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MINIMALLY INVASIVE THERAPY IN THE TREATMENT OF PLANTAR HEEL PAIN

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CERTIFICAN

Que la memoria de Tesis Doctoral titulada "**Minimally invasive therapy in the treatment of plantar heel pain",** presentada por Don Zaid Habib Alboloushi ha sido realizada bajo nuestra dirección, reúne los requisitos necesarios de calidad, originalidad y presentación y está en condiciones de ser sometida a valoración por el Tribunal seleccionado por la Universidad de Zaragoza encargada de juzgarla**.**

Y para que así conste, firmamos el presente certificado.

Zaragoza, a 8 de Enero de 2021

Fdo: Pablo Herrero Gallego Fdo: Eva Mª Gómez Trullén

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INDEX

ABBREVIATIONS

(ACFAS) American College of Foot and Ankle Surgeons

(ACh) Acetylcholine

(AChE) Acetylcholine esterase

(ACP) Autologous conditioned plasma

(ASCIs) Acid-sensing ion channels

(ATP) Adenosine triphosphate

(ATrPs) Active Trigger Points

(BK) Bradykinin

(BMI) Body Mass Index

(BoNT/A) Botulinum-neuro-toxin type - A

(BoNT/B) Botulinum-neuro-toxin type - B

(BoNT/C) Botulinum-neuro-toxin type - C

(BOTOX) Botulinum toxin

(CI) Confidence interval

(CNS) Center Nervous System

(COL2) Collagen type II

(CONSORT) Consolidated Standards of Reporting Trails and encompasses various initiatives

(CSI's) Corticosteