Effectiveness of trigger point dry needling for plantar heel pain

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Abstract

Aim: To evaluate the effectiveness of trigger point dry needling for plantar heel pain.

Design: A systematic review of the literature was first conducted to evaluate the effectiveness of trigger point dry needling for plantar heel pain. This was followed by a Modified Delphi study to develop a consensus-driven trigger point dry needling treatment for plantar heel pain. Finally, a randomised controlled trial (RCT) was conducted to evaluate the effectiveness of trigger point dry needling for plantar heel pain.

Setting: The modified Delphi Study was completed using the online survey tool SurveyMonkey®. The RCT was conducted at a university-based clinic.

Participants: The Modified Delphi study included 30 experts in the use of trigger point dry needling. In the RCT, 84 participants with plantar heel pain were randomly allocated to a group that received either real or sham trigger point dry needling.

Outcome measures: In the RCT, the primary outcome measures were a Visual Analogue Scale (VAS) and the Foot Health Status Questionnaire (FHSQ). Secondary outcome measures included the Depression, Anxiety and Stress Scale (DASS-21).

Results: The results of the Modified Delphi study indicated that 93% of experts agreed with a consensus-driven dry needling treatment for plantar heel pain to be used in a RCT. In the RCT, significant effects favoured real trigger point dry needling over sham trigger point dry needling for pain at the primary end point of six weeks (adjusted mean difference: VAS first step pain -14.4mm, 95% CI -23.5 to -5.2; FHSQ foot pain 10.0 points, 95% CI 1.0 to 19.1), although the between group difference was lower than the minimal important difference.

Conclusion: Dry needling provided statistically significant improvements in plantar heel pain but the magnitude of this effect was lower than what is considered clinically meaningful to people with plantar heel pain.

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Statement of authorship

This thesis consists primarily of work by the author that has been published or accepted for publication as described in the text. Except where reference is made in the text of the thesis, this thesis contains no other material published elsewhere or extracted in whole or in part from a thesis submitted for the award of any other degree or diploma. No other person's work has been used without due acknowledgment in the main text of the thesis. This thesis has not been submitted for the award of any degree or diploma in any other tertiary institution.

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i. Cotchett MP, Landorf KB, Munteanu SE, Raspovic AM: Effectiveness of dry needling and injections of myofascial trigger points associated with plantar heel pain: a systematic review. *J Foot Ankle Res* 2010, 3:18.

ii. Cotchett MP, Landorf KB, Munteanu SE, Raspovic AM: Consensus for dry needling for plantar heel pain (plantar fasciitis): a modified Delphi study. *Acupunct Med* 2011, 29: 193-202.

iii. Cotchett MP, Landorf KB, Munteanu SE, Raspovic AM. Effectiveness of trigger point dry needling for plantar heel pain: study protocol for a randomised controlled trial. *J Foot Ankle Res* 2011, 4:5.

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i. Levinger P, Murley GS, Barton CJ, Cotchett MP, McSweeney SR, Menz HB. A comparison of foot kinematics in people with normal and flat-arched feet using the Oxford Foot Model. *Gait Posture* 2010, 32: 519-523.

Conference and workshop presentations

Cotchett MP, Landorf KB, Munteanu SE, Raspovic AM. What is the protocol for dry needling for plantar heel pain? *Victorian Podiatry Conference*, Melbourne, Australia (20th March, 2010). Lecture delivered by Matthew Cotchett.

Cotchett, MP. Is trigger point dry needling more than an effective placebo? Workshop for the Institute of Registered Myotherapists of Australia (IRMA), Melbourne, Australia (9th October, 2011). Workshop delivered by Matthew Cotchett.

Cotchett, MP. Trigger point dry needling for plantar heel pain. Workshop for the Institute of Registered Myotherapists of Australia (IRMA), Melbourne, Australia (9th October, 2011). Workshop delivered by Matthew Cotchett.

Cotchett, MP. Trigger point dry needling. Workshop for the Australian Podiatry Association, Sports and Biomechanics Interest group, Melbourne, Australia (18th August, 2011). Workshop delivered by Matthew Cotchett.

Cotchett MP, Landorf KB, Munteanu SE. Dry needling for plantar heel pain. The Australasian College of Podiatric Surgeons – clinical sessions, Melbourne, Australia (18th May, 2013). Lecture delivered by Matthew Cotchett.

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Conference posters

Cotchett MP, Landorf KB, Munteanu SE, Raspovic AM: Consensus for dry needling for plantar heel pain (plantar fasciitis): a modified Delphi study. *MYOPAIN 2010,* Toledo, Spain (October 3-7, 2010). Poster presented by Matthew Cotchett.

Abbreviations

BMI: Body mass index

CI: Confidence interval

DASS-21: Depression, Anxiety and Stress scale (short version)

FHSQ: Foot Health Status Questionnaire

LTR: Local twitch response

MRI: Magnetic resonance imaging

MTrP: Myofascial trigger point

SE: Standard error

SF-36: The Short Form (36) Health Survey

VAS: Visual analogue scale

CHAPTER 1

"We tend to endorse the complexity of the brain and its fundamental role in what we experience. Unless, of course, we are talking about pain"

Lorimer Moseley[1]

1.0. Introduction

1.1. Background to the problem

Plantar heel pain is a common source of pain and disability, being one of the most prevalent musculoskeletal foot conditions. The condition is characterised by a gradual onset of pain beneath the inferior aspect of the heel, which is particularly pronounced upon weightbearing after periods of rest but often increases with prolonged periods of standing and walking. Pain is predominantly reproduced upon palpation of the medial tubercle of the calcaneus where the plantar fascia, abductor hallucis, flexor digitorum brevis and abductor digiti minimi orginate.

One national study of medical doctors in the United States during the years 1995 to 2000 found that approximately one million patient visits to physicians per year were for plantar heel pain.[2] In the United Kingdom, an evaluation of 55,033 musculoskeletal consultations from 12 general practices in North Staffordshire, found that 4,500 consultations (8.0%) related to foot and ankle problems, and of these, 339 consultations (7.5%) related to plantar fasciitis.[3] In a population-based study of 3,206 people aged 20 years or older in Australia, 3.6% of the sample indicated that they had pain underneath their heel.[4]

Plantar heel pain predominantly affects middle-aged as well as older adults as shown in a study of 784 North American community-dwelling residents aged 65 years or older where 7.0% reported pain and tenderness beneath the heel.[5] Plantar heel pain is also estimated to contribute 8.0% of all injuries related to running.[6] The high prevalence of plantar heel pain is associated with a large economic burden to the community. Tong and Furia[7] projected that in 2007 the annual economic cost of plantar heel pain was between $US192 to $US376 million dollars to third party payers.

Like many regional and widespread musculoskeletal conditions such as shoulder, neck

and low back pain, plantar heel pain is an umbrella term that encompasses a range of pathologies that cause pain beneath the heel. Historically, most cases of inferior heel pain were thought to relate to inflammation of the plantar fascia, and as such, the term *plantar fasciitis*[8] was used. In addition, the name *heel spur syndrome*[9] has also been commonly used due to the strong association between the presence of a plantar calcaneal spur and pain beneath the heel.[10] The exact source of pain in this condition is unclear; hence the use of the term *plantar heel pain* highlights the potential involvement of multiple structures including the plantar fascia, muscle, tendon and bone.

Despite the prevalence of plantar heel pain, there is limited evidence supporting interventions for this condition. Numerous interventions are used to treat plantar heel pain, however two systematic reviews have concluded that there are few interventions that are supported by good evidence.[11,12] In addition to standard therapies, trigger point dry needling, which involves insertion of needles into a myofascial trigger point (MTrP), is increasingly used by practitioners to treat pain associated with MTrPs for a range of musculoskeletal disorders. Two systematic reviews provide evidence for the effectiveness of dry needling. Tough et al.[13] found that dry needling of MTrPs, associated with neck, shoulder, low back, knee and hamstring pain, was significantly better than sham or placebo for pain. While, Kietrys et al.[14] found that dry needling was superior to sham or placebo in the short term for upper quarter (i.e. shoulder, neck and head) myofascial pain.

This thesis set out to broadly investigate the effectiveness of trigger point dry needling for plantar heel pain. Findings from the studies conducted in this thesis will contribute substantially to the body of knowledge of an intervention that has become increasingly popular in the management of musculoskeletal conditions.

1.2. Aims of the thesis

Primary aim

The primary aim of the thesis was to evaluate the effectiveness of trigger point dry needling for plantar heel pain.

Secondary aim

The secondary aim was to:

- evaluate the association between psychological variables with the pain and disability of plantar heel pain, and
- evaluate the association of depression, anxiety and stress with plantar heel pain.

1.3. Objectives of the thesis

In order to achieve the aims of the thesis, the following objectives were established:

i. critically review the literature (e.g. prevalence, aetiology, pathology and management) relating to plantar heel pain, with a focus on treatment with trigger point dry needling;
ii. systematically review the literature that has evaluated the effectiveness of trigger point dry needling and injections of MTrPs associated with plantar heel pain;
iii. conduct a consensus study, using a modified Delphi technique, to determine how experts use dry needling for plantar heel pain, which could be used in a randomised controlled trial;
iv. conduct a randomised controlled trial to evaluate the effectiveness of dry needling for plantar heel pain;
v. use baseline data from the randomised controlled trial to investigate if symptoms of depression, anxiety and/or stress are associated with foot pain and foot function in adults with plantar heel pain;
vi. conduct an observational study to compare symptoms of depression, anxiety and stress in adults with and without plantar heel pain.

1.4. Research Questions

The specific research questions to be addressed were:

i. is dry needling (and/or injections) of MTrPs effective for reducing pain in adults with plantar heel pain?
ii. can consensus be gained for a standard protocol for dry needling for plantar heel pain?
iii. is dry needling more effective at reducing pain beneath the heel in adults with plantar heel pain compared to sham dry needling?
iv. are symptoms of depression, anxiety or stress associated with foot pain and foot function in adults with plantar heel pain?

v. do symptoms of depression, anxiety and stress increase the likelihood of having plantar heel pain in adults?

1.5. Overview of the thesis

The thesis is set out in the following manner:

Chapter 1. Introduction

Chapter 1 introduces the research problem and provides an overview of the aims and objectives of the thesis.

Chapter 2. Literature review

Chapter 2 provides an overview of plantar heel pain including the anatomy, pathology, aetiology and management of plantar heel pain. This chapter discusses the association between plantar heel pain and MTrPs, and management using dry needling.

Chapter 3. Effectiveness of dry needling (and injections) of myofascial trigger points associated with plantar heel pain: a systematic review

Chapter 3 provides the results of a systematic review that helped define the research question for this thesis. Based on the findings of the review, a randomised controlled trial to evaluate the effectiveness of trigger point dry needling for plantar heel pain was conducted. Chapters 2 and 3 provide the rationale for the studies presented in the latter chapters of the thesis.

Chapter 4. Consensus for dry needling for plantar heel pain: a modified Delphi study

To ensure the randomised controlled trial had external validity, a treatment protocol was required that had broad consensus from experts practising in the area. This chapter presents the results of a consensus study used to develop the protocol for the dry needling intervention that was used in the randomised controlled trial.

Chapter 5. Effectiveness of trigger point dry needling for plantar heel pain: a randomised controlled trial

Chapter 5 presents the results of the randomised controlled trial that evaluated the effectiveness of trigger point dry needling for plantar heel pain. This chapter addresses the primary aim of the thesis.

Chapter 6. Psychological factors associated with foot pain and foot function in adults with plantar heel pain

Symptoms of depression, anxiety and stress are common in people with chronic musculoskeletal pain. In chapter 6, baseline data from the randomised controlled trial was used to evaluate the association between symptoms of depression, anxiety and stress with the pain and disability of plantar heel pain.

Chapter 7. The association between depression, anxiety and stress with plantar heel pain: an observational study

Chapter 7 presents the results of an observational study that compared levels of depression, anxiety and stress in people with and without plantar heel pain. Logistic regression modelling was used to investigate if each emotional state increases the likelihood of having plantar heel pain.

Chapter 8. Conclusion

Chapter 8 provides an overview of the studies conducted in this thesis and answers to the research questions posed.

CHAPTER 2

2.0. Literature review

2.1. Background

The aim of this chapter is to explore, in depth, those areas that are central to this thesis including a background to plantar heel pain, MTrPs and trigger point dry needling. To complete this task, the chapter comprises two sections. The first section commences with an overview of plantar heel pain, including the prevalence, pathology, aetiology and management of this condition. This section also highlights the diagnostic criteria that are used in the randomised controlled trial that evaluated the effectiveness of trigger point dry needling for plantar heel pain (Chapter 5). Furthermore, it features a discussion on why trigger point dry needling was explored as an additional therapy for plantar heel pain. Finally, this section emphasises the shortage of high quality evidence supporting factors that are associated with plantar heel pain, and the need to explore the role of emotional states in this condition.

The second section commences with an explanation of the link between the presence of MTrPs and plantar heel pain. The nature of MTrPs is explored in detail to highlight the criteria used to diagnose MTrPs in the randomised controlled trial. The chapter then progresses to a discussion of the mechanisms of action of trigger point dry needling. Finally, the chapter concludes with a review of the evidence for the effectiveness of trigger point dry needling for myofascial pain and the need for a systematic review to evaluate the effectiveness of trigger point dry needling for plantar heel pain.

2.2. Objective

To critically review the literature relating to plantar heel pain, with a focus on treatment with trigger point dry needling.

2.3. Anatomy of the plantar heel region

The plantar heel region is comprised of the calcaneus, muscle and tendons (spread over two layers), and three neurovascular bundles (Figure 2.1). Overlying but intimately related to the plantar heel intrinsic muscles is a thickened band of connective tissue called

the plantar fascia. The plantar fascia attaches to the periosteum of the plantar surface of the calcaneus and is adjacent to other structures that attach to this region including muscles and tendons of abductor hallucis, flexor digitorum brevis, abductor digiti minimi, and quadratus plantae (Figure 2.2).

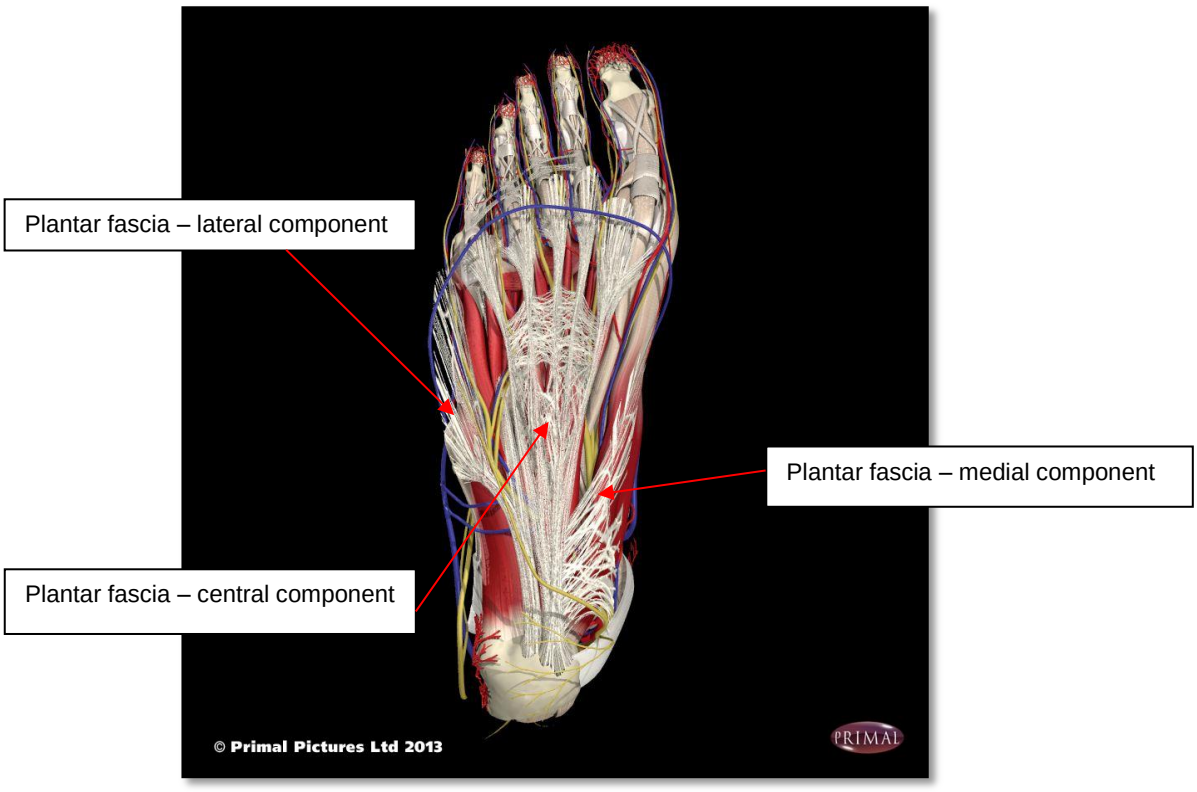

Figure 2.1. Anatomical diagram highlighting the various components of the plantar fascia.

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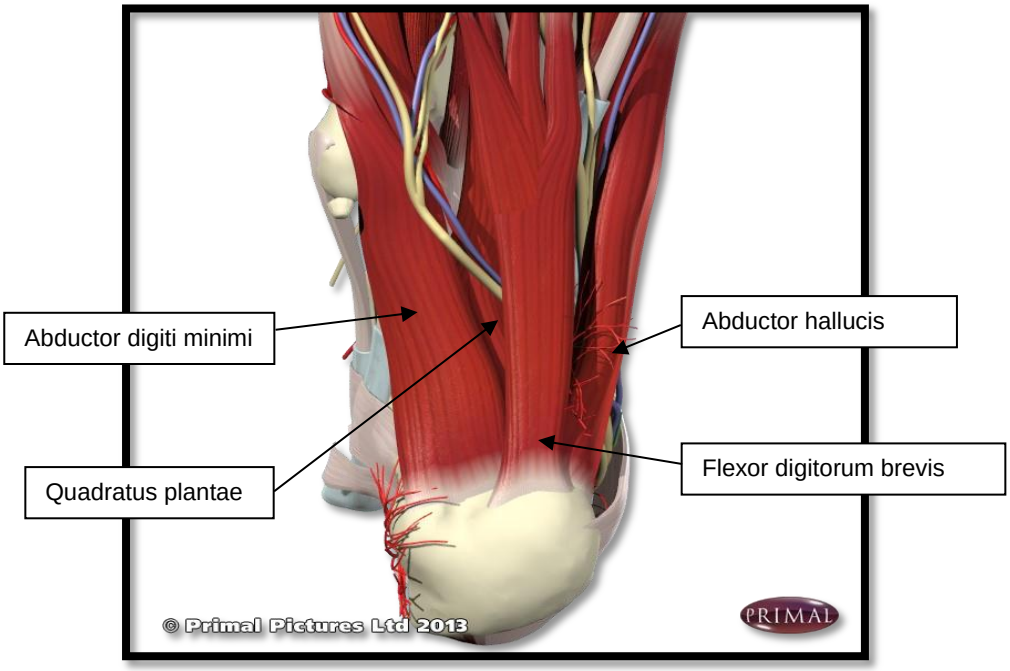


Figure 2.2. Anatomical diagram highlighting the muscles of layer one and two of the heel.

Figure reproduced from Primal Pictures (Ltd 2013).

2.4. Origin of plantar heel pain

Pain beneath the heel can be neurologic, vascular, arthritic, neoplastic or traumatic in origin.[15] However, it is generally accepted that a mechanical overload of soft tissue structures beneath the heel, most specifically the plantar fascia, is the most common source of pain in this region.[16] An overload of the plantar fascia, and associated changes to its connective tissue structure, is most often referred to as *plantar fasciitis*,[17] although it has been suggested the term *plantar fasciosis* might be more appropriate.[18] The term *plantar heel pain* is also used frequently in the literature, as it highlights the involvement of other structures and tissues (e.g. muscle and bone), which might be associated with an overload of the plantar fascia in people with plantar fasciitis.[15]

Symptoms

Patients with plantar heel pain typically present with an insidious onset of pain in the medial, plantar heel region. Symptoms are usually unilateral but can present bilaterally in approximately 40% of cases.[19-23] Bilateral symptoms should raise suspicion of a

spondyloathropathy (e.g., reactive arthritis, psoriatic arthropathy, ankylosing spondylitis).[16] The type of pain can vary from symptoms that are initially sharp and localised to pain that is deep, dull and poorly localised.[16] Symptoms are worse upon weightbearing after periods of rest and often improve with initial activity. Although, it is common for symptoms to be worse at the end of the day, particularly following prolonged periods of standing and walking. Nocturnal symptoms are uncommon, and should alert the clinician to other conditions including cancer, infection, and neuropathic pain.[16] The onset of plantar heel pain often coincides with a change in the type or increased level of activity, or a change in footwear.[17]

Signs

The physical examination should be conducted with the patient both non-weightbearing and weightbearing and include active and passive movements, muscle tests, nerve tests, palpation and other special tests (e.g. the tarsal tunnel syndrome test;[17] the windlass test;[17] and an assessment of foot posture using a reliable and valid measure such as the Foot Posture Index.[24]) The key diagnostic feature of *plantar heel pain* is localised tenderness at the proximal insertion of the plantar fascia.[17] However, there are no studies that have evaluated the diagnostic accuracy of the clinical signs and symptoms for plantar heel pain.

2.5. Factors associated with plantar heel pain

Despite the prevalence of plantar heel pain, the aetiology remains uncertain but is generally accepted to be multifactorial. Establishing the cause of plantar heel pain is difficult for two reasons. Firstly, there is a vast array of structures in the region including fascia, muscle, tendon, nerve and bone that are interconnected and could all be responsible for generating pain. Secondly, studies that have investigated risk factors for plantar heel pain have thus far been observational cross-sectional, which do not provide high level evidence for evaluating risk factors.[25-30] Hence, causal relationships between 'risk' factors with plantar heel pain cannot be inferred. Prospective longitudinal studies are necessary to establish risk factors but these have yet to be conducted. This section highlights a number of factors that are associated with plantar heel pain including imaging and histological findings, physical and functional variables, and health-related quality of life. It is important to highlight these factors because Chapters 6 and 7 of this

thesis investigate several psychological variables that are associated with foot pain and function that increase the likelihood of having plantar heel pain.

2.5.1. Imaging and histological findings associated with plantar heel pain

This section will address pathological changes within the plantar fascia, intrinsic musculature and calcaneus that are associated with plantar heel pain.

Plantar fascia pathology

Pathological changes within the plantar fascia are common in people with plantar heel pain and are generally considered the primary source of pain in this population. Histological examination of specimens obtained from the proximal attachment of the plantar fascia in people with plantar heel pain shows collagen necrosis, increased mucoid ground substance, angiofibroblastic hyperplasia, chondroid metaplasia, and matrix calcification.[31]

Diagnostic musculoskeletal ultrasound and/or magnetic resonance imaging (MRI) are considered the modalities of choice for differentiating the various pathologies that occur in and around the plantar fascia. Investigation using diagnostic musculoskeletal ultrasound has identified: (i) fusiform swelling of the plantar fascia with hypoechogenic areas, (ii) loss of reflectivity of the plantar fascia with the central component most commonly affected, and (iii) mild vascular in-growth close to the enthesis.[32] In a systematic review with meta-analysis of diagnostic ultrasound findings associated with plantar heel pain (11 studies, n = 813), it was shown that the plantar fascia of plantar heel pain participants was 2.2 mm thicker than control participants (95% CI = 1.6 to 2.7 mm, $p < 0.001$).[10]

MRI features of plantar heel pain show fusiform thickening of the plantar fascia. Consistent with findings based on ultrasonography, it was found (in the systematic review cited above: 2 studies, n = 241) that the plantar fascia of people with plantar heel pain was 3.4 mm thicker than control participants (95% CI = 1.8 to 4.9 mm, $p < 0.001$).[10] In addition, perifascial oedema has also found to be common in regions both superficial and deep to the plantar fascia.[33] A combination of ultrasonography, MRI and histological findings in the region of the calcaneal enthesis suggest a loss of organised tissue structure, which is consistent with features of tendon pathology.[10]

Calcaneal pathology

While musculoskeletal ultrasound and MRI are considered the modalities of choice for evaluating soft tissue changes in the plantar heel region, radiography, computed tomography and MRI can be used to assess bone abnormalities associated with plantar heel pain. Plain film x-ray is commonly used by health professionals for the assessment of plantar heel pain with a focus on the presence or absence of a subcalcaneal spur. McMillan et al.[10] found that participants with plantar heel pain were more likely to have radiographic evidence of subcalcaneal spurs than control participants (OR = 8.5, 95% CI = 4.1 to 17.1, $p < 0.001$).

In addition to the association between plantar heel pain and calcaneal spurs, oedema within the calcaneus can be seen in a subset of people with plantar heel pain. A retrospective study that reviewed the MRI findings of 112 patients with plantar heel pain found that bone marrow oedema was evident in 20 of 44 (45%) of patients with atypical features (e.g. night pain, an acute onset of pain and neurological symptoms).[34] Interestingly, bone marrow oedema was present in the majority of those with long standing symptoms of plantar heel pain.

Intrinsic muscular pathology

While it is clear that pathological changes in the plantar fascia are common in people with plantar heel pain, pathological changes of the plantar intrinsic musculature have largely been ignored. This is surprising given that one of the key physical examination measures, to aid diagnosis, involves eliciting pain at the medial calcaneal tubercle.[17] While a positive palpation test might indicate involvement of the plantar fascia, it is also likely, given the anatomical location, to suggest pathology within the muscle and/or tendon of abductor hallucis, flexor digitorum brevis or abductor digiti minimi, which have a common origin on the medial calcaneal tubercle.

A recent case-matched, observational study highlights the association between plantar heel pain and changes to the plantar intrinsic musculature. Chundru et al.[28] found that plantar fasciitis was significantly associated with atrophy of abductor digiti minimi (OR 3.4, 95% CI 1.3 to 8.6). In another cross-sectional study, Chang et al.[29] compared the volume of plantar intrinsic foot musculature in participants with unilateral chronic plantar

fasciitis with their healthy contralateral foot. The study found that the mean volume of intrinsic forefoot muscles were 67.5 cm^3 (SD = 18.9) for the healthy foot, and 63.4 cm^3 (SD = 14.8) for the foot with plantar heel pain. This finding represented a 5.2% difference in the volume of the intrinsic muscles, which was statistically significant (p = 0.03). Due to the cross-sectional nature of the study designs employed by Chang et al.[29] and Chundru et al.,[28] it is not possible to establish the temporal association between plantar heel pain and intrinsic muscle atrophy. Nonetheless, it has been hypothesised that atrophy of the plantar intrinsic muscles might exacerbate the load placed on a swollen or degenerate plantar fascia.[29]

In summary, a number of pathological findings are associated with plantar heel pain, including the presence of a calcaneal spur, an oedematous plantar fascia, calcaneal oedema, and atrophy of plantar forefoot musculature. However, these findings do not imply causation, and are more likely to be associated with the pathological process of plantar heel pain.

2.5.2. Physical and functional characteristics associated with plantar heel pain

In addition to local pathological changes within the plantar fascia and surrounding tissues, physical and functional impairments are also associated with plantar heel pain. The highest level of evidence, that has evaluated the association of physical and functional factors with plantar heel pain, is derived from a systematic review by Irving et al.[25] The review indicated that increased BMI in a non-athletic population has a strong association (based on a large Cohen's *d* effect size)[35] with plantar heel pain. This finding was largely based on a case-matched observational study that found that people with a BMI >30kg/m^2 are 5.6 times more likely (95% CI 1.9 to 16.6) to have plantar heel pain.[36] Weak evidence (based on a small Cohen's *d* effect size)[35] was found for associations between plantar heel pain and increased age, decreased ankle dorsiflexion, decreased first metatarsophalangeal joint dorsiflexion and prolonged standing. A more recent case-matched observational study found that people with a pronated foot posture (i.e. a *Foot Posture Index* score of ≥4)[24] are 3.7 times more likely (95% CI 1.6 to 8.7) to have plantar heel pain.[26]

2.5.3. Health-related quality of life of people with plantar heel pain

Plantar heel pain is not only associated with physical and functional impairments but it has been found to have a negative impact on health-related quality of life. In an

observational study, Irving et al.[27] evaluated health-related quality of life of participants with and without plantar heel pain, using the Foot Health Status Questionnaire (FHSQ). The group with plantar heel pain demonstrated significantly poorer foot-specific health-related quality of life. General health-related quality of life was also significantly poorer evidenced by lower scores on domains measuring vigour, social capacity and physical activity.

2.5.5. Summary of factors associated with plantar heel pain

In summary, the aetiology of plantar heel pain is unclear. Although difficult to conduct, longitudinal studies are required to establish risk factors (i.e. predictors) for plantar heel pain. More investigation needs to be directed to the role of plantar intrinsic muscles as a source of pain and dysfunction in this population. In addition, psychosocial factors associated with plantar heel pain, which have received considerable attention in the aetiology of other musculoskeletal conditions,[37] have largely been ignored in this population. In Chapter 6, the association between depression, anxiety and stress with the pain and disability of plantar heel pain is explored. In addition, Chapter 7 will highlight the results of an observational study that investigated whether symptoms of depression, anxiety and stress increase the likelihood of having plantar heel pain.

2.6. Management of plantar heel pain

Despite the prevalence of plantar heel pain and the numerous list of factors associated with the condition, there are few interventions that are supported by good evidence.[11,12] Two clinical practice guidelines have been developed. The *American Physical Therapy Association,*[17] provides an overview of the levels and grades of evidence. In contrast, the *American College of Foot and Ankle Surgeons*, provides an evidenced based management algorithm, and recommends a multi-faceted, tiered, treatment approach (Figure 2.3).[15] Initial options include padding and strapping, stretching exercises, over the counter foot orthoses, shoe recommendations, oral and injectable anti-inflammatories. Second tier options for patients with minimal improvement at six weeks include night splints, custom foot orthoses, cast or boot immobilisation, or a program of non-invasive manual therapy for a further four to six weeks. Surgery is recommended as a last resort and usually only after failure of at least six months of conservative therapy.[15]

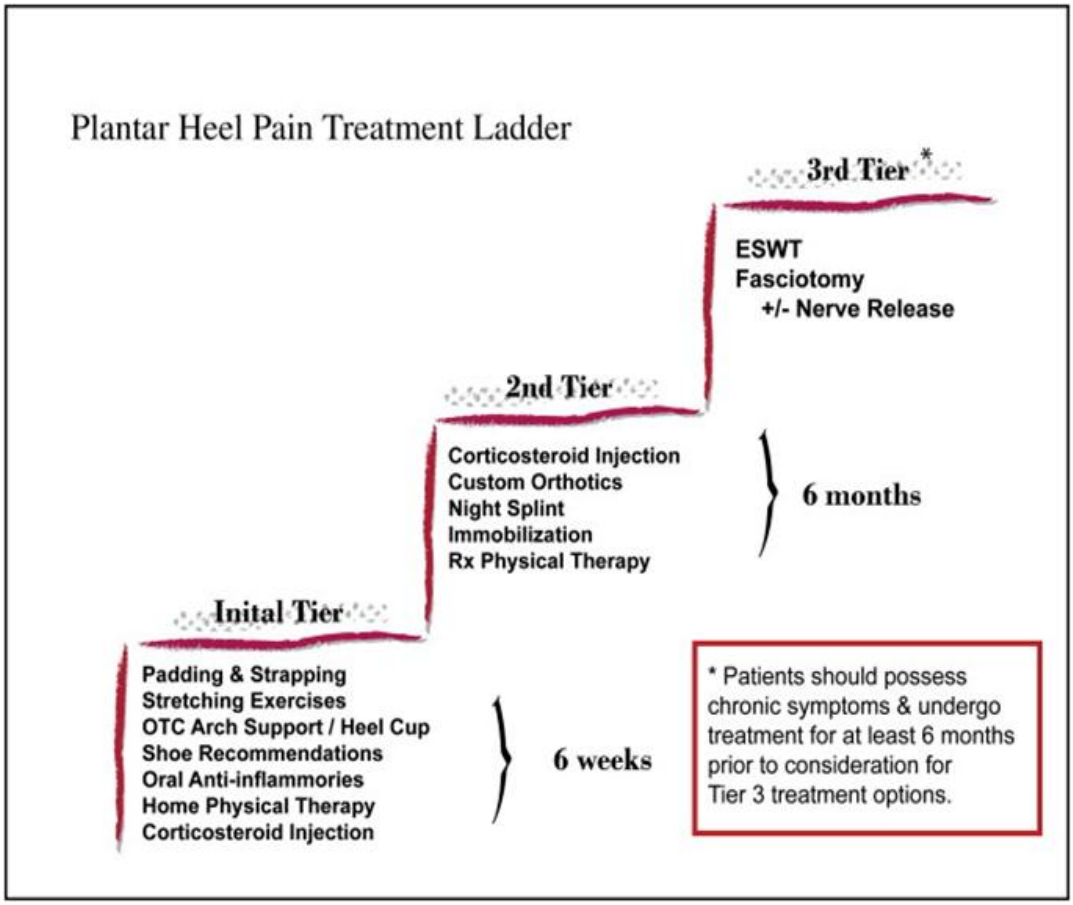


Figure 2.3. The stepwise approach for the treatment of plantar heel pain as recommended by the American College of Foot and Ankle Surgeons.

Taken from Thomas et al. [15]

There are other interventions that practitioners use to manage plantar heel pain that are not included in the guidelines set out by the *American College of Foot and Ankle Surgeons*[15] or the *American Physical Therapy Association.*[17] One of these interventions is trigger point dry needling. This form of manual therapy is increasingly used by practitioners to treat MTrPs associated with myofascial pain.[38] The next section highlights the association between MTrPs and plantar heel pain and why they are considered an important target for treatment in this population. This will be followed by a detailed overview on the nature of MTrPs, the proposed mechanism of action of trigger point dry needling, and the effectiveness of trigger point dry needling for myofascial pain.

2.7. Myofascial trigger points and plantar heel pain

As discussed earlier in this review of the literature (Section 2.5.1), the muscular system has received little attention as a cause of plantar heel pain. Travell and Simons[39] proposed that the presence of MTrPs within the plantar intrinsic foot musculature and muscles proximal to the foot might play an important role in plantar heel pain. A MTrP is defined as "A *hyperirritable spot in skeletal muscle that is associated with a hypersensitive palpable nodule in a taut band. The spot is painful on compression and can give rise to characteristic referred pain, referred tenderness, motor dysfunction and autonomic phenomena" (page 5).*[40] Travell and Simons[39] wrote: *"The fact that many of the symptoms and signs of plantar fasciitis are also characteristic of several myofascial pain syndromes raises the question as to whether TrPs may be contributing significantly to the chronic overload of the plantar aponeurosis in many of these patients. The muscles most likely to be involved are the intrinsic flexors of the toes, the gastrocnemius and soleus. The area of heel pain and tenderness of plantar fasciitis matches partly the referred patterns of the soleus, quadratus plantae and abductor hallucis muscles" (p 510) (Figure 2.4, 2.5 and 2.6).*

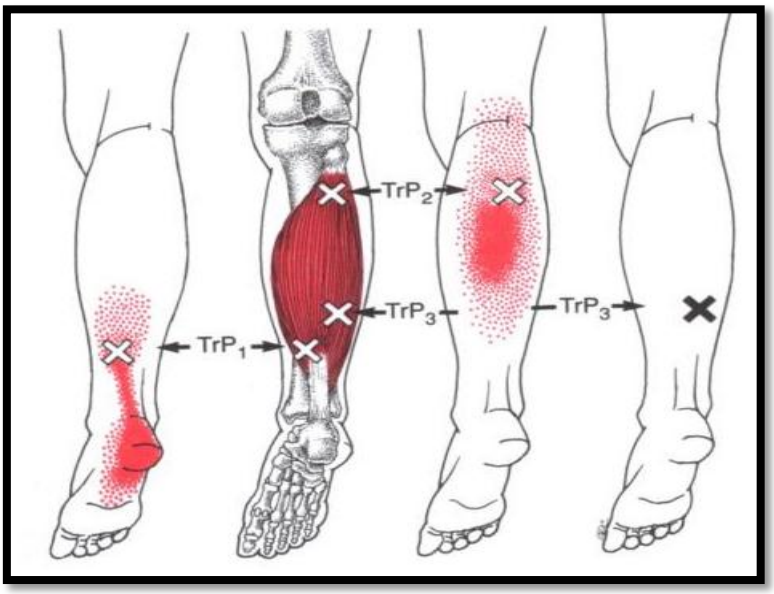


Figure 2.4. The proposed association between a MTrP in the soleus muscle and plantar heel pain.

Taken from Simons et al.[40]

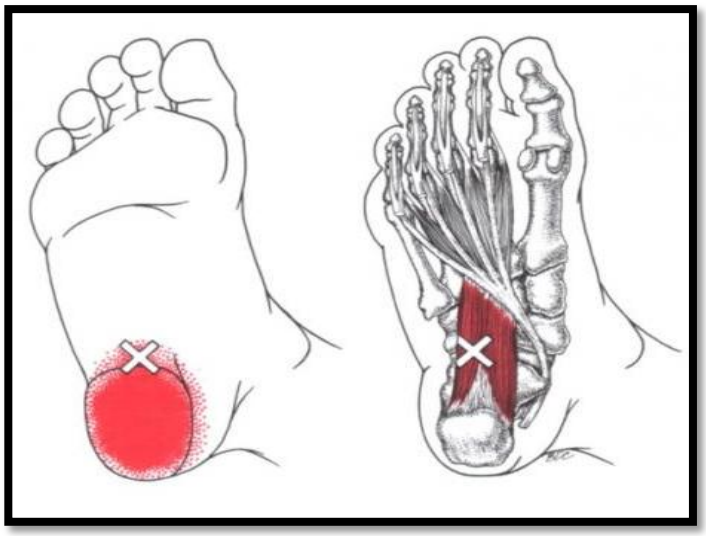


Figure 2.5. The proposed association between a MTrP in the quadratus plantae muscle and plantar heel pain.

Taken from Simons et al.[40]

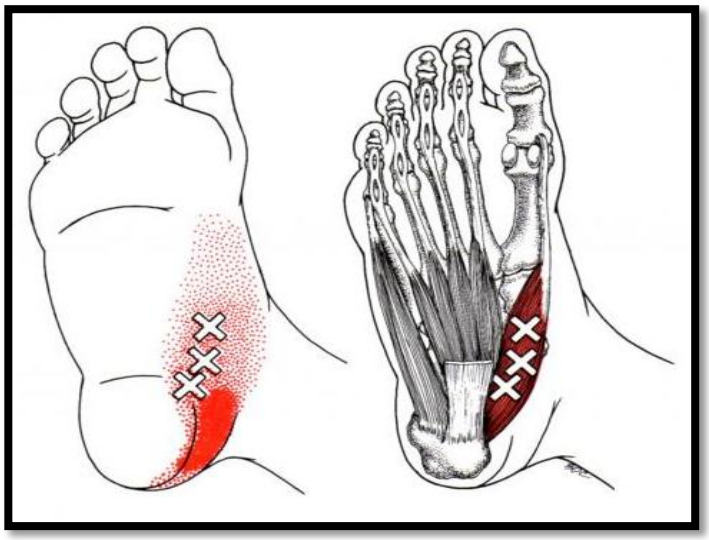


Figure 2.6. The proposed association between a MTrP in the abductor hallucis muscle and plantar heel pain.

Taken from Simons et al.[40]

It is important to note that there have been no observational or prospective longitudinal studies that have investigated the association between MTrPs and plantar heel pain. At this stage, the association is purely hypothetical, although Chapter 4 (a Delphi study) highlights that experts worldwide commonly assess and treat MTrPs within the soleus, quadratus plantae and abductor hallucis muscles in patients with plantar heel pain.

As the primary aim of this thesis is to evaluate trigger point dry needling for plantar heel pain, it is essential that the nature of MTrPs be reviewed. The following subsections will describe the prevalence, anatomy, physiology, diagnostic features and the impact of MTrPs on pain and function. Many of these descriptions form the basis for the assessments performed in Chapter 5 of this thesis (a randomised controlled trial that evaluated trigger point dry needling for plantar heel pain).

2.7.1. Classification of MTrPs

MTrPs are classified as either active or latent. An active MTrP can cause spontaneous local and/or referred pain in response to movement. In contrast, a latent MTrP point does not cause pain unless it is stimulated by palpation, needling or injections, although they may give rise to some signs of active trigger points, albeit to a lesser extent.[40] MTrPs may also be defined as a primary or key MTrP, or a secondary or satellite MTrP.[41] It has been suggested that a primary MTrP is the precursor for secondary MTrPs and inactivation of the primary MTrP can subsequently eliminate the activation of secondary MTrPs.[41]

2.7.2. Prevalence of MTrPs

Latent and active MTrPs are common in people that are healthy or those that that are experiencing pain, although most prevalence studies are focused on the upper half of the body.[42-46] The prevalence of MTrPs in the lower extremity is unclear, although a recent cross-sectional study evaluated the prevalence of MTrPS in the triceps surae of 220 healthy participants.[47] Overall, latent MTrPs were found in the soleus, and medial and lateral heads of gastrocnemius (range 13% to 30%). MTrPs were most prevalent in the medial gastrocnemius (118/220, 53%), followed by the lateral gastrocnemius (89/220, 40%) and soleus (62/220, 28%). As described in Chapter 4 (a Delphi survey), experts that use dry needling for plantar heel pain commonly target MTrPs in the gastrocnemius and soleus muscles.

2.7.3. Diagnostic features of MTrPs

A diagnosis of pain associated with MTrPs is obtained following a thorough evaluation of the patient's medical history and presenting complaint. The approach is no different to the assessment that would be conducted when evaluating a patient with a musculoskeletal disorder such as plantar heel pain, although there is the additional focus of identifying MTrPs. While there are some novel imaging[48] and microdialysis techniques[49] to identify a

MTrP, none have proven to be a gold standard diagnostic tool, so clinicians are reliant on their palpation skills and evaluation of the patient's history.

Patient history

The patient with myofascial pain will describe a poorly localised, deep, dull, diffuse aching pain, with pain referrals with or without deep tissue hyperalgeisa or allodynia.[50] Symptoms are often exacerbated by activity and performance of certain movements, although some gentle exercise and stretching of the muscle might result in an alleviation of symptoms. Often, the patient with myofascial pain will describe certain activities preceding the onset of pain and dysfunction including: (i) a sudden overload of muscle, (ii) repetitive activity and activation of muscle, or (iii) sustained contraction of muscle in a shortened position.[50] Myofascial pain may be accompanied by dysaesthesias or paraesthesias and be present at a site distant to the original site of injury. Symptoms can vary in severity between patients and also vary in intensity over the course of the problem in the same patient.[50]

MTrP identification

The patient's description of the presenting complaint alerts the clinician to the possibility of a myofascial pain syndrome, however it is often difficult to differentiate pain that is arising from muscle, tendon, fascia, ligament, capsule or bone based entirely on subjective information. Evaluation of muscle, as part of the musculoskeletal assessment, involves manual and functional muscle testing, inspection for evidence of atrophy or hypertrophy, and palpation to discern tone and the presence of MTrPs.

As previously stated, there are no gold standard clinical tests to identify MTrPs, therefore the clinician must rely on a list of essential criteria and confirmatory observations.[40] A recent systematic review concluded that substantial variability existed among researchers in regards to criteria used to diagnose a MTrP.[51] Only 12 of 57 studies, that reported using criteria outlined by Simons et al.[40] used the criteria correctly. The four most common criteria applied by the studies were: (i) 'tender spot in a taut band', (ii) 'patient pain recognition', (iii) 'predicted pain referral pattern', and (iv) 'local twitch response' (LTR). The authors concluded that there is inadequate consensus regarding criteria underlying and defining myofascial pain syndromes and further research is required to evaluate the

reliability and validity of MTrP diagnostic criteria. Section 2.7.8. discusses the reliability of MTrP palpation for the diagnosis of MTrPs.

Palpation

MTrPs can be palpated using a flat palpation (Figure 2.7) or pincer palpation technique (Figure 2.8).[52] A flat palpation technique involves drawing the fingers across the muscle, at right angles to the muscle fibres. In contrast, a pincer technique involves grasping the muscle, and the MTrP, between the tip of the thumb and the index finger to draw it away from the surrounding tissue.

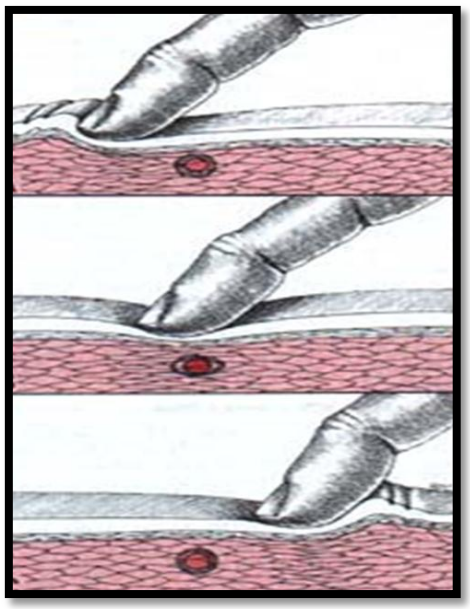


Figure 2.7. Flat palpation of a MTrP.

Taken from Simons et al.[40]

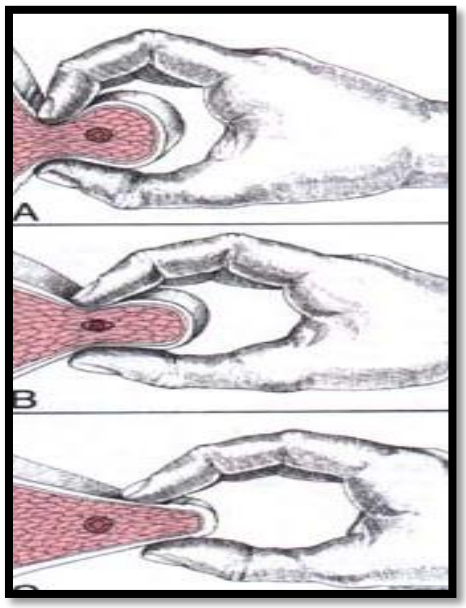


Figure 2.8. Pincer palpation of a MTrP.

Taken from Simons et al.[40]

The aim of palpation is to identify a taut band in the muscle and an area of tenderness in the taut band. The clinician is further guided by a characteristic pattern of referred pain,

and pain familiar to the patient upon palpation of the tender point.[52] On occasion, it is possible to produce a LTR on palpation of a MTrP. A LTR represents a brief contraction of muscle fibres, surrounding the MTrP, that is mediated by a spinal cord reflex[53] and is believed to confirm the presence of a MTrP.[54] In the following sections, the presence of a LTR, in response to trigger point dry needling, will be discussed in detail.

2.7.4. Pathological features of a MTrP

The pathology of a MTrP has been largely informed by findings in animals, although recent novel applications of ultrasound technology have been used to differentiate MTrP tissue from normal myofascial tissue. Using ultrasound imaging, Sikdar et al.[48] found that MTrPs in the upper trapezius muscle of humans appeared as elliptically shaped focal areas of hypoechogenicity measuring on average 0.16 ± 0.11 cm^2 in size (Figure 2.9). The differences in echogenicity between MTrP tissue and normal tissue suggest disorganisation of muscle fibre orientation and structure.[48]

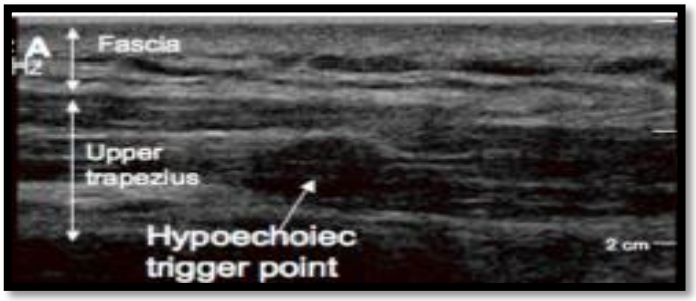


Figure 2.9. Gray scale imaging of a MTrP in the upper trapezius. The MTrP is represented by the elliptically shaped area of hypoechogencity.

Taken from Sikdar et al.[48]

To date, there have been no histological studies that have evaluated MTrPs in humans, although a study reported in a German language journal reported findings of "contraction knots" being observed within tender nodules of muscle (in German, "myogelose") biopsied from humans.[55] Simons and Stolov[56] were the first to publish biopsy results of a MTrP region. Histological examination of a MTrP in canines revealed 'contraction knots' within parts of individual muscle fibres with evidence of severely shortened sarcomeres (Figure 2.10). The fibre outside the contraction knot was wider, which suggested stretching of the muscle fibre. Each contraction knot was approximately 100 micrometres in diameter; approximately twice the diameter of a normal muscle fibre or equal to the length of a motor endplate. Multiple contraction knots were evident in each MTrP biopsied.

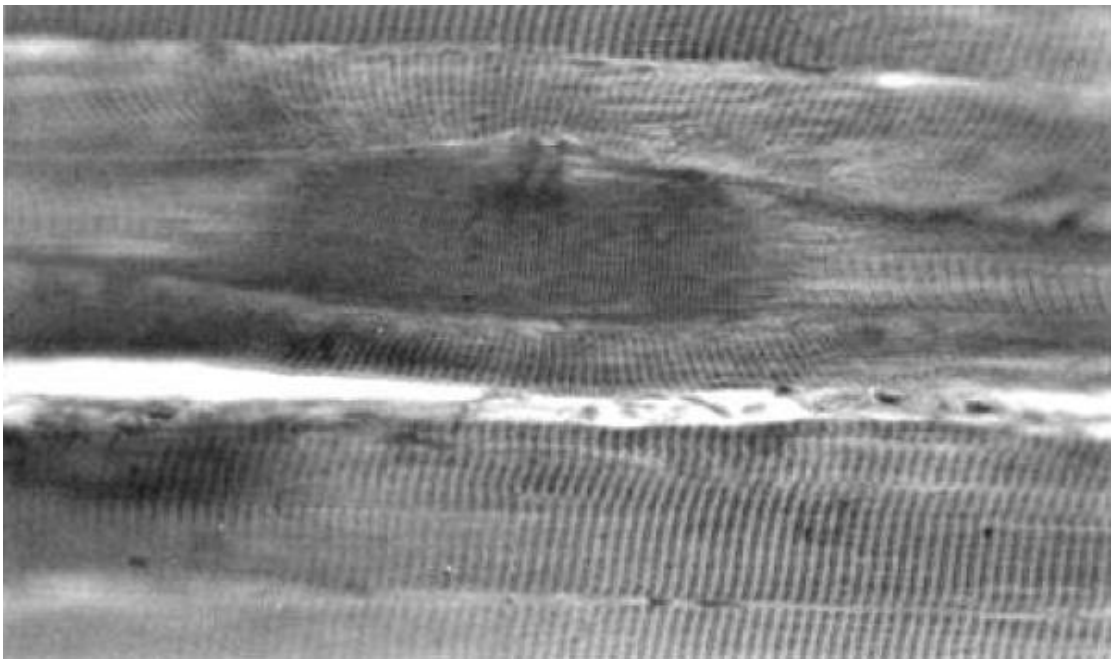


Figure 2.10. Histological examination of a contraction knot from the canine gracilis muscle.

Taken from Simons and Stolov[56]

Mense[57] states that the term contraction knot, while established in the literature as a feature of a MTrP, is not entirely accurate. The term contraction suggests shortening of a muscle fibre secondary to action potentials along the alpha motor neuron and excitation of the adjacent muscle membrane. If a MTrP developed secondary to the propagation of action potentials at the motor endplate, there would be a shortening of the entire muscle fibre. As a MTrP is localised to a part of a single muscle fibre, it must therefore be due to a physiological contraction of the sarcomeres *"in the absence of electrical activation of the muscle cell membrane"* (*p 94).*[57] Mense[57] also proposed that the palpable nodule of a MTrP probably reflects the aggregation of multiple contraction knots as palpation of a single contraction knot in a muscle fibre would not be possible due its small diameter.

Hong and Simons[58] proposed an anatomical model of a MTrP that includes a sensitive and active locus, which together constitute a MTrP locus (Figure 2.11). This model is largely based on observations from MTrP injections[54,59] and a histological study.[60] Hong et al.[60] conducted a histological study of sensitive loci within a myofascial trigger spot (equivalent to a MTrP in humans) of the biceps femoris muscle of a rabbit. The authors identified a small nerve fibre near the sensitive locus, which may have been responsible for the transmission of noxious stimuli to the spinal cord and consequently, the site from which a LTR was elicited. Hence, sensitive loci are thought to be sensitised nociceptors.[58] An active locus is the location from which spontaneous electrical activity or endplate potentials can be generated from an active MTrP.[58]

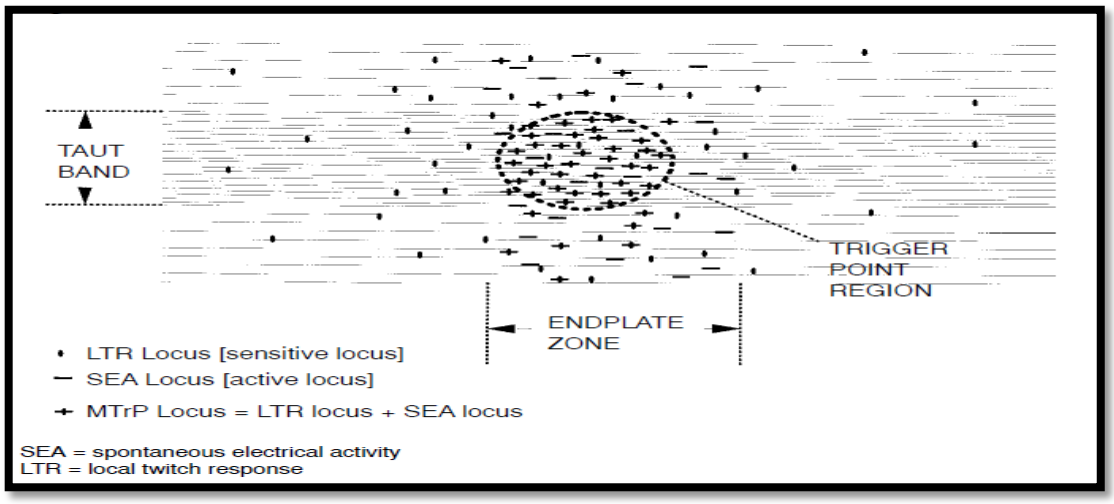


Figure 2.11. Sensitive and active loci around the MTrP region.

Taken from Hong.[61]

The model proposed by Hong and Simons[58] was supported by a study by Kuan et al.,[62] that found a myofascial trigger spot has sensory (afferent) and motor (efferent) connections with the spinal cord, similar to normal muscle tissue. Kuan et al.[62] injected the tracer *horseradish peroxidase* into myofascial trigger spots (identified by the presence of endplate noise) of the biceps femoris in anaesthetised rats. Two days later, the spinal cord and dorsal root ganglia were removed and sectioned to identify tracings of horseradish peroxidase. The tracer was found in the ventral horn of L5 and the dorsal root

ganglion of L3, L4 and L5 with the highest concentration in L5. This finding suggests that the locus of the MTrP has motor connections via neurons in the ventral horn of the spinal cord and sensory connections via neurons in the dorsal root ganglia.

In summary, the pathological features of a MTrP have been partially informed from research using animal and human models. Unfortunately, there is only one study that has evaluated the histological features of a MTrP in humans. The limited studies that have investigated the pathological features of a MTrP indicate the presence of contraction knots within single muscle fibres that appear as an area of hypoechogenicity under musculoskeletal ultrasound. In animal models, a MTrP has sensory and motor connections with the spinal cord.

Having examined the pathological characteristics of a MTrP it is now necessary to consider the physiology of the MTrP region. The next subsection highlights that a MTrP is not just a region with disorganised muscle structure, but it is also electrically active, which helps to explain the aetiology of MTrPs.

2.7.5. Physiology of a MTrP

Electrophysiology

At the site of painful MTrPs, Hubbard and Berkoff[63] discovered "spontaneous electrical activity" (low-amplitude noise-like action potentials of 10-50 microvolts), which was later defined as endplate noise.[40] Simons et al.[64] found that endplate noise is more prevalent in the endplate zone close to a MTrP than in an endplate zone outside a MTrP region. Simons et al.[64] proposed that the elevated endplate noise within a MTrP was due to excessive acetylcholine release (in the peripheral nervous system, acetylcholine is a neurotransmitter released by neurons to activate acetylcholine receptors on skeletal muscle fibres). Recent investigations found the administration of botulinum toxin, which can inhibit acetylcholine release, restored dysfunctional motor endplates.[65] This finding provides some evidence for the excessive release of acetylcholine from the motor endplate close to MTrPs.

The importance of endplate noise in the pathophysiology of MTrPs is also supported by Kuan et al.,[66] who found that the prevalence of endplate noise was higher in participants

with active MTrPs compared to those with latent MTrPs ($p < 0.01$). Furthermore, the prevalence of endplate noise was highly correlated with pain intensity ($r = 0.742$) and pressure pain thresholds ($r = -0.716$).

Blood flow

Mense[57] postulated that the presence of a bulbous contraction knot might compress the capillaries that supplied the MTrP leading to tissue hypoxia. Mense[57] supported this hypothesis with evidence from a German study[55] that found the centre of myogeloses exhibited substantial hypoxia. It was further proposed that reduced oxygen supply would inhibit inflow of ATP to overcome physiological contraction of sarcomeres. As a consequence, the physiological contraction of sarcomeres would be maintained leading to further tissue hypoxia.[50]

Sikdar et al.[48] evaluated blood flow of MTrP tissue within the upper trapezius of humans using duplex Doppler imaging and found distinct differences in the waveform patterns of MTrP tissue compared with normal tissue. Active MTrPs were associated with sustained retrograde diastolic flow, compared to normal myofascial tissue, which implies increased vascular bed resistance. An increase in vascular resistance might compromise blood flow to the MTrP, leading to tissue hypoxia, which is believed to be a key physiological development that contributes to pain and tenderness in people with myofascial pain.[50]

Biochemical environment

Shah et al.[49] used a microdialysis probe incorporated into a 30 gauge hypodermic needle to assay the biochemical environment surrounding a MTrP. The needle was inserted into: (i) the acupuncture point GB-21 (correlating to a MTrP) of the upper trapezius muscle in participants with neck pain, (ii) a latent trigger point of the trapezius in participants without neck pain, and (iii) the acupuncture point LV-7 (non-MTrP site) of the gastrocnemius in participants with no neck pain. The concentrations of bradykinin, substance P, calcitonin gene-related peptide, tumour necrosis factor alpha, interleukin 1 (IL-1), IL-6, IL-8, serotonin, and norepinephrine were elevated compared with the latent and normal group. The concentration of the aforementioned chemicals was similar in the latent and normal groups.

In the discussion above, the morphological and physiological characteristics of a MTrP have been considered. Essentially, a MTrP represents an area of muscle fibre disorganisation with compromised blood supply and an elevated concentration of chemicals associated with pain and inflammation. However, more research is required to evaluate the pathology and physiology of MTrPs in other regions of the body, particularly in the lower extremities, as such information has largely been derived from the upper quarter of the body. This discussion forms a platform for describing the mechanisms proposed to explain the formation of a MTrP, which will now be covered.

2.7.6. Mechanism to explain the formation of a MTrP

A number of theories have been proposed to explain the formation of a MTrP, although the *integrated trigger point hypothesis*[40] and the *expanded MTrP hypothesis*[52,67] has gained most support. The theory has been influenced by histological examinations by Simons et al.,[56] electrodiagnostic work of Hubbard and Berkoff[63], Simons et al.,[64,68] and biochemical assays conducted by Shah et al.[49]

The expanded MTrP hypothesis proposes that excessive release of acetylcholine from the motor endplate, triggers the uptake of Ca^{2+} in the sarcoplasmic reticulum of the postsynaptic muscle fibre, which leads to sustained sarcomere shortening and endogenous muscle contraction of selected fibres with the muscle. The role of increased intracellular Ca^{2+} of the sarcoplasm and its association with endplate noise and the development of muscle contraction is highlighted by Hou et al.[69] who found that the Ca^{2+} channel blocker, Verapamil, inhibited electrical activity of myofascial trigger spots in rabbits.

Sustained sarcomere shortening is thought to compromise circulation to the region of the MTrP leading to an hypoxic state.[67] As mentioned previously, Sikdar et al.[48] recently found increased vascular resistance at the site of active MTrPs, which supports the finding of hypoxia within MTrPs.[50] This, in turn, might promote increased acetylcholine release reinforcing the contracted state of the MTrP region.[70] Tissue ischaemia also leads to the release of sensitising substances, which stimulate nociceptors. Stimulation of peripheral nociceptors might produce peripheral sensitisation, activation of dorsal horn neurons via stimulation of nociceptive afferent neural pathways and even central sensitisation.[67]

To this point, a MTrP is hypothesised to form due to a dysfunctional motor endplate leading to a local muscle contracture. However, it is unclear what is initially responsible for this lesion, although it is generally considered to follow muscle overload.[52] Having examined the aetiology of a MTrP, it is now necessary to consider how the hypothetical mechanism to explain the formation of a MTrP contributes to the key clinical features of MTrPs.

2.7.7. Clinical manifestations of MTrPs

Local pain

Pain emanating from the region of a MTrP is a key diagnostic feature of a myofascial pain syndrome. Local muscle pain, in the region of a MTrP, reflects the presence of a noxious stimulus and the stimulation of polymodal nociceptors.[50] These nociceptors are easily sensitised by chemicals released from various sources (e.g. prostaglandins, histamine, bradykinin, serotonin – from platelets; and calcitonin gene-related peptide and substance P – from nociceptor terminals). This process is referred to as primary hyperalgesia or peripheral sensitisation.[50]

The presence of these biochemicals in MTrPs[49] helps to explain the tenderness associated with MTrP palpation. Clinical studies have found that pressure pain thresholds are lower at sites of MTrPs, compared to normal MTrP free tissue,[71] suggesting the presence of tissue sensitivity and a focal area of peripheral sensitisation.[50]

Referred pain

Referred pain from a MTrP is a common phenomenon and is characterised by pain that is felt at a site remote from the noxious stimulus. For example, MTrPs in the soleus muscle are theorised to refer pain to the plantar aspect of the heel, which might be misdiagnosed as plantar heel pain or plantar fasciitis.[39] Symptoms are similar to pain arising from the MTrP (i.e. somatic pain) and normally occur within myotomes and sclerotomes innervated by the same spinal segment, although there is evidence that pain can be referred to adjacent spinal segments.[72] Most commonly, muscle refers pain to deep somatic structures such as joints, ligaments, tendons and other muscles, rather than to the skin.[72]

The common thought is that referred pain can be partly explained by the *convergence-projection theory* proposed by Ruch[73] and modified by Graven-Nielsen and Mense.[74] This theory is based on the assumption that nociceptive dorsal horn or brainstem neurons receive nociceptive input from different tissues including muscle, joint, viscera and skin. If a neuron in the dorsal horn receives convergent input from multiple sites (e.g. a proximal and a distal muscle), higher centres of the brain will be unable to ascertain the exact location of the lesion in the periphery. As a result, a mislocalisation of pain occurs.[74]

Other theories to explain the mechanisms of referred pain include the branched-axon theory[75] and the thalamic-convergence theory.[76] The branched axon theory suggests that an afferent fibre from two different tissues is bifurcated before connecting to the dorsal horn, although this type of neuron is considered uncommon. This theory has not gathered strong support because it cannot explain the delayed appearance of referred pain.[77] In contrast, the thalamic-convergence theory suggests that referred pain develops due to summation of inputs from the tissue under stress and the area of referred pain. Rather than converging on neurons in the spinal cord, this theory suggests that convergence occurs within the brain. Similar to the branched-axon theory, the thalamic-convergence theory has gained little empirical support pain.[77]

While the *convergence-projection theory* is the primary concept to explain referred pain,[74] it is unable to explain how referred pain can occur outside the spinal segment linked to the peripheral injury or why referred pain takes seconds to minutes to develop.[74] Another proposed model, that can explain most features of referred pain, relates to changes in *dorsal horn connectivity.*[78] According to this theory, dorsal horn neurons that were previously latent begin to respond to other neighbouring neurones that are activated by the noxious stimulus. The excitation or sensitisation of the previously latent neuron then causes the perception of referred pain.

Taut band

The expanded MTrP hypothesis,[52,67] as discussed in Section 2.7.6, proposes the most plausible explanation for the pathogenesis of a taut band, although the mechanism is not fully understood. At the centre of this hypothesis is a functional disturbance of the motor endplate that follows excessive acute or repetitive chronic muscle loading.[52] This

subsequently results in an endogenous contraction of sarcomeres, which is felt as a taut band on palpation.[52]

Local twitch response

A LTR represents a brief contraction of muscle fibres, surrounding a MTrP, that is mediated by a spinal cord reflex. An LTR can be elicited by manual strumming (with a finger) or dry needling of a MTrP, and its presence is believed to be associated with a favourable clinical outcome.[54] Hong[59] proposed that a LTR is elicited following stimulation of nociceptors in the sensitive locus of a MTrP. A LTR requires an intact afferent nerve and normal spinal cord integrity.[79] LTRs will be evaluated in detail in Section 2.8.1.

Central sensitisation

As outlined above, the presence of several neuropeptides, immune and inflammatory mediators surrounding a MTrP suggest the presence of nociceptor sensitivity and peripheral sensitisation. However, it has been proposed that MTrPs are also associated with central sensitisation. This phenomenon relates to an increase in the excitability of neurons in central nociceptive pathways within the central nervous system, and increased synaptic function, leading to pain hypersensitivity (particularly allodynia and hyperalgesia).[50]

Evidence to support the role of central sensitisation in the maintenance of MTrP pain arises from research that found that mechanical stimulation of latent MTrPs, compared to stimulation of non-MTrP tissue, can induce central sensitisation in healthy participants and produce increased pressure hypersensitivity in extra-segmental tissue.[80] Functional MRI brain imaging has also found that pain evoked by nociceptor stimulation of MTrPs was significantly associated with hyperactivity of the somatosensory regions of the brain compared with healthy controls.[81]

Muscle inhibition

The presence of MTrPs has been associated with disorganised patterns of muscle recruitment, in synergistic muscles. Lucas et al.[82] used surface electromyography to compare the timing of muscle activity in a group of people with latent MTrPs of the pectoralis minor, serratus anterior, and middle deltoid muscles compared to a group

without latent MTrPs in the same muscles. All participants performed a loaded elevation of the arm in the scapular plane and the timing of onset of muscle activation was compared between groups. The results found that in the group with latent MTrPs, loaded elevation of the arm was associated with an inconsistent ordering of muscle activation compared to the control group. The authors proposed that the presence of latent MTrPs, and the variability in muscle activation patterns, might predispose people to shoulder pathologies and reduced movement efficiency in this region.

The impact of MTrPs on motor function is further highlighted in a study by Ibarra et al.[83] The authors found that the presence of latent MTrPs in the posterior deltoid muscle was associated with increased muscle activity during agonist (i.e. anterior deltoid) muscle contraction. This finding suggests that there is reduced antagonist reciprocal inhibition and unbalanced muscle activation patterns, which might be an initiating factor for motor dysfunction in the shoulder girdle.[83]

To summarise, a MTrP exhibits a motor abnormality (i.e. a taut band, muscle inhibition and a LTR) and a sensory abnormality (i.e. pain), which are associated with local or central manifestations. Simple criteria have been proposed to locate a MTrP, although identification requires skilful palpation. This review will now consider the reliability of MTrP examination, which is important for the interpretation of the results in Chapter 5 of this thesis (a randomised controlled trial that evaluated dry needling for plantar heel pain).

2.7.8. Reliability of MTrP palpation for the diagnosis of MTrPs

As discussed in Section 2.7.3, there is no gold standard tool for the diagnosis of MTrPs in a clinical setting. As a consequence, clinicians rely, somewhat controversially, on a list of criteria to identify a MTrP (i.e. palpation of a taut band, palpation of a painful nodule in a taut band, a predictable pain referral pattern, pain recognition, a LTR and a jump sign). There have been three systematic reviews that have evaluated the reliability of MTrP examination.[84-86] Of the studies included in the three systematic reviews, the reliability of MTrP examination focused primarily on muscles of the neck, shoulder, thorax, abdomen, lumbar and gluteal regions. One study included an investigation of the reliability of MTrP examination of the soleus muscle.[87] The majority of studies investigated the interrater reliability of identifying individual signs of MTrPs including the presence of a taut band, tenderness, pain recognition, referred pain, jump sign and a LTR.

In their systematic review, Lucas et al.[85] provided a summary of the interrater reliability of MTrP examination and reported the Cohen's kappa coefficient (κ) scores as an estimate of the reliability for individual signs of a MTrP. The results indicated that κ scores ranged from: -0.08 to 0.75 for the presence of a taut band, 0.22 to 1.0 for tenderness, 0.57 to 1.0 for pain recognition, -0.13 to 0.84 for referred pain, -0.05 to 0.57 for a local twitch response, and finally, 0.07 to 0.71 for the presence of a jump sign. Clearly, the range of values for the interrater reliability for various features of a MTrP is large. In addition, the interrater reliability appears to vary depending on the muscle examined, the level of rater experience, and whether training was implemented prior to the rating period. For example, an interrater reliability study by Bron et al.[88] (which was the study of the highest methodological quality reported in two of the systematic reviews)[85,86] found that the reliability of identifying the presence of a taut band, referred pain, LTR and a jump sign was high in the anterior deltoid, biceps brachii and infraspinatus muscles, which might have been associated with the expertise of the raters and extensive prestudy training.

Overall, the three systematic reviews[84-86] that have evaluated the interrater reliability of individual signs of a MTrP found that the level of agreement was highly variable and depends on the muscle examined and the accessibility of a MTrP. The reliability might also be associated with the expertise of the clinician. The systematic reviews suggest that there is no reliable test that can be consistently used across a variety of muscles for the diagnosis of MTrPs. Furthermore, there is no evidence to indicate the reliability of MTrP examination within the foot, which presents a limitation in our understanding of the association between MTrPs and plantar heel pain.

For the randomised controlled trial presented in Chapter 5 (an evaluation of trigger point dry needling for plantar heel pain) the following criteria to identify a MTrP were used: presence of a taut band, pain on palpation of a tender spot in a taut band, patient recognition of pain on sustained compression over the tender point, a LTR and pain referral. Similar criteria were previously employed by two randomised controlled trials that evaluated MTrP manual therapy for plantar heel pain[89] and dry needling for whiplash associated pain.[90]

Having discussed the clinical features of a MTrP, and the reliability of diagnostic criteria used to identify a MTrP, the next section includes a detailed description of trigger point dry needling – an increasingly used manual therapy technique to manage pain associated with MTrPs.

2.8. Management of MTrPs using trigger point dry needling

The previous section began with a discussion of the hypothetical association between MTrPs and plantar heel pain. It was then followed by a description of the pathology, aetiology, clinical features, and criteria used to diagnose a MTrP. Once a clinician has carefully identified a MTrP via palpation, a number of treatments have been recommended to 'inactivate' it including, massage, injections (e.g. local anaesthetics, botulinum toxin, corticosteroids and saline), acupuncture, dry needling, anti-depressants, and muscle relaxants.[91] The following section will review the definition, origin, and mechanism of action of dry needling. For an in-depth review of non-invasive treatments for myofascial pain, the reader is referred to Rickards.[92]

2.8.1. Trigger point dry needling: definition and origins

Trigger point dry needling is an increasingly used manual therapy technique for the management of myofascial pain. This technique involves the insertion of a needle (usually a solid filament needle) into a muscle to reduce pain and improve function. Despite the common use of trigger point dry needling, there is debate over its origins and efficacy. In addition, there is limited evidence that has evaluated the effectiveness of dry needling for myofascial pain. The following section provides a general discussion of the origins of dry needling and its relationship to traditional Chinese acupuncture. This will be followed by a detailed description of the efficacy and effectiveness of dry needling for myofascial pain.

There is no universal definition for dry needling and debate continues regarding its origin and relationship to traditional Chinese acupuncture. The earliest observations of practitioners inserting needles into tender spots and trigger points within muscle did so without consideration of traditional Chinese acupuncture concepts.[38] It is argued that the technique of dry needling for muscle pain was not developed until the late 1970s, and largely evolved from injections of MTrPs.[38]

In contrast, Janz and Adams[93] assert that *"The relationship between the biomedical foundation of trigger point dry needling and clinical practice describes a variation of classical acupuncture rather than the invention of a new theory".*[93] Janz and Adams[93] maintain that dry needling of MTrPs is the equivalent to needling *Ah Shi* points in traditional Chinese medicine. *Ah Shi* points represent a third class of acupuncture points outside the primary (channel) and secondary (non-channel) points and are treated for muscle pain and spasm. Further to this, the *American Association of Acupuncture and Oriental Medicine*[94] state that physical therapists are *"re-titling"* and *"re-packaging"* a subset of acupuncture techniques with the term dry needling.

Recently, dry needling of MTrPs has been considered a variation of Western Medical Acupuncture,[95] and can be practised by acupuncturists and non-acupuncturists. In 2009, the *Editorial Board of Acupuncture in Medicine*,[95] defined the term Western Medical Acupuncture as *"An acupuncture approach that interprets acupuncture phenomena according to current understanding of the body's structures and function, and integrates acupuncture with western medicine".* The organisational movement, *Western Medical Acupuncture* strives to explain the effects of acupuncture according to the best available scientific evidence, without a strong influence from Chinese acupuncture principles. For simplicity, the term *dry needling* will be used in this thesis to describe the insertion of an acupuncture needle to influence the physiology of MTrP tissue both locally and at a distant site in the body.

Despite the uncertainty surrounding the origins of dry needling, it became increasingly popular, from a medical perspective, following the work of Steindler,[96] Travell and Rinzler[97] and Lewit.[98] In 1979, the Czechoslovakian physician Karel Lewit[98] conducted a pivotal trial that found dry needling was highly effective for the management of MTrPs in patients with myofascial pain. Although, like many early clinical trials that evaluated the effectiveness of an intervention, the findings might have been overestimated due to the absence of a control group. Recently, a systematic review conducted by Cummings and White[91] found that dry needling was equally effective as an injection of local anaesthetic, botulinum toxin or corticosteroid for myofascial pain, suggesting that the mechanical effect of the inserted needle, and not the injectable substance, might be responsible for the effect on pain.

MTrP dry needling technique

Dry needling most commonly involves the insertion of an acupuncture needle through the skin, subcutaneous tissue, fascia and into muscle. Once positioned in a muscle, the needle can be manipulated in a variety of ways. However, there is debate as to the most appropriate technique to employ and the type of response to elicit. Clinicians that use dry needling to treat pain associated with MTrPs generally insert a needle into the muscle and then use an in and out,[99] screwed in and out,[100] sparrow pecking,[90] or fan technique[101] to elicit somatic type symptoms and a LTR. As mentioned earlier, a LTR represents a brief contraction of muscle fibres, surrounding the MTrP, which is mediated by a spinal cord reflex.[53] Identification of a LTR helps confirm the presence of a MTrP.[54]

The inducement of a LTR is generally recommended to achieve a positive clinical outcome. In fact, some proponents of dry needling recommend that all LTRs need to be abolished to achieve a positive outcome[54] – a supposition described by many authors.[41,49,79,99,100,102] Although, sound evidence to support this unique observation of dry needling is lacking. Most authors cite a study by Hong et al.[54] that evaluated the effectiveness of trigger point injection and deep dry needling in patients with myofascial pain of the upper trapezius. Participants that experienced multiple LTRs with dry needling had a statistically significant decrease in pain immediately after treatment compared to a group that did not experience LTRs with dry needling. The conclusion of the study was that it is *"essential to elicit local twitch responses during trigger point injection or dry needling for maximum effectiveness"*. However, while the elicitation of LTRs might have an immediate impact on pain, the results do not indicate that an LTR is required to produce a positive outcome beyond the immediate effect. Nevertheless, in Chapter 5 of this thesis (a randomised controlled trial that evaluated the effectiveness of dry needling for plantar heel pain) an attempt was made to elicit a LTR upon stimulation of a MTrP. This goal was recommended by 26 out of 30 (86%) of experts worldwide that use dry needling for plantar heel pain (refer to Chapter 4).

To summarise, dry needling involves the insertion of a needle through skin and into muscle in order to influence the physiology of MTrP tissue. Various techniques can be employed to manipulate the needle once it is in muscle, although it is recommended that the needle elicit a LTR to facilitate a positive outcome. The following section considers

the proposed mechanisms that explain the effect of dry needling, which might help elucidate the positive outcomes derived from trials that have evaluated dry needling for various musculoskeletal disorders.

2.8.2. Dry needling: mechanism of action

Considerable focus has been placed on the aetiology, pathology, physiology, and diagnostic criteria of MTrPs (refer to Section 2.7.3), however the underlying mechanism of dry needling MTrPs to reduce symptoms remains unclear. The therapeutic effect of dry needling can be explained by a combination of specific effects, non-specific effects, non-treatment related effects and if implemented, co-interventions.[103] Specific effects are based on theory underlying an intervention's mechanism of action. In contrast, a non-specific effect represents a change in symptoms, which cannot be explained by the specific effect of the needle, but are incidental elements of the treatment (e.g. patient expectations, patient beliefs, credibility of the interventions, and the alliance between the clinician and practitioner).[104] Finally, non-treatment related effects refer to the changes in symptoms that reflect phenomenona such as the natural progression of the disease and regression to the mean.[103]

The mechanism to explain the specific effect of dry needling, has largely been based on animal models and has been derived from research that has evaluated the efficacy of traditional Chinese acupuncture and Western Medical Acupuncture, not specifically research that has evaluated dry needling.[105] Nevertheless, the following section will focus on the specific effects of dry needling that have been derived from MTrP research. Where there are gaps in the literature, reference will be made to a proposed mechanism of action based on research that has evaluated the efficacy of traditional Chinese acupuncture, which could arguably be translated to the technique of dry needling. This section will conclude with an overview of the non-specific effects of dry needling on pain.

Local effects to explain dry needling analgesia

It has been proposed that insertion of a needle, into a MTrP, stimulates sensitive loci or nociceptors in the region of the motor endplate.[54] This leads to a spread of action potentials around the local neural network via the axon reflex.[106] Stimulation of these nociceptors results in the release of local neuropeptides, cytokines and catecholamines.[49] Shah et al.[49] evaluated the biochemical milieu of a MTrP (which is considered to overlap

with the Gall Bladder 21 acupoint) within the upper trapezius of participants with neck pain and found the concentration of inflammatory and pain mediators increased steadily with the introduction of a specifically designed hollow needle. The increase in concentration of certain mediators including calcitonin gene-related peptide, nerve growth factor, vasointestinal active peptide and neuropeptide Y, which all promote vasodilation, might be responsible for the erythema commonly seen on the skin during needle penetration.[101] If these chemicals promote vasodilation in the region of a MTrP, an increase in blood flow might aid the removal of pain inducing substances.[49] Indeed, it has been found that a single dry needling intervention of a MTrP, within the upper trapezius muscle, increased blood flow and oxygen saturation in the immediate vicinity of the MTrP for 15 minutes after removal of the needle.[107]

In the experiment conducted by Shah et al.,[49] the needle was advanced until a LTR was recorded. Ten minutes after the LTR was elicited, the concentration of Substance P and Calcitonin gene-related peptide, surrounding a MTrP, was significantly less than baseline levels ($p < 0.02$). It is unclear how long substance P and calcitonin gene-related peptide might remain at the lower concentration following an LTR, nor is it clear if the decrease in both chemicals was clinically significant. Nevertheless, a reduction in the concentration of these chemicals is consistent with the common finding post needling of reduced pain and focal tenderness at the site of a MTrP.

The results of Shah et al.[49] outlined above have not been reproduced since in humans. However, the concentration of chemicals associated with pain, inflammation and hypoxia has since been evaluated in an animal model. Hseish et al.[108] compared the effect of a single dry needling intervention (to elicit multiple LTRs) versus a sham dry needling intervention (the needle was inserted into subcutaneous tissue) on the concentration of β-endorphin, substance P, tumour necrosis factor-α, cyclooxygenase-2, hypoxia inducible factor-1α, inducible nitric oxide synthase and vascular endothelial growth factor in rabbits. In addition, the study compared the effect of five dry needling interventions over five days, versus a sham intervention on the concentration of the same biochemicals.[108] The study found that levels of substance P were significantly reduced following a single dry needling intervention of the biceps femoris muscle compared to the sham intervention ($p < 0.05$). This was accompanied by a significant short-term increase in β-endorphin in

local tissue and serum ($p < 0.05$), suggesting a short-term analgesic effect for dry needling. Compared to the sham intervention, the group of rabbits that received five interventions of dry needling over five days had a significant increase in substance P, tumour necrosis factor-α, cyclooxygenase-2, hypoxia inducible factor-1α, inducible nitric oxide synthase and vascular endothelial growth factor within the muscle immediately after the course of treatment, ($p < 0.05$). Substance P was also increased in the dorsal root ganglion and β-endorphin was reduced in the serum. The authors suggest that repetitive, daily sessions of dry needling might be associated with muscle damage that increases the concentration of biochemicals associated with pain and inflammation. In contrast, short term needling (i.e. a single intervention) might be more effective for reducing pain. Further human studies are required to evaluate levels of endogenous opioids in response to single and multiple dry needling sessions of MTrPs, and changes associated with symptoms.

Neurological mechanisms to explain dry needling analgesia – segmental

In addition to local effects, dry needling is proposed to produce analgesia by influencing neural mechanisms at a segmental level.[109] This mechanism suggests that needling produces analgesia by influencing pain inhibitory mechanisms at the level of the spinal cord that is associated with the damaged tissue.

Three key observations provide a scientific basis for understanding this mechanism of dry needling. Firstly, by using an animal model, it has been discovered that a myofascial trigger spot has sensory (afferent) and motor (efferent) connections with the spinal cord, similar to normal muscle tissue.[62] Secondly, insertion of an acupuncture needle stimulates all somatic afferent nerve fibres including Aα, β, δ and C-fibres.[109] In addition, Hseih et al.[79] found that an intact afferent nerve and normal spinal segment integrity is essential for eliciting a LTR and evaluating endplate noise from a MTrP. Thirdly, it has been found that a single session of dry needling of MTrPs in the supraspinatus muscle evoked short-term segmental anti-nociceptive effects.[110] Taken together, it is plausible that stimulation of nociceptors in a MTrP by an acupuncture needle causes discharge of neural impulses along the length of all types of afferent fibres, activating neurons in the dorsal horn. However, how an acupuncture needle inserted into a MTrP facilitates segmental analgesia is still unclear, although it has been suggested that the afferent input to the spinal cord

might stimulate opioidergic mechanisms. Indeed, research that evaluated the efficacy of traditional Chinese acupuncture found that manual acupuncture of an acupoint in the rat hind limb triggered increased release of enkephalin-like material from the spinal cord.[111]

Neurological mechanisms to explain dry needling analgesia – extrasegmental effects
Local and segmental mechanisms are not entirely sufficient to explain analgesia induced by dry needling, as needling of specific points within muscle can alleviate pain outside the spinal segment linked to the noxious stimulus. Hence, dry needling is proposed to instigate extrasegmental analgesia.

Evidence from human studies provides partial support for dry needling induced extrasegmental analgesia. Chou et al.[100] dry needled latent MTrPs in the arm of participants with shoulder pain, and evaluated endplate noise, pressure pain thresholds and pain intensity of active MTrPs within the upper trapezius muscle. They found that a single session involving a remote "screwed in-and-out" technique (to elicit multiple LTRs), compared to simple needling (insertion of a needle without eliciting an LTR) and placebo needling (a non-penetrating acupuncture needle adhered to the skin), produced a significant reduction in self-reported pain (55% ± 13% reduction in pain in the "screwed in and out" dry needling group versus a 6% ± 7% reduction in pain in the placebo group). The between-group difference in pain was statistically significant ($p < 0.05$). This result might suggest that needling of a distant MTrP might activate segmentally and non-segmentally related neurons to produce analgesia.[100]

To explain the extrasegmental effects of dry needling, it has been suggested that a painful stimulus induced by an acupuncture needle at the site of the painful MTrP activates diffuse noxious inhibitory control, a special form of descending pain inhibition.[79] This phenomenon describes a process whereby a painful stimulus (e.g. insertion of an acupuncture needle) can inhibit spinal neurons outside their own segmental receptive fields, using supraspinal, endorphinergic and serotoninergic neurons.[112] The role of diffuse noxious inhibitory control to explain acupuncture analgesia has been questioned as many forms of acupuncture are not painful, and techniques described by Hong[54], Tsai et al.,[99] and Chou et al.[100] are rarely practiced in the West.[101] In addition, laboratory experiments have found that diffuse noxious inhibitory control is only responsible for

short-lived analgesia, and therefore cannot explain the onset of pain relief a few days post treatment.[113]

Neurological mechanisms to explain dry needling analgesia – central effects

Dry needling and acupuncture is also reported to have central effects. A recent meta-analysis highlighted changes in functional brain activity that occur in response to insertion of acupuncture needles into the body, compared to a range of non-penetrating sham or placebo needles (the non-penetrating needles used as a comparison were similar to the sham needles used in Chapter 5 [a randomised controlled trial that evaluated the effectiveness of dry needling for plantar heel pain]).[114] The meta-analysis did not focus on the impact of acupuncture needle insertion at specific acupuncture points, but rather, the overall effect of needle insertion into the body. In addition, the analysis did not include the various acupuncture points that were needled in each study.

The analysis found a statistically significant increase ($p < 0.05$) in brain activity in regions including the insula, thalamus, anterior cingulate cortex, secondary somatosensory cortex, primary visual cortex, superior temporal cortex, superior temporal gyrus, amygdala and cerebellum. Some of these brain regions including the insula, thalamus and secondary somatosensory cortex constitute the sensorimotor cortical network and are involved in the sensory component of pain (i.e. type, level, quality and duration).[114]

A statistically significant decrease in brain activity ($p < 0.05$) with insertion of acupuncture needles into the body, was also found in areas including the medial prefrontal cortex, subgenual anterior cingulate cortex, caudate, amygdala, posterior cingulate cortex, thalamus, parrahippocampus, and cerebellum.[114] Deactivation of some of these areas including the medial prefrontal cortex, subgenual anterior cingulate cortex, caudate, amygdala and parrahippocampus suggests deactivation of the limbic-paralimbic neocortical network.[114] As this network is involved in processing the affective and cognitive components of pain, it has been hypothesised that alleviation of pain induced by insertion of an acupuncture needle might be due to the deactivation of this network.[114] In the meta-analysis, non-penetrating acupuncture needles were also associated with activation and deactivation of areas of the brain, similar to the response following needle insertion, although the effect was not statistically significant (exact *p* values were not reported).

In summary, insertion of an acupuncture needle stimulates afferent nerve fibres and facilitates the release of mediators associated with pain and inflammation. Some mediators are associated with vasodilation of local blood vessels, which might aid in the removal of pain and inflammatory mediators. Stimulation of the afferent nerve fibres leads to a discharge of neural impulses to the corresponding spinal segment but also adjacent spinal segments. At a segmental level, it is proposed that endogenous opioids are released to suppress noxious stimuli from the MTrP. Afferent signals from the acupuncture needle ascend via the spinothalamic tract and stimulate supraspinal levels, and potentially activate diffuse noxious inhibitory control mechanisms. The afferent stimulus also activates brain nuclei associated with the pain matrix, a centre involved in modulating the sensory, affective and cognitive components of pain.

Other mechanisms to explain dry needling analgesia - local effects (connective tissue effects)

As just described, dry needling is proposed to have an effect on pain by influencing the peripheral and central nervous systems, however dry needling might demonstrate a specific effect by influencing connective tissue remodelling. It has been proposed that insertion and manipulation of an acupuncture needle results in mechanical coupling between the needle and connective tissue.[115] This leads to deformation of the surrounding connective tissue and generation of a signal to the cells of the extracellular matrix, which include fibroblasts. Langevin et al.[116] found that acupuncture needle insertion and rotation caused rearrangement of the intracellular cytoskeleton particularly fibroblasts. At the same time, mechanoreceptors and nociceptors might also be activated, thereby influencing sensory afferent input.

Previous research has shown that reorganisation of the cytoskeleton induced by a mechanical load can facilitate cell contraction, migration, and protein synthesis.[117] This in turn, might have important local and distant effects including the release and generation of growth factors, cytokines, vasoactive substances, degradative enzymes, and structural matrix.[118] Changes in the composition of connective tissue milieu could subsequently influence sensory afferent input to the spinal cord and higher centres via a process of neuromodulation.[115] Although the study by Langevin et al.[116] was focused on traditional

Chinese acupuncture, the results might have important ramifications for understanding the mechanisms underpinning dry needling.

Other mechanisms to explain dry needling analgesia - local effects (inhibition of endplate noise)

Local mechanisms to explain the effect of dry needling might relate to the impact of LTRs on endplate noise (low-amplitude noise-like action potentials of 10-50 microvolts).[63] Previous research has found that endplate noise is prevalent in the endplate zone close to a MTrP,[64] and is positively correlated with pain intensity.[66] Chen et al.[119] evaluated the inhibitory effect of dry needling on endplate noise within myofascial trigger spots in rabbit skeletal muscle and found that the elicitation of multiple LTRs had an inhibitory effect on endplate noise. The authors postulated that the insertion of a needle into the endplate zone, and the subsequent reduction in endplate noise, might be a mechanism to explain reduced pain intensity in patients with pain associated with MTrPs.

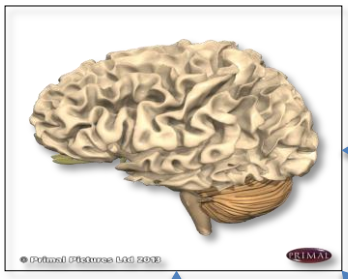
The non-specific effects of dry needling

As discussed at the beginning of this section, the therapeutic effect of dry needling is a result of both specific and non-specific effects. Specific effects include alterations to the local biochemical environment surrounding a MTrP and/or stimulation of the pain matrix of the brain. Non-specific effects include improvements in symptoms that are not related to the specific effect of the needle but rather the patient's beliefs, expectations, and/or the alliance between the clinician and patient. However, it is unclear how much of the therapeutic effect can be attributed to the specific effect of the needle, and how much to the context in which the needle is delivered (i.e. non-specific effects).

A recent systematic review and meta-analysis of acupuncture trials for pain did find, however, that acupuncture was superior to sham or placebo acupuncture for a range of conditions including back and neck pain, osteoarthritis, chronic headache and shoulder pain ($p < 0.001$).[120] The effect sizes for comparison between acupuncture and sham acupuncture were 0.37, 0.26, 0.15 and 0.62 for non-specific back and neck pain, osteoarthritis, chronic headache and shoulder pain respectively. Although, this finding suggests that the specific effect of acupuncture is only modest and that other non-specific effects may play an important role in the overall effectiveness of acupuncture.

This result had important ramifications for the design of the randomised controlled trial presented in Chapter 5 (a comparison of the effectiveness of real and sham dry needling for plantar heel pain). If the non-specific effects of dry needling and/or acupuncture are considered significant, it was essential to control for them (using a sham control group and participant blinding) to ensure the specific effect of dry needling could be isolated.

Overall, it is difficult to separate the specific and non-specific effects of dry needling and Western Medical Acupuncture. It does appear, however, that the context in which acupuncture is delivered is clearly important, and arguably central to the therapeutic effect of acupuncture. In Chapter 5 of this thesis, methods to control non-specific effects of dry needling for the randomised controlled trial are discussed. Figure 2.12 presents a simplified schematic to show the proposed mechanisms of dry needling for pain.

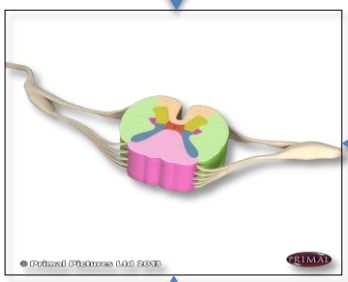


Central effects

- Specific effect: Stimulation of the pain matrix of the brain.
- Non-specific effect: patient's beliefs, expectations, and/or the alliance between the clinician and patient.

Brainstem: Extra-segmental effects

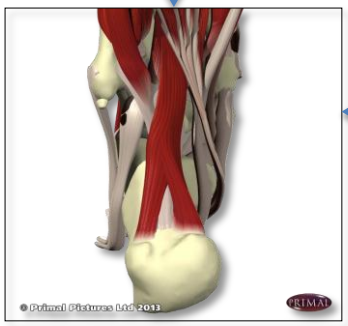
- Stimulation of the Periacqueductal grey and activation of descending inhibitory pain control.
- Diffuse noxious inhibitory control.



Spinal cord: Segmental effects

Segmental anti-nociceptive effects (release of opioid peptides (e.g. Enkephalin).

Stimulation of local nocicepetors activates afferent and efferent connections with the spinal cord.



Local effects

- Stimulation of local nociceptors in the region of a MTrP (e.g. quadratus plantae).
- Release of neuropeptides, cytokines, and catecholamines.
- Vasodilation – increased blood flow and oxygen saturation.
- Increase in B endorphins in tissue and serum.
- Connective tissue remodelling.

Figure 2.12. Simplified schematic highlighting the potential mechanism of dry needling for pain.

Of equal importance to understanding the mechanism of dry needling is a discussion of its effectiveness, which has important implications for clinicians, patients, health insurance and government funding agencies (e.g. Medicare in Australia, National Health Service in the United Kingdom, etc.). The next section provides an overview of systematic reviews that have evaluated the effectiveness of dry needling for myofascial pain.

2.8.3. Effectiveness of dry needling for myofascial pain

Four systematic reviews have evaluated the effectiveness of dry needling for pain associated with MTrPs.[13,14,91,121] In the most recent systematic review (that also conducted meta-analysis), Kietrys et al.[14] found dry needling for upper quarter myofascial pain was significantly better than sham or placebo interventions immediately post treatment [standardised mean difference on a 0 to 10 point VAS = 1.06 (95% CI 0.05 to 2.06)]. At 4 weeks post treatment, a large effect was also found in favour of dry needling [standardised mean difference on a 0 to 10 point VAS = 1.07 (95% CI -0.21 to 2.35)], although the result was not statistically significant. In another systematic review with meta-analysis of trials that evaluated dry needling for shoulder, neck, knee, low back and hamstring pain[13] it was found that dry needling of MTrPs was significantly better than placebo for pain [weighted mean difference on a 100mm VAS = 16.67 (95% CI 3.23 to 30.11)].

In both systematic reviews,[13,14] the I^2 value was extremely high (i.e. >75%), indicating that there was substantial heterogeneity, which raises the issue of whether it was appropriate to combine the selected trials in a meta-analysis.[122] Therefore, the validity of the findings is questionable and therefore, evidence for the effectiveness of dry needling for myofascial pain is uncertain. In addition, the methodological quality of trials included in one review were not reported[13] while the other indicated that methodological limitations were reported in all studies, which were extensive in some cases (the internal validity of the studies ranged from 23 to 40 out of a possible score of 48 based on the *MacDermid Quality Checklist Score*).[14] Both reviews highlighted the need for high quality, adequately powered, randomised controlled trials, to evaluate the effectiveness of dry needling for reducing pain. Finally, the systematic review by Tough et al.[13] did not find any randomised controlled trials that evaluated dry needling for plantar heel pain.

2.9. Conclusion

This literature review chapter has provided an overview of plantar heel pain, MTrPs and dry needling of MTrPs associated with myofascial pain in order to provide background and context for the remainder of this thesis. The chapter began with a description of the anatomy of the plantar heel region, a description of the signs and symptoms of plantar heel pain, and factors associated with the condition. The chapter then highlighted the lack of research that has investigated the involvement of the intrinsic musculature and psychological factors associated with the disorder, which is the focus of Chapter 6 and Chapter 7 of this thesis. The role of MTrPs in the development of plantar heel pain, and subsequently, the management of this condition with dry needling (a manual therapy technique commonly used to manage pain associated with MTrPs) was discussed.

The chapter then described the pathology, physiology and aetiology of a MTrP, clinical manifestations of pain associated with MTrPs, and the reliability of MTrP examination. This section highlighted that a MTrP exhibits motor and sensory abnormalities, which can be associated with both peripheral and central sensitisation. The mechanism to explain the formation of MTrP is hypothetical but is believed to be secondary to a dysfunctional motor endplate, sustained sarcomere shortening, local tissue ischaemia and stimulation of local nociceptors.

The chapter concluded with a description of dry needling, a technique similar to acupuncture but based on vastly different philosophies. It was proposed, based on the available research, that dry needling might help reduce pain by having a local effect on MTrP tissue and/or an effect at a segmental, extrasegmental or central level as has been proposed for traditional and Western Medical Acupuncture. In addition, dry needling might reduce pain via non-specific effects, which relate to the context that the intervention is delivered. However, the relative contribution of specific and non-specific effects is unclear, which has important ramifications for the design of the randomised controlled trial to evaluate dry needling for plantar heel pain presented in Chapter 5. In order to isolate the specific effect of the needle it was important to control non-specific effects of the intervention.

Finally, the effectiveness of dry needling for myofascial pain was explored by accessing the findings from the most recent systematic reviews. These findings highlight that dry needling is more effective than placebo for pain for a range of musculoskeletal disorders. Although, due to quality issues of the trials evaluated in these reviews, there is a need for more high quality randomised controlled trials to evaluate the effectiveness of dry needling. This will ensure greater validity and will allow more definitive conclusions to be made. Moreover, none of the reviews included any studies that had evaluated the effectiveness of dry needling for plantar heel pain. With this in mind, the next chapter describes a systematic review, which was conducted to evaluate the effectiveness of dry needling for plantar heel pain.

CHAPTER 3

3.0. Effectiveness of trigger point dry needling (and injections) of myofascial trigger points associated with plantar heel pain: a systematic review

3.1. Background

As highlighted in Chapter 2, dry needling is increasingly used by clinicians for the management of myofascial pain. However, the most recent systematic review of dry needling for myofascial pain distributed across all parts of the body did not include studies that specifically evaluated dry needling for plantar heel pain.[13] Therefore, the aim of this chapter was to systematically review the literature evaluating the effectiveness of dry needling (and injections) of MTrPs associated with plantar heel pain.

This systematic review was published in the peer-reviewed journal *Journal of Foot and Ankle Research*:

Cotchett MP, Landorf KB, Munteanu SE, Raspovic AM: Effectiveness of dry needling and injections of myofascial trigger points associated with plantar heel pain: a systematic review. *J Foot Ankle Res* 2010, 3:18. (http://www.jfootankleres.com/content/3/1/18)

3.2. Objective

To systematically review the literature that has evaluated the effectiveness of trigger point dry needling and injections of MTrPs associated with plantar heel pain.

3.3. Research question

Is dry needling (and/or injections) of MTrPs effective for reducing pain in adults with plantar heel pain?

3.4. Methods

Types of studies

All clinical trials included in this review were obtained from peer-reviewed journals investigating the effectiveness of dry needling and/or injections of MTrPs associated with plantar heel pain. Randomised controlled and quasi-experimental (an experiment that lacks either randomisation of participants or control group(s) or both) trials examining the effectiveness of trigger point dry needling and/or injections for plantar heel pain were included. The decision to include quasi-experimental trials was based on the lack of randomised controlled trials to draw evidence from; hence we attempted to obtain an overview of what was known to date. Including non-randomised trials in systematic reviews can be appropriate when there are a limited number of randomised trials available.[123] Further, Linde et al.[124] conducted a systematic review of randomised and non-randomised trials that evaluated the effectiveness of acupuncture for chronic headache and found that non-randomised trials of good quality yielded positive responses to treatment that were similar to randomised controlled trials. The authors concluded the inclusion of high quality non-randomised controlled trials into a systematic review might add to the generalisability of the findings. Letters to the editor, opinion pieces and editorials were excluded.

Types of participants

A clinical trial was included if the participants were diagnosed with plantar heel pain. All participants were over the age of 18 and had experienced symptoms of any duration. A trial was only included if the participant's plantar heel pain was managed by treatment of MTrPs in the lower extremity and/or foot. The rationale for this decision was based on the assumption that some forms of plantar heel pain might occur secondary to MTrPs in plantar heel muscles (i.e. abductor hallucis and quadratus plantae) and/or referred pain from the soleus muscle.[39] A trial was excluded if the participant's plantar heel pain was associated with a vascular or neurological disease, arthritis (degenerative and inflammatory) or fibromyalgia.

Types of Intervention

Clinical trials were included if they investigated the effectiveness of dry needling and/or injections (local anaesthetics, steroids, botulinum toxin A and/or saline) of MTrPs for plantar heel pain. Trials were excluded if they involved needling of traditional acupuncture points as the sole treatment because the relationship between traditional acupuncture points and MTrPs is unclear.[125] However, it has been suggested that there

might be a correlation between MTrPs and a class of acupuncture points referred to as Ah Shi points (pain points). Ah Shi points are a class of acupuncture points positioned outside the traditional Chinese meridians and are commonly treated by traditional acupuncturists for painful conditions including muscle spasm.[126] Given the uncertainty of this relationship, we included trials that utilised acupuncture only if it was combined with dry needling or injection of MTrPs.

Types of outcome measures

A trial was included if any of the following primary outcome measures were used: Visual Analogue Scale; The Foot Health Status Questionnaire; The Foot Function Index or any other health-related quality of life measure. Secondary outcome measures investigating physiological changes (e.g. joint range of motion and pressure pain threshold) following the intervention were included providing at least one of the aforementioned primary outcome measures was reported.

Search methods for identification of studies

In April 2010 the following electronic databases were used to search the literature: Ovid MEDLINE (1950 to date), Ovid EMBASE (from 1988 to date), Ovid AMED (from inception), CINAHL (1982 to date), SPORTDiscus (from inception) and AMI (1968 to date). A full electronic search strategy from the EMBASE database is included in Table 3.1.

Table 3.1. Search strategy: Embase search strategy, April, 2010

#	Searches	Results
1	exp Lower Extremity/	40728
2	exp Therapeutics/	2166711
3	exp Myofascial Pain Syndromes/	1620
4	exp "Outcome and Process Assessment (Health Care)"/ or exp "Quality of Life"/ or exp "Outcome Assessment (Health Care)"/ or exp Questionnaires/ or exp Treatment Outcome/	659724
5	exp Heel Pain/ or exp Pain Assessment/ or exp Foot Pain/ or exp Musculoskeletal Pain/	31966
6	exp fasciitis/	3790
7	exp methodology/	1073381
8	(leg* or calf or calves or foot or feet or ankle* or toe* or plantar fascia or plantar aponeurosis or plantar ligament or area).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]	551324
9	(needl* or acupuncture or inject*).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]	372382
10	(trigger area* or trigger point* or "myofascial trigger point pain" or "myofascial pain components" or taut band).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]	967
11	(systematic review or "randomised controlled trial" or RCT or qausi experimental or "single subject design" or comparative study).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]	170767
12	VAS or “visual analogue scale” or “visual analysis scale” or “activities of daily living” or “quality of life” or “pressure pain threshold” or algometry	131691
13	9 or 2	2418925
14	6 or 3 or 10	5928
15	5 or 12 or 4	704415
16	11 or 7	1179426
17	1 or 8	560575
18	13 and 14 and 15 and 16 and 17	89

In addition, experts in the field of MTrP therapy were questioned about their knowledge of further articles not captured in the database search. The reference lists of all included articles were hand searched for trials meeting the inclusion criteria. Finally, Google Scholar and SUMsearch were searched for grey literature (information that has not been published, or if published is not readily accessible). No language restrictions were applied.

Study selection

Two investigators (MC and an impartial assessor) independently scanned the title and abstracts for information fulfilling the inclusion criteria. If a decision could not be made it was retained until the full text was obtained. A full text of all potentially eligible articles was then accessed and reviewed by both assessors to ensure eligibility. Discrepancies between the two reviewers were resolved using a third assessor (KBL).

Data Extraction

A data extraction form was modified from an existing standardised extraction form produced by the Centre for Reviews and Dissemination.[127] The content of the form included topics relevant to acupuncture and trigger point dry needling research as recommended by the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA).[128] Relevant data (means, mean differences, standard deviations, and *p* values) were extracted from the selected articles by two of the investigators (MC and SEM). Any disagreement between the authors was discussed with KBL and a general consensus agreed upon.

Assessment of methodological quality

Two reviewers (MC and an impartial assessor) independently assessed the methodological quality of the included articles using the Quality Index (QI)[129] tool, which has been shown to have high internal consistency (KR-20: 0.89), good test-retest reliability (r = 0.88) and inter-rater reliability (r = 0.75). The original Quality Index is a 27-point checklist which covers four domains: internal validity, external validity, reporting and power. The literature has not established cut off values for the Quality Index methodological quality assessment tool. Downs and Black[129] stated that "the value of a single global score needs to be tested by reviewers making such an assessment before rather than after using the 27 item checklist" (p. 381). The use of a single summary score

or global score has been criticised in the literature as it might eliminate sources of heterogeneity among the results.[130]

For this systematic review, three items were modified. First, for Item 10, two points were allocated to trials that utilised confidence intervals as well as *p* values for the main outcomes as confidence intervals provide more information regarding the magnitude and precision of a treatment effect.[131] Second, Item 25 was removed as it has been shown that case mix adjustment cannot reduce the extent of bias in non-randomised trials.[130] Finally, Item 27 was removed as a minimally important difference using the visual analogue scale has not been calculated for MTrP interventions in participants with plantar heel pain.

3.5. Results

A flow diagram of the study selection process is presented in Figure 3.1. A total of 342 studies were identified through database and other sources. Following inspection of the titles and abstracts, 334 were excluded. Of the 8 remaining studies, a full text of unpublished data (identified from conference abstracts) by Imamura et al.[132] and Sconfienza[133] could not be obtained from the authors. Further analysis of the full text from the remaining 6 studies resulted in 3 clinical trials fulfilling the inclusion criteria[134-136] (Table 3.2) and 3 trials were excluded.[137-139]

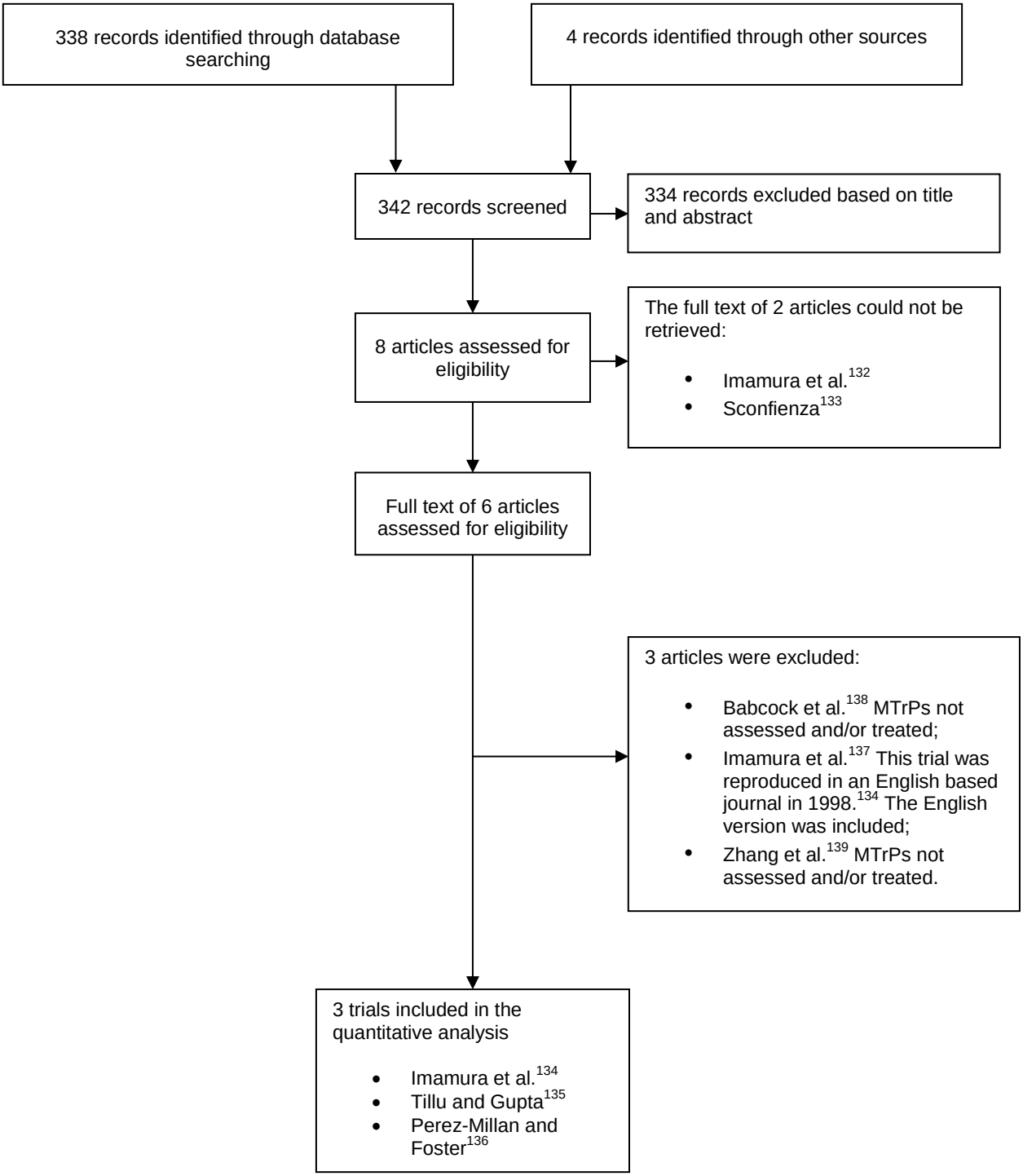


Figure 3.1. Flow of information through the systematic review

Table 3.2. Characteristics of included studies

Trial	Design	Number allocated to experimental and control groups	Mean age in years (SD)	% Female	Mean duration of disease in months (SD)	Exclusion criteria	Criteria used to identify the MTrP
Tillu and Gupta[135]	Quasi-experimental (one group)	Experimental = 18	49.1 (10.7)	72.3%	25.1 (10.7)	History of heel surgery or cortisone injection in last three months	Not reported
Imamura et al.[134]	Quasi-experimental (two groups, non-randomised)	Experimental = 15 (Actual number is unclear but it would appear that 20 were recruited and 5 dropped out) Control = 9 at discharge.	Experimental: 50.0 (12.2) Control: 44.0 (Not reported)	89.7%	27.0 (Not reported)	Not reported	MTrP[a] identified via palpation (local tenderness and taut band)
Perez-Millan and Foster[136]	Quasi-experimental (one group)	Experimental = 11	39.5 (12.7)	72.8%	39.0 (5.0)	Not reported	Not reported

[a]MTrP = Myofascial trigger point

Quality of the evidence

The inter-rater reliability of total Quality Index scores was not calculated due to the small number of trials included. Perfect agreement was recorded on all items except question 4 where there was 67% agreement between the assessors.

