 20, p < 0.01$).

Changes in McGill’s Pain Questionnaire for affective (MPQA) scores observed from week 1 to week 3 ($U = 72, p = 0.04$), 4 ($U = 72, p = 0.04$), and 5 ($U = 72, p = 0.04$) were significantly different between the two groups.

Median (IQR) of McGill’s Pain Questionnaire for present pain intensity (MPQPPI) for the intervention group, when the intervention group was in the follow up phase at week 5, was 0.00 (0.00 to 22.36) whereas for the control group it was 30.52 (23.42 to 36.84). The Mann-Whitney U test found the difference between the two groups at week 5 to be statistically significant ($U = 44, p = 0.02$). Reductions in MPQPPI scores of the intervention group [median (IQR) = -3.41 (-16.31 to 1.58) at week 4; -9.47 (-22.63 to -4.27) at week 5] were larger in comparison to the control group [2.10 (-4.47 to 9.47) at week 4; 6.31 (-3.68 to 11.84) at week 5]. The reductions reported at week 4 ($U = 46.00, p = 0.03$) and week 5 ($U = 28.00, p < 0.01$) were statistically significant between the two groups.

**Analysis as a Single Cohort**

**Parametric variables**

Sitting navicular height of the left foot showed significant improvements at the third treatment [paired t (13) = -2.14, $p = 0.05$] and at the follow up sessions [paired t (13) = -2.10, $p = 0.05$] in comparison to measures at the baseline. Improvements of sitting navicular height of the right foot were noted as significant since participants received the second treatment session: paired t (13) = -2.50, $p = 0.02$ at the second treatment; paired t (13) = -4.79, $p < 0.01$ at the third treatment; paired t (13) = -5.76, $p < 0.01$ at the follow up.
Figure 6: Changes in sitting and standing navicular height, navicular drop and sitting and standing navicular position for the single cohort

<table>
<thead>
<tr>
<th>Sitting navicular height</th>
<th>Standing navicular height</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Changes (mm)</strong></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>TX1</td>
</tr>
<tr>
<td>Navicular drop</td>
<td>TX2</td>
</tr>
<tr>
<td>Navicular height</td>
<td>TX3</td>
</tr>
<tr>
<td>Changes (mm)</td>
<td>Follow up</td>
</tr>
</tbody>
</table>

Note: Error bars = Standard deviation

Week 1 - week 5 = the immediate start group started treatments from week 2 to week 4 while the delayed start group was a control group, i.e. no treatment was given.

Tx = the commencement of treatment. Three treatments were completed immediately following the measures taken on weeks 2, 3, and 4.

No significant differences were found.
There were improvements in standing navicular height and navicular drop while the right foot showed greater improvement (Figure 6). None of improvements, however, were noted to be statistically significant ($p > 0.11$). Similar improvements (right foot > left foot) in sitting and standing navicular position angles were reported, but the improvements failed in establishing statistical significance ($p > 0.17$).

**non-parametric variables**

The median (IQR) of MPQS was 2.50 (1.00 to 5.00) at baseline, 2.00 (0.00 to 8.00) at the first treatment, 1.00 (0.00 to 5.00) at the second treatment, 1.00 (1.00 to 4.00) at the third treatment, and 0.50 (0.00 to 1.00) at follow up. The Wilcoxon signed rank test showed that median MPQS scores at the second (60% reduction from the baseline, $Z = -3.01$, $p < 0.01$), third (60% reduction from the baseline, $Z = -4.17$, $p < 0.01$), and follow-up session (80% reduction from the baseline, $Z = -4.50$, $p < 0.01$) elicited statistically significant improvements. Statistical significance was noted in MPQA scores only at the first treatment ($Z = -2.44$, $p = 0.01$) and the follow-up ($Z = -1.897$, $p = 0.05$). The Wilcoxon signed rank test indicated that the 74% of median (IRQ) reduction in MPQPI reported at the follow up, 6.31 (0.00 to 15.79), in comparison to the baseline measure [24.21 (8.42 to 46.31)] was statistically significant ($Z = -4.37$, $p < 0.01$).
DISCUSSION

To the best of our knowledge, this is the first prospective study using a mixed research design of a randomised controlled trial and single cohort, to explore the effectiveness of osteopathic treatment with home-based exercises in individuals with progressed flexible pes planus. Foot exercises in this study were performed for balance training and to help elevate the medial longitudinal foot arch through raising passive tension of the tibialis posterior muscle, and stretching calf as well as abduct hallucis muscles. In general, there were improvements over time in sitting navicular height and sitting and standing navicular position angles when the intervention was introduced. Nevertheless, the variability precludes confidence that the variability is not owing to chance due to small sample size. In contrast, the consistency in occurrence of statistically and clinically significant improvement was observed only in the measures of the pain sensitivity and the present pain intensity of the short form McGill’s pain questionnaire, both in analysis as a randomised controlled trial and a single cohort. A difference was observed in short form McGill’s pain questionnaire measures of a single cohort analysis between the left and right foot. The difference between the left and right foot, however, is most likely a result of chance variation.