Table 3.3 presents the results from the quality assessment. All included studies were of a poor methodological quality. The total score of the Quality Index ranged from 7/27 to 12/27 with a mean Quality Index score of 10/27 across the three trials. The internal validity domain rated most poorly across the trials due to the presence of selection,[134-136] detection,[134] statistical,[134] performance,[134-136] and attrition bias.[134] In addition, all three trials used secondary outcome measures that were not valid and reliable.

Table 3.3. Evaluation of trial quality

Quality Index items	Imamura et al.[134]	Tillu and Gupta[135]	Perez Millan and Foster[136]
Reporting			
1. Study hypothesis/aim/objective	1	1	1
2. Main outcomes	1	1	1
3. Characteristics of the participants	0	0	0
4. Interventions of interest	0	1	0
5. Distributions of principal confounders in each group	0	0	0
6. Main findings	0	1	1
7. Estimates of random variability for main outcomes	1	0	1
8. All the important adverse events that may be a consequence of intervention	0	0	0
9. Characteristics of patients lost to follow-up	0	1	1
10. Actual probability values for main outcomes	0	1	0
External validity			
11. Were subjects who were asked to participate representative of the entire population from which they were recruited?	1	1	0
12. Were subjects who were prepared to participate representative of the entire population from which they were recruited?	0	0	0
13. Were the staff, places, and facilities representative of the treatment the majority of subjects received?	1	0	1
Internal validity (bias)			
14. Was an attempt made to blind subjects to the intervention they received?	0	0	0
15. Was an attempt made to blind those measuring main outcomes of the intervention?	0	0	0
16. If any of the results of the study were based on “data dredging”, was this made clear?	0	1	1
17. Do analyses adjust for different lengths of follow-up?	0	1	1
18. Were appropriate statistical tests used to assess the main outcomes?	1	1	1
19. Was compliance with the intervention reliable?	1	1	1

Table 3.3. Evaluation of trial quality ("continued")

20. Were main outcome measures reliable and valid?	0	0	0
Internal validity (selection bias)			
21. Were patients in different intervention groups recruited from the same population?	0	0	0
22. Were subjects in different intervention groups recruited over the same period of time?	0	0	0
23. Were subjects randomized to intervention groups?	0	0	0
24. Was the randomized intervention assignment concealed from both patients and staff until recruitment was complete and irrevocable?	0	0	0
[a]25. Was there adequate adjustment for confounding in the analyses from which main findings were drawn?	x	x	x
26. Were losses of subjects to follow-up taken into account?	0	1	1
Power			
[a]27. Did the study have sufficient power to detect a clinically important effect where the probability for a difference due to chance was less than 5%?	x	x	x
Total score (/27)	**7**	**12**	**11**

Instructions for use

For Q 1-9 one point is allocated for Yes and zero points for No.

For Q 5 two points are allocated for Yes, one point for Partially and zero points for No.

For Q 10 two points are allocated for Yes, one point for Partially and zero points for No.

For Q 11-27 one point is allocated for Yes, zero points for No and zero points for Unable to Determine.

[a]Item removed.

Trial characteristics

All trials had a quasi-experimental design with pre-test and post-test measures. Imamura et al.[134] conducted a quasi-experimental trial with a non-randomised control group to evaluate the effectiveness of 1% lidocaine injections of MTrPs in combination with physical therapy or conventional therapy alone within the foot and leg (Table 3.4). The physical therapy component included heat application for 20 minutes and faradic stimulation over the area treated for another 20 minutes. Stretching exercises were prescribed (3 times per day for 15 seconds) after heat application. In addition, relaxation

exercises were issued to some participants if required. In contrast, the control group received conventional therapy, although the details were not included.

Table 3.4. Types of interventions, treatment regime and outcome measures

Trial	Intervention	Trigger points and Acupuncture points selected for treatment	Outcome measure	Number of treatment sessions per week
Tillu and Gupta[135]	25mm acupuncture needle (diameter unknown) inserted for 15 minutes and stimulated every 5 minutes for 5 sec. Needle was manipulated to produce *de qi.* No control group.	(i) Acupuncture points KI.3; BL.60 and SP.6 (ii) Gastrocnemius [a]MTrP and heel MTrP. Specific location of MTrP in the heel and calf not identified.	(i) Visual analogue scale (ii) Verbal pain score Outcome measures recorded at 4 and 6 weeks post baseline.	4 sessions of acupuncture/1 per week. If symptoms were not resolved after this period, 2 sessions (1 per week) of acupuncture and dry needling were implemented.
Imamura et al.[134]	22-25 gauge needle repetitively inserted and withdrawn with injection of 1% lidocaine into the [a]MTrP plus [b]standard therapy. Control group received conventional conservative therapy but not outlined in the methods.	Medial head of Gastrocnemius; Soleus; Tibialis posterior; Popliteus; Abductor hallucis; Peroneus Longus and Flexor digitorum brevis	(i) Duration of treatment (ii) Visual analogue scale (iii) Pressure pain threshold Outcome measures recorded at discharge, 6 and 24 months	The number of sessions and times per week varied between the groups
Perez-Millan and Foster[136]	10-120mm acupuncture needle (0.20-0.25mm diameter); plus electrostimulator (2-4 Hz) for 20-30 minutes. No control group.	(i) Acupuncture points KI.1, 3, 6; BL.60, 67; GB 44 (ii) [a]MTrPs points in the heel and arch regions	(i) Visual analogue scale (ii) [c]Foot function index questionnaire Outcome measures recorded at 6 weeks post baseline	6 sessions/1 per week

Table 3.4. Types of interventions, treatment regime and outcome measures (“continued”)

[a]MTrP = Myofascial trigger point.

[b]Standard therapy = implemented once per day for three days following the injection: included: (i) heat (20min) and faradic stimulation over affected area for 20min, (ii) stretching for three days, 3 times per day for 15 seconds after hot pack application, (iii) participants advised to avoid walking and standing for two days post injection.

[c]Foot function index questionnaire used in this trial was not validated.

Tillu and Gupta investigated the effectiveness of a four-week course of traditional acupuncture followed by a two-week course of trigger point dry needling combined with acupuncture. This trial was not a cross-over design in the strict sense, rather all participants received the course of treatment in the same order. In contrast, Perez-Millan and Foster[136] investigated the effectiveness of trigger point needling combined with electro-acupuncture. Tillu and Gupta[135] and Perez-Millan and Foster[136] did not include a control group for comparison (refer to Table 3.4 for a description of the trigger point dry needling and injection details).

The characteristics used to identify a MTrP were not described by Tillu and Gupta[135] or Perez-Millan and Foster,[136] however Imamura et al.[134] used the common criteria of a taut band and local tenderness to diagnose a MTrP. In addition, three trials varied in; the muscles that were treated; the size and type of needles used; the response elicited, and the duration of needle insertion. The treatment schedules were generally similar across the trials with weekly treatments for a period of six weeks. All three trials used a visual analogue scale as the primary outcome measure, although there was variability in the secondary outcome measures used.

Evidence for the effectiveness of dry needling and/or injections of MTrPs associated with plantar heel pain

As clinical heterogeneity of the included trials was evident the findings of the included studies were combined using a narrative rather than a quantitative approach. As such, meta-analysis was not performed. Table 3.5 provides a detailed description of the mean differences between and within groups for the trial by Imamura et al.[134] and mean differences within groups for Tillu and Gupta[135] and Perez-Millan and Foster.[136]

Table 3.5. Mean differences between groups and within groups of included studies

Trial	Difference between groups	Differences within groups		
Tillu and Gupta[135]	[a]N/A (one group only)	(i) [b]VAS pain: @ 4 weeks (34.7% improvement, $p < 0.001$) @ 6 weeks (67.9% improvement, $p < 0.001$) @ 6 weeks vs 4 weeks, (difference 33.2%, $p = 0.047$) (ii) Verbal pain score (% of improvement): 40.2 (40.1%) @ 4 weeks and 65.9 (32.8%) @ 6 weeks		
			Intervention	**Control**
Imamura et al.[134]	Duration of treatment (weeks): Significantly less in intervention group (83.9% difference between the groups, $p < 0.05$)	(i) Mean duration of treatment in weeks (SD)	3.4 (2.2)	21.1 (19.5)
		(ii) [b]VAS pain:		
		@ discharge	58.4% improvement, $p = 0.003$	54.9% improvement, $p < 0.05$
		@ 6 months	67.1% improvement, $p = 0.007$	Values not reported at 6 months
		@ 2 years	67.1% improvement $p = 0.002$	Values not reported at 12 months
		(iii) [d]PPT (gastrocnemius):		
		@ discharge	130% increase, $p = 0.001$	[d]PPT not reported for control
		@ 6 months	71% increase, $p = 0.009$	
		@ 2 years	55% increase, $p = 0.023$	

Table 3.5. Mean differences between groups and within groups of included studies ("continued")

		(iv) [d]PPT (medial calcaneal tubercle) at:		
		@ discharge	106% increase, $p = 0.004$	[d]PPT not reported for control
		@ 6 months	Values not reported at 6 months	
		@ 2 years	143% increase, $p = 0.007$	
Perez-Millan and Foster[136]	[a]N/A (one group only)	(i) [b]VAS pain: @ 6 weeks (46% improvement, $p < 0.001$)		
		(ii) [e]Foot function index questionnaire scores: significantly less pain for 10 out of 12 items		

[a]N/A = Not applicable

[b]VAS = Visual analogue scale

[c]MTrP = Myofascial trigger point

[d]PPT= Pressure pain threshold

[e]Foot function index was not validated

Imamura et al.[134] found a statistically significant decrease in pain for the use of 1% lidocaine injections and standard therapy for the MTrP injection group at discharge (58.4% improvement, $p = 0.003$), six months (67.1% improvement, $p = 0.007$) and two years (67.1% improvement, $p = 0.002$). Similarly, a statistically significant decrease in pain was found for the control group at discharge (54.9% improvement, $p < 0.05$, the exact p value was not reported); however there was no follow-up at six months or two years for this group. Imamura et al.[134] found a statistically significant decrease in the duration of treatment between the injection and control groups (3.4 weeks versus 21.1 weeks respectively). Importantly the only between-group comparison made in this trial was for the total duration of treatment.

The other two trials by Tillu and Gupta[135] and Perez-Millan and Foster[136] only included a treatment group and no comparison was made to a control group. Nevertheless, Tillu and Gupta[135] observed a statistically significant improvement in pain for a two-week course of dry needling and acupuncture when compared to a previous four-week period of acupuncture treatment ($p = 0.047$). Finally, Perez-Millan and Foster[136] found a significant improvement in pain for the use of dry needling and electro-acupuncture ($p < 0.001$).

3.6. Discussion

The aim of this study was to conduct a systematic review of the literature to evaluate the evidence for the effectiveness of dry needling and/or injections of MTrPs associated with plantar heel pain. The search strategy found three quasi-experimental trials. One trial compared the effectiveness of 1% lidocaine injections combined with standard therapy to standard therapy alone. A second trial evaluated the effectiveness of trigger point dry needling combined with electro-acupuncture, whereas a third trial evaluated the effectiveness of acupuncture followed by a period of acupuncture combined with trigger point dry needling. However, it is important to note that all trials were of poor methodological quality.

There were two major reasons for the low quality of the included trials. First, the internal validity of all three trials was potentially threatened. Tillu and Gupta[135] and Perez-Millan and Foster[136] did not include a control to compare the intervention to and therefore, the relationship between the dependent and independent variable might have been influenced

by non-intervention effects, such as the natural course of the disorder. Imamura et al.[134] did compare the intervention to a control, however there was no evidence that the participants were randomised. Consequently, the two groups might not have been equivalent at baseline making it difficult to determine if the outcomes were a reflection of the intervention or differences in prognostic characteristics of the two groups at baseline. The internal validity of the trial by Imamura et al.[134] might have also been threatened due to a 25% loss of participants at discharge. As there was no reference to an intention-to-treat analysis the characteristics of the two groups may have become different as the trial progressed, which could have affected the estimate of the treatment effect. Further threats to internal validity might have occurred in all three trials, as no attempt was made to blind those responsible for measuring the outcomes.

Second, reporting of the trial rationale,[134-136] eligibility criteria,[135,136] study population,[134-136] details of the researcher's background,[134-136] needling and injection details,[134-136] control intervention,[134] and results,[134-136] were all incomplete. Imamura et al.[134] did provide details of the muscles that were injected, however there was insufficient information which muscles were treated during each session, the number of injections (total and per muscle), and the depth of needle insertion. In addition, Tillu and Gupta[135] and Perez-Millan and Foster[136] did not report which muscles were dry needled in the foot, the number of needles inserted into a MTrP, the depth of needle insertion, or the needle response elicited during dry needling of a MTrP. The presence of a local twitch response during trigger point dry needling is suggested to help confirm the presence of a MTrP and is associated with a positive therapeutic outcome.[54] Furthermore, sensations described by the patient as a result of needling might be predictive of the analgesic response.[140]

The reporting in two trials also failed to provide sufficient detail of the criteria used to identify a MTrP. While Imamura et al.[134] used the common criteria of a taut band and local tenderness to diagnose a MTrP, Tillu and Gupta[135] and Perez-Millan and Foster[136] did not provide any information regarding the diagnosis of a MTrP. As there is considerable variability in the criteria used to identify MTrPs[51] and the reliability of trigger point palpation has not been reported in the lower extremity and foot, it is imperative that researchers outline detailed diagnostic criteria used to identify MTrPs.[51] This would ensure that the methods used to diagnose MTrPs is transparent and can be reproduced.

This systematic review has a number of implications for further research. First, to reduce bias it is essential that when evaluating the effectiveness of dry needling and/or injections of MTrPs associated with plantar heel pain that rigorous randomised controlled trial (RCT) methodology be used. In addition, future RCTs should be designed based on criteria that are recognised for the quality assessment of randomised controlled trials.[141] Second, it is necessary that outcome measures used are reliable and valid and include both foot-specific and generic measures.[142] Finally, it is highly recommended that the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) be used to ensure transparency. This should also include detailed information about the criteria used to identify the presence of a MTrP as there is substantial variability in the criteria used. This will ensure that such trials include sufficient information for the methodology to be critiqued and allow comparisons to be made with similar investigations.

This systematic review also needs to be viewed in light of some limitations. Two of the included trials[135,136] combined trigger point dry needling with acupuncture. While the two techniques have a number of similarities they are vastly different conceptually. Furthermore, an assessment of the effectiveness of trigger point dry needling and/or injections might be problematic when it is combined with acupuncture as it makes it difficult to isolate the effectiveness of either technique. Hence, the results can only be generalised to people with plantar heel pain where both interventions are implemented.

3.7. Conclusion

This systematic review found limited evidence for the effectiveness of dry needling and/or injections of MTrPs associated with plantar heel pain. Two trials were found but the quality was poor and serious threats to internal validity were evident. In addition, the reporting of the methodology in these trials was inadequate, which limits comparisons with other investigations. As such, it would be impossible to replicate these studies. Future trials in this area need to be parallel-group randomised controlled trials that contain adequate measures to reduce bias. It is also strongly recommended that trials investigating the effectiveness of trigger point dry needling and/or injections provide

detailed reporting consistent with the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA).

In response to the findings of the systematic review, a randomised controlled trial was conducted to evaluate the effectiveness of dry needling for plantar heel pain (Chapter 5). However, prior to conducting the randomised controlled trial, a protocol to guide the use of dry needling for plantar heel pain required development. The next Chapter presents the findings of a study that involved surveying experts worldwide to gauge their opinions about dry needling for plantar heel pain. The aim was to develop a dry needling treatment, based on a consensus opinion, that could be used in a trial to evaluate the effectiveness of dry needling for plantar heel pain.

CHAPTER 4

4.0. Consensus for dry needling for plantar heel pain: a modified Delphi study

4.1. Background

Chapter 3 provided the results of a systematic review that evaluated the effectiveness of trigger point dry needling for plantar heel pain. The aim of this chapter was to systematically review the literature evaluating the effectiveness of dry needling (and/or injections of MTrPs) associated with plantar heel pain. Two studies included in the review[135,136] found a statistically significant reduction in pain, for the use of dry needling in combination with traditional Chinese acupuncture, but the methodological quality of both studies was poor. Therefore, further good quality evaluations of dry needling are required to help inform practice. Further, to ensure these trials have external validity, a treatment protocol is required that has a broad consensus from experts practising in the area. Treatment protocols to evaluate the effectiveness of acupuncture for tennis elbow[143] and depression[144] have been developed by consensus, although at present no protocol for plantar heel pain has been documented. The aim of this study was to seek information from experts that use dry needling for plantar heel pain, in order to develop a consensus-driven treatment protocol to be used in the randomised controlled trial (Chapter 5).

The findings of this modified Delphi study were published in *Acupuncture in Medicine* in 2011:

Cotchett MP, Landorf KB, Munteanu SE, Raspovic AM: Consensus for dry needling for plantar heel pain (plantar fasciitis): a modified Delphi study. *Acupunct Med* 2011, 29: 193-202 (http://aim.bmj.com/content/29/3/193.abstract).

4.2. Objective

To conduct a consensus study, using a modified Delphi technique, to determine how experts use dry needling for plantar heel pain, which could be used in a randomised controlled trial.

4.3. Research question

Can consensus be gained for a standard protocol for dry needling for plantar heel pain?

4.4. Methods

Consensus method

Approval for this study was obtained from the La Trobe University, Faculty of Health Sciences Human Ethics Committee (reference number FHEC09/200 – Appendix 1). A modified Delphi process was used to develop a consensus for use of dry needling for plantar heel pain. This process attempts to achieve a convergence of opinion among experts on a specific topic, over a series of rounds or iterations.[145] The advantage of this method is that participants remain anonymous during all rounds of the survey and can express opinions without influence of dominant characters.[145]

Selection of experts

Little consensus exists for the definition of an expert and also the criteria used to select experts for consensus studies.[146] We selected experts based on topics that have arisen in the literature, which have defined experts based on knowledge, and the capacity to influence policy.[146,147]

Experts with knowledge of dry needling for plantar heel pain

Therapists involved in the instruction and facilitation of dry needling courses were considered leaders in the profession with substantial knowledge of the study topic. In addition, the Delphi panellists also considered authors of peer-reviewed articles to be leaders within the profession, although there is no guideline to determine how many peer-reviewed articles need to be published before an author is considered an expert.[148] Nevertheless, some researchers have used this criterion previously to select experts for consensus studies.[149] For our study, we considered the chief investigators of each of these publications to be experts and invited them to participate.

Experts with the ability to influence policy

Therapists that were members of a professional association and linked to an acupuncture and dry needling interest group were invited to participate. The Delphi panellists

considered these therapists to have first-hand experience with dry needling with the potential to influence clinical practice guidelines within their profession.

Methods to reduce bias in the selection of experts

To minimise bias in selection of experts and increase the external validity of the study,[146] we invited a heterogenous sample consisting of therapists from multiple countries that practised varying treatment rationales. Invited participants were also largely unknown to the Delphi panellists.[150]

Expert identification

Participants were identified in July 2009 using two methods. First, a nomination process was used whereby well-respected individuals within the target population were chosen.[151] For our study, a physical therapist with 17 years clinical experience, and the author of 9 peer-reviewed articles in the field of myofascial pain, nominated 8 therapists who she considered leaders within the profession. Second, an internet search was performed by the chief investigator to locate dry needling courses taught worldwide. The email address corresponding to the course and/or the course instructor(s) was identified and saved for future correspondence. In addition, an internet search of acupuncture and dry needling special interest groups within physiotherapy, osteopathy, myotherapy, podiatry and medical associations worldwide, was conducted. Nominated experts and therapists linked to dry needling courses and special interest groups were sent an email invitation to participate.

The Delphi panellists

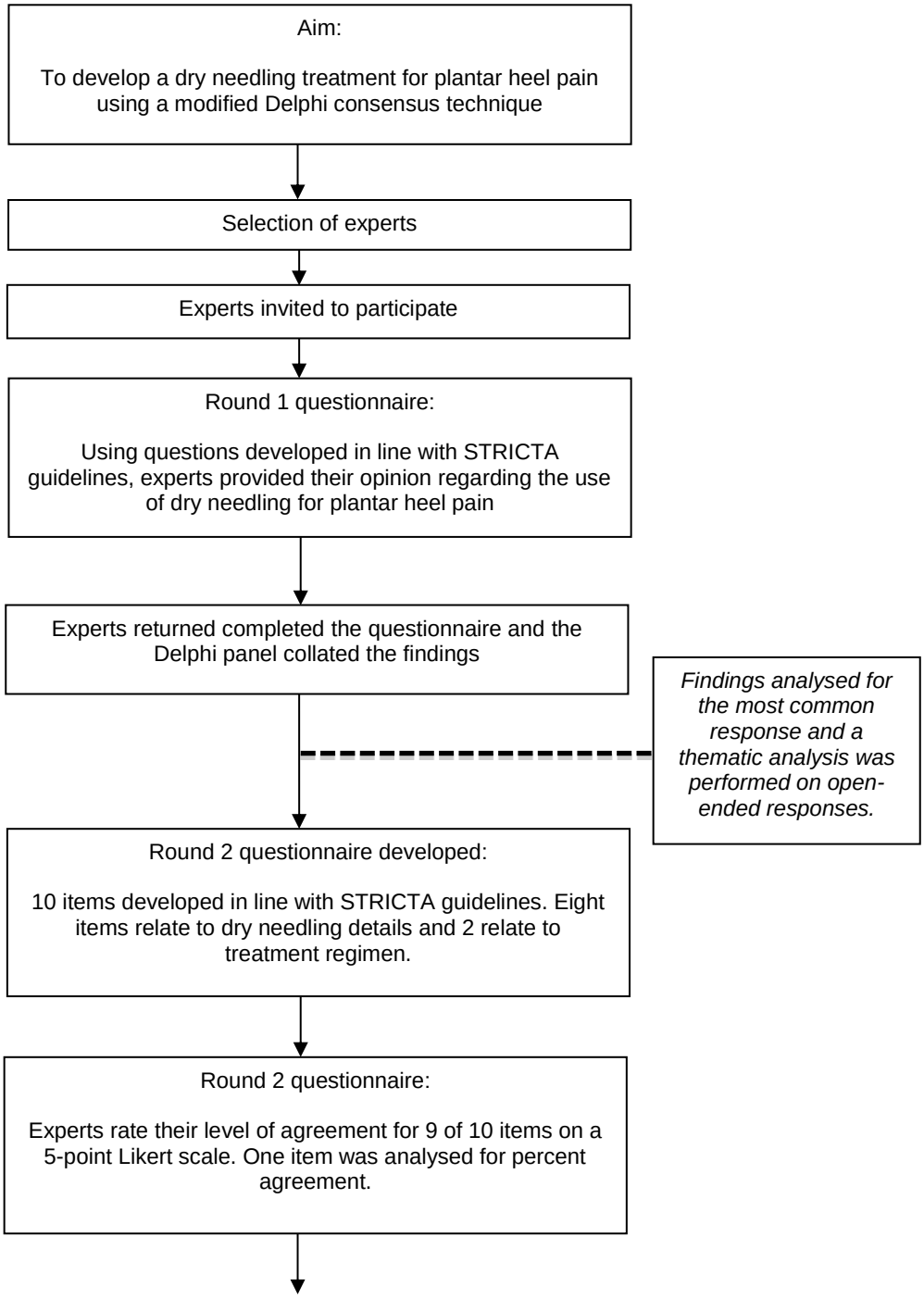
The survey was constructed by 2 physical therapists, each with more than 8 years of dry needling experience and 4 university-based podiatrists (the investigators on this project) with an average of 17 years of practice-related experience, including the management of plantar heel pain.

Procedure

In order to develop a dry needling protocol, with specific details of needling techniques, we used a modified Delphi process that incorporated a structured questionnaire with the opportunity for open-ended responses in Round 1. This is a common method employed when there is adequate information regarding the issue of interest.[152] Similar to a

traditional Delphi process, we developed a list of items in Round 2 based on Round 1 responses. However, instead of asking participants to rank order or prioritise items in Rounds 2 and 3 (i.e. to develop consensus), we rephrased items following Round 2 based on highlighted themes. This approach is often undertaken in a modified Delphi process to move toward consensus.[153]

Figure 4.1 highlights the flow of information throughout the study. The initial invitation contained a Uniform Resource Locator (URL) to the Survey Monkey™ website (www.surveymonkey.com) that included the Participant Information Sheet, Consent Form and Round 1 of the survey. This website was used to deliver the questionnaire in all rounds of the study. Participants were asked to complete the survey electronically, within two weeks of receiving the email. Up to two reminders were sent to those participants that did not complete the survey in a pre-specified time (two weeks). All participants provided electronic consent to participate.


Aim:
To develop a dry needling treatment for plantar heel pain using a modified Delphi consensus technique
Selection of experts
Experts invited to participate
Round 1 questionnaire:
Using questions developed in line with STRICTA guidelines, experts provided their opinion regarding the use of dry needling for plantar heel pain
Experts returned completed the questionnaire and the Delphi panel collated the findings
Findings analysed for the most common response and a thematic analysis was performed on open-ended responses.
Round 2 questionnaire developed:
10 items developed in line with STRICTA guidelines. Eight items relate to dry needling details and 2 relate to treatment regimen.
Round 2 questionnaire:
Experts rate their level of agreement for 9 of 10 items on a 5-point Likert scale. One item was analysed for percent agreement.

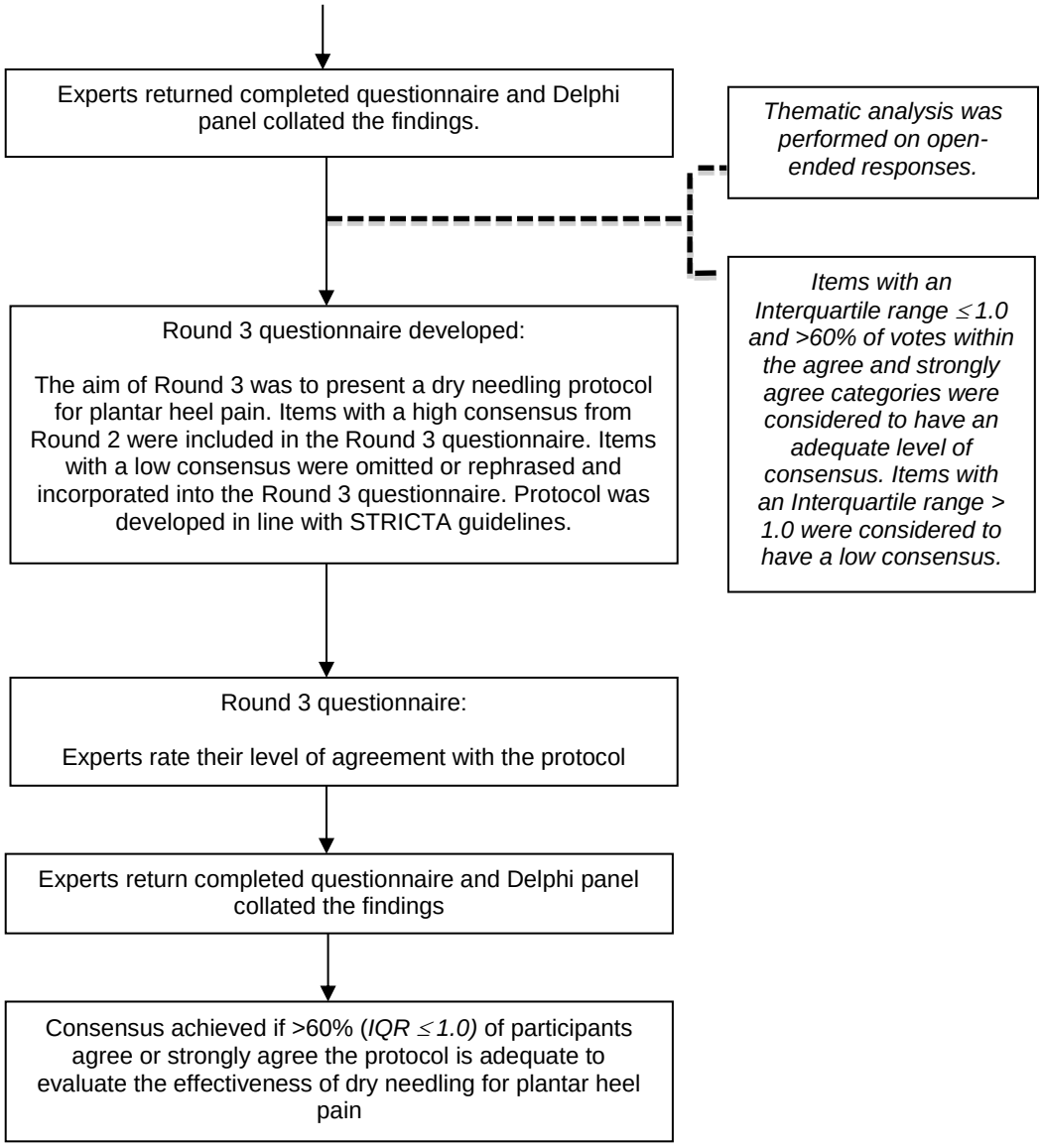


Figure 4.1. Flow of information through the modified Delphi study.

In Round 1, participants answered a series of questions and provided comments relating to their use of dry needling for plantar heel pain (refer to Appendix 2). Each question related to a section of the Standards for Reporting Interventions in Controlled trials of Acupuncture (STRICTA) guidelines.[154] After completed surveys had been received by the chief investigator, the quantitative data and open-ended responses were analysed by the Delphi panel (see Data analysis below).

In Round 2, participants were presented with the results of Round 1. The Delphi panel generated a list of 10 items considered a priority for development of a dry needling protocol for plantar heel pain taking into account Round 1 responses of the participants (refer to Appendix 3). The 10 items selected were subjectively chosen by the panel, however the items reflected the content of the STRICTA guidelines, which are heavily weighted toward reporting of 'needling details' and less to 'needling rationale', 'treatment regime' and use of 'co-interventions'. Therefore, we asked participants to answer 8 statements relating to 'needling details' and 2 to treatment regime. No items relating to use of co-interventions were incorporated because our planned trial was not designed to include alternate therapies.

For 9 of the 10 items, participants were required to rate their level of agreement on a 5-point Likert scale (from 1 indicating strongly disagree to 5 indicating strongly agree). For the 10th item, participants were asked to select the optimal needle retention time in minutes when dry needling for plantar heel pain.

The findings of Rounds 1 and 2 were used to form the Round 3 questionnaire (see Appendix 4). In this final round (i.e. Round 3), a dry needling protocol for plantar heel pain was proposed. The protocol was presented in line with the STRICTA guidelines and included information relating to treatment rationale, needling details and treatment regime. Participants were asked to indicate their level of agreement with the proposed protocol.

Data analysis

In Round 1, the Delphi panel analysed quantitative and qualitative data (i.e. from the open-ended responses). Both forms of data were exported to a Microsoft Excel

spreadsheet and placed into a category linked to the STRICTA guidelines. The categories included:

(i) Treatment rationale;
(ii) Muscles dry needled;
(iii) Depth of needle insertion;
(iv) Number of needles inserted;
(v) Needle retention time;
(vi) Manual needle stimulation;
(vii) Needle response sought;
(viii) Treatment regime.

For each category, the Delphi panel performed a thematic analysis[155] to identify and list key themes from open-ended responses. In addition, data from the structured questions were analysed for the percent agreement for each statement. Items with greater than 60% support were considered to have an acceptable level of agreement. The use of percentage measures, to represent the collective responses of participants, is also common in the Delphi process[148] although there is no consensus on what percentage of participant responses constitutes an acceptable level of agreement.

The combination of themes originating from open-ended responses and analysis of quantitative data from the structured questions helped form the Round 2 questionnaire, which was linked to the STRICTA guidelines. Items from Round 1 that displayed >60% agreement were included in the questionnaire while items with <60% support were rephrased to reflect what the majority of respondents indicated in Round 2. The questionnaire consisted of 10 items and was phrased using wording that was commonly used in open-ended responses made by participants.

The level of consensus for items 1 to 9 was determined by calculating the median, interquartile range (IQR) and percent agreement. Subsequently, each item was rated according to its level of consensus. Items with an IQR ≤ 1.0 and >60% of votes within the 'agree' and 'strongly agree' categories were considered to have an adequate level of consensus while items with an IQR > 1.0 were considered to have a low consensus.[156-158]

Item 10, which asked participants to discuss needle retention time, was not analysed using the IQR because an answer to the question could not be measured on a Likert scale (i.e. an ordinal scale). Instead, the Delphi panellists analysed the percent agreement in 5 time intervals.

At the end of Round 2 consensus ratings and open-ended responses were exported to a Microsoft Excel spreadsheet and placed into a category linked to the STRICTA guidelines, similar to Round 1. A thematic analysis was undertaken to highlight the majority theme. Items that displayed an adequate level of consensus (IQR ≤ 1.0 and >60% of votes within the 'agree' and 'strongly agree' categories) were considered an important component of a dry needling treatment for plantar heel pain and were subsequently placed in a protocol presented to participants in Round 3. The Delphi panel discussed items that displayed a low level of consensus and a decision was made to rephrase or remove each item so that a move toward consensus could be achieved. The rephrased item was then included in a protocol that was presented in Round 3. The procedure to rephrase items between rounds is a process not uncommon to a Delphi process and was conducted recently in a study that explored the use of specific statistical tests to measure consensus among a group of participants.[153]

The protocol presented in Round 3, consisted of 10 items. Each item was based on sections outlined in the STRICTA guidelines. Consensus for the proposed dry needling protocol for plantar heel pain was achieved if greater than 60% of participants (IQR ≤1) agreed that the protocol was adequate for a clinical trial to evaluate the effectiveness of dry needling for plantar heel pain.

4.5. Results

Round 1

The response rate was 75% (n = 30). Of the 75% that did respond, the chief investigator knew four participants personally and the other three members of the Delphi panel knew none. Of the 30 participants, the majority were from Australia (53%, n = 16) while 9 other countries were represented including the United Kingdom 11% (n = 3), United States of America 11% (n = 3), Spain 7% (n = 2), Belgium 3% (n = 1), Ireland 3% (n = 1), Japan

3% (n = 1), Netherlands 3% (n = 1), New Zealand 3% (n = 1) and South Korea 3% (n = 1). An invitation was also sent to therapists in Brazil, Canada, Denmark, Germany and Turkey but none responded.

The results of Round 1 are presented in Table 4.1. In regards to treatment rationale, 93% (n = 28) of participants practised dry needling according to the MTrP model. However, 33% (n = 10) of participants practised MTrP dry needling in combination with the radiculopathy model; 7% (n = 2) with traditional Chinese acupuncture; 3% (n = 1) with Western Medical Acupuncture; 3% (n = 1) with the Baldry technique and 3% (n = 1) with a 'layering approach'. Two participants did not employ the MTrP model but rather applied a "neurophysiological" approach.