Possible mechanism of decrease in standing navicular height

A surprising observation from the intervention in the group A (the immediate start group) was the findings of the decreased standing navicular height and increased navicular drop after the first intervention. This is because we expected the standing navicular height might increase and the navicular drop possibly decreased with the intervention as previous studies found the decreased navicular drop and increased navicular height with the intervention, combining orthoses and/or exercises. The reasoning behind the greater decrease in standing navicular height of the intervention group and thereby increased navicular drop may be due to neuro-musculoskeletal effects of cross fibre and Muscle Energy Technique resulting in passive stretch of the tibialis posterior muscle, which was targeted by our intervention. On contrary, the findings of the decreased standing navicular height and increased navicular drop after the first intervention could be accidentally transposed due to the small number of participants.

The popping sarcomere hypothesis refers to muscle damage induced by muscle stretch when a muscle is stretched beyond optimal length resulting in very non-uniform lengthening of sarcomeres. If sarcomeres are stretched beyond their maximum length, the longest
sarcomere becomes the weakest. Consequently, the longest sarcomere can be over-stretched more easily. Continued sarcomere stretch in turn results in easier stretching of other sarcomeres and therefore easier stretching of muscle fibres. Stretched muscle fibres become weaker until compensations are gained by arising passive tension for decreased active tension through strengthening exercise. This is possibly the same phenomenon observed in our study - decreased standing navicular height. The intervention we used in the study included cross fibre and eccentric Muscle Energy Technique on the tibialis posterior muscle. The repetitively and non-uniformly stretched tibialis posterior muscle during the intervention may have resulted in muscle stretches beyond its optimum level. Consequently, weaker tibialis posterior muscle may have resulted in decreased navicular height in a standing position and thereby increased navicular drop. Alternatively, the 100% exercise adherence reported by patients may be due to participants’ reporting bias (a conscious or unconscious desire to please the researchers).

Another possible phenomenon, which could account for the decreased standing navicular height, is muscle fatigue derived from the central nervous system or from the peripheral nervous system in the form of reduced motor drive and, thus, the excitation-contraction coupling mechanism within muscles becoming altered. Prolonged fatigue results in local adaptation and such adaptations include reduction of calcium release from the sarcoplasmic reticulum due to changes in the excitation-contraction coupling. In order to back to its normal state, the excitation-contraction coupling mechanism requires at least three hours after moderate activity while 33 hours after intense activity. The tibialis posterior muscle is the primary muscle in maintaining the navicular height and always engaged with movements and activities. In the current study, participants attended sessions in the afternoon upon finishing their work. Already fatigued muscles underwent further stretches during interventions and measures were taken without allowing recovery time for the tibialis posterior muscle. Increased fatigue in the muscle fibre may have resulted in reduction of calcium release within the sarcoplasmic reticulum and, consequently, diminished contraction of the tibialis posterior muscle and thereby decreased navicular height in a standing position (weight bearing). Thus, we recommend that further studies use supervised exercises rather than home-based exercises and, when possible, allow at least three hours recovery time before the taking of measures. Additionally, a low resistance Thera band is suggested as our participants reported difficulty in continuing exercises due to frequent cramping, which is considered one
of potential weaknesses of our study.

**Clinical importance of pain perception change**

Frequent use of both tibialis anterior and posterior muscles along with the impaired windlass mechanism due to the over pronation of feet are one of prime factors causing anterior leg, foot insole, and navicular tuberosity pain in pes planus. 34,35 Participants in this study reported long term tibialis anterior muscle, foot insole, and medial navicular tuberosity pain at the eligibility assessment. With the intervention, MPQS and MPQPPI showed 80% improvement and 74% improvement at follow-up in comparison to the measures at baseline. Younger, McCue, and Mackey36 proposed that pain reduction of at least 30% should be considered to be clinically significant and the standard of 30% of pain reduction is the core in measuring headache intervention.36 Osteopathic intervention study on low back pain found 76.7% of improvement with osteopathic intervention in comparison to 43.3% of improvement in the control group administered with naproxen, ibuprofen, acetaminophen, cyclobenzaprine, and the combination of acetaminophen with codeine. 37 Cruse et al. concluded both interventions showed clinical significance while osteopathic intervention, shown 76.7% improvement, to be more clinically significant in managing low back pain. 37 Despite the exact magnitude of clinical outcomes in managing symptoms of progressed flexible pes planus not measured, our results indicate that the magnitude of change shown in 80% improvement of pain sensitivity and 74% of present pain intensity at follow-ups may be clinically significant.

The results of our study also support the findings of the previous study by Evans, Scutter and Iasiello who proposed the use of navicular heights in measuring clinical changes due to decreased validity of navicular drop in accordance with foot conditions38 such as flexible pes planus. Navicular drop is widely believed to be an indicator of elevated susceptibility to pronation-related injuries and therefore has been used to measure the severity of pes planus. Isolation of small localised changes, however, could be equally important because the validity of the navicular drop has been questioned. 40-43 Vinicombe, Raspovic and Menz found the intraclass correlation coefficients of the navicular drop test to exist within the range of 0.33 and 0.76. 44 Evans, Scutter and Iasiello observed the consistently low reliability and validity of the navicular drop test and consequently proposed the inclusion of navicular heights when measuring clinical changes.38 Morrison, Durward, Watt and Donaldson
suggested the use of navicular height should be limited to individuals over the age of 16 years due to the occurrence of low inter and intra tester reliability of navicular height in children aged 4~6 and 8~15 years old adolescents.\textsuperscript{45} Therefore our findings (the increase of navicular drop in flexible pes planus due to largely improved sitting navicular heights at follow up) support the importance of small localised changes over navicular drop identified in previous studies\textsuperscript{38, 45, 38, 45}.

Like most clinical investigations, our study was associated with a number of methodological weaknesses that could threaten the validity of our conclusions. Since the changes in short form McGill’s pain questionnaire measures were not observed for the delayed start group, this may indicate a positive impact of intervention on the condition. The relationship may not be strong with our data, however, due to small sample size (n = 14) and our study design. The best way to determine the effects of any intervention is through a randomised controlled trial since this minimises the probability of other external factors influencing observed improvements, such as natural resolution of the symptomatic condition or resolution by exercises. One problem we observed was a no treatment group where the participants were not blind to the fact that they were going to have no treatment at follow up visits. Consequently the drop off of 10 participants was due to one of methodological weaknesses.

Our study was designed to allow two different analyses: a randomised controlled trial and a single cohort. In this study outcomes of baseline were recorded four times in the delayed start group while immediate start group had one baseline measure. Comparison between groups was made for the first five-week duration in order to investigate whether the effectiveness of osteopathic intervention with the exercises existed only in the intervention group. Duration of first five weeks of the study therefore took advantage of a randomised controlled trial by comparing between groups, in order to minimise the weakness of our study. In addition, the single cohort component was analysed in order to supplement methodological weaknesses. We feel, therefore, that despite such biases, our study results support our hypothesis that use of osteopathic intervention with home based exercises can be beneficial to progressed flexible pes planus, warranting further investigation. For future studies, we recommend the use of a randomised controlled trial model to investigate the effectiveness of only osteopathic manipulative treatment in comparison to various contemporary treatment regime, orthoses/correction shoes or exercises or combination of with a larger sample size.
CONCLUSION

Our study found the osteopathic manipulative treatment with home based exercise to be beneficial in reducing the pain sensitivity and intensity experienced in individuals with progressed flexible pes planus, but failed in increasing standing navicular heights. The improvements of MPQS and MPQPPI in this study are possibly clinically significant as MPQS and MPQPPI reduced by 80% and 74% at follow up respectively. Further studies may confirm and add to this first report of this intervention.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

ACKNOWLEDGEMENTS

Special thanks to all participants who volunteered their time to be part of this project.
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SECTION 3: APPENDICES
Appendix A: Ethics Approval Letter

Note: The name of the researcher, chulwan = chulwan is a type error

Chulwan Kim  
68 Marina View Drive  
Watakerre  
Auckland  
25.10.12

Dear Chulwan,

Your file number for this application: 2012-1085  
Title: Effectiveness of osteopathic manipulative treatment (OMT) with home based exercises on progressed flexible pes planus (flatfeet).

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

Start date: 24.10.12  
Finish date: 24.10.13

Please note that:

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

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

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

Yours sincerely,

Gillian Whalley  
Deputy Chair, UREC

cc: Jamie Mankin  
Cynthia Almeida
Appendix B: Participant information

RESEARCH INFORMATION FOR THE PARTICIPANTS

Title
Effectiveness of osteopathic manipulative treatment and home-based exercises on progressed flexible pes planus (flatfeet)

You are invited to participate in our research investigation. Please read carefully through this information sheet before you make a decision about volunteering.