Table 4.1. Round 1 findings - a breakdown of participants' responses to specific details relating to dry needling for plantar heel pain (N=30)

Section of STRICTA[a] guidelines	Item from Round 1 questionnaire	Response to item	n	%
Treatment rationale	Model	MTrP[b] model	28	93.3
		Radiculopathy model	10	33.3
		Other	6	20.0
		Non-responders	0	
Dry needling details	Muscles dry needled	Soleus	24	80.0
		Quadratus plantae	22	73.3
		Gastrocnemius	21	70.0
		Abductor hallucis	17	56.7
		Flexor digitorum brevis	17	56.7
		Posterior tibial	10	33.3
		Flexor digitorum longus	10	33.3
		Abductor digiti minimi	9	30.0
		Multifidus	8	26.6
		Flexor hallucis longus	7	23.3
		Peroneus longus	7	23.3
		Non-responders	0	
	Needle length and diameter	Depends on muscle dry needled	27	90.0
		Other	3	10.0
	Number of insertions per muscle	1	2	6.7
		2	11	36.7
		3	8	26.6
		4	2	6.7
		5	3	10.0
		10	1	3.3
		Non-responders	3	10.0
	Needle response(s) sought	Local twitch response	26	86.7
		Dull ache, heaviness, distension	28	93.3
		Needle grasp	26	86.7
		“Jump” sign	22	73.3
		Non-responders	1	3.3

Table 4.1. Round 1 findings - a breakdown of participants' responses to specific details relating to dry needling for plantar heel pain (N=30) ("continued")

	Needle retention time (minutes)	<1	10	33.3
		1	1	3.3
		2	1	3.3
		5	4	13.3
		10	5	16.7
		11-15	3	10.0
		16-20	1	3.3
		30+	1	3.3
		Non-responders	4	13.3
	Manual needle stimulation (i.e. lifting, thrusting; in and out motion)	Always	12	40.0
		Very often	6	20.0
		Sometimes	5	16.7
		Rarely	4	13.3
		Never	1	3.3
		Non-responders	2	6.7
Treatment regimen	Number of treatment sessions	1	0	0
		2	0	0
		3	3	10.0
		4	8	26.6
		5	8	26.6
		6	6	20.0
		7	1	3.3
		8	1	3.3
		Non responders	3	10.0
	Frequency of treatment:			
	In the first week	Weekly	18	60.0
	In the second week	Weekly	19	63.3
	In the third week	Weekly	14	46.7
	In the fourth week	Weekly	20	66.7
	In the fifth week	Weekly	18	60.0
	In the sixth week	Weekly	11	36.7
		Non responders	0	

[a]STRICTA = STandards for Reporting Interventions in Controlled Trials of Acupuncture.

[b]MTrP = Myofascial trigger point.

Note 1: The total number of responses relating to the *treatment rationale, muscles dry needled and needle response sought,* did not add up to 30 as multiple answers were accepted.

Note 2: Refer to Appendix 2 for an outline of the Round 1 questionnaire.

Note 3: Refer to Appendix 5 for a list of all muscles dry needled by participants.

When questioned about needling details there was substantial variability amongst participants for: (i) muscles dry needled (a total of 35 different muscles (mean = 7, SD = 6) were 'usually' dry needled for plantar heel pain (Appendix 5 – this table was included as a *Supplementary file* in the published manuscript), (ii) optimal needle retention time (range, <1 minute to 30+ minutes), (iii) number of needle insertions per muscle (range, 1 to 10), and (iv) number of treatment sessions to manage a patient with plantar heel pain (range 3 to 8). In contrast, responses were more consistent with regards to depth of needle insertion; use of manual needle stimulation; type of response elicited and frequency of treatment following the first consultation.

Based on the results of Round 1, participants in Round 2 were informed that the MTrP model would be adopted for use during subsequent development of the dry needling treatment protocol as 93% of participants used this rationale. In addition, as the range of muscles dry needled by participants was large (35 in total) it would not be possible to effectively dry needle 35 different muscles in a standard consultation of 20 to 30 minutes. As the aim of the study was to develop a treatment protocol that could be pragmatically applied in a clinical setting, the Delphi panelists presented two items in Round 2 (Item 1 and 2) to determine if participants would prefer a trial that was, (i) standardised,[139] with a fixed number of muscles to be dry needled, (ii) semi-standardised,[159] which would include a set number of muscles and an additional pre-specified list of muscles that could be assessed based on the participant's presentation, or (iii) pragmatic,[160] which would involve dry needling any muscle that was clinically relevant. Participants were also given the opportunity to respond to these items in an open-ended manner.

Round 2

All 30 participants (100% response rate) completed the survey in Round 2. Five of 9 items (item numbers 1, 3, 4, 5 and 7*)* met the criteria to be included in the dry needling protocol that was to be proposed in Round 3 (Table 4.2).

Table 4.2. Round 2 findings - participants' responses to 10 items that were formulated, based on the results of Round 1 (N=30)

Items from Round 2 questionnaire (statements posed to participants based on responses from Round 1. Participants were asked to rate their level agreement to each statement on a 5-point Likert scale, with 1 indicating *strongly disagree* to 5 *strongly agree*)	Median response (IQR)[a]	Percentage rated 4 or 5	Level of consensus	Item incorporated into final protocol (Round 3)?	Item rephrased for final protocol (Round 3)?
Item Number					
1. Assessment and dry needling of soleus, gastrocnemius, quadratus plantae, flexor digitorum brevis and/or abductor hallucis is important to be effective in the treatment of plantar heel pain?	4 (1)	86%	Moderate	Yes	No
2. To ensure that a total of five muscles are dry needled, assessment and dry needling of additional muscles including adductor digiti minimi, tibialis posterior, flexor hallucis longus, flexor digitorum longus, peroneus longus, extensor halluces longus, extensor digitorum longus, tibialis anterior, peroneus brevis, peroneus tertius, gluteus medius and/or gluteus minimus, would be adequate in the treatment of plantar heel pain?	4 (1.75)	60%	Low	No	Yes
3. The number of needle insertions per muscle depends on the total number of [b]MTrPs to be dry needled	4 (1)	80%	Moderate	Yes	No
4. Manual stimulation of the acupuncture needle is required to produce an appropriate response (sensation, local twitch response or to reproduce the patient's symptoms)	4 (1)	80%	Moderate	Yes	No

Table 4.2. Round 2 findings - participants' responses to 10 items that were formulated, based on the results of Round 1 (N=30) ("continued")

5.	Manual stimulation of the acupuncture needle is reduced if the patient is sensitive to needle stimulation	4 (1)	93%	Moderate	Yes	No
6.	The intensity of needle stimulation should be increased if the patient has had a poor response and there was not an exacerbation of symptoms following the previous visit	4 (1)	50%	Low	No	Item removed
7.	Do you agree that a clinical trial lasting six weeks, with one treatment per week is adequate to assess the effectiveness of dry needling for plantar heel pain?	4 (1)	87%	Moderate	Yes	No
8.	During the course of a clinical trial, treatment should be ceased if the participant's symptoms resolve prior to the course of the dry needling treatment	4 (2)	63%	Low	No	Yes
9.	The duration of needle insertion is shortened if the patient is sensitive to needle stimulation	4 (2)	57%	Low	No	Yes
10.	On average, following manual stimulation of the acupuncture needle to produce an appropriate response (sensation, local twitch response (LTR) or to reproduce the patient's symptoms) how long would you leave the needle in situ?	a. Removed immediately – (n = 8, 26.7%) b. <1 minute – (n = 10, 33.3%) c. 1-5 minutes – (n = 5, 16.7%) d. 6-10 minutes – (n = 5, 16.7%) e. 11-20 minutes – (n = 2, 6.7%)				

[a]IQR, interquartile range

[b]MTrP, myofascial trigger point

Note: Refer to Appendix 3 for an outline of the Round 2 questionnaire

Substantial variability was evident for the optimal needle retention time. Based on the findings in Round 2, a dry needling protocol for plantar heel pain was presented in Round 3 rather than a third structured survey. Items that did not meet the criteria for inclusion in the protocol proposed in Round 2, were either removed or amended and then presented in the final round, Round 3. Table 4.3 provides an explanation for amendment of items that displayed substantial variability in responses.

Table 4.3. Explanation for amending items that did not meet consensus criteria in Round 2 (amended for Round 3)

Item from Round 2 to be amended for Round 3	Explanation for amending the item
Item 2	
To ensure that a total of five muscles are dry needled, assessment and dry needling of additional muscles including adductor digiti minimi, tibialis posterior, flexor hallucis longus, flexor digitorum longus, peroneus longus, extensor halluces longus, extensor digitorum longus, tibialis anterior, peroneus brevis, peroneus tertius, gluteus medius and/or gluteus minimus, would be adequate in the treatment of plantar heel pain?	Participants were reluctant to standardise treatment and limit the total number of muscles to be dry needled to 5, as this would not normally occur in clinical practice. Hence, to increase external validity of a clinical trial we proposed that synergists, antagonists and more proximal muscles, which might impact on soleus, gastrocnemius, quadratus plantae, flexor digitorum brevis and abductor hallucis should be assessed and dry needled if MTrPs were present.
Item 6	
The intensity of needle stimulation should be increased if the patient has had a poor response and there was not an exacerbation of symptoms following the previous visit?	50% ([a]IQR>1.0) of participants *agreed* or *strongly agreed* with Item 6, however a number of participants stated that a poor response to treatment should be followed by a revision of the treatment plan rather than increasing the intensity of needle stimulation. Therefore, Item 6 was not presented in the proposed treatment protocol. Instead, we suggested that if a patient has a poor response to dry needling, the patient should be re-assessed and MTrPs in other muscles treated.
Item 8	
During the course of a clinical trial, treatment should be ceased if the participant's symptoms resolve prior to the course of the dry needling treatment?	63% (IQR>1.0) of participants *agreed* or *strongly agreed* with Item 8, although some participants suggested that cessation of treatment should reflect resolution of symptoms and also clinical findings relevant to the presenting complaint. A statement in Round 3 was generated to reflect this opinion.

Table 4.3. Explanation for amending items that did not meet consensus criteria in Round 2 (amended for Round 3) ("continued")

Item 9	
The duration of needle insertion is shortened if the patient is sensitive to needle stimulation?	57% (IQR>1.0) of participants agreed or strongly agreed with Item 9. To accommodate a wider range of opinions, we proposed that manual stimulation of the acupuncture needle will be reduced if the patient is sensitive to needle stimulation. If this action is insufficient to reduce the painful stimulus, the manipulation will be ceased and the needle left in situ for 5 minutes. If the painful stimulus is still not tolerated by the patient the needle will be removed.
Item 10	
On average, following manual stimulation of the acupuncture needle to produce an appropriate response, how long would you leave the needle in situ?	As there was divergence of opinion in response to this statement and as there is no current recommendation for optimal needle retention time for dry needling MTrPs associated with plantar heel pain, we proposed the needle remain in situ for 5 minutes, after an appropriate response had been achieved. This needle retention time would accommodate 75% of responses to item 10.

[a]IQR (interquartile range)

Note: Item numbers displayed in Table 4.3 correspond to the item numbers presented in Table 4.2

Round 3

Twenty eight participants (93% response rate) completed the survey in Round 3. One participant failed to respond and the Delphi panellists excluded another because the participant did not routinely use dry needling as a first line management for plantar heel pain. The median level of agreement was 4 on a 5-point Likert scale (IQR = 1). Eighty seven percent of respondents either strongly agreed (29%, n = 8) or agreed (58%, n = 19) with the proposed protocol, which was developed with a clinical trial to evaluate the effectiveness of dry needling for plantar heel pain in mind. Only 4% (n = 1) *disagreed* with the proposed protocol. Table 4.4 provides a detailed description of the dry needling treatment protocol based on the results of the previous two rounds. Following completion of Round 3, the Delphi panel decided to exclude the posterior tibial muscle as a structure to be dry needled due to a recent publication that highlighted the hazardous nature of needling the posterior tibial muscle without ultrasound guidance.[161]

Table 4.4. Dry needling protocol for plantar heel pain that was presented in the final round, Round 3

Consultation	Treatment will be conducted within a 30-minute timeframe. The participant will be lying down.
Rationale	Myofascial trigger point ([a]MTrP) model
MTrP diagnosis	Criteria used to identify a MTrP will include a list of essential criteria and a list of observations that help confirm the presence of a MTrP.[40] A flat palpation or pincer grip technique will be used to locate a MTrP.[52]
Dry needling details	1. *Brand of acupuncture needle*: Seirin® J-Type or Hwa-To® Ultraclean 2. *Muscles to be dry needled*. Muscles to be assessed first will include those harbouring MTrPs that might be responsible for the participant's pain including the soleus, quadratus plantae, flexor digitorum brevis, and abductor hallucis muscles. Synergists and antagonists of these muscles will also be assessed for MTrPs. These muscles will include the gastrocnemius, flexor digitorum longus, flexor hallucis longus, peroneus longus, peroneus brevis, tibialis anterior, extensor hallucis longus, extensor digitorum longus, adductor hallucis, abductor digiti minimi, lumbricales and interossei. In addition a search will be undertaken for MTrPs in muscles which might be influencing the participant's loading of the aforementioned muscles. These muscles will include the piriformis, gluteus maximus, gluteus medius, gluteus minimus, tensor fascia latae, adductor longus, adductor magnus, adductor brevis, semitendinosis, semimembranosis, and biceps femoris. 3. *Needle length and diameter*. Needle length will be determined by the location of the MTrP to be dry needled. Most commonly the needle length will range from 30 to 75mm. The diameter of the needle will be 0.30mm but will be varied depending on the participant's tolerance to insertion of the needle. A smaller diameter needle may be used if needle insertion is uncomfortable. 4. *Needle insertions per muscle*. The number of needle insertions per muscle will depend on: the number of MTrPs to be dry needled; participant's tolerance to needle insertion; responsiveness of the tissue to dry needling; and level of post needle soreness for a specific muscle.

Table 4.4. Dry needling protocol for plantar heel pain that was presented in the final round, Round 3 (‘continued”)

	5. *Response elicited*. Dry needling of a MTrP will attempt to elicit an appropriate response such as a: local twitch response (LTR); sensation such as a dull ache, heaviness, distension, pressure or bruising; and/or a reproduction of the participant's symptoms. If an appropriate response is not elicited the needle will be removed and the participant re-examined. 6. *Manipulation of the acupuncture needle*. Following insertion, the acupuncture needle will be withdrawn partially and advanced repeatedly to produce an appropriate response. If the participant is sensitive to insertion of the needle the manipulation will be reduced. If this action is insufficient to reduce the painful stimulus, the manipulation will be ceased and the needle left in situ. Alternatively, the needle may be replaced with a needle that has a smaller diameter. *7. Needle retention time*. The needle will remain in the muscle for as long as it takes to produce an appropriate response and is tolerated by the participant. Once this has occurred the needle will be left in situ for 5 minutes. This will allow sufficient time for the stimulus to subside in participants that are sensitive to the treatment.
Treatment regimen	The clinical trial will involve 1 treatment per week for 6 weeks. Treatment will be ceased if a participant's symptoms resolve prior to the course of the dry needling treatment. However, if a participant experiences a relapse within the 6 week treatment period they will be offered further weekly treatment (s) until the end of the 6 week course.

[a]MTrP, Myofascial trigger point

4.6. Discussion

In preparation for future clinical trials to evaluate the effectiveness of dry needling for plantar heel pain, we conducted a modified Delphi process to develop and obtain consensus for a dry needling protocol. Experts in the use of dry needling for plantar heel pain, from varying allied health and medical backgrounds, participated in this project by indicating their level of agreement regarding specific dry needling issues. Questions put to the participants were in accordance with the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA).[154]

Following a series of three rounds, 93% of the experts surveyed agreed that the dry needling protocol proposed would be adequate for a clinical trial to evaluate the effectiveness of dry needling for plantar heel pain. This is the first study to have established a protocol for the use of dry needling for plantar heel pain. The protocol provides a detailed outline of a dry needling treatment including: treatment rationale; muscles to be assessed; type of acupuncture needle used; depth of needle insertion; needle response elicited; use of manual needle stimulation; needle retention time; frequency and total duration of treatment.

Although not a limitation, the final protocol established by consensus underwent one minor modification after Round 3 without approval from the Delphi participants. The Delphi panelists removed the posterior tibial muscle as a structure that might be assessed and if appropriate, dry needled. This was in response to a recent study recommending that needle insertion into the tibialis posterior only be undertaken using ultrasound guidance due to close proximity of neurovascular bundles.[161]

The study also needs to be viewed in light of some limitations. First, the criteria used to select experts might not have adequately identified participants with sufficient clinical experience. The criteria set were based on themes that are commonly used to define experts.[146] While we believe the criteria were sufficient to identify experts we did not set a criterion for the minimum number of years of clinical and/or research experience to be included in the study. While 63% of participants had practised dry needling for more than 5 years, 37% of participants had practised dry needling for less than this. While it may be argued that practitioners with less than 5 years of dry needling experience might not be

experts, we believe it would be unreasonable to suggest that a set number of years are required before a therapist developed expertise. In addition, it was difficult to locate a sufficient number of therapists that had practised dry needling for a long period of time. As dry needling was only popularised in the late 1970's,[98] the list of therapists with extensive experience with dry needling will take time to develop.

Second, we might have considered a criterion based on how frequently participants dry needled for plantar heel pain. While 73% (n = 22) of participants indicated that they 'usually' or 'always' used dry needling for plantar heel pain, 23% (n = 7) of participants were neutral and one participant did not use it as a first line treatment for plantar heel pain. Despite these results, we do not believe this issue affected the outcome because participants might still demonstrate expertise when they decide to use dry needling for plantar heel pain. Nevertheless, future studies may choose to consider this issue when developing inclusion criteria for selection of experts.

Third, 46% (n = 14) of participants were physiotherapists and the remainder were made up of medical practitioners, podiatrists, myotherapists, osteopaths and researchers. A limitation of this selection might be that nearly half of participants were physiotherapists, although we believe this reflects the increased use of dry needling amongst physiotherapists compared with other professions.[102] However, we recognise that there is no good-quality data to support this assertion.

Fourth, the survey results may not entirely reflect the views of experts worldwide. Fifty three percent (n = 16) of participants were from Australia while 9 other countries represented the remaining 14 participants. It might have been more appropriate and valid had we invited an even number of experts from multiple countries to assist in developing consensus. For example, if we had a greater percentage of experts from Asia in our sample it might have revealed increased use of the traditional Chinese medicine model for the treatment of plantar heel pain. Further, had experts from Canada responded to the invitation, the radiculopathy model might have been favoured as this model originated in Vancouver.

An additional limitation of our study might be the absence of a second structured survey in Round 3. This process involves administering the same survey from Round 2 in Round

3, which allows participants to alter their response in view of group findings and enables stability of participants' responses to be assessed.[153] However, because a high level of agreement had been achieved in Round 2 for the majority of key variables, we chose to present a treatment protocol in Round 3 that reflected the findings of the previous two rounds. The rationale for this approach was supported by the fact that only one person disagreed with the proposed protocol in Round 3. If there was substantial disparity (i.e. IQR >1.0), it would have been shown by greater disagreement at this stage.

4.7. Conclusion

In preparation for future clinical trials, a modified Delphi process was used to develop and obtain consensus for a dry needling protocol for plantar heel pain. Ninety three percent of participants agreed that the proposed protocol, including treatment rationale, needling details, frequency and total duration of treatment was adequate to be used in a clinical trial to evaluate the effectiveness of dry needling for plantar heel pain. The next chapter presents the results of a randomised controlled trial that evaluated trigger point dry needling for plantar heel pain, using the dry needling treatment developed by consensus presented in this chapter.

CHAPTER 5

5.0. Effectiveness of trigger point dry needling for plantar heel pain: a randomised controlled trial

5.1. Background

The systematic review presented in Chapter 3 highlighted the limited evidence for the effectiveness of dry needling for plantar heel pain and the need for high quality randomised controlled trials to be conducted. This chapter presents a randomised controlled trial that evaluated trigger point dry needling for plantar heel pain. The dry needling treatment used in the trial was based on the opinions of experts worldwide that use this technique for plantar heel pain (refer to Chapter 4).

The protocol for this randomised controlled trial was published in the *Journal of Foot and Ankle Research* in 2011:

Cotchett MP, Landorf KB, Munteanu SE, Raspovic AM. Effectiveness of trigger point dry needling for plantar heel pain: study protocol for a randomised controlled trial. *J Foot Ankle Res* 2011, 4:5. (http://www.jfootankleres.com/content/4/1/5).

The findings of the randomised controlled trial were accepted for publication in the peer reviewed journal *Physical Therapy* in 2014. The manuscript presented in this chapter has been formatted in US English (i.e. American English), according to the author guidelines of *Physical Therapy*:

Cotchett MP, Munteanu SE, Landorf KB. Effectiveness of trigger point dry needling for plantar heel pain: a randomized controlled trial. *Phys Ther* 2014, 94(8): doi: 10.2522/ptj.20130255 (Published online before print, 3 April 2014).

5.2. Objective

To conduct a randomised controlled trial to evaluate the effectiveness of dry needling for plantar heel pain

5.3. Research question

Is dry needling more effective at reducing pain beneath the heel in adults with plantar heel pain compared to sham dry needling?

5.4. Methods

Study design

We conducted a parallel group, participant blinded, randomized controlled trial comparing the effectiveness of trigger point dry needling and sham dry needling. Ethics approval was obtained from the La Trobe University's Faculty Human Ethics Committee (No. 10-015) (refer to Appendix 6 for a copy of the ethics approval letter and Appendix 7 for the Participant Information Sheet that was given to each participant. All participants signed informed consent). The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN: 12610000611022).

Acknowledgements

The authors would like to acknowledge that following trial registration, three changes were made to the Methods. These changes included the addition of: (i) a Visual Analogue Scale to record 'first step pain', (ii) the inclusion of the Credibility and Expectancy Questionnaire, and (iii) selection of six weeks as the primary endpoint to evaluate the effectiveness of dry needling for plantar heel pain. All changes made to the Methods were included in our protocol paper, which was published on the 23rd of January 2011,[162] prior to the first participant being recruited on the 8th of February 2011.

This study was funded by the Australian Podiatry Education and Research Foundation (APERF). The authors would like to acknowledge the assistance of Mr Andrew McMillan with recruitment of participants.

Setting and participants

Participants were recruited through local and major metropolitan daily newspapers (refer to Appendix 8). Inclusion criteria were: aged 18 years or older; clinical diagnosis of plantar heel pain (plantar fasciitis) in accordance with the Clinical Guidelines linked to the International Classification of Function, Disability, and Health from the Orthopedic

Section of the American Physical Therapy Association;[17] plantar heel pain for 1 month or longer; first step pain during the previous week rated at least 20 mm on a 100 mm visual analogue scale (VAS); and no previous history of acupuncture or dry needling. We excluded people with: potential contra-indications to dry needling; more serious causes of heel pain (e.g. fractures, infections, cancer); conditions that could have confounded the results (e.g. systemic inflammatory disorders); and treatment for plantar heel pain in the previous four weeks. All treatments were conducted at the La Trobe University Health Sciences Clinic, Melbourne, Australia.

Randomization

A simple, block randomization procedure was used to allocate participants to the real or sham dry needling group. An external person not directly involved in the trial used a random number generator to create an allocation sequence, containing 100 allocations (50 experimental and 50 control) under the knowledge that we would recruit fewer than this – see statistical analysis below. The allocation sequence was concealed from the researcher (MPC) enrolling and assessing participants – each participant's allocation was contained in sequentially numbered sealed and stapled opaque envelopes. Each envelope, containing the allocation, was opened immediately after all baseline measures were recorded. This method has been used previously[20] and has been recommended by the CONSORT group.[163]

MTrP diagnosis

MTrPs were identified using a list of essential criteria and a list of observations that help confirm the presence of a MTrP, including (i) a tender point within a taut band of skeletal muscle, (ii) a characteristic pattern of referred pain, (iii) patient recognition of pain on sustained compression over the tender point, and (iv) a local twitch response (LTR) elicited on dry needling of the taut band.[40] A flat palpation or pincer technique was used to palpate a MTrP depending on the muscle being assessed.

Interventions

The protocol, including needling details and treatment regimen, was formulated by general consensus[164] and was guided by the MTrP model (Table 5.1). Participants were treated by a registered podiatrist (MC) who had 12 years of clinical experience and 4 years dry needling experience. The real and sham dry needling treatments consisted of 1

treatment per week, of 30 minutes duration, for 6 weeks. Participants were followed for 12 weeks. To prevent participants determining their allocation, a curtain was placed across the thoracic spine and cushions were positioned between the participant's legs. If the participant's symptoms were bilateral both limbs were treated.

Table 5.1. Details of the trigger point dry needling intervention, implemented in the trial, consistent with the STRICTA[a] recommendations

Dry needling details	*Brand of acupuncture needle*: Seirin® J-Type (Seirin Corporation: 13-7 Yokosuna-Nishicho, Shimizu-ku, Shizuoka City, Shizuoka 424-0036, Japan) or Hwa-To® Ultraclean (Suzhou Medical Appliance Factory. 14 West Qi Lin Lance, Suzhou, China). *Muscles dry needled*. Muscles assessed first included those harbouring [b]MTrPs that might have been responsible for the participant's pain including the Soleus, Quadratus Plantae, Flexor Digitorum Brevis and Abductor Hallucis muscles. Synergists and antagonists of these muscles were also assessed for MTrPs. In addition, a search was undertaken for MTrPs in muscles, which might have influenced the participant's loading of the aforementioned muscles, including the Piriformis, Gluteus Maximus, Gluteus Medius, Gluteus Minimus, Tensor Fascia Latae, Adductor Longus, Adductor Magnus, Adductor Brevis, Semitendinosus, Semimembranosus and Biceps femoris. *Needle length and diameter*. Not pre-specified but typically ranged from 30 to 75 mm, and the diameter 0.30 mm. *Needle insertions per muscle*. The number of needle insertions per muscle depended on: the number of MTrPs to be dry needled; participant's tolerance to needle insertion; responsiveness of the tissue to dry needling; and level of post needle soreness for a specific muscle. *Response elicited*. Dry needling of a MTrP attempted to elicit sensations such as aching, soreness, pressure and if possible a local twitch response (LTR). *Manipulation of the acupuncture needle*. Following insertion, the acupuncture needle was withdrawn partially and advanced repeatedly. *Needle retention time*. The needle remained in the muscle for as long as it took to produce an appropriate response and was tolerated by the participant. Once this occurred the needle was left in situ for 5 minutes.

[a]STRICTA, STandards for Reporting Interventions in Clinical Trials of Acupuncture.

[b]MTrP, Myofascial trigger point.

Real dry needling

A detailed explanation of the real dry needling intervention including treatment rationale, dry needling details and treatment regime is outlined in Table 5.1.

Sham dry needling

Non-penetrating sham acupuncture needles (50 mm x 0.30 mm) were prepared using a protocol outlined by Tough et al.[165] and sterilised prior to each treatment. At the commencement of the treatment, a sham needle was removed from its packaging to simulate removal of a real acupuncture needle. Once the MTrP was identified by palpation, the sham needle, within its guide tube, was placed on the skin overlying the MTrP. The needle was tapped, to simulate needle insertion, and the guide tube immediately removed, while maintaining needle contact with the skin. The needle was subsequently manipulated, using an 'up and down' motion, six or seven times.[90] After five minutes, the chief investigator mimicked removal of the needle by placing a finger on either side of the point treated and pretended to remove the sham needle. A real acupuncture needle was disposed in a sharps container simulating the noise and effects associated with sharps disposal.

Outcome measures

All primary outcome measures were performed at baseline, 2, 4, 6 and 12 weeks and secondary outcome measures were performed at baseline, 6 and 12 weeks. Outcomes were measured prior to participants receiving treatment and were administered by an external person not directly involved in the trial.

The primary outcome measures included: (i) 'first step pain' (pain when getting out of bed in the morning) over the previous week measured by a 100 mm VAS, and (ii) foot pain measured by the pain subscale of the Foot Health Status Questionnaire (FHSQ),[166] a 0-100 point scale where 0 is worst foot health and 100 is best foot health.

The secondary outcome measures included: (i) foot function and general foot health measured by the FHSQ;[166] (ii) physical and mental health measured by the MOS Short-Form 36 Health Survey (SF-36) version 2;[167] (iii) depression, anxiety and stress measured

by the 21-item Depression, Anxiety and Stress Scale Short-Form 21 (DASS-21);[168] which uses a 4-point severity/frequency scale where a score of 0 indicates the symptom "did not apply to me at all" and a score of 3 indicates the symptom "applied to me very much, or most of the time" for each item; (vi) self-reported magnitude of symptom change[169] measured on a 15 point Likert scale ranging from +7 ("A very great deal better") to -7 ("A very great deal worse"); and (vii) foot posture was evaluated using the Foot Posture Index.[24]

Participants also completed the Credibility/Expectancy Questionnaire (CEQ),[170] after the first treatment only, to measure the perceived credibility and their expectations of the treatment. Participants also documented their level of activity in the previous week, at baseline, using the 7-day Physical Activity Recall (PAR) questionnaire.[171] Finally, participants were asked at each treatment, and during the 12 week follow up if they had experienced any adverse events, used other co-interventions, taken pain relieving medication for their heel pain, or developed any new medical condition(s).

Statistical analysis

To preserve baseline groups developed by randomization, and to avoid overestimating the effectiveness of dry needling, all analyses were conducted on an intention to treat basis.[172] All participants were analyzed in the group to which they were randomized regardless of (i) the treatment actually received, (ii) deviations from the trial protocol; and (iii) withdrawal from the trial. To account for missing data (16/420 VAS measures; 16/1880 FHSQ pain measures; 66/2016 SF36 measures; 30/474 CEQ measures and 20/756 DASS21 measures) we used the multiple imputation method.[173] In total, five imputed data sets were created to avoid inaccuracy that might evolve from a single imputation.[174] Baseline measures and intervention group were included as variables predictive of missing values. All analyses were completed using SPSS® version 19 and we considered $p < 0.05$ to be statistically significant. The primary end-point for predicting the effectiveness of dry needling for plantar heel pain (using the primary outcome measures) was six weeks. If the participant had bilateral symptoms, data from the most painful side was recorded and analysed, to satisfy the assumption of independent data.[175]

Continuous outcomes measured at 2, 4, 6, and 12 weeks were analyzed using an analysis of covariance[176] with baseline scores included as covariates.[177] Our decision to run an

analysis of covariance, which was pre-specified in the trial registration and protocol paper,[162] was to account for regression to the mean, which may have occurred if there were chance differences in baseline scores.[178]

Prior to running an ANCOVA we tested for several assumptions to assure validity of the analysis including linearity of the covariate, homogeneity of regression slopes, homoscedasticity and homogeneity of variances, normality and the presence of outliers.[179] The results of the ANCOVA assumption testing revealed the absence of substantial violations. Cohen's *d* was calculated to quantify the magnitude of the difference between both groups at the primary endpoint.[35] To further estimate the interventions' effectiveness, we calculated: (i) the number needed to treat (NNT) for the primary outcome measures, which were based on the number of participants that changed greater than the pre-specified MID (ii) the number needed to harm (NNH) for the difference in frequency of adverse events between the two groups, and (iii) the absolute risk reduction (ARR) for participant-reported use of co-interventions. Independent *t*-tests were used to evaluate the difference between groups for each question relating to the assessment of treatment expectancy and rationale credibility, and the level of activity in the previous week for each participant.

We determined a sample size of 76 prior to commencement of the trial. This sample size provided 80% power to detect a minimally important difference of 13 points (SD = 21) in the pain subscale of the FHSQ.[169] An alpha level 0.05 and a 5% drop out rate were factored into the calculation. This sample size was also sufficient to detect a minimally important difference of 19 mm (SD = 28) for the other primary outcome measure, 'first-step' pain measured on a VAS.[169]

5.5. Results

Study recruitment and follow up

One hundred and ninety eight participants were screened for eligibility and 84 participants were enrolled. The first and last enrollments occurred on February 8th and October the 7th, 2011, respectively. The flow of participants through the trial is illustrated in Figure 5.1. In total, 81 participants (96.4%) completed the 6 week follow up and 79 participants (94.0%) completed the 12 week follow up. For those recruited into the trial, a

total of 238 real dry needling visits (mean ± SD = 5.8 ± 0.6 per participant) and 250 sham dry needling visits (mean ± SD = 5.8 ± 0.8 per participant) were conducted over the course of the study. The mean ± SD time between each treatment was 7.0 ± 0.3 days for the real dry needling group and 6.9 ± 1.1 days for the sham dry needling group.

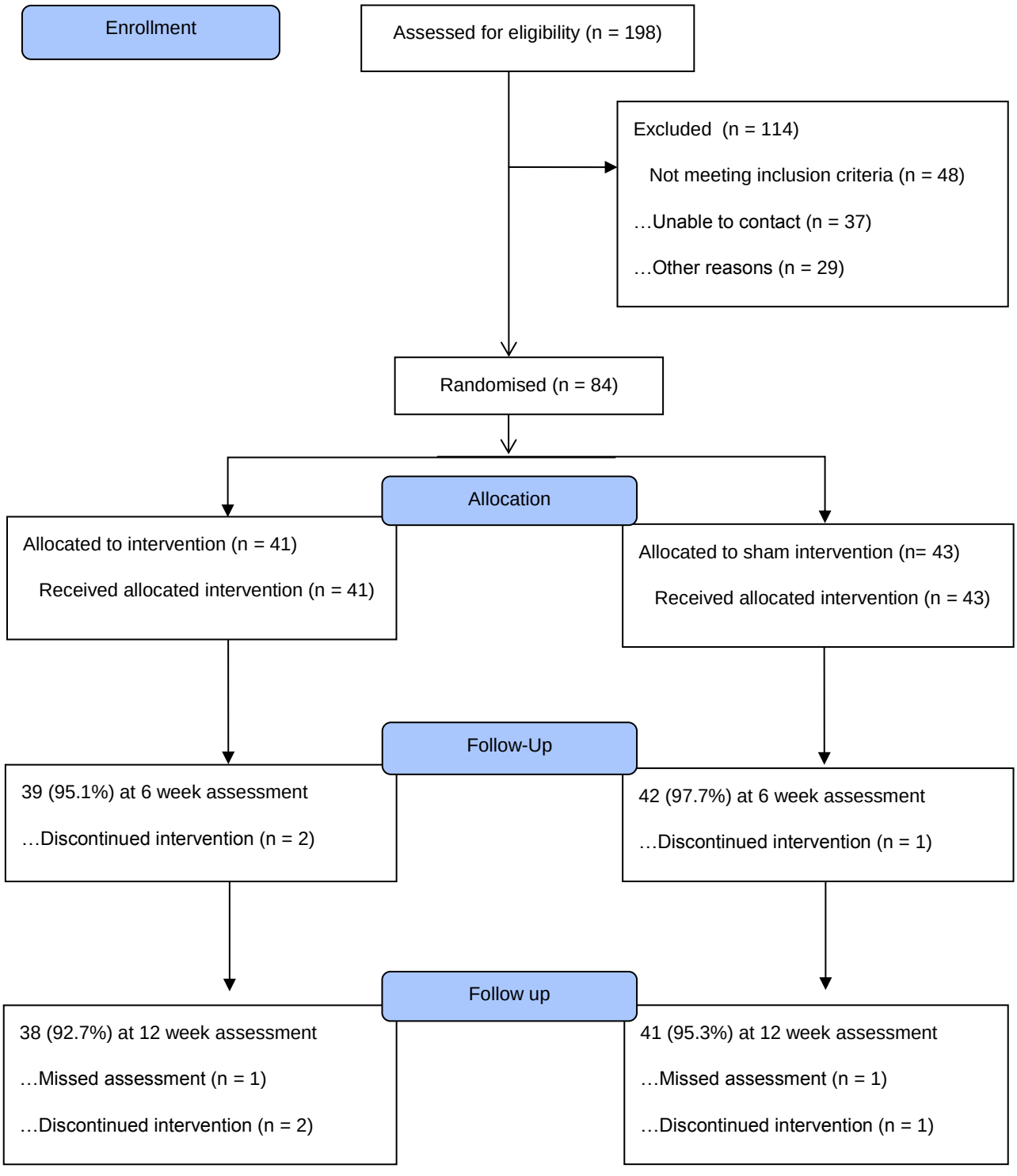


Figure 5.1. Study participant flow diagram in the randomized controlled trial

Baseline characteristics

Baseline characteristics of study participants are listed in Table 5.2. Participants had a mean ± SD age of 56.1 ± 12.2 years and 52% were male. The mean ± SD duration of plantar heel pain was 13.6 ± 12.2 months (range 1 to 95). All baseline characteristics were similar across groups. Although outcome measures for foot pain and function were slightly different, the ANCOVA model we used accounted for such confounding factors (i.e. adjusted for baseline differences in outcome measures).