Principle Researcher
Chulhwan Kim (Bachelor of Engineering, Bachelor of Pharmacology, Bachelor of Mathematics, Bachelor of Applied Science [Human Biology], Certificate in photography), is currently in his 2nd year of the Masters of Osteopathy program at Unitec New Zealand.

Our Purpose
This study will measure the effects of osteopathic treatment with a home-exercise program on pain and foot arch in people with progressed flexible flatfeet. Flexible flatfeet is characterised by no arch on weight bearing (e.g. standing) but reappearance of foot arch with no weight bearing (e.g. sitting or lying).

In general, ‘Flexible flatfeet’ is a very common condition within children and adults but this condition has been frequently ignored due to the confusion with developmental flatfeet which is usually spontaneously resolved before the age of 10. Ignored flexible flatfeet, which progresses after the age of 10, increases vulnerability to a large range of muscular symptoms including easy-fatigue, pain and tenderness on leg and foot muscles.

The primary aim of this study is to see whether an osteopathic treatment plan with home exercise programme can provide benefits in maintaining foot arch and resolving pain. By
taking part in this study you are helping us discover if osteopathic treatment and exercise helps people who suffer from progressed flexible flatfeet.

**Your voluntary participation**
Your participation in this study is entirely voluntary, and you may withdraw at any time during the study. Each participant will receive a $10 worth exercise theraband.

**Who may participate?**
You are eligible to participate if you:

- Are between 18 and 60 years of age
- Can understand and follow instructions in either English or Korean
- Gain an arch with no pressure on the foot but upon standing loses a medial arch or have been diagnosed as having bilateral flexible pes planus (flatfeet)
- Have pain and discomfort/tiredness of foot muscles after long periods of standing and/or use of the feet

You will not be eligible to participate if you have:

- Structural and systemic pathologies including fractures
- An abnormally shaped calcaneus (we can help you identify this)
- Been taking medication which influences muscular function
- Been receiving physical therapy for the foot or ankle
- Been diagnosed as having rigid flatfeet (i.e. rigid pes planus)
- Flexible flatfeet, which is a part/consequence of other underlying pathologies. E.g. tibialis posterior tendon rupture or flexor retinaculum rupture or foot ligament damage or rupture
- Severe pain in the lower extremities which may need medical attention

Please feel free to contact the lead researcher if you are unsure about your eligibility.
What will happen in the study?
Should you agree to participate in the study, you will be required to attend eight sessions, once a week for eight weeks. There will be a baseline period for one to four weeks where measures will be taken but treatment will not be provided. Following this period, you will receive both three osteopathic treatments (1 per week for a three week period) and three simple home-based exercises to perform for the same three week period. Finally, a follow-up period of one to four weeks of measures without treatment will follow.

- **Home-exercise**
  All participants will be asked to perform exercises over a three-week course of this study. The exercises prescribed are based on scientific literature. Each participant will receive automated emails and or SMS text message reminders. A three-week calendar will also be provided and each participant should give each day a tick when he/she does the exercises.

- **Osteopathic treatment**
  Each treatment session will take approximately 20 minutes. For effective osteopathic treatment you will be required to undress to shorts or underwear. Osteopathic techniques to be used are those that are regularly used in the Student Osteopathic Clinic. The osteopathic treatment will be carried out by a student osteopath currently completing their Masters of Osteopathy program at Unitec New Zealand, and will be supervised by a registered osteopath.

- **Data collection**
  Before and after each treatment session, a photographic image will be taken and you will be asked to fill a simple questionnaire. Each questionnaire will take no more than 2-3 minutes to complete. You will be required to rate the level of pain you experience before and after treatment is performed. Osteopathic treatment will be performed by the principle researcher.

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. Should you be randomised to the osteopathic treatment group, your name will be recorded on a case history form as per usual clinical policy. However, in all other instances of information collection your identity will remain anonymous and you will simply have an identification number. If
the information you provide is reported or published, this will be done in a way that does not identify you as its source. All the data recorded will be stored in a password-locked computer and archived in a locked file room in the Unitec Student Osteopathic Clinic and will be stored for a minimum of 5 years. Access to this data will be limited to the principle researcher, the research supervisor, the osteopathic tutors at the Student Osteopathic Clinic, and yourself.

**Discomforts/risks and benefits**

Manual therapy treatment (of which osteopathy shares similarities) has been shown to be beneficial for people suffering from acute ankle ligament sprain and decreasing muscular pain.