Table 5.2. Baseline characteristics of participants for intervention groups[a]

Variable	Real dry needling (n=41)	Sham dry needling (n=43)
Age (years)	54.4 (12.4)	57.8 (12.0)
Sex, n (%), male	17 (41.4)	27 (62.8)
Height (cm)	168.2 (10.7)	171.1 (8.8)
Weight (kg)	86.6 (22.6)	82.9 (13.2)
Body Mass Index (kg/m^2)	30.3 (5.7)	28.4 (4.4)
Foot Posture Index	3.1 (1.4)	2.8 (1.5)
Duration of symptoms (months)	13.4 (14.1)	13.7 (17.3)
Medical conditions[b], n (%)		
Heart disease	1 (2.6)	2 (4.3)
Hypertension	13 (28.9)	8 (21.7)
Hypercholesterolaemia	13 (31.6)	10 (23.9)
Lung disease	4 (10.5)	0 (0.0)
Osteoarthritis	4 (10.5)	5 (10.9)
Thyroid disease	1 (2.6)	2 (4.3)
Depression	2 (5.3)	2 (4.3)
Anxiety	0 (0.0)	1 (2.2)
Education, (years)	14.9 (2.8)	15.8 (3.2)
First step pain, VAS[c]	67.7 (20.9)	58.5 (19.5)
Pain, FHSQ[d]	32.9 (22.1)	40.2 (19.7)
Foot function, FHSQ	45.4 (26.0)	52.6 (22.1)
General foot health, FHSQ	46.2 (31.8)	42.4 (29.0)
Health-related quality of life (SF-36 physical component)[e]	43.4 (9.0)	44.5 (8.7)

Table 5.2. Baseline characteristics of participants for intervention groups[a] ("continued")

Health-related quality of life (SF-36 mental component)	49.3 (10.7)	49.9 (8.3)
Depression, DASS-21[f]	6.4 (7.9)	6.5 (7.0)
Anxiety, DASS-21	3.8 (4.5)	3.8 (4.5)
Stress, DASS-21	10.9 (10.0)	8.5 (8.0)
Level of activity in the previous week, PAR[g]	290.5 (54.1)	303.9 (90.1)

[a]Values are mean (SD) unless stated.
[b]A co-morbidity was defined as any medical condition, reported by a participant, for which they were taking medication.
[c]VAS, Visual Analogue Scale (higher values indicate greater levels of heel pain when getting out of bed in the morning).
[d]FHSQ, Foot Health Status Questionnaire (0 corresponds to the worst foot health; 100, the best).
[e]SF-36, 36-Item Short Form Health Survey (0 corresponds to the worst quality of life; 100, the best.
[f]DASS21, Depression, Anxiety and Stress scale (higher scores indicate more symptoms).
[g]PAR, Physical Activity Recall Questionnaire (values correspond to total weekly energy expenditure in kcal/kg/wk.

Primary outcomes

Both groups showed decreased pain at the primary end-point of six weeks, however there were significant between-group effects that favored real dry needling over sham dry needling (Table 5.3). For 'first step pain', the adjusted mean difference was -14.4 mm (95% CI -23.5 to -5.2, $p = 0.002$). For foot pain using the FHSQ, the adjusted mean difference was 10.0 points (95% CI 1.0 to 19.1, $p = 0.029$). Even though the FHSQ finding was statistically significant, it did not quite reach the MID of 13 points. Cohen's *d* was -0.49 for the effect of dry needling on 'first step' pain, and 0.33 for the effect of dry needling on foot pain using the FHSQ. The number needed to treat, based on the percentage of participants that met the MID for both primary outcomes, was 4 (95% CI 2 to 12) (i.e. four patients would need to be administered the treatment in order for one patient to benefit).

Table 5.3. Mean scores and mean differences between groups for primary outcome measures[a]

Variable	Real dry needling	Sham dry needling	Adjusted mean difference (95% CI)	*P*-value	Cohen's *d*
First step pain, VAS[b]					
Baseline	67.7 (20.9)	58.5 (19.5)			
2 weeks	51.6 (22.0)	52.7 (23.8)	-8.3 (-15.6 to -1.0)	0.026*	
4 weeks	38.1 (23.0)	42.6 (24.1)	-9.2 (-18.7 to 0.3)	0.058	
6 weeks	**28.6 (19.0)**	**38.3 (25.0)**	**-14.4 (-23.5 to -5.2)**	**0.002***	**-0.49**
12 weeks	20.9 (19.4)	29.9 (23.3)	-12.5 (-21.6 to -3.4)	0.007	
Pain, FHSQ[c]					
Baseline	32.9 (22.1)	40.2 (19.7)			
2 weeks	47.7 (21.0)	47.1 (19.2)	5.0 (-2.0 to 12.0)	0.158	
4 weeks	60.7 (20.6)	52.7 (20.7)	11.6 (3.8 to 19.5)	0.004*	
6 weeks	**63.0 (20.5)**	**55.7 (23.4)**	**10.0 (1.0 to 19.1)**	**0.029***	**0.33**
12 weeks	72.2 (18.9)	65.7 (20.5)	9.1 (1.1 to 17.0)	0.026*	

[a]Values are mean (SD) unless stated.

[b]VAS, Visual Analogue Scale (higher values indicate greater levels of heel pain when getting out of bed in the morning).

[c]FHSQ, Foot Health Status Questionnaire (0 corresponds to the worst foot health; 100, the best).

Note: The bold entries are the primary end-points, nominated prior to commencement of the trial.

*Statistically significant at $p < 0.05$

Other than the primary end-point of six weeks, there were few significant findings (Table 5.3). At 4 weeks, the adjusted mean difference for foot pain using the FHSQ was 11.6 points (95% CI 3.8 to 19.5, $p = 0.004$). At 12 weeks, the adjusted mean difference for 'first step pain' was -12.5 mm (95% CI -21.6 to -3.4, $p = 0.007$) and for foot pain using the FHSQ was 9.1 points (95% CI 1.1 to 17.0, $p = 0.026$).

Secondary outcomes

At six and 12 weeks, there were no significant differences in health-related quality of life between groups (Table 5.4). For level of depression, the adjusted mean difference was -2.0 (95% CI -3.4 to -0.7, $p < 0.001$) at 6 weeks (Table 5.4).

Table 5.4. Mean scores and mean difference between groups for secondary outcome measures at 6 and 12 weeks[a]

Variable	Real dry needling	Sham dry needling	Adjusted mean difference (95% CI)	*P*-value
Foot function, FHSQ				
Baseline	45.4 (26.0)	52.6 (22.1)		
6 weeks	65.6 (24.8)	69.3 (25.7)	-0.7 (-9.8 to 8.3)	0.875
12 weeks	77.2 (21.7)	79.5 (18.1)	-0.5 (-7.8 to 6.8)	0.889
General foot health, FHSQ[b]				
Baseline	46.2 (31.8)	42.4 (29.0)		
6 weeks	48.2 (29.2)	43.6 (27.5)	4.2 (-6.8 to 15.1)	0.457
12 weeks	52.4 (26.0)	57.9 (24.0)	-7.4 (-17.3 to 2.5)	0.141
Health-related quality of life, SF36[c] (physical component)				
Baseline	43.4 (9.0)	44.5 (8.7)		
6 weeks	45.9 (8.3)	46.4 (9.0)	-0.3 (-2.9 to 2.3)	0.837
12 weeks	46.3 (8.8)	48.3 (7.3)	-1.3 (-4.1 to 1.4)	0.344
Health-related quality of life, SF36 (mental component)				
Baseline	49.3 (10.7)	49.9 (8.3)		
6 weeks	52.5 (8.1)	51.8 (11.0)	1.3 (-1.3 to 3.9)	0.323
12 weeks	52.1 (8.0)	54.6 (7.9)	-2.1 (-4.9 to 1.7)	0.136

Table 5.4. Mean scores and mean difference between groups for secondary outcome measures at 6 and 12 weeks[a] ("continued")

Depression, DASS-21[d]				
Baseline	6.4 (7.9)	6.5 (7.0)		
6 weeks	3.8 (5.7)	5.7 (6.9)	-2.0 (-3.4 to -0.7)	<0.001*
12 weeks	4.5 (6.3)	3.0 (4.3)	1.4 (-0.4 to 3.2)	0.154
Anxiety, DASS-21				
Baseline	3.8 (4.5)	3.8 (4.5)		
6 weeks	2.4 (3.5)	2.8 (5.1)	-0.3 (-2.2 to 1.6)	0.722
12 weeks	3.2 (5.3)	2.3 (3.1)	0.7 (-1.2 to 2.6)	0.420
Stress, DASS-21				
Baseline	10.9 (10.0)	8.5 (8.0)		
6 weeks	7.8 (8.5)	6.9 (7.6)	1.0 (-0.9 to 2.9)	0.315
12 weeks	7.3 (8.4)	4.7 (5.4)	1.5 (-0.9 to 4.0)	0.394

[a]Data are expressed as mean (SD).
[b]FHSQ, Foot Health Status Questionnaire (0 corresponds to the worst foot health; 100, the best).
[c]SF-36, 36-Item Short Form Health Survey (0 corresponds to the worst quality of life; 100, the best.
[d]DASS21, Depression, Anxiety and Stress scale (higher scores indicate more symptoms).
*Statistically significant at $p < 0.05$.

In relation to self-reported use of co-interventions, no significant differences were found between the real and sham dry needling groups at 6 weeks (5/41, 12.2% *versus* 4/43, 9.3%) or at 12 weeks (6/41, [13.6%] *versus* 11/43, [25.6%]) (refer to Appendix 9 – this table was included as a *Supplementary file* in the published manuscript).

All cases of immediate adverse events related to needle site pain and were transient in nature. Minor, transitory adverse events were reported at 70 real dry needling appointments (32%) compared with one appointment (<1%) in the sham dry needling group. This difference in frequency of adverse events between the two groups equates to an Absolute Risk Increase (ARI) of 31% (95% CI 23% to 35%) and a NNH of 3 (95% CI

1 to 5). The most common delayed adverse event (i.e. adverse events occurring between one and seven days post treatment) was bruising followed by an exacerbation of symptoms. Delayed adverse events in the real dry needling group were reported at 8 real dry needling appointments (3%) compared with 1 case (<1%) in the sham group. This difference in frequency of adverse events between the two groups equates to an ARI of 3% (-0.5% to 6%) and a NNH of 33 (95% CI 18.6 to 184.7). No serious adverse events (e.g. leading to days off work or hospital admission) were reported.

After the first treatment, there was no significant difference between the two groups in their expectations of improvement in plantar heel pain. There was also no significant difference between groups regarding how believable, convincing and logical the treatment appeared (refer to Appendix 10 – this table was included as a *Supplementary file* in the published manuscript).

Details of needling

The most frequently treated muscles were soleus, gastrocnemius, quadratus plantae, flexor digitorum brevis and abductor hallucis (Table 5.5). Less frequently needled muscles included abductor digiti minimi, and flexor hallucis longus. Treatments averaged four needles per session (range 2 to 8), each retained for 5 minutes.

Table 5.5. Localisation and frequency of [a]MTrPs dry needled in the real and sham dry needling groups

Muscle	Real	Sham
Soleus	291	314
Gastrocnemius	247	275
Quadratus plantae	132	146
Flexor digitorum brevis	92	108
Abductor hallucis	84	91
Abductor digiti minimi	61	53
Flexor hallucis longus	58	53
Mean number of needle insertions per participant	4 (range 2 to 8)	4 (range 2 to 8)

[a]MTrP, Myofascial trigger point

Note: values represent the number of MTrPs needled per muscle over the course of the study

5.6. Discussion

The aim of this trial was to evaluate the effectiveness of dry needling for plantar heel pain. At the primary end-point of six weeks, a statistically significant difference in 'first step' pain (measured on a VAS) and foot pain (measured on the FHSQ) was found in favor of real dry needling. However, these results did not quite reach the previously calculated MIDs used in our sample size calculation. Nonetheless, the 95% CIs included the values of the MID for 'first step pain' and the pain domain of the FHSQ indicating that dry needling for plantar heel pain might have clinical importance. In an attempt to explore this further, we calculated effect sizes (Cohen's *d*), which were medium in magnitude.[35] In addition, the NNT at six weeks was four (i.e. four patients would need to be treated with dry needling to achieve one beneficial outcome). When assessing the secondary outcomes, we found significant reductions in 'first step' pain and foot pain at 12 weeks favoring real dry needling, although again, these did not reach the pre-specified MIDs. Differences between groups in foot pain at two and four weeks were less

convincing. Accordingly, dry needling appears to reach its peak effect after six weeks treatment and beyond.

The main strengths of this trial are; it had an appropriate sample size, had high compliance, had a three-month follow-up, the participants were blinded, the interventions were found to be credible, and we used a dry needling treatment developed by consensus. However, there were some limitations that need to be considered as well. First, the practitioner (MC) implementing the treatment was not blinded to the intervention, which might have contributed to bias, although results of the Credibility and Expectancy Questionnaire suggest we treated both groups equally. Second, the number and duration of treatments were restricted, which would not normally occur in clinical practice, although from our previous consensus study,[164] 30 experts worldwide agreed upon this protocol. Third, the statistical analysis only included an evaluation of between-group effects and did not include a model that evaluated a group by time interaction. Fourth, the dry needling technique conducted in the study was only performed by a single podiatrist, which might affect the generalizability of the findings. Fifth, the participants recruited into the trial might not be entirely representative of people with plantar heel pain as there might be systematic differences between those people who are willing to participate in an experiment and those who elect not to participate.[180] Sixth, it might be expected that with a significant reduction in pain there might also be an improvement in foot function. However, our study was not powered to detect changes in foot function that might be considered clinically worthwhile.[169] Finally, the unique criteria used in this study to diagnose MTrPs have proven to be challenging from a clinical trial perspective as the criteria has limited reproducibility and validity.[85] Nevertheless, we used MTrP diagnostic criteria that clinicians implement in everyday practice and any issue with the reproducibility of the criteria would largely be negated as both groups were assessed in a similar manner.

The results of our study are consistent with a meta-analysis which found that acupuncture was superior to sham for chronic pain,[120] and two meta-analyses which established that dry needling of MTrPs was significantly better than sham and usual care for pain.[13,14] Our findings are also similar to other studies that evaluated the effectiveness of MTrP needling for plantar heel pain.[135,136] Tillu and Gupta[135] found a significant improvement in 18 adults with plantar heel pain (68% improvement) with 2 weeks (1 treatment per week)

of dry needling of the calf and heel regions, following a 4 week period of Chinese acupuncture. Perez-Milan and Foster[136] also demonstrated a significant reduction in pain (46% improvement) in 18 participants with plantar heel pain with a 6 week (1 treatment per week) program of Chinese Medicine acupuncture and dry needling of the heel and arch. However, these trials were case series of poor methodological quality,[181] which lacked control groups. Therefore, the effects of the MTrP treatment are likely to have been overestimated due to confounding and possible bias.

The effect of dry needling for plantar heel pain found in this trial might be explained by non-specific and specific elements of the treatment.[103] It is widely recognized that non-specific components of an acupuncture treatment, such as time spent in the consultation, patient expectations, the practitioner/patient alliance, and credibility of the intervention might affect the outcome.[182] The extent to which these factors contributed to the effect found in our trial is unclear. However, we believe the difference between groups for pain scores is due to the specific effect of the acupuncture needle as we controlled for non-specific treatment effects using rigorous randomized controlled trial methods. This argument is supported by the findings of our Credibility and Expectancy Questionnaire whereby there was no difference between the two groups.

A number of mechanisms might help explain the effect of dry needling over sham dry needling in this trial, although the current physiological mechanisms to explain the effects of dry needling are largely derived from research involving traditional acupuncture. Nevertheless, dry needling has been proposed to influence pain by impacting on the biochemical environment and local blood flow surrounding a MTrP, and ultimately the central nervous system. Shah et al.[49] found that dry needling significantly reduced the concentration of Substance P and Calcitonin gene-related peptide surrounding a MTrP following the elicitation of a local twitch response, albeit only temporarily, in participants with myofascial pain of the neck. In an animal model, Hseish et al.[108] found that levels of substance P were reduced following a single dry needling intervention of the biceps femoris muscle, which was accompanied by a short-term increase in β-endorphin in local tissue and serum, suggesting a short term analgesic effect for dry needling. Cagnie et al.[107] found that a single dry needling intervention of a MTrP, within the upper trapezius muscle, increased blood flow and oxygen saturation in the immediate vicinity of the

MTrP for 15 minutes, after removal of the needle. It has been proposed that increased blood flow to the region might aid the removal of pain inducing substances.[49]

In addition to local effects, dry needling is proposed to produce analgesia by influencing neural mechanisms.[109] In a recent meta-analysis of changes in brain activity associated with acupuncture needle insertion, Chae et al.[114] found that the insertion of an acupuncture needle activated and deactivated areas of the brain involved in the sensory, cognitive, and affective dimensions of pain. Following control tactile stimulation, which included non-penetrating sham needles similar to those used in our trial, changes in the activity levels of structures linked to these areas were significantly lower than that produced by needle insertion. Hence, the small specific effect of needling found in our study, beyond that of the sham comparison, might be explained by differences in the extent to which the pain matrix of the brain was influenced.

While the results of our trial found that real dry needling produced medium (Cohen's *d* effect size) reductions in foot pain beneath the heel, its value must also be considered in the context of the inconvenience of the intervention. It was clear from our trial that real dry needling frequently generates immediate adverse events, such as needle site pain. We estimated that for every three people with plantar heel pain treated with dry needling, one person will experience an immediate adverse event. While these were relatively mild and transitory, patients need to be informed of this prior to treatment so they can weigh up the benefits against these adverse effects.

5.7. Conclusion

The primary aim of this trial (and this thesis more broadly) was to evaluate the effectiveness of trigger point dry needling for plantar heel pain. The findings show that dry needling has some beneficial effect on the pain associated with this condition. However, therapists must consider whether this effect outweighs the elevated risk of immediate adverse events, even though these are mild and transitory. It is also possible that dry needling may have larger effects when combined with other treatments. Therefore, future work could add to this study by evaluating the effectiveness of this intervention when used in a multi-modal approach.

In this trial, a number of secondary outcomes were also evaluated including symptoms of depression, anxiety and stress using the DASS-21. For other musculoskeletal conditions such chronic back, hip, and knee pain, it is widely recognised that mood and anxiety disorders are prevalent[37,183-187] and associated with pain and physical function.[186,188] In order to explore the role of emotional states in people with plantar heel pain further, the next chapter (Chapter 6) will address the secondary aim of this thesis, which was to evaluate the impact of depression, anxiety and stress on foot pain and function in people with plantar heel pain. Following this, Chapter 7 will investigate whether depression, anxiety and stress increase the likelihood of having plantar heel pain (Chapter 7).

CHAPTER 6

6.0. Psychological factors associated with foot pain and foot function in adults with plantar heel pain

6.1. Background

Mental health disorders are prevalent in the community and are the main contributors to global years lived with disability (i.e. years of productive life lost due to disability).[189] Of these mental health disorders, mood disorders (e.g. major depression) and anxiety disorders (e.g. generalised anxiety disorder) are ranked second and seventh, respectively, for the most years lived with disability worldwide. To highlight the prevalence further, one in five people aged 16 to 85 had a mental health disorder in Australia in 2007.[190] Anxiety disorders affected 14% of the population, while affective or mood disorders affected 6% of the population.[190] Women were more likely to have a mental health disorder, with a higher rate of anxiety and affective disorders.[190]

In people with chronic musculoskeletal pain, the presence of depression and anxiety has been found to be associated with increased pain and reduced physical function. In a prospective cohort study of 500 participants with chronic musculoskeletal pain of the low back, hip, and knee, the presence of depression and anxiety was independently associated with increased pain.[186] Depressive symptoms are associated with reduced functional status across the cervical, upper, lumbar and lower extremity regions in patients with chronic musculoskeletal pain.[188] In addition, anxiety has been found to have a detrimental impact on physical function in patients with chronic musculoskeletal pain of the low back, hip and knee.[186]

The role of emotional states such as depression, anxiety and stress has largely been ignored in the aetiology of plantar heel pain. In addition, little is known about the impact of each emotional state on the level of pain and function in people with plantar heel pain. Historically, research that has investigated the aetiology of plantar heel pain has focused on intrinsic biological factors and extrinsic or environmental issues.[25] For other musculoskeletal conditions of the body, the role of anxiety and mood disorders are also considered important for the aetiology of the disease.[191]

Importantly, no research has specifically investigated the association between emotional states and the severity of pain and level of function in people with plantar heel pain. An awareness of emotional states such depression, anxiety and stress that explain the variance in foot pain and foot function in patients with plantar heel pain may provide support for evaluating and addressing these factors in people with this disorder. Therefore, the aim of this chapter was to determine if symptoms of depression, anxiety, and/or stress are associated with foot pain and foot function in people with plantar heel pain.

The findings of this chapter were published in the peer-reviewed journal *Clinical Rheumatology* in 2014.

Cotchett MP, Erbas B, Whittaker G. Psychological factors associated with foot pain and foot function in people with plantar heel pain. *Clin Rheum* 2014, doi: 10.1007/s10067-014-2565-7 (http://link.springer.com/article/10.1007/s10067-014-2565-7/fulltext.html).

6.2. Objective

To use baseline data from the randomised controlled trial to investigate if symptoms of depression, anxiety and/or stress are associated with foot pain and foot function in adults with plantar heel pain.

6.3. Research question

Are symptoms of depression, anxiety or stress associated with foot pain and foot function in adults with plantar heel pain?

6.4. Methods

This study reports on data recorded from all participants recruited as part of a randomised controlled trial that evaluated the effectiveness of trigger point dry needling for plantar heel pain (refer to Chapter 5). The measures used in this study were issued during the baseline assessment of the randomised controlled trial, prior to participants being randomised to an intervention.

Participants

The inclusion and exclusion criteria were presented in Chapter 5.

Outcome measures

Foot pain and foot function were evaluated using section 1 of the FHSQ.[166] The properties of the FHSQ, including the reliability and validity of the assessment tool, were presented in Chapter 5.

Age, sex, height, weight, BMI, and duration of heel pain symptoms were recorded by participants at the baseline consultation of the randomised controlled trial, prior to randomisation. In addition, levels of symptoms familiar to depression, anxiety and stress were measured using the Depression, Anxiety and Stress Scale short version (DASS-21).[168] Participants were required to indicate the presence of a symptom over the preceding week, rating each item from 0 ('did not apply to me at all over the last week') to 3 ('applied to me very much', or 'most of the time over the past week'). The DASS-21 has been shown to be reliable, have adequate construct validity, and strong convergent and discriminant validity.[168]

Data analysis

An assessment of the normality of data was conducted prior to statistical analysis both graphically (inspection of histograms) and numerically (evaluation of skewness and kurtosis). The histogram for both foot pain and foot function suggest close symmetry. Skewness and kurtosis values for foot pain were 0.31 and -0.52 respectively, while skewness and kurtosis values for foot function were 0.07 and -0.97 respectively.

Univariate data analysis

Correlation coefficients between variables were used to assess crude associations. Inter-correlations between predictor variables were evaluated to detect levels of association and avoid issues relating to multi-collinearity. An a priori hypothesis was made to evaluate depression, anxiety and stress separately in models with foot function and foot pain if there was a high degree of correlation between the psychological factors. Collinearity statistics (Tolerance and VIF values) were also calculated as a measure of the correlation between the predictor variables.

Independent samples t-tests were used for univariate comparisons between men and women. Regression models for continuous outcomes were used to examine the contribution of potential predictors to variations in foot pain and foot function.

Multivariate data analysis

We began with a baseline model with age, sex and BMI to control for these variables irrespective of their association with the outcome variable. The decision to control age, sex and BMI was made a priori to decrease unexplained variability. BMI has been found to influence physical function in patients with plantar heel pain, and age and sex are commonly controlled for in case control studies that have evaluated factors associated with the presence of plantar heel pain.[26,27,36] Then, using a hierarchical approach we entered each predictor variable (i.e. duration of heel pain symptoms, depression, anxiety and stress) individually to examine associations with the criterion variables irrespective of their univariate associations with the outcome variables following the approach by Sun and colleagues.[192] No other predictor variables were entered into the model, as we did not have other data available that might confound the outcome.

To examine possible differences between predictor variables and each outcome by males and females we stratified the data by sex, and then fitted interaction terms in the regression models (i.e. a psychological variable was entered in the first step, and the interaction term [sex x psychological variable] was entered in the second step).

All statistical tests were 2-tailed, and a *p* value of less than 0.05 was considered to be statistically significant. R square was used to evaluate the amount of variance in the criterion variable that was accounted for by the model. All analyses were completed using IBM® SPSS® software, version 19.

6.5. Results

Eighty-four participants were recruited between February 8th and October 7th, 2011. Baseline characteristics of study participants are listed in Table 6.1. Participants had a mean ± SD age of 56.1 ± 12.2 years and 52% were male. The mean ± SD duration of plantar heel pain was 13.6 ± 12.2 months (range 1 to 95). Scores on the outcome variables (i.e. foot pain and foot function) were normally distributed.

Table 6.1. Descriptive statistics of participant characteristics[a]

Variable	N=84	Range	Males N=43	Female N=41	*P* value[d]
Age	56.07 (12.19)	24 - 82	56.98 (13.90)	55.12 (10.19)	0.489
Height	169.72 (9.76)	147.50 – 196.00	176.43 (7.44)	162.68 (6.36)	<0.001*
Weight	83.90 (18.38)	49.80 – 141.00	89.89 (19.38)	79.02 (15.66)	0.006*
BMI	29.25	20.9 – 44.30	28.76 (5.13)	29.76 (5.15)	0.372
Duration of heel pain (months)	13.6 (12.2)	1 - 95	15.12 (19.24)	11.37 (11.94)	0.363
DASS-21[b]					
Depression	6.80 (7.41)	0 – 26	5.77 (5.96)	7.17 (8.77)	0.392
Anxiety	4.17 (5.64)	0 – 28	4.09 (4.77)	3.56 (4.20)	0.589
Stress	10.47 (9.90)	0 – 38	9.30 (7.96)	10.05 (10.21)	0.709
FHSQ[c]					
Foot Pain	40.83 (21.08)	0 – 90.62	40.88 (22.18)	32.21 (19.16)	0.059
Foot Function	49.82 (23.98)	0 – 100	55.09 (21.05)	42.83 (25.94)	0.020*

[a]Values represent mean ± SD

[b]DASS-21, Depression, Anxiety Stress Scale – Short version; FHSQ, Foot Health Status Questionnaire. Higher values indicate more symptoms.

[c]FHSQ, Foot health Status Questionnaire. 0 corresponds to the worst foot health, 100, the best.

[d]Values calculated using an independent *t* test.

*Significance at $p < 0.05$

Univariate analysis

Significant inter-correlations were evident for the following demographic variables: height and weight (r = 0.56, $p < 0.001$); height and sex (r = 0.71, $p < 0.001$); and weight and sex (r = 0.30, $p = 0.006$). In regards to inter-correlations between the psychological variables, a significant correlation was found between depression and stress (r = 0.76, $p < 0.001$), although a significant correlation was not found between anxiety and depression (r = 0.12, $p = 0.275$), and anxiety and stress (r = 0.04, $p = 0.699$). The variables sex, BMI, stress and depression were significantly correlated with foot function, while sex and depression had an association with foot pain, which trended towards significance. Results of the univariate correlations between predictor and criterion variables are outlined in Appendix 11 – this table was included as a *Supplementary file* in the final manuscript

Mean values for symptoms of depression, anxiety and stress were within the normal rating according to DASS-21 severity scales.[193]

Table 6.1 highlights mean differences between males and females for participant characteristics. Males were found to be taller (t = 9.08, $p < 0.001$) and heavier (t = 2.82, $p = 0.006$). Females reported poorer foot function (t = 2.38, $p = 0.020$), and greater foot pain, although differences for foot pain approached statistical significance.

Multivariate analysis

Based on the significant correlation between stress and depression, identified in the univariate analysis, both psychological factors were evaluated separately in a model. Anxiety was evaluated in models with stress or depression.

Criterion variable: Foot function

Age, sex and BMI explained 10% of the variability in foot function. In a model with age, sex, BMI and stress, results of the regression analysis indicated that four predictors explained 17% of the variance in foot function (R2 = 0.17, F (4, 79) = 5.23, $p = 0.001$) (Table 6.2). It was found that stress significantly predicted foot function ($\beta = -0.29$; $p = 0.006$) as did BMI ($\beta = -0.24$; $p = 0.020$) and sex ($\beta = -0.23$; $p = 0.024$). To determine the moderating effects of sex, interaction terms between sex and stress were calculated. An interaction term between sex and stress was significant ($p = 0.015$). The association between stress and foot function was significant for females ($\beta = -0.50$; $p = 0.001$) but not significant for males ($\beta = 0.01$; $p = 0.929$) (Table 6.3). In females, stress contributed an additional 20% of the variance in foot function scores beyond age and BMI.

Table 6.2. The association between stress and foot function in participants with plantar heel pain

Model		β	SE[a] B	Adjusted R Square	Δ R2	*P* value
1.	Age	-0.15	0.21	0.10	0.13	0.240
	Sex	-0.24	5.15			0.016*
	BMI	-0.22	0.50			0.040
2.	Age	-0.19	0.20	0.17	0.08	0.072
	Sex	-0.23	4.86			0.024*
	BMI	-0.24	0.48			0.020*
	Stress	-0.29	0.27			0.006*
3.	Age	-0.15	0.20	0.22	0.06	0.129
	Sex	0.03	6.97			0.818
	BMI	-0.22	0.47			0.030
	Stress	0.53	0.90			0.127
	Sex x Stress	-0.89	0.53			0.015*

[a]S.E, standard error.

*Significant at the $p < 0.05$

Table 6.3. The association between stress and foot function in females with plantar heel pain

Model		β	SE[a] B	Adjusted R Square	Δ R2	*P* value
1.	Age	-0.11	0.41	<0.01	0.05	0.490
	BMI	-0.17	0.81			0.292
2.	Age	0.12	0.35	0.24	0.25	0.387
	BMI	-0.17	0.70			0.235
	Stress	-0.50	0.35			0.001*

[a]S.E, standard error.

*Significant at the $p < 0.05$

A model containing age, sex, BMI and depression accounted for 16.0% of the variance in foot function scores (R2 = 0.16, F (4, 79) = 4.96, $p = 0.001$). Significant variables included depression (β = -0.28; $p = 0.009$), sex (β = -0.21, $p = 0.032$), and BMI (β = -0.22; $p = 0.037$) (Table 6.4). The interaction between sex and depression was also significant ($p = 0.002$) in a regression model.

Table 6.4. The association between depression and foot function in participants with plantar heel pain

Model		β	SE B	Adjusted R Square	Δ R2	*P* value
1.	Age	-0.15	0.21	0.10	0.13	0.240
	Sex	-0.24	5.15			0.016*
	BMI	-0.22	0.50			0.040
2.	Age	-0.20	0.21	0.16	0.07	0.056
	Sex	-0.21	4.89			0.032*
	BMI	-0.22	0.48			0.037*
	Depression	-0.28	0.33			0.009*
3.	Age	-0.16	0.20	0.25	0.09	0.113
	Sex	0.05	6.25			0.682
	BMI	-0.16	0.46			0.107
	Depression	0.84	1.18			0.024*
	Sex x Depression	-1.21	0.68			0.002*

[a]S.E, standard error.

*Significant at $p < 0.05$

Similar to stress, depression had a significant association with foot function in females (β = -0.53; $p < 0.001$), but not in males (β = 0.15; $p = 0.326$) and contributed and additional 24% of the variance in function scores (Table 6.5).

Table 6.5. The association between depression and foot function in females with plantar heel pain

Model		β	SE B	Adjusted R Square	Δ R2	*P* value
1.	Age	-0.11	0.41	<0.01	0.05	0.490
	BMI	-0.17	0.81			0.292
2.	Age	-0.21	0.35	0.29	0.29	0.135
	BMI	-0.06	0.69			0.680
	Depression	-0.53	0.41			<0.001*

[a]S.E, standard error.

*Significant at $p < 0.05$

Anxiety was not a significant predictor of foot function (β = -0.02; $p = 0.818$), and did not explain additional variance in foot function beyond a model with age, sex, and BMI. Anxiety remained a non-significant predictor of foot function when added to stress (β = -0.036; $p = 0.724$) or depression (β = -0.06; $p = 0.583$). When the data was stratified by sex, anxiety was not significant in a model, on its own, or when added to stress or depression.

Criterion variable: Foot pain

Age, sex and BMI explained 0.7% of the variance in foot pain. When the data was stratified by sex, depression was a significant predictor in a model with females (β = -0.41; $p = 0.013$) and contributed an additional 16% of the variance in foot pain scores beyond age and BMI (Table 6.6). In males, depression was not a significant predictor in the model ($p = 0.829$).

Table 6.6. The association between stress and foot pain and depression and foot pain in females with plantar heel pain

Model		β	SE B	Adjusted R Square	Δ R2	*P* value
1.	Age	-0.06	0.31	-0.05	<0.01	0.711
	BMI	0.01	0.61			0.973
2.	Age	-0.07	0.30	0.06	0.13	0.660
	BMI	0.01	0.58			0.961
	Stress	-0.36	0.29			0.024*
1.	Age	-0.06	0.31	-0.05	<0.01	0.711
	BMI	0.01	0.61			0.973
2.	Age	-0.13	0.30	0.09	0.16	0.402
	BMI	0.09	0.58			0.577
	Depression	-0.41	0.34			0.013*

[a]S.E, standard error.

*Significant at $p < 0.05$

A model with age, sex, BMI and stress contributed to 1.7% of the variation in foot pain scores. When the data was stratified according to sex, a model containing age, female sex, BMI and stress accounted for 6.4% of the variance in foot pain scores. Stress was a significant predictor in this model (β = -0.36; $p = 0.024$) (Table 6.6). Stress was not a significant predictor in males ($p = 0.190$).

Anxiety did not contribute additional variance in a model beyond the controlled variables. Anxiety was not a significant predictor of foot pain when added to a model with age, sex and BMI (β = -0.04; $p = 0.744$); or when included in a model with stress (β = -0.04; $p = 0.783$) or depression (β = -0.02; $p = 0.892$). Anxiety remained a non-significant predictor of foot pain when the data was stratified by sex.

6.6. Discussion

Analysis of baseline data obtained from a randomised controlled trial that evaluated trigger point dry needling for plantar heel pain found that, after accounting for age, sex

and BMI, symptoms of depression, stress but not anxiety were associated with reduced self-reported foot function. Depression, anxiety and stress were not significantly associated with foot pain scores in participants with plantar heel pain. When the data was stratified according to sex, female participants drove the association between depression, stress, foot pain and foot function in that a negative association was found for females, but not in males. In addition, females reported lower foot function performance and higher levels of foot pain.

To our knowledge, no previous studies have adopted a hierarchical multiple regression approach to evaluate the association between depression, anxiety, stress with foot pain and foot function in people with plantar heel pain. We found that depression and stress were independent predictors of foot pain and foot function, although females, and not males drove this effect. For foot function, the interaction term (depression by sex and stress by sex) was statistically significant, which suggested the slope that predicts a change in foot function, as scores for stress or depression increase, was significantly different between males and females. Interestingly, for foot pain, interaction terms were not significant, which suggested that regression lines to predict foot pain from stress and depression were similar and parallel for females and males. Failure to identify a significant interaction might have been due to insufficient statistical power as a result of an inadequate sample size. When the interaction terms were not included in the model, coefficients for sex, stress and depression had a significant effect on foot pain scores.

Our finding that sex moderates the association between depression, foot pain and foot function is consistent[194,195] but also contradictory to some studies,[196,197] albeit in different populations. An explanation for the contrasting findings is uncertain but might reflect differences in the patient populations evaluated (i.e. type of pain condition), and other clinical and social issues of relevance to sex that might influence pain, including severity and duration of symptoms, age of participants,[198] influence of race and culture,[199] and presence of co-morbidities.[198]

In our study, a significant association between stress with self-reported pain and self-reported function was also found. This is consistent with previous research that found stress was associated with pain and disability in participants with musculoskeletal

pain.[200-202] While our findings do not provide definitive support for a causal relationship between stress, foot pain and foot function in people with plantar heel pain, further longitudinal studies might help clarify this association.

Our findings are important for the management of plantar heel pain and suggest psychological variables might have been ignored as an associate of foot function and foot pain in females. However, due to our cross-sectional study design, establishing causal relationships and the directionality of associations between variables is not appropriate. In addition, it would be premature to recommend methods to manage levels of stress or depression in females with plantar heel pain. A more efficacious design to determine the strength of the association between psychological variables and foot pain and foot function would be a comparative cross sectional design or ultimately a prospective longitudinal study.