There are minimal potential risks involved in this study. Mild stiffness and discomfort may be experienced following an osteopathic treatment or exercise. Osteopathic techniques to be used will be discussed prior to be conducted and your consent will be sought.

**Compensation may be available in the unlikely event of injury of negligence**

Should you incur a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act 2002. You may or may not be entitled to ACC compensation, depending on several factors such as whether or not you are an earner. ACC will usually cover a proportion of income lost due to a physical injury, this does not cover mental injury unless as a direct result from a physical injury. ACC cover may affect your right to sue. Please contact your nearest ACC office for further information (0800 735 566) or visit their website: [www.acc.co.nz/claimscare/making-a-claim/medicalmisadventure/index.html](http://www.acc.co.nz/claimscare/making-a-claim/medicalmisadventure/index.html).

Please contact us if you need further information about the study.

**Contact Details**

Chulhwan Kim  
Phone: 021 133 1213  
Email: flatfeet.research@gmail.com

Mr Jamie Mannion
Phone: 021 062 9007

Email:

**UREC REGISTRATION NUMBER: (2012-1085)**

This study has been approved by the UNITEC Research Ethics Committee from (24.October.2012) to (24.October.13). 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 C: Consent Form

Participant consent form

Effectiveness of osteopathic manipulative treatment with home based exercises on progressed flexible pes planus (progressed flexible flatfeet)

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 the please sign the bottom. If you have any questions please ask the researcher before signing this form.

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

- I understand that I don't have to be part of this if I don't want to and I may withdraw at any time prior to the completion of the research project.

- 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 and relevant clinical staff.

- I understand that all the information I give will be stored securely on a computer at Unitec for a period of 5 years.
- I understand that my discussion with the researcher will be recorded on a case history form as per usual clinical policy.

- 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: ………………………………

Principle Researcher: …………………………… Date: ………………………………

UREC REGISTRATION NUMBER: (2012-1085)
This study has been approved by the UNITEC Research Ethics Committee from (24.October.2012) to (24.October.2013). If you have any complaints or reservations about the ethical conduct of this research, you may contact the Committee through the UREC Secretary (ph.: 09 815-4321 ext. 6162). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.
Appendix D: Short form McGill’s pain questionnaire

**SHORT FORM McGill PAIN QUESTIONNAIRE and PAIN DIAGRAM**

Date: ________________________________
Name: ________________________________

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

<table>
<thead>
<tr>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Throbbing</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>2. Shooting</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>3. Stabbing</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>4. Sharp</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>5. Cramping</td>
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<td>______</td>
</tr>
<tr>
<td>6. Drawing</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>7. Hot-burning</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>8. Aching</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>9. Heavy</td>
<td>______</td>
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<td>10. Tender</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>11. Splitting</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>12. Tingling-Exhausting</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>13. Squeezing</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>14. Fearful</td>
<td>______</td>
<td>______</td>
</tr>
<tr>
<td>15. Cruel-Punishing</td>
<td>______</td>
<td>______</td>
</tr>
</tbody>
</table>

Mark or comment on the above figure where you have your pain or problems.

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

<table>
<thead>
<tr>
<th>No Pain</th>
<th>Worst Possible Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>S / 33</td>
<td>A / 12 VAS / 10</td>
</tr>
</tbody>
</table>
Appendix E: General editorial released into local newspapers

For immediate release

START:

**Local student exploring new treatment options for flexible flatfoot**

Chulhwan was born in South Korea and did military service in Korean Air Force for four years. During military screening Chulhwan discovered that he had progressed flexible flatfeet and subsequently suffered from various foot complications during military training and later life. Chulhwan has always wanted to improve his condition and has an active interest in helping others. When he came to New Zealand in 2000 he studied pharmacology and mathematics at the University of Auckland. However, his interest in helping people guided him to study Osteopathy at Unitec. While studying, he learned that Osteopathy was capable of improving various foot conditions however he noticed that there was no evidence to support manual treatments for flexible flat-foot. Chulhwan’s strong research interest started here.

“Flatfoot is a very common condition in children and adults, however, it is not considered as a functional abnormality or limitation of the lower extremities” said Chulhwan. Flexible flatfoot, a type of flat foot, shows a normal arch during non-weight bearing position such as sitting, and flattens out when weight-bearing. Unfortunately, flexible flatfoot is often ignored in children due to misunderstanding in the developmental flattened arch. Chulhwan explained that “when flexible flatfoot is ignored over the age of 10 it is called ‘progressed flexible flatfoot’ which puts an individual at risk of numerous foot deformities and pain including stress fracture, plantar fasciitis, Achilles tendinitis, and patella-femoral joint pain, to name a few”.

Current primary treatment options for flexible flatfoot are limited to wearing correction shoes or foot orthoses with exercises. However, the treatment effectiveness is reliant on wearing these devices. Chullwan reported that “there is the potential for more lasting improvements following manual therapy and exercise, however scientific evidence is yet to confirm this”.

66
Chulhwan is now inviting 30 participants who have flexible flat foot to participate in an eight-week study where participants will receive free osteopathic treatment and prescribed corrective exercises. Participants will be provided with a $10 theraband for free.

For more information, or to apply for this study, please go to
www.researchstudies.co.nz/flatfoot

END

For more information please contact Chulhwan on 021 133 1213 or email flatfeet.research@gmail.com
MONICA TISCHLER

FLAT-OUT: West Harbour resident Chulhwan Kim, 36, suffers from flatfeet and is left in excruciating pain after standing or walking for long periods.

Chulhwan Kim is flat-out most days from juggling work, study and fatherhood. Having a busy schedule is a mean feat for the West Harbour resident who suffers from progressed flexible flatfeet, a condition leaving him in excruciating pain after standing or walking for long periods.

Mr Kim, 36, is completing a masters degree in osteopathy at Unitec and is in search of 30 Auckland flatfeet sufferers for an eight-week assignment as part of his course.

Mr Kim says the primary treatment options for flatfeet are limited to wearing correction shoes and there's potential for manual therapy and exercise to give long-term improvement.
He'll explore this in his project by using osteopathic treatment not given by most podiatrists or physiotherapists.

"Osteopathic treatment consists of passive and active treatments as well as lifestyle modifications," Mr Kim says.

"What physiotherapists usually do is give ultrasound treatment and apply ice, then refer to a podiatrist who'll measure the foot and make the correct shoes."

Mr Kim found there's no long-term solution.
"In our treatment we use balance ligament tension which is related to balancing out ligament problems."

"I was thinking that treatment could help more long-term," he says.

Flatfeet occurs when the arch of the foot collapses, leaving the entire sole of the foot in contact with the ground.

There's no real indication as to what causes flatfoot but dancing or injuries can increase the changes of developing it.

Mr Kim first realised he suffered from the condition when he was 18 years old and in air force military training in South Korea.

"I did an eligibility test and found it difficult. We had to do 25km marches and I suffered a lot of bruising on my feet."

Tissue on Mr Kim's feet would turn hard and he'd experience excruciating pain up and down his legs.

"It was so sore and difficult. It was really achy and then a sharp pain."
After moving to New Zealand in 2000 with his wife, the pain remains but Mr Kim hopes his project will offer some hope to himself and other sufferers.

Unitec lecturer and clinical development co-ordinator Graeme Saxby will work alongside Mr Kim on the project.

Mr Saxby says flatfeet is common among children.

"But what should happen with most people is when they start walking and putting weight on their feet, an arch should develop."

He says the project will look at tuning muscles and train them to spread the load when holding weight.

Call Mr Kim on 021 133 1213 or email flatfeet.research@gmail.com to apply for the study.

Participants chosen receive free osteopathic treatment and prescribed corrective exercises.

Visit researchstudies.co.nz/flatfoot for more information about flatfeet.

- © Fairfax NZ News
Appendix G: Recruitment Poster

Do You Have Flatfeet?

YOU ARE INVITED TO PARTICIPATE IN A RESEARCH STUDY

The research study aims to investigate the effectiveness of osteopathic treatment with home based exercises on progressed flexible flatfeet. You must be aged between 18 and 60 years of age and have flatfeet on standing (no foot arch) while reappearance of foot arch on sitting.

You may be required to attend 8 weekly 30-minute treatments (free) at Unitec (Mt Albert).

These sessions will involve being guided through evidence based osteopathic treatment with exercises, while the activity of your feet are being painlessly recorded.

If you are interested in receiving more information regarding this study, please visit:

www.researchstudies.co.nz/flatfoot

or contact me on the details provided.

Chulhwan Kim email: flatfeet.research@gmail.com
txt: 021-133-1213
## Appendix H: Tables and graphs

### Table 1. Sitting, standing navicular heights and navicular drop for a randomised controlled trial component

<table>
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<th>Week 3</th>
<th>Week 4</th>
<th>Week 5</th>
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<td></td>
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* p values are from the Welch’s t-test for the difference between the immediate and delayed start group in SitNH, StandNH, ND, SitNP and StandNP at the week 1, 2, 3, 4, and 5. Data are presented as mean value ± SD for SitNH, StandNH, ND.