The main strengths of this study are that participants were not gathered from pain clinics, which may be unrepresentative of musculoskeletal pain in the general population. Second, the DASS-21 contains few somatic items that may inflate scores in people with musculoskeletal pain. However, this study should be viewed in light of some limitations. First, our study used a cross sectional design which means we were unable to evaluate the temporal aspects of the associations and establish a causal relationship. It is also possible that previously unmeasured independent variables might explain more of the variance in outcome including: (i) physical factors such as fat mass,[203] body fat distribution,[204] thickness of the plantar fascia,[10] radiographic evidence of a calcaneal spur[10] and variations in foot posture (ii) environmental factors including characteristics of footwear, hours standing, and occupation and activities of daily living,[25] and (iii) other psychological factors such as coping strategies and fear avoidance beliefs.[205] Second, participants were recruited from a larger randomised controlled trial, which had strict inclusion and exclusion criteria. As a result, the sample may not reflect the general population of people with plantar heel pain. Third, this study used a self-report method for collecting data from participants, which is not ideal when measuring complex psychological constructs.[206] An attempt was made to reduce these limitations by using a relatively large sample.

6.7. Conclusion

After accounting for age, sex and BMI, symptoms of stress and depression were significantly associated with self-reported foot function, but not foot pain, in participants with plantar heel pain. When the data were stratified according to sex, significant associations between depression, stress, foot pain and foot function were found for female participants. To establish the strength (i.e. causality) of this association, further prospective longitudinal studies are required.

While this chapter investigated levels of depression, anxiety and stress in adults with plantar heel pain, the results do not indicate if each emotional state is associated with the presence of plantar heel pain. Therefore, the next chapter compares levels of depression, anxiety and stress in adults with and without plantar heel pain to determine if each emotional state increased the likelihood of having the condition.

CHAPTER 7

7.0. The association between depression, anxiety and stress in adults with plantar heel pain: an observational study

7.1. Background

In the previous chapter (Chapter 6) the association between depression, anxiety and stress with foot pain and foot function in adults with plantar heel pain was investigated. While levels of each emotional state were investigated in a sample of adults with plantar heel pain, there was no control group (i.e. adults without plantar heel pain). Hence, it is unclear if the symptoms of depression, anxiety and stress are associated with the presence of plantar heel pain. Therefore, the aim of this chapter was to investigate levels of depression, anxiety, and stress in people with and without plantar heel pain to determine if the presence of such symptoms increased the likelihood of having the condition.

The findings of this chapter will be submitted to the peer-reviewed journal *Journal of Physiotherapy* in 2014. This chapter has been formatted according to the requirements of the *Journal of Physiotherapy*.

7.2. Objective

To conduct an observational study to compare symptoms of depression, anxiety and stress in adults with and without plantar heel pain.

7.3. Research question

Do symptoms of depression, anxiety or stress increase the likelihood of having plantar heel pain?

7.4. Methods

Design

We conducted an observational study to determine if there was an association between depression, anxiety, and stress with plantar heel pain. Ethics approval was obtained from the La Trobe University's Faculty Human Ethics Committee (No. 10-247) (refer to Appendix 12). Participants with plantar heel pain were recruited consecutively between

February 8th 2011 and October 7th 2011, while participants without heel pain were recruited between 13th February 2012 and 6th of May 2013.

Participants

Data for the case group was obtained from the first 45 participants that were recruited as part of a RCT that evaluated the effectiveness of trigger point dry needling for plantar heel pain (refer to Chapter 5 for a description of the RCT including the eligibility criteria). Participants were recruited through local and major metropolitan daily newspapers.

The control group, that is people without plantar heel pain, consisted of participants that were matched to the group with plantar heel pain for age (± 2 years) and sex. Participants were recruited consecutively, once a match was established with a participant with plantar heel pain. The first 45 participants, without plantar heel pain, that could be matched to a participant with plantar heel pain were recruited into the study. Advertisements seeking volunteers for the control group commenced after the last participant was recruited into the RCT. The recruitment methods and exclusion criteria for this group were the same as for the group with plantar heel pain, although all control participants did not report a history of musculoskeletal pain, of the lower extremity, in the past year.

All assessments were conducted at the La Trobe University Health Sciences Clinic. At the initial consultation, a range of descriptive characteristics was recorded including sex, age, weight, height, years of education, and medical history. Participants with plantar heel pain were also required to self-report: (i) duration of symptoms (months), (ii) side affected (left, right or bilateral), and (iii) the severity of pain beneath the heel over the previous week.

Outcome measures

Core symptoms of depression, anxiety and stress were measured using the 21 item Depression, Anxiety and Stress Scale short version (DASS-21).[168] The DASS-21 contains three self-report scales, with seven statements each relating to the emotional states of depression, anxiety and stress. Participants were required to read and rate each statement from 0 (‘did not apply to me at all over the last week’) to 3 (‘applied to me very much’ or ‘most of the time over the past week’). Total scores for each subscale (depression, anxiety

and stress) were calculated where greater scores indicate worse health. The DASS-21 has been shown to be reliable, have adequate construct validity, and strong convergent and discriminant validity.[168]

Level of foot pain, in participants with plantar heel pain, was measured by the pain subscale of the Foot Health Status Questionnaire (FHSQ), which has been found to be a reliable and valid measure of foot-specific health-related quality of life.[166] The FHSQ pain subscale contains four items resulting in the calculation of a pain score ranging from 0 to 100 points, with 0 representing worst foot health (or worst pain in the case of the pain subscale) and 100 representing best foot health.

Data analysis

Data analysis was conducted in two stages. First, we used Pearson's r correlation coefficients to assess crude associations between variables, and paired samples *t*-tests for mean differences between groups with and without plantar heel pain. Chi square (χ^2) and Fisher's exact tests were used to compare groups for the frequency of comorbidities. Normality of data was explored and confirmed prior to statistical analysis both graphically (inspection of histograms) and numerically (evaluation of skewness and kurtosis).

Second, logistic regression was conducted to determine if independent variables including symptoms of depression, anxiety or stress (after adjusting for age, gender, BMI, and years of education) increased the likelihood of having plantar heel pain (i.e. the dependent variable). Depression, anxiety and stress were evaluated as a continuous measure rather than as a dichotomous variable (i.e. 'normal' or 'clinical') as emotional syndromes such as depression and anxiety are believed to occur along a continuum rather than exist as a specific disease entity.[207]

An a priori hypothesis was made to evaluate depression, anxiety and stress separately in models if there was a high degree of correlation between the psychological variables. All statistical tests were 2-tailed, and a *p* value of less than 0.05 was considered to be statistically significant. No other independent variables were entered into the model, as we did not have other data available that might influence the outcome. All analyses were completed using IBM® SPSS® software (version 19).

7.5. Results

Participant characteristics are shown in Table 7.1. Participants had a mean ± SD age of 53 ± 12 years and 51% were male. For the plantar heel pain group, the mean ± SD level of foot pain (points on the FHSQ pain subscale) was 40 ± 21 and the mean ± SD duration of pain was 10 ± 9.5 months (range 1 to 36). Thirty-six cases of plantar heel pain were unilateral, while 9 cases were bilateral. The group with plantar heel pain had less years of education (mean difference = -1.4, 95% CI [-2.6 to -0.10]) and an increased BMI (mean difference = 3.6, 95% CI [1.8 to 5.5]). There were no significant differences in the prevalence of co-morbidities between groups (Table 7.2)

Table 7.1. Comparison of participants' characteristics[a]

Variable	Case Group (n = 45)	Control group (n = 45)	*P* value[d]
Age	53 (12)	52 (13)	0.623
Sex, n (%), male	23 (51)	23 (51)	
Height, cm	168 (10)	169 (8)	0.735
Weight, kg	84 (20)	73 (13)	0.006
Body mass index	29 (5.5)	25 (4.4)	< 0.001*
Years of education	15 (2.4)	16 (3.8)	0.033*
Pain, FHSQ[b]	40 (21)	N/A	
Duration of heel pain, months	10 (9.5)	N/A	
DASS-21[c]			
…*Depression*	6.1 (6.9)	1.7 (3.2)	< 0.001*
…*Anxiety*	4.2 (5.5)	1.6 (2.9)	0.004*
…*Stress*	10 (9.7)	5.3 (5.6)	0.002*

[a]Values are means and SDs unless otherwise stated.
[b]FHSQ = Foot Health Status Questionnaire (0 corresponds to the worst foot health, 100, the best).
[c]DASS-21 = Depression, Anxiety and Stress Scale – 21 (Higher values indicate more symptoms).
[d]Univariate analysis evaluated using a dependent t test.
*Significant at $p < 0.05$

Table 7.2. Comparison of self-reported comorbidities of participants[a]

Comorbidity[b]	Case (n = 45)	Control (n = 45)
Heart disease	0 (0.00)	2 (4.4)
Hypertension	8 (17)	4 (8.9)
Hypercholesterolaemia	9 (20)	7 (15)
Smoker	0 (0.0)	2 (4.4)
Lung disease	2 (4.4)	1 (2.2)
Thyroid disease	2 (4.4)	2 (4.4)
Osteoarthritis		
Spine	13 (28)	12 (26)
Hip	3 (6.7)	4 (8.9)
Knee	6 (13)	6 (13)
Foot	8 (17)	4 (8.9)

[a]Values are number (%).
[b]A co-morbidity was defined as any medical condition, reported by a participant, for which they were taking medication. Chi square and Fisher's exact test did not reveal any statistically significant differences between groups for any self-reported co-morbidity.

The plantar heel pain group had greater levels of depression (mean difference = 4.4, 95% CI [2.3 to 6.5]), anxiety (mean difference = 2.6, 95% CI [0.9 to 4.3]) and stress (mean difference = 4.8, 95% CI [1.9 to 7.8]) (Table 7.1). Significant inter-correlations were evident for the following independent variables: depression and stress ($r = 0.7$, $p < 0.001$); depression and anxiety ($r = 0\ 7$, $p < 0.001$); stress and anxiety ($r = 0.6$, $p < 0.001$). Based on the significant correlations between depression, anxiety and stress, each of these psychological factors was evaluated separately in a logistic model (after controlling for age, sex, BMI and years of education).

A model including depression was statistically significant χ^2 (5) = 32, $p < 0.001$. The five independent variables in the model accounted for 41% of the variance in the dependent variable. The overall percentage of correctly classified cases was 70%. Of the five independent variables entered, only two contributed significantly to the predictive ability of the model (i.e. depression and BMI) (Table 7.3).

Table 7.3. Association between depression and plantar heel pain

	B	SE[b]	Wald	*P*	Odds Ratio (95% CI[a])
Sex, female	0.64	0.58	1.2	0.268	1.9 (0.61 to 5.9)
Age	-0.01	0.02	0.02	0.893	1.0 (0.96 to 1.0)
BMI	0.20	0.06	9.6	0.002*	1.2 (1.1 to 1.4)
Education	-0.16	0.09	3.6	0.058	0.86 (0.72 to 1.0)
Depression	0.28	0.09	10	0.001*	1.3 (1.1 to 1.6)

[a]CI = confidence interval
[b]SE, standard error
*Significant at $p < 0.05$

A model including anxiety was also statistically significant χ^2 (5) = 24, $p < 0.001$ The model as a whole explained 32% of the variance in pain status, and correctly classified 71% of cases. As shown in Table 7.4, anxiety and BMI were the only variables that contributed significantly to the overall model.

Table 7.4. Association between anxiety and plantar heel pain

	B	SE[b]	Wald	*P*	Odds Ratio (95% CI[a])
Sex, female	0.24	0.52	0.22	0.636	1.3 (0.46 to 3.5)
Age	-0.01	0.02	0.03	0.862	1.0 (0.96 to 1.0)
BMI	0.17	0.06	8.5	0.003*	1.2 (1.1 to 1.3)
Education	-0.16	0.08	3.5	0.061	0.86 (0.73 to 1.0)
Anxiety	0.23	0.09	6.6	0.010*	1.3 (1.1 to 1.5)

[a]CI = confidence interval
[b]SE, standard error
*Significant at $p < 0.05$

A model including stress was statistically significant χ^2 (5) = 26, $p < 0.001$. The model explained 34.4% of the variance in plantar heel pain, and correctly classified 76% of cases. Of the five predictor variables entered in the model only two were statistically significant (BMI and stress) (Table 7.5). Increasing symptoms of stress were associated with an increased likelihood of having plantar heel pain.

Table 7.5. Association between stress and plantar heel pain.

	B	SE[b]	Wald	*P*	Odds Ratio (95% CI[a])
Sex, female	0.25	0.53	0.23	0.636	1.3 (0.46 to 3.6)
Age	0.01	0.02	0.86	0.770	1.0 (0.97 to 1.1)
BMI	0.19	0.06	10	0.002*	1.2 (1.1 to 1.4)
Years of education	-0.15	0.08	3.3	0.069	0.86 (0.73 to 1.0)
Stress	0.14	0.05	9.1	0.003*	1.2 (1.1 to 1.3)

[a]CI = confidence interval
[b]SE, standard error
*Significant at $p < 0.05$

7.6. Discussion

The aim of this study was to evaluate the association between symptoms of depression, anxiety, and stress with the presence of plantar heel pain. Participants with plantar heel pain had higher levels of depression, anxiety and stress than participants without plantar heel pain. In logistic regression models, with depression, anxiety and stress evaluated separately, each emotional state made a statistically significant contribution to the model after controlling for age, gender, BMI and years of education. The findings suggest that with increasing symptoms of depression, anxiety and stress the likelihood of having plantar heel pain increases.

An important consideration in interpreting the results of the present study is the extent to which our participants could be considered representative of the population. For the group without plantar heel pain, symptoms of depression, anxiety and stress were consistent with normative data for the general adult Australian population aged 25 to 90 years.[208] For the plantar heel pain group, the level of pain,[19,20,26,209] duration of symptoms,[19-21,209] BMI[19-21,26,209], age, [19-21,26,209] and percentage of females[26,209] were similar to other studies that have evaluated risk factors and interventions for plantar heel pain.

The magnitude of the effect size reported in this study should be put in context of other intrinsic and extrinsic factors shown to increase the likelihood of having plantar heel pain. Similar observational studies, using the same populations, that have investigated factors associated with plantar heel pain have found that individuals with less than zero degrees of ankle dorsiflexion are 23 times more likely to have plantar heel pain compared to individuals with greater than 10 degrees of ankle dorsiflexion;[36] individuals with a

pronated foot posture are 3.7 times more likely to have plantar heel pain;[26] those above 30 kg/m^2 are 2.9 times more likely to have plantar heel pain; [26] those that stand for long periods throughout the day are 3.6 times more likely to have plantar heel pain;[36] and finally, people with a calcaneal spur[10] or a plantar fascia greater than 4mm in thickness[10] are 8 times and 100 times more likely to have plantar heel pain respectively.

A comparison of our findings to other observational studies is difficult because each emotional state was measured on a continuous scale rather than creating dichotomous independent variables and clinical cut-offs (e.g. "normal" vs "clinical" or "high" vs "low"). However, our study found that for every one point increase in depression, anxiety and stress, the likelihood of having plantar heel pain increased by 1.3, 1.3 and 1.2 times respectively. For example, a 5 point increase in depression, anxiety or stress using the DASS-21 would increase the likelihood of having plantar heel pain by 6.5, 6.5 and 6.0 times respectively.

Despite the association between emotional states and plantar heel pain, our study needs to be viewed in light of its limitations. First, an evaluation of the model suggests that other variables not included might influence the likelihood of having plantar heel pain, including the thickness of the plantar fascia,[10] radiographic evidence of a calcaneal spur,[10] variations in foot posture,[26] types of footwear, hours standing,[25] income[210] and psychosocial factors.[210] Future studies are required to identify whether the inclusion of other potential factors can more effectively explain the variation in the dependent variable. Second, our study used a cross-sectional design limiting the ability to establish a causal relationship between psychological symptoms and plantar heel pain.

7.7. Conclusion

Symptoms of depression, anxiety and stress were found to be higher in participants with plantar heel pain than without plantar heel pain. After controlling for age, gender, BMI and years of education, depression, anxiety and stress significantly increased the likelihood of having plantar heel pain. Longitudinal investigations are required to investigate the temporal relationship between variables including emotional states with plantar heel pain.

Chapter 8

8.0. Conclusion

8.1. Background

Plantar heel pain is a common and disabling condition that has a negative impact on health-related quality of life. Many interventions are used to manage plantar heel pain, although there is limited good quality evidence to support their use. In addition to standard treatments for plantar heel pain, dry needling is a form of manual therapy that is increasingly used to manage pain associated with MTrPs. In people with plantar heel pain, MTrPs within the soleus, abductor hallucis and quadratus plantae muscles are thought to contribute to the pain associated with the condition. However, evidence to support the use of dry needling for plantar heel pain is unclear. Therefore, the aim of this thesis was to evaluate the effectiveness of dry needling for plantar heel pain. The secondary aim was to investigate whether psychological factors are associated with the pain and disability of plantar heel pain, and also increase the likelihood of having the condition.

In order to address the aims of this thesis, a number of research questions were presented. In reference to each research question, the following results were found:

i. Is dry needling (and/or injections) of myofascial trigger points effective for reducing pain in adults with plantar heel pain?

A systematic review (Chapter 3) was conducted to evaluate the effectiveness of dry needling and/or injections of MTrPs associated with plantar heel pain. The review found three quasi-experimental trials: two trials had evaluated dry needling of MTrPs in combination with traditional Chinese acupuncture, while the third trial evaluated 1% lidocaine injections of MTrPs in combination with physical therapy. All three trials found a statistically significant reduction in pain, although the methodological quality of all studies was poor making definitive conclusions about the effectiveness of dry needling and/or injections for plantar heel pain difficult. The review highlighted that the current evidence did not allow definitive conclusions to be made regarding the effectiveness of dry needling for plantar heel pain. This study highlighted the need for a high quality

randomised controlled trial to evaluate the effectiveness of dry needling for plantar heel pain.

ii. Can consensus be gained for a standard protocol for dry needling for plantar heel pain?

Prior to conducting a randomised controlled trial to evaluate the effectiveness of dry needling for plantar heel pain it was important to develop a dry needling treatment that reflected the practise of experts worldwide (Chapter 4). Therefore, a Modified Delphi study was conducted, using 30 experts worldwide that use dry needling for plantar heel pain. After three iterations, 93% of experts agreed with a dry needling treatment that could be used in a randomised controlled trial to evaluate dry needling for plantar heel pain. Key features of the treatment included: (i) a treatment guided by the MTrP model; (ii) a pragmatic approach to dry needling MTrPs, although the initial focus should be on those muscles that might be associated with pain beneath the heel (i.e. soleus, abductor hallucis and quadratus plantae muscles); (iii) manipulation of the needle to evoke classic somatic type symptoms and if possible a local twitch response; and (iv) a treatment that involved one treatment per week for six weeks.

iii. Is dry needling more effective at reducing pain beneath the heel in adults with plantar heel pain compared to sham dry needling?

Using the dry needling treatment protocol for plantar heel pain, developed by consensus, a randomised controlled trial was conducted to evaluate dry needling for plantar heel pain (Chapter 5). The results found that significant effects favoured real dry needling over sham dry needling for pain at the primary end point of six weeks (adjusted mean difference: *VAS first step pain* -14.4mm, 95% CI -23.5 to -5.2; *FHSQ foot pain* 10.0 points, 95% CI 1.0 to 19.1), although the between group difference was lower than the minimal important difference. In addition, the frequency of minor transitory adverse events was significantly greater in the real dry needling group (70 real dry needling appointments [32%] compared with only sham dry needling appointment [<1%]).

iv. Are symptoms of depression, anxiety or stress associated with foot pain and foot function in adults with plantar heel pain?

In the randomised controlled trial (Chapter 5), secondary outcomes included an evaluation of symptoms of depression, anxiety and stress in response to real versus sham

dry needling. To further explore the role of emotional states in adults with plantar heel pain, the aim of this study was to evaluate the association between depression, anxiety and stress with the pain and disability of plantar heel pain (Chapter 6). Using a hierarchical regression analysis, demographic variables entered into the model first, including age, sex and BMI, explained 10% of the variability in foot function. The addition of depression and stress in separate models explained an additional 7.3% and 8.1% of foot function scores respectively. In their respective models depression was a significant predictor ($\beta = -0.28$; $p = 0.009$) as was stress ($\beta = -0.29$; $p = 0.006$). Females drove the effect between stress and foot function ($\beta = -0.50$; $p = 0.001$) and depression and foot function ($\beta = -0.53$; $p < 0.001$). In females, the addition of stress to a model containing age and BMI, contributed an additional 20% of the variance in foot function scores, while the addition of depression contributed an additional 24% of the variance.

In regression models for foot pain, depression, anxiety and stress did not contribute significantly to pain scores. However, when the data was stratified by sex, stress was a significant predictor in females ($\beta = -0.36$; $p = 0.024$), but not in males. In a separate model, depression was also significantly associated with foot pain in females ($\beta = -0.41$; $p = 0.013$), but not in males. In females, stress and depression contributed an additional 13% and 16% of the variance in foot pain scores respectively, beyond the variance explained by age and BMI.

v. Do symptoms of depression, anxiety and stress increase the likelihood of having plantar heel pain in adults?

The evaluation of psychological associates of foot pain and foot function in adults with plantar heel pain covered in the study above, revealed the importance of considering emotional states when evaluating the pain and disability of plantar heel pain. However, levels of each emotional state in the previous study were not compared to a control group, which could help determine if symptoms of depression, anxiety and stress could increase the likelihood of having plantar heel pain. Therefore, the aim of this study was to compare levels of depression, anxiety and stress in adults with and without plantar heel pain (Chapter 7). This observational study found that symptoms of depression, anxiety and stress were significantly higher in adults with plantar heel pain, compared to a group matched by age (± 2 years) and sex. Depression, anxiety and stress increased the

likelihood of having plantar heel pain by 1.3 (95% CI 1.1 to 1.6), 1.3 (95% CI 1.1 to 1.5) and 1.2 (95% CI 1.1 to 1.3) times respectively.

8.2. Conclusions

With reference to the primary and secondary aims of this thesis the following conclusions can be made:

Primary aim

The primary aim of the thesis was to evaluate the effectiveness of trigger point dry needling for plantar heel pain.

In the short term treatment of plantar heel pain, real dry needling is more effective at reducing pain than sham dry needling. However, the between-group difference was less than a value that is considered clinically meaningful to an adult with plantar heel pain. To explore the size of the effect further, the magnitude of the effect (Cohen's *d*) was medium, which is consistent with common treatments for plantar heel pain (e.g. prefabricated foot orthoses, an ultrasound guided cortisone injection, and taping). Despite the findings, the magnitude of this effect should be considered against the frequency of adverse events. Although these adverse events were mild and transitory, patients with plantar heel pain that are to receive dry needling should be made aware of these so that they can weigh up the benefits and risks of the treatment.

Secondary aim

- To evaluate the association between psychological variables with the pain and disability of plantar heel pain, and
- To evaluate the association of depression, anxiety and stress with plantar heel pain.

Analysis of baseline data from the randomised controlled trial (Chapter 5) revealed that symptoms of depression and stress are associated with foot function, but not foot pain, in adults with plantar heel pain. However, when the data was stratified by sex, it was females who drove a negative association between depression and stress with foot pain and foot function. These findings are important for the assessment and management of

plantar heel pain and suggest that emotional states might have been overlooked as factors associated with the pain and disability of plantar heel pain, particularly in females.

To further explore the role of psychological variables in adults with plantar heel pain, an observational study was conducted. Levels of depression, anxiety and stress were found to be higher in adults with plantar heel pain compared to adults without the condition. Furthermore, it was found that with increasing symptoms of depression, anxiety and stress the likelihood of having plantar heel pain increases.

Due to the cross-sectional nature of both studies, it is not possible to establish causal relationships between emotional states and plantar heel pain. As such, it would be premature to recommend managing psychological symptoms to treat and/or prevent plantar heel pain. Prospective longitudinal studies are required to establish the strength of the associations found in these analyses.

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Appendices

Appendix 1: Ethics approval (Chapter 4)

La Trobe University
Faculty of Health Sciences
MEMORANDUM

TO: Mr Matthew Cotchett
Department of Podiatry

SUBJECT: *Reference:* **FHEC09/200**

Student or Other Investigator:

Title: **Dry needling for plantar fasciitis: A modified Delphi process to define a standardised treatment protocol**

DATE: 19 November, 2009

The Faculty Human Ethics Committee's (FHEC) reviewers have considered and approved the above project. You may now proceed.

Please note that the Informed Consent forms need to be retained for a minimum of 5 years. Please ensure that each participant retains a copy of the Informed Consent form. Researchers are also required to retain a copy of all Informed Consent forms separately from the data. The data must be retained for a period of 5 years.

Please note that any modification to the project must be submitted in writing to FHEC for approval. You are required to provide an annual report (where applicable) and/or a final report on completion of the project. A copy of the progress/final report can be downloaded from the following website: http://www.latrobe.edu.au/rgso/forms-resources/forms/ethic-prog-final.rtf

Please return the completed form to The Secretary, FHEC, Faculty of Health Sciences Office, La Trobe University, Victoria 3086.

If you have a student/s involved in this project, a copy of this memorandum is enclosed for you to forward to the student(s) concerned.

pp **Neil McDonald**
Secretary
Faculty Human Ethics Committee
Faculty of Health Sciences

Appendix 2: Round 1 questionnaire (Chapter 4)

Copy of Dry needling for plantar fasciitis

Consent

PROJECT TITLE

DRY NEEDLING FOR PLANTAR FASCIITIS: A MODIFIED DELPHI PROCESS TO DEFINE A STANDARDISED TREATMENT PROTOCOL

I (the participant) have read and understood the participant information sheet and any questions I have asked have been answered to my satisfaction. I agree to participate in the project, realising that I may withdraw from the study at any time and may request that no data arising from my participation are used, up to four weeks following the completion of my participation in the research. I agree that research data provided by me or with my permission during the project may be included in a thesis, presented at conferences and published in journals on the condition that neither my name nor any other identifying information is used.

1. By placing a tick in the check box I am consenting to my involvement in this research project. Place the cursor over the check box and click Yes to consent. To remove the tick in the check box, re-click the mouse.

◯ Yes

◯ No

PLEASE RETAIN A COPY OF THE CONSENT FORM FOR YOUR RECORDS

Copy of Dry needling for plantar fasciitis

Outline of questionnaire

The questionnaire is comprised of 5 sections as outline below. The time it should take to complete each section is in brackets.

Section 1: Practitioner background (1 minute)

Section 2: Needling rationale (1 minute)

Section 3: Needling details (6 minute)

Section 4: Treatment regimen (1 minute)

Section 5: Co-interventions (1 minute)

Copy of Dry needling for plantar fasciitis

Section 1: Practitioner Background

This is Section 1 of a total of 5 sections. It should take approximately 1 minute to complete

To complete questions 1 to 4 place the cursor over the drop down box and click the mouse to expose the drop down list

To complete question 5 place the cursor over the round button and click the mouse to select your answer

1. In which country do you reside?

2. Type of practitioner

Other (please specify)

3. How many years have you worked in clinical practice?

4. How many years have you practiced dry needling?

5. I would usually or always use dry needling to treat plantar fasciitis

- ◯ Strongly Agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly Disagree

Please add additional comments to section 1 here.

Copy of Dry needling for plantar fasciitis

Section 2: Needling Rationale

This is Section 2 of a total of 5 sections. It should take approximately 1 minute to complete

1. What conceptual model(s) provides the framework for your use of dry needling in the management of patients with plantar fasciitis? To complete the question place the cursor over the check box and click the mouse corresponding to your answer(s). To remove your answer, re-click the mouse.

- ☐ Myofascial trigger point model
- ☐ The radiculopathy model
- ☐ Traditional Chinese Medicine model
- ☐ Other

Other (please specify)

2. The following are some of the characteristics used to diagnose a myofascial trigger point. Please rate there level of importance from very important to not at all important. To complete the answer place the cursor over the round button and click the mouse corresponding to its level of importance. To undo your answer re-click the round button.

	Very important	Quite important	Fairly important	Slightly important	Not at all important
Tenderness within a taut band	◯	◯	◯	◯	◯
Pain recognition on palpation of a tender point within a taut band.	◯	◯	◯	◯	◯
Referred pain on palpation of a tender point within a taut band.	◯	◯	◯	◯	◯
Point tenderness quantified by algometry. Pressure pain threshold 2kg/cm lower at a tender versus a non tender taut band	◯	◯	◯	◯	◯
Reduced pain on palpation of a taut band following a specific myofascial trigger point therapy	◯	◯	◯	◯	◯
Local twitch response	◯	◯	◯	◯	◯
Jump sign	◯	◯	◯	◯	◯
Reduced joint range of motion	◯	◯	◯	◯	◯

Other (please specify)

Copy of Dry needling for plantar fasciitis

Section 3: Needling Details

This is Section 3 of a total of 5 sections. It should take approximately 6 minutes to complete

1. In the table below:
i. Select the muscle(s) that you would most commonly dry needle for plantar fasciitis.
ii. Select the needle length that you would most commonly use for the selected muscle
iii. Select the needle diameter that you would most commonly use for the selected muscle
To complete your answers place the cursor over the drop down box and click the mouse to expose the drop down list. If a specific length or diameter is not available select a size that is closest to the one that you would usually use.

	Select yes for the muscle(s) that you would most commonly dry needle in patient's with plantar fasciitis	Needle length most commonly used (mm)	Needle diameter most commonly used (mm or inches)
Abductor digiti minimi			
Abductor hallucis			
Quadratus plantae			
Flexor Digitorum Brevis			
Gastrocnemius			
Soleus			
Tibialis posterior			
Flexor hallucis longus			
Flexor digitorum longus			
Peroneus longus			
Peroneus brevis			
Peroneus tertius			
Tibialis anterior			
Extensor hallucis longus			
Extensor digitorum longus			
Adductor longus			
Adductor magnus			
Adductor brevis			
Gracilis			
Obturator externus			
Pectineus			
Biceps femoris			
Semitendinosis			

Copy of Dry needling for plantar fasciitis

Semimembranosis			
Rectus femoris			
Vastus medialis			
Vastus lateralis			
Vastus Intermedius			
Tensor fascia latae			
Iliopsoas			
Sartorius			
Gluteus maximus			
Gluteus medius			
Gluteus minimus			
Piriformis			
Quadratus femoris			
Obturator internus			
Gemelli			
Multifidus			
Iliocostalis Thoracis/Lumborum			
Longissimus			
Quadratus lumborum			

Other (please specify)

2. What brand of acupuncture needle do you most commonly use to treat a patient with plantar fasciitis?

Other (please specify)

3. Does the length of the acupuncture needle vary depending on the muscle you are dry needling?

Additional comments

Copy of Dry needling for plantar fasciitis

4. What is the average number of needle insertions per muscle that you would perform to treat a patient with plantar fasciitis?

Other (please specify)

5. What is the average amount of time (minutes) you would insert a needle when treating a patient with plantar fasciitis?

Additional comments

6. How often would you incorporate manual stimulation of the needle with techniques such as lifting, thrusting and rotation?

Additional comments

7. What sensations, felt by the patient or yourself, most often occur during a successful treatment using dry needling for plantar fasciitis? Please rate the likelihood of occurence from Almost always to Never. To complete your answer place the cursor over the round button and click the mouse corresponding to its likelihood of occurence.

	Almost always	Often	Sometimes	Seldom	Never
The patient feels a sensation such as an ache, numbness, soreness, distension or heaviness in the proximity of or distal to the site of needle insertion	◯	◯	◯	◯	◯
A muscle twitch felt by yourself or the patient	◯	◯	◯	◯	◯
A jolt or shock felt by the patient	◯	◯	◯	◯	◯
A grasp of the needle felt by yourself	◯	◯	◯	◯	◯

Other (please specify)

Copy of Dry needling for plantar fasciitis

Section 4: Treatment Regimen

This is Section 4 of a total of 5 sections. It should take approximately 1 minute to complete

1. What is the average number of sessions you would use to treat a patient with plantar fasciitis?

Other (please specify)

2. On average how frequently would you perform dry needling for plantar fasciitis following the first consultation? In the column headed Frequency of treatment place the cursor over the drop down box and click the mouse to expose the drop down list. Using your mouse scroll down the list to select your answer.

	Frequency of treatment
In the first week?	
In the second week?	
In the third week?	
In the fourth week?	
In the fifth week?	
In the sixth week?	
In the seventh week?	
In the eighth week?	

Copy of Dry needling for plantar fasciitis

Section 5: Co-interventions

This is the final section. It should take approximately 1 minute to complete

1. Is it important to implement dry needling in conjunction with education and other therapies to treat plantar fasciitis?

2. For the selected co-interventions below, how often would you recommend its use with dry needling to treat your patients with plantar fasciitis? To complete the answer place the cursor over the round button and click the mouse corresponding to the frequency of use. To undo your answer re-click the round button.

	Always	Very Often	Sometimes	Rarely	Never
Calf Stretching	◯	◯	◯	◯	◯
Plantar fascia stretching	◯	◯	◯	◯	◯
Restrictive Foot Taping	◯	◯	◯	◯	◯
Activity Modification	◯	◯	◯	◯	◯
Footwear advice	◯	◯	◯	◯	◯
Orthotic therapy	◯	◯	◯	◯	◯

Other (please specify)

Appendix 3: Round 2 questionnaire (Chapter 4)

DRY NEEDLING FOR PLANTAR FASCIITIS: A MODIFIED DELPHI

Round Two: Introduction

The Delphi panelists have devised ten statements for which we would like you to indicate your level of agreement. The statements are divided into a number of sections:

Section 1: Muscles to be dry needled

Section 2: Needle retention time

Section 3: Needle stimulation

Section 4: Treatment schedule

DRY NEEDLING FOR PLANTAR FASCIITIS: A MODIFIED DELPHI

Rationale for the dry needling treatment

The results of the first round of the survey found that participants practise dry needling using the:

- MTrP model (93%)
- Radiculopathy model in combination with the MTrPt model (30%)
- Traditional chinese medicine model in conjunction with the MTrP model (7%)
- Neurophysiological approach (7%)
- Traditional chinese medicine model in conjunction with the MTrP model and radiculopathy model (3%)
- Layering approach with needling of segmental and extrasegmental points in conjunction with the MTrP model (3%)

Please note that the percentage value for each model does not add up to 100% as some participants treat using multiple models.

The results of the survey found that the model by which the participant practised determined the muscles that they dry needled. Participants that practice using the MTrP model (93%) and the radiculopathy model (30%) most commonly dry needled soleus, quadratus plantae, gastrocnemius, abductor hallucis and the flexor digitorum brevis muscles. However, the 30% of participants that practised using the radiculopathy model also needled multifidus, longissimus, Iliocostalis thoracis/lumborum and the quadratus lumborum muscles.

Based on the high percentage of participants that practice using the MTrP model a consensus has been established to use the MTrP model as the rationale for the dry needling treatment in the planned RCT.

Hence for the statements that follow please consider that the dry needling treatment in the planned RCT will be conducted:

- **Using the MTrP model;**
- **Within a 20-30 minute consultation due to the time and financial restrictions of a clinical trial.**

DRY NEEDLING FOR PLANTAR FASCIITIS: A MODIFIED DELPHI

Section 1: Selection of muscles to be dry needled

The results of Round One found that participants "almost always" dry needled the following muscles (percentage of responses are in brackets and the muscle most commonly dry needled is in bold. For a more detailed description of the results refer to the PowerPoint presentation attached to your email):

- **Soleus (80%)**
- Quadratus plantae (73%)
- Gastrocnemius (70%)
- Abductor hallucis (56%)
- Flexor digitorum brevis (56%)
- Posterior tibial (30%)
- Flexor digitorum longus (30%)
- Multifidus (26%)
- Flexor hallucis longus (23%)
- Peroneus longus (20%)
- Gluteus medius (20%)
- Gluteus minimus (20%)
- Longissimus (20%)
- Iliocostalis (20%)
- Peroneus brevis (17%)
- Peroneus tertius (13%)
- Extensor digitorum longus (13%)
- Tibialis anterior (10%)
- Extensor hallucis longus (10%)
- Quadratus lumborum (10%)

In addition analysis of the results found:

- The **average** number of muscles dry needled was **7 (SD = 6)**
- The **median** number of muscles dry needled was **5**
- The **range** (minimum - maximum) of muscles dry needled was **22** (1-23)

For the planned RCT, we would like you to indicate your level of agreement with a semi-standardised protocol.

The protocol would aim to resemble an individualised treatment practised in accordance with the MTrP model.

The protocol would involve dry needling of up to five muscles, as the Round One results revealed that the median number of muscles dry needled by the participants was 5.