IM= immediate start group; DL = delayed start group
SitNH = navicular height in a sitting position; StandNH = navicular height in a standing position; ND = navicular drop; SitNP = navicular position angle in a sitting position; StandNP = navicular position angle in a standing position.
Table 2. MPQ measures for a randomised controlled trial component

<table>
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<th>Variable</th>
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<th>Week2</th>
<th>Week3</th>
<th>Week4</th>
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*p values are from the Mann-Whitney U test for the difference of MPQS, MPQA and MPQPPI between the two groups for five weeks. Data are presented as median (interquartile range 25%-75%) for MPQS, MPQA and MPQPPI.

IM= immediate start group; DL = delayed start group
MPQS = McGill’s pain short form questionnaire sensitivity; MPQA = McGill’s pain short form questionnaire affective; MPQPPI = McGill’s pain short form questionnaire present pain intensity
Table 3. Sitting, standing navicular heights and navicular drop for a single cohort component

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<td>15.57±5.57</td>
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<td>0.70</td>
<td>0.58</td>
<td>0.71</td>
<td>0.51</td>
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<tr>
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<td>R</td>
<td>0.19</td>
<td>0.55</td>
<td>0.16</td>
<td>0.14</td>
<td></td>
</tr>
<tr>
<td>SitNP (degree)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>L</td>
<td></td>
<td>7.07±9.22</td>
<td>8.50±8.90</td>
<td>6.51±10.52</td>
<td>6.50±11.08</td>
<td>5.50±13.71</td>
</tr>
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<td>6.52±7.32</td>
<td>7.30±8.18</td>
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<td>5.15±8.95</td>
<td>3.59±8.87</td>
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<td>p value*</td>
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<td>0.72</td>
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<td>R</td>
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<td>0.52</td>
<td>0.17</td>
<td></td>
</tr>
<tr>
<td>StandNP (degree)</td>
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<tr>
<td>p value*</td>
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<td>R</td>
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<td>0.88</td>
<td>0.71</td>
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*p values are from the paired samples t-test for the differences between baseline and measures of the first, second, third and follow up. Data are presented as mean value ± SD for SitNH, StandNH, ND, SitNP and StandNP.

IM= immediate start group; DL = delayed start group
SitNH = navicular height in a sitting position; StandNH = navicular height in a standing position; ND = navicular drop; SitNP = navicular position angle in a sitting position; StandNP = navicular position angle in a standing position.
Table 4. MPQ measures for a single cohort component

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<th>Variable</th>
<th>Baseline</th>
<th>Tx1</th>
<th>Tx2</th>
<th>Tx3</th>
<th>FU</th>
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<td>&lt;0.01</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
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<tr>
<td>p value*</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>MPQA</td>
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<td>(0.00~2.00)</td>
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<td>0.66</td>
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<td>p value*</td>
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<tr>
<td>MPQPPI</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*p values are from the Wilcoxon Signed Rank tests for the difference of MPQS, MPQA and MPQPPI from baseline to treatment 1, treatment 2, treatment 3 and follow up. Data are presented as median (interquartile range 25%-75%) for MPQS, MPQA and MPQPPI.

MPQS = McGill’s pain short form questionnaire sensitivity; MPQA = McGill’s pain short form questionnaire affective; MPQA = McGill’s pain short form questionnaire present pain intensity.
Figure 1: Changes in MPQ measures for the randomised controlled trial component

MPQS
MPQA
MPQPPI

Note: Blue coloured and shaded bars represent the immediate start group; Red coloured bars are for the delayed start group.
The immediate start group started treatments from week 2 to week 4 while the delayed start group was a control group, i.e. no treatment was given.
MPQS = short form McGill’s pain questionnaire for sensitivity; MPQA = short form McGill’s pain questionnaire for effectiveness; MPQPPI = short form McGill’s pain questionnaire for presence of pain intensity; Im = Immediate start group; DL = Delayed start group.
A number in outliers indicates participant number.
* denotes \( p < 0.05 \)
** denotes \( p < 0.01 \)
Figure 2: Changes in MPQ measures for a single cohort component

Note: Week 1 - week 5 = the immediate start group started treatments from the week 2 to week 4 while the delayed start group was a control group. i.e., no treatment was given.

Tx = treatment; Im = Immediate start group; DL = Delayed start group; FU = follow up; MPQS = short form McGill’s pain questionnaire for sensitivity; MPQA = short form McGill’s pain questionnaire for affective; MPQPPI = short form McGill’s pain questionnaire for present pain intensity.

A number in outliers indicates a participant number.