The chief investigator would be obliged to assess and dry needle trigger points within the the soleus, gastrocnemius, quadratus plantae, flexor digitorum brevis **and/or** abductor hallucis muscles as the results of Round One revealed that these muscles were "almost always" dry needled by 56% to 80% of participants. If less than five muscles are dry needled, the chief investigator could assess additional muscles selected from a pre-specified list. This list would include muscles that were dry needled "almost always" by 10%-30% of the Round One participants including Abductor digiti minimi, Tibialis posterior, Flexor hallucis longus, Flexor digitorum longus, Peroneus longus, Extensor hallucis longus, Extensor digitorum longus, Tibialis anterior, Peroneus brevis, Peroneus tertius, Gluteus medius and Gluteus minimus.

DRY NEEDLING FOR PLANTAR FASCIITIS: A MODIFIED DELPHI

1. Please indicate the extent to which you agree or disagree with the statements below. To make a selection place the cursor over the button corresponding to your answer and click the mouse.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Assessment and dry needling of soleus, gastrocnemius, quadratus plantae, flexor digitorum brevis **and/or** abductor hallucis is important to be effective in the treatment of plantar fasciitis.	◯	◯	◯	◯	◯
To ensure a total of five muscles are dry needled, assessment and dry needling of additional muscles including ADM, TP, FHL, FDL, PL, EHL, EDL, TA, PB, PT, G Min **and/or** G Med, would be adequate in the treatment of plantar fasciitis.	◯	◯	◯	◯	◯

2. Additional comments

Abbreviations ADM = Abductor digiti minimi; TP = Tibialis posterior; FHL = Flexor hallucis longus; FDL = Flexor digitorum longus; PL = Peroneus longus; PB = Peroneus brevis; PT = Peroneus tertius; TA = Tibialis anterior; EHL = Extensor hallucis longus; EDL = Extensor digitorum longus; G Med = Gluteus medius; G Min = Gluteus minimus.

DRY NEEDLING FOR PLANTAR FASCIITIS: A MODIFIED DELPHI

Section 2: Needle retention time and total number of needle insertions per ...

In Round One of the survey participants were asked how long a needle was kept in situ when treating a patient with plantar fasciitis. The results are presented below (the value that occurred most often is in bold). For a more detailed examination of the results please refer to the PowerPoint presentation attached to your email.

- **Less than 1 minute: 38%**
- 1 minute: 4%
- 2 minutes: 4%
- 5 minutes: 15%
- 10 minutes: 18%
- 11-15 minutes: 12%
- 16-20 minutes: 4%
- 30+ minutes: 4%

In addition participants were asked about the number of needle insertions that they would perform per muscle to treat a patient with plantar fasciitis. The survey found:

- 1 insertion: 8%
- **2 insertions: 45%**
- 3 insertions: 12.5%
- 4 insertions: 8%
- 5 insertions: 12.5%
- 10 insertions: 4%

1. On average, following manual stimulation of the acupuncture needle to produce an appropriate response (sensation, local twitch response (LTR) or to reproduce the patient's symptoms) how long would you leave the needle in situ? Please assume the dry needling is being practised according to the MTrP model and is being conducted within a 20-30 minute consultation.

- ☐ The needle is removed immediately
- ☐ < 1 minute
- ☐ 1-5 minutes
- ☐ 6-10 minutes
- ☐ 11-20 minutes

2. Please indicate your level of agreement with the following statement. To choose your answer place the cursor over your selection and click the mouse.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
The duration of needle insertion is shortened if the patient is sensitive to stimulation.	◯	◯	◯	◯	◯

3. The number of needle insertions per muscle depends on:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
The total number of MTrP's to be dry needled, i.e., a muscle with a larger number of MTrP's would require more needle insertions.	◯	◯	◯	◯	◯

4. Additional comments

DRY NEEDLING FOR PLANTAR FASCIITIS: A MODIFIED DELPHI

Section 3: Manual stimulation of the needle

In the first round of the survey participants were asked about the frequency of manual needle stimulation when treating plantar fasciitis. The results are presented below (the value that occurred most often is in bold). For a more detailed examination of the results please refer to the PowerPoint presentation attached to your email.

- **Always (42%)**
- Very often (22%)
- Sometimes (18%)
- Rarely (14%)
- Never (3%)

1. For the statement below please indicate the extent to which you agree or disagree. To make a selection place the cursor over the button corresponding to your answer and click the mouse.

	Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
Manual stimulation of the acupuncture needle is required to produce an appropriate response (sensation, LTR or to reproduce the patient's symptoms).	◯	◯	◯	◯	◯
Manual stimulation of the acupuncture needle is reduced if the patient is sensitive to stimulation.	◯	◯	◯	◯	◯
The intensity of needle stimulation should be increased if the patient has had a poor response and there was not an exacerbation of symptoms following the previous treatment.	◯	◯	◯	◯	◯

2. Additional comments

DRY NEEDLING FOR PLANTAR FASCIITIS: A MODIFIED DELPHI

Section 4: Treatment regimen

In the first survey participants were asked about the average number of sessions that they would usually use to treat a patient with plantar fasciitis (the value that occurred most often is in bold). For a more detailed examination of the results please refer to the PowerPoint presentation attached to your email. The results were:

- 3 treatments: 11%
- **4 treatments: 30%**
- **5 treatments: 30%**
- 6 treatments: 22%
- 7 treatments: 4%
- 8 treatments: 4%

In addition participants were asked to state how frequently they would perform dry needling for plantar fasciitis following the first consultation. The survey found (the value that occurred most often is in bold):

- In the first week?: **Weekly (60%)** ; Every three days (30%); Every six days (6.7%); Every four days (3.3%)
- In the second week?: **Weekly (63%)**; Every three days (16%); Every five days (6.7%); Every six days (6.7%); Every two days (3.3%); Every four days (3.3%)
- In the third week?: **Weekly (83%)**; Every three days (3.3%); Every six days (3.3%); Every five days (3.3%)
- In the fourth week?: **Weekly (91%)**; Every three days (3.3%); Every six days (3.3%)
- In the fifth week?: **Weekly (100%)**
- In the sixth week?: **Weekly (100%)**
- In the seventh week?: **Weekly (100%)**
- In the eighth week?: **Weekly (100%)**

1. When answering the final question please consider the financial and time constraints associated with a clinical trial.

For the statements below please indicate the extent to which you agree or disagree. To make a selection place the cursor over the button corresponding to your answer and click the mouse.

	Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
Do you agree that a clinical trial lasting six weeks, with one treatment per week, is adequate to assess the effectiveness of dry needling for plantar fasciitis?	◯	◯	◯	◯	◯
During the course of the clinical trial, treatment should be ceased if the participant's symptoms resolve prior to the course of the dry needling treatment.	◯	◯	◯	◯	◯

2. Additional comments

Appendix 4. Round 3 questionnaire (Chapter 4)

Dry needling for plantar fasciitis: a modified delphi process (round three)

1. Introduction

The first two rounds of the survey revealed that there is variability in:

- the rationale for using dry needling for plantar fasciitis,
- the technical aspects of dry needling, and
- the treatment schedule employed amongst experts that use dry needling for plantar fasciitis.

The next page provides a detailed description of a proposed protocol to investigate the effectiveness of dry needling for plantar fasciitis. The protocol is based on the opinions obtained in the first two rounds taking into account the variable nature of what the experts told us in the previous two rounds. A major finding of previous rounds of this survey was that the participants were reluctant to deliver a standardised treatment which would reduce the individualised approach common in clinical practice. In response to your feedback and to increase external validity of our planned trial we have decided not to delivery the same treatment to all participants. Instead, we will use a treatment that is flexible and individualised to each participant.

We would like you to indicate whether you believe the following protocol is acceptable for a clinical trial to evaluate the effectiveness of dry needling for plantar fasciitis given the aforementioned variability amongst practitioners. When making your decision please consider that our trial is attempting to assess the effect of dry needling. While testing the effect of a single intervention such as dry needling ignores the multifaceted nature of plantar fasciitis treatment we need to isolate it from other interventions to enable us to evaluate the specific effect of the dry needling stimulation.

Dry needling for plantar fasciitis: a modified delphi process (round three)

2. Dry needling for plantar fasciitis: a protocol for a randomised controlled ...

1. Dry needling rationale

The dry needling treatment will be practised according to the myofascial trigger point (MTrP) model. The radiculopathy and traditional chinese medicine models will not be used in this trial as the results found that only a small percentage of the experts surveyed practise according to these models.

2. Treatment setting

The treatment will be conducted in the La Trobe University Health Sciences Clinic, Bundoora, Melbourne, Australia.

3. Consultation time

The treatment will be conducted within a 30 minute consultation.

4. Dry needling details

- *Brand of acupuncture needle*: Seirin J-Type or Hwa-To Ultraclean.
- *Muscles to be dry needled*. The muscles to be assessed first will include those harbouring myofascial trigger points that might be responsible for the participant's pain including the soleus, quadratus plantae, flexor digitorum brevis and abductor hallucis muscles.

  Synergists and antagonists of these muscles will also be assessed for MTrPs. These muscles will include the Abductor digiti minimi, Adductor hallucis, Gastrocnemius, Tibialis posterior, Flexor hallucis longus, Flexor digitorum longus, Peroneus longus, Peroneus brevis, Peroneus tertius, Tibialis anterior, Extensor hallucis longus and Extensor digitorum longus muscles.

  In addition a search will be undertaken for MTrPs in muscles which might be influencing the participant's loading of the soleus, quadratus plantae, flexor digitorum brevis and abductor hallucis muscles. These muscles will include the Piriformis, Gluteus maximus, Gluteus medius, Gluteus minimus, Tensor fascia latae, Adductor longus, Adductor magnus, Adductor brevis, Semitendinosis, Semimembranosis and Biceps femoris muscles.
- *Needle length and diameter*. The needle length will be determined by the location of the MTrP to be dry needled. Thicker and deeper muscles will require longer needles. Most commonly the needle length will range from 30 to 75mm. The diameter of the needle will be 0.30mm but will be varied depending on the participant's tolerance to insertion of the needle. A smaller diameter needle may be used if needle insertion is uncomfortable.
- *Needle insertions per muscle*. The number of needle insertions per muscle will depend on:
  - The number of MTrPs to be dry needled;
  - The participant's tolerance to needle insertion;
  - The responsiveness of the tissue to dry needling;
  - The level of post needle soreness for a specific muscle. For example, the number of needle insertions into the gastrocnemius might need to be reduced if the participant experiences excessive post needle soreness.
- *Response elicited*. Dry needling of a MTrP will attempt to elicit an appropriate response such as a: local twitch response (LTR); a sensation such as a dull ache, heaviness, distension, pressure or bruising; and/or a reproduction of the participant's symptoms. If an appropriate response is not elicited the needle will be removed and the participant re-examined.
- *Manipulation of the acupuncture needle*. Following insertion, the acupuncture needle will be withdrawn partially and advanced repeatedly (also referred to as an 'in and out', 'push and pulling' or 'sparrow pecking' motion) to produce an appropriate response. If the participant is sensitive to insertion of the needle the manipulation will be reduced. If this action is insufficient to reduce the painful stimulus, the manipulation will be ceased and the needle left in situ. Alternatively, the needle may be replaced with a needle that has a smaller diameter.

Dry needling for plantar fasciitis: a modified delphi process (round three)

- *Needle retention time*. The results revealed variability in the optimal duration of dry needling once an appropriate response has been achieved. We have therefore proposed that the needle remain in the muscle for as long as it takes to produce an appropriate response and is tolerated by the participant. Once this has occurred the needle will be left in situ for 5 minutes. This will allow sufficient time for the stimulus to subside in participants that are sensitive to the treatment.

5. Treatment regimen

- The clinical trial will involve one treatment per week for six weeks.

- Treatment will be ceased if the participant's symptoms resolve prior to the course of the dry needling treatment. However, if the participant experiences a relapse within the six week treatment period they will be offered further weekly treatment(s) until the end of the six week course.

6. Practitioner background

The practitioner performing the dry needling treatment is the chief investigator of this project, Mr Matthew Cotchett. Matthew has been practising for 11 years and commenced dry needling in 2007. He has completed Level I and Level II trigger point dry needling courses accredited by the Australian Physiotherapy Association.

***Important points to consider**.

Prior to stating your level of agreement with the proposed protocol we would like you to consider the following points:

- The results of this project highlighted the difficulties in establishing a dry needling protocol for plantar fasciitis when there was such variability in the treatment rationales and treatment delivery among the experts surveyed. Therefore, we have attempted to establish a protocol that incorporates the opinions of all experts surveyed and reflects the practice of most practitioners worldwide that use dry needling for plantar fasciitis.

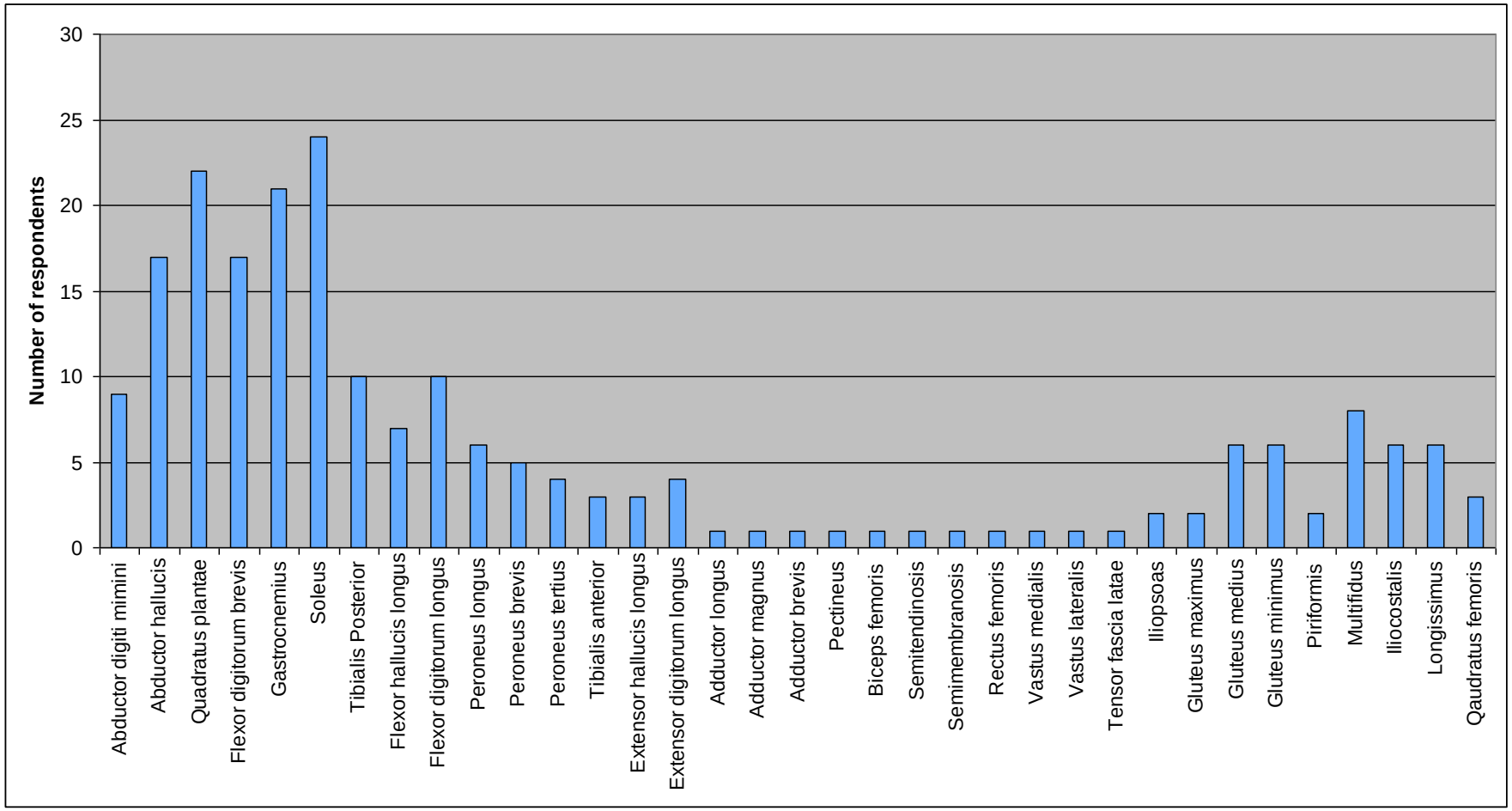
- The results from the survey found that it was important to address perpetuating factors and the treatment protocol if the participant has a poor response. As we are assessing the specific effect of dry needling, using a randomised controlled trial methodology, we cannot address perpetuating factors. Doing so might negate the true effect of the dry needling treatment. Because participants will want to remain active, the only perpetuating factor that will be addressed is the participant's level of activity during the trial. Participants will be advised that they can continue undertaking activities, however their pain is not allowed to reach level 5 on the visual analogue scale (VAS), where 0 is no pain and ten is the worst pain imaginable, during the activity. The pain is allowed to reach 5 on the VAS but should be subsided by the following morning.

1. Please indicate your level of agreement with the following statement

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
The protocol described above is acceptable for a clinical trial to evaluate the effectiveness of dry needling for plantar fasciitis.	◯	◯	◯	◯	◯

2. Additional comments

Appendix 5. List of muscles most commonly needled by experts (Chapter 4)



Appendix 6. Ethics approval (Chapter 5)

LA TROBE UNIVERSITY

RESEARCH SERVICES

MEMORANDUM

To:	**Dr Karl Landorf, School of Podiatry, Faculty of Health Sciences** **Mr. Matthew Cotchett, School of Podiatry, Faculty of Health Sciences**
From:	**Secretary, La Trobe University Human Ethics Committee**
Subject:	**Review of Human Ethics Committee Application No. 10-015**
Title:	**The effectiveness of trigger point dry needling for plantar heel pain (plantar fasciitis): a randomised controlled trial**
Date:	**25 June 2010**

Thank you for your recent correspondence in relation to the research project referred to above. The project has been assessed as complying with the *National Statement on Ethical Conduct in Human Research*. I am pleased to advise that your project has been granted ethics approval and you may commence the study.

The project has been approved from the date of this letter until 29 February 2012.

Please note – The UHEC finds that the Participant Information Sheet is very long and cumbersome and you are highly advised to simplify its contents before using it in recruitment.

Please note that your application has been reviewed by a sub-committee of the University Human Ethics Committee (UHEC) to facilitate a decision about the study before the next Committee meeting. This decision will require ratification by the full UHEC at its next meeting and the UHEC reserves the right to alter conditions of approval or withdraw approval. You will be notified if the approval status of your project changes.

The following standard conditions apply to your project:

- **Limit of Approval.** Approval is limited strictly to the research proposal as submitted in your application while taking into account any additional conditions advised by the UHEC.
- **Variation to Project.** Any subsequent variations or modifications you wish to make to your project must be formally notified to the UHEC for approval in advance of these modifications being introduced into the project. This can be done using the appropriate form: *Ethics - Application for Modification to Project* which is available on the Research Services website at *http://www.latrobe.edu.au/research-services/ethics/human.htm*. If the UHEC considers that the proposed changes are significant, you may be required to submit a new application form for approval of the revised project.
- **Adverse Events.** If any unforeseen or adverse events occur, including adverse effects on participants, during the course of the project which may affect the ethical acceptability of the project, the Chief Investigator must immediately notify the UHEC Secretary on

telephone (03) 9479 1443. Any complaints about the project received by the researchers must also be referred immediately to the UHEC Secretary.

- **Withdrawal of Project.** If you decide to discontinue your research before its planned completion, you must advise the UHEC and clarify the circumstances.

- **Annual Progress Reports.** If your project continues for more than 12 months, you are required to submit an *Ethics - Progress/Final Report Form* annually, **on or just prior to 12 February**. The form is available on the Research Services website (see above address). Failure to submit a Progress Report will mean approval for this project will lapse. An audit may be conducted by the UHEC at any time.

- **Final Report.** A Final Report (see above address) is required within six months of the completion of the project or by **30 August 2012.**

If you have any queries on the information above or require further clarification please contact me through Research Services on telephone (03) 9479-1443, or e-mail at:

humanethics@latrobe.edu.au.

On behalf of the University Human Ethics Committee, best wishes with your research!

Ms Barbara Doherty
Administrative Officer (Research Ethics)
University Human Ethics Committee

Postal details:
Research Services
La Trobe University Bundoora, Victoria 3086
P: (03) 9479 - 1443
F: (03) 9479 - 1464
http://www.latrobe.edu.au/research-services/ethics/

Appendix 7. Participant Information Sheet (Chapter 5)

Item 1: Project title
EFFECTIVENESS OF TRIGGER POINT DRY NEEDLING FOR PLANTAR HEEL PAIN (PLANTAR FASCIITIS): A RANDOMISED CONTROLLED TRIAL

This research project is being conducted as part of Mr Matthew Cotchett's PhD.

Item 2: Aims
The aim of our investigation is to examine the effectiveness of trigger point dry needling for plantar heel pain (plantar fasciitis).

Item 3: Rationale
Plantar heel pain is common and painful, however the optimal treatment for this disorder remains unclear. Consequently, an alternative therapy such as trigger point dry needling is increasingly being used as an adjunctive treatment by health practitioners. The findings from this trial will provide evidence for the effectiveness of trigger point dry needling for plantar heel pain.

Item 4: Test procedure
Inclusion and exclusion criteria

As a participant in this study you **must**:

1. Be over the age of 18 years;
2. Have pain in your heel for at least one month that is aggravated by weightbearing activities;
3. Be able to complete the questionnaires used in this study;
4. Have a willingness to not receive or implement any form of physical therapy such as foot orthoses, night splints, calf stretching, massage therapy, footwear modifications, foot taping and/or foot injections of the foot and or lower limb during the duration of the trial.

As a participant in this study you **must not**:

1. Be using anti-coagulants such as warfarin (except for acetylsalicylic acid at dosages up to 325mg/day);
2. Be pregnant,
3. Have received dry needling or acupuncture treatment for any condition;
4. Have significant vascular disease of the lower limbs and feet;
5. A chronic or uncontrolled medical condition that might preclude participation in the study such as: cancer; inflammatory disorders (e.g., rheumatoid arthritis); neurological abnormalities and/or chronic pain that has a musculoskeletal origin;
6. Have had a history of surgery to the plantar fascia of your painful foot;
7. Have had a previous injection of anaesthetic or cortisone or other agent(s) into the heel or arch region in the previous three months;
8. Have been included in any other trial or study in the previous three months;
9. Have a known hypersensitivity to metals.

Part A: Screening procedure
To confirm the presence of plantar heel pain, and determine your eligibility to be entered into the study, an initial assessment will be required. This will be conducted at the Health Sciences Clinic at La Trobe University. The initial assessment is expected to take **60 minutes**. This assessment will be conducted by one of the study investigators and will involve:

- An assessment of your medical history;
- Clinical assessment of your plantar heel pain;
- Measurement of your height, weight and hip to waist circumference ratio;

- Clinical assessment of your foot type.

Part B. Treatment procedure
After the initial assessment you will be allocated to one of two groups. The groups are selected by chance. Participants in one group will receive trigger point dry needling while participants in the other group will receive a sham trigger point dry needling intervention. Each potential participant has an approximate 50% chance of receiving the real treatment and an approximate 50% chance of receiving the sham treatment. It is important that you do not know which group you have been allocated to.

What does the treatment involve?
During each treatment session the chief investigator will examine muscles of your hip, thigh, leg and foot for the presence of trigger points or taut bands within a muscle. The examination involves assessing the strength of individual muscles and palpating the muscle to identify a trigger point. This is non-invasive. You will remain clothed during the procedure, however you will be advised to wear loose fitting clothes so that the top of the hip region can be adequately assessed. Appropriate draping techniques (only the part of the body being treated is exposed) will be also be used to limit skin exposure.

During the treatment session a blind will be positioned at the level of your lower back so that you cannot see which treatment you are receiving. A separate disposable acupuncture needle will be used for each trigger point treated. The length of the needle will vary from 30mm to 75mm (diameter 0.30mm) depending on the muscle to be treated.

Each trigger point will be treated using a dry needling or sham dry needling intervention depending on the group to which you have been allocated. Both the right and left lower limbs will be treated if you experience pain in both heels.

Time commitments
If you choose to participate in this project you will be required to receive 1 treatment per week for a total of six weeks. Each treatment will take approximately **30 minutes**.

What are we assessing?
Throughout the six weeks of the trial we will give you a number of questionnaires to complete.

- The amount of pain and disability caused by your plantar heel pain;
- The amount of pain felt in your heel, upon getting out of bed (if both feet are affected you will be asked to record the pain in your most painful foot);
- Your general health-related quality of life;
- Your beliefs and expectations of the treatment;
- Your level of depression, anxiety and stress;
- The name and amount of any pain-relieving medications that are taken during the study period.

In addition you will be mailed a questionnaire at 3 months. The questionnaires will measure the same variables listed above. Self-addressed reply-paid envelopes will be provided.

Use of pain relieving medications and other forms of treatment during the study period
As a participant in this study you must discontinue taking all pain relieving medications (except paracetamol (Panadol®), up to 4g/day:

- For at least 14 days before the first treatment with dry needling or sham dry needling;
- During the study period (3 months after the treatment with dry needling or sham dry needling.

You are allowed to take paracetamol (Panadol®), up to 4g/day, during the study period. However, you must

discontinue its use at least 24hrs before the:

- Initial assessment;
- Follow up assessments at 2, 4, 6 and 12 weeks after the treatment.

It is possible that limiting the amount of (or altering) pain medication or treatment may cause an increase in pain in your heel.

You are encouraged not to receive any new treatment for your plantar heel pain (e.g., foot orthoses, calf stretching, night splints, massage therapy, acupuncture and/or injections into the foot) during the study period (3 months).

Activity during the study
During the study, you will be permitted to continue any exercise during the trial, however pain is not to exceed level 5 on a visual analogue scale (VAS) where 0 is 'no pain' and 10 is 'worst pain imaginable', during the exercise/activity. While pain up to level 5 is acceptable, if the amount of pain felt in your heel felt when you get out of bed increases from one week to the next you will be advised to lower the level of exercise.

Item 5: Funding body
Funding for this project has been obtained from the Australian Podiatry Education Research Fund (APERF).

Item 6: Potential harms and risks
The amount of adverse effects associated with trigger point dry needling is considered low. The most common side effects are pain and muscle soreness which are generally mild and do not last beyond a few days. Rare cases of infection have been reported after trigger point dry needling. To reduce the risk of infection the chief investigator will wear surgical gloves and your skin will be prepared with an antiseptic solution prior to insertion of the needle. Furthermore, the acupuncture needles are single use sterile needles.

Advice for dealing with adverse effects caused by the treatment with dry needling or sham dry needling
There may be slight pain, stiffness or bruising following treatment of the muscle(s). It is recommended that you:

- Take pain relievers by mouth such as paracetamol (Panadol®) up to 4g/day);
- Rest during the period immediately following the treatment;
- Avoid any strenuous activities (such as jogging or tennis) or prolonged weightbearing activities for 24 hours following the treatment;
- Drink plenty of water.

If any of these effects fail to reduce despite following the advice above, if you develop other unpleasant effects, or if you have any concerns, you are advised to contact the chief investigator of this study (Mr Matthew Cotchett), phone 9479 5776 email: <m.cotchett@latrobe.edu.au>. Mr Matthew Cotchett will arrange to consult with you at the Health Sciences Clinic, La Trobe University to advise you on how to deal with the harmful effect(s) and determine the need for further referral, if any.

Completion of the Depression, Anxiety and Stress Scale (DSS-21) and SF-36
During the course of the trial, you will be asked to complete the Depression, Anxiety and Stress Scale (DASS-21) and SF-36. Some of the questions asked in the questionnaires (particularly the DASS-21 questionnaire), may be associated with certain risks, however the risk of occurrence is low. For example, you may feel anxious or distressed, either because of links with unpleasant experiences or because you are uncertain what the questions mean. Additionally, the questionnaires might unearth some sensitive and/or

uncomfortable feelings and memories. It is important to note that there are no right or wrong answers for each of the questionnaires because your response reflects your own experiences. If completion of the questionnaire is too confronting and/or places undue stress on you, you will be given the option of withdrawing from the study. In addition, you will be encouraged to discuss your involvement and emotional response to the survey with your General Practitioner.

Item 7: Publication and other use of results
Data will be recorded in the form of written questionnaires. The completed questionnaires will be accessible for up to 15 years after which point the data will be destroyed. The results from this study will be displayed in a thesis format. It is possible that they will also be presented at a conference, or published in a peer-reviewed journal. It should be noted however that participant information would be expressed anonymously (e.g. participant 1, participant 2, etc), with no mention of the participants names or personal details. Furthermore results of the study will be made available to each participant upon request. This may entail a mailing of results to your home residence, or if you prefer, a discussion with Mr Matthew Cotchett in person. Only the Primary Investigator and other researchers listed in Item 12 (below) will have access to your data.

The results obtained from this study may also be used in future research projects. However, only the researchers involved in this study will be able to identify you from the data we use in future projects. Such projects may include studies investigating how factors such as anxiety, depression and/or stress influence treatment outcomes in people with plantar heel pain. Other projects include investigating risk factors and characteristics associated with plantar heel pain.

In instances where other researchers (Honours and/or Postgraduate students) will need access to your data for future research projects, the Human Ethics Committee will be advised and requested to grant permission to do so.

Item 8: Expected benefits of being in the study
Plantar heel pain is a condition that can be disabling and painful. Hence, if your symptoms reduce with either the real or sham treatment your health-related quality of life might improve. However, there is a chance that the intervention may not result in improvement in your symptoms. In addition, your involvement might help practitioners make informed decisions about the use of this treatment method, which will in turn optimise the benefits to the patients they manage with this condition.

Item 9: Costs to the participants
As a participant in the trial, you do not have to pay for any of the treatments. However, you will be expected to fund your own transport to and from La Trobe University.

Item 10: Withdrawal from the trial
Participating in the trial is completely voluntary on your part. There are no disadvantages, penalties or adverse consequences for not participating or for withdrawing prematurely from the research. You have the right to withdraw from active participation in this project at anytime and, further, to demand that data arising from your participation are not used in the research project provided that this right is exercised within four weeks of the completion of your participation in the project. **You are asked to complete the "Withdrawal of Consent Form" or to notify the investigator by e-mail or telephone that you wish to withdraw your consent for your data to be used in this research project.**

Item 11: Deception
A form of deception will be used in this trial, as you will be blinded to the treatment you receive. However, you will be randomly allocated to receive either the real or sham dry needling treatment and will have a 50% chance of receiving either treatment. At the end of the trial period you will be informed of the intervention that you received. If you received the sham intervention you will be offered a further six week course of the real intervention providing the real dry needling is found to be beneficial.

Item 12: Enquiries

Any questions regarding this project may be directed to Mr Matthew Cotchett of the Department of Podiatry on telephone number +61 3 9479 5776 or e-mail < m.cotchett@latrobe.edu.au >. If you have any complaints or queries that the investigator has not been able to answer to your satisfaction, you may contact the Secretary, Human Ethics Committee, Research Services, La Trobe University, Victoria, 3086, (ph: +61 3 9479 1443), email: (humanethics@latrobe.edu.au).

The contact details of the other investigators of this study are shown below:

Other investigators	**email**	**phone**
Dr Karl B Landorf	k.landorf@latrobe.edu.au	(03) 9479 5300
Dr Shannon E Munteanu	s.munteanu@latrobe.edu.au	(03) 9479 5866
Dr Anita Raspovic	a.raspovic@latrobe.edu.au	(03) 9479 5835

Appendix 8. Advertisement (Chapter 5)

Appendix 9. Participant reported use of co-interventions and pain relieving medication during the trial[a] (Chapter 5)

Additional intervention	0 to 6 weeks		7 to 12 weeks	
	Real dry needling (n=41)	Sham dry needling (n=43)	Real dry needling (n=41)	Sham dry needling (n=43)
Podiatry	2 (4.8)	2 (4.6) (	4 (9.7)	5 (11.6)
Physiotherapy	2 (4.8)	0 (0.0)	0 (0.0)	1 (2.3)
Cortisone injection	0 (0.0)	0 (0.0)	1 (2.4)	3 (6.9)
Extracorporeal shock wave therapy	0 (0.0)	0 (0.0)	1 (2.4)	1 (2.3)
Pain relieving medication[b]				
Over-the-counter	1 (2.4)	1 (2.3)	0 (0.0)	1 (2.3)
Prescription drugs	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)

[a]Data are expressed as number (%). Some participants used more than one co-intervention

[b]Analgesics, steroidal and non-steroidal anti-inflammatories.

Appendix 10. Assessments of treatment expectancy and rationale credibility recorded after the first treatment[a] (Chapter 5)

Question of treatment expectancy and rationale credibility	Real dry needling	Sham dry needling	Mean difference (95% CI)	*P*-value
At this point how logical does this treatment offered to you seem?	6.8 (1.4)	6.9 (1.5)	-0.1 (-0.7 to 0.6)	0.841
At this point, how successfully do you think this treatment will be in reducing your heel pain?	6.7 (1.4)	6.5 (1.1)	0.3 (-0.3 to 0.8)	0.344
How confident would you be in recommending this treatment to a friend who experiences similar problems?	6.9 (1.2)	7.0 (1.1)	-0.1 (-0.6 to 0.4)	0.702
By the end of the treatment, how much improvement in your heel pain do you think will occur?[b]	6.9 (1.2)	7.0 (1.1)	-0.1 (-0.6 to 0.4)	0.715
At this point, how much do you really feel that the treatment will help you to reduce your heel pain?	6.6 (1.6)	6.5 (1.3)	0.2 (-0.5 to 0.8)	0.601
By the end of the treatment period, how much improvement in your heel pain do you really feel will occur?[b]	6.3 (1.9)	6.6 (1.8)	-0.1 (-1.0 to 0.7)	0.727

[a]Data are expressed as mean (SD). The credibility expectancy questionnaire (CEQ) was used to evaluate the therapy credibility (0 corresponds to not credible; 10 very credible) and participant expectancy for improvement (0% corresponds to 0% expectation of improvement; 100%, full improvement). 95% CI = confidence interval.

[b]Question relating to participant expectations.

Appendix 11. Univariate statistical analysis of correlations between potential predictors and FHSQ foot pain and FHSQ foot function[ab] (Chapter 6)

	Foot pain		Foot function	
Potential predictor	Correlation	*P*-value	Correlation	*P*-value
Age	0.04	0.726	-0.11	0.336
Sex	-0.21	0.059	-0.24	0.020*
Height	0.10	0.450	0.08	0.362
Weight	-0.14	0.956	0.01	0.222
Body Mass Index	-0.03	0.768	-0.23	0.038*
Duration of heel pain	-0.04	0.725	-0.01	0.948
Depression	-0.21	0.062	-0.27	0.013*
Anxiety	0.05	0.661	-0.01	0.930
Stress	-0.15	0.165	-0.27	0.016*

[a]Correlations evaluated using Pearson correlation coefficients for continuous variables.
[b]Point biserial correlation coefficient was used to evaluate the relationship between Age, Foot function and Foot pain.
*Significant at the $p < 0.05$ level.
Note: This table appeared as a Supplementary file in the published manuscript.

Appendix 12. Ethics approval (Chapter 7)

La Trobe University
Faculty of Health Sciences
MEMORANDUM

TO: Dr Karl Landorf
Dr Shannon Munteanu
Dr Anita Raspovic
Mr Glen Whittaker
Department of Podiatry

SUBJECT: *Reference:* **FHEC10/247**

Student or Other Investigator: Matthew Crotchett

Title: **Depression, anxiety and stress in people with plantar heel pain (plantar fasciitis): a case control study**

DATE: 25 January, 2011

The Faculty Human Ethics Committee's (FHEC) reviewers have considered and approved the above project. You may now proceed.

Please note that the Informed Consent forms need to be retained for a minimum of 5 years. Please ensure that each participant retains a copy of the Informed Consent form. Researchers are also required to retain a copy of all Informed Consent forms separately from the data. The data must be retained for a period of 5 years.

Please note that any modification to the project must be submitted in writing to FHEC for approval. You are required to provide an annual report (where applicable) and/or a final report on completion of the project. A copy of the progress/final report can be downloaded from the following website: http://www.latrobe.edu.au/rgso/forms-resources/forms/ethic-prog-final.rtf

Please return the completed form to The Secretary, FHEC, Faculty of Health Sciences Office, La Trobe University, Victoria 3086.

If you have a student/s involved in this project, a copy of this memorandum is enclosed for you to forward to the student(s) concerned.

Neil McDonald
Secretary
Faculty Human Ethics Committee
Faculty of Health Sciences