* denotes $p < 0.05$

** denotes $p < 0.01$
Appendix I: Instruction for authors

International Journal of Osteopathic Medicine

Source: http://www.journalofosteopathicmedicine.com/authorinfo

The Editors of the Journal welcome contributions for publication from the following categories: Letters to the Editor and Editorials, Reviews and Original Research articles, Commentaries, Clinical Practice articles (Case Studies) with educational value and Protocols. The Guidelines are separated into the following sections:

A Online Submission
B Types of Contributions
C General Guidance
D Preparation of the Manuscript
E Specific Guidance for Original Research Articles
F Specific Guidance for Protocols
G Post Acceptance

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(B) TYPES OF CONTRIBUTIONS - word limits exclude tables, figures and reference list.

Letters to the Editor (up to 1,000 words)
As is common in biomedical journals the Editorial Board welcomes critical responses to any aspect of the journal. In particular, letters that point out deficiencies and that add to, or further clarify points made in a recently published work, are welcomed. The Editorial Board reserves the right to offer authors of papers the right of rebuttal, which may be published alongside the letter.

Reviews and Original Articles (2,000 - 5,000 words)
These should be either (i) reports of new findings related to osteopathic medicine that are supported by research evidence. These should be original, previously unpublished works; or (ii) a critical or systematic review that seeks to summarise or draw conclusions from the established literature on a topic relevant to osteopathic medicine.

Short review (1,500-3,000 words)
The drawing together of present knowledge in a subject area, in order to provide a background for the reader not currently versed in the literature of a particular topic. Shorter in length than and not intended to be as comprehensive as that of the critical or systematic review paper. These papers typically place more emphasis on outlining areas of deficit in the current literature that warrant further investigation.

Research Note (up to 1,500 words)
Findings of interest arising from a larger study but not the primary aim of the research endeavour, for example short experiments aimed at establishing the reliability of new equipment used in the primary experiment or other incidental findings of interest, arising from, but not the topic of the primary research. Includes further clarification of an
experimental protocol after addition of further controls, or statistical reassessment of raw data.

Preliminary Findings (1,500-2,500 words)
Presentation of results from pilot studies which may establish a solid basis for further investigations. Format similar to original research report but with more emphasis in discussion of future studies and hypotheses arising from pilot study.

Commentaries (up to 2,000 words)
Includes articles that do not fit into the above criteria as original research. Includes commentaries and essays especially in regards to history, philosophy, professional, educational, clinical, ethical, political and legal aspects of osteopathic medicine.

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

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

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

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

**Protocols (1,500 - 2,000 words)**
The IJOM accepts the submission of protocols of randomised interventions, systematic reviews and meta-analyses, observational studies, and selected phase I and II studies (novel intervention for a novel indication; a strong or unexpected beneficial or adverse response; or a novel mechanism of action), with the overall aim to encourage good principles in clinical research design.

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

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Papers which focus on osteopathic education in the clinical/practice environment and in academia are welcomed for a new section of the International Journal of Osteopathic Education. Papers from academics involved in the teaching of students in the classroom are welcomed alongside those from clinical staff involved in the education of osteopaths in practice, through post-qualifying education and training initiatives. It is essential that the evidence-base to education is developed and this is reflected in papers submitted for publication. In alignment with the journal's overall Aims and Scope, papers submitted for consideration of publication should be relevant to an international audience, even if they are national in scale of study. The editorial team wish to encourage submission of papers that demonstrate:

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

At submission stage, authors of reviews and original research articles are required to provide three to four bullet points outlining the manuscript implications for clinical practice.

**(E) SPECIFIC GUIDANCE FOR ORIGINAL RESEARCH ARTICLES**

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

**Introduction**

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

**Materials and Methods**

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

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

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

**Discussion**

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

**Conclusion**

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

**CONSIDERATIONS SPECIFIC TO TYPES OF RESEARCH DESIGNS**

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Example of suggested format (note the use of author initials).

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

(F) SPECIFIC GUIDANCE FOR PROTOCOLS

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

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and should not exceed 200 words.

• Background, including rationale and any previous systematic review(s).

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• Principal investigator(s); contact details.

• Aim(s).

• Design (randomised, double-blind) - including inclusion and exclusion criteria;
intervention(s)/method; primary and secondary endpoint(s); side-effects reporting and
quantification

• Statistical analysis - including sample size and power calculations; type of analysis;
statistical testing.

• Ethical issues - including ethics committee approval; informed consent form and
information sheet.

• Publication plan.

• Time required - an estimation of the time required to run the protocol should be given per
separate step and for the whole protocol, including reporting.
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(G) POST ACCEPTANCE

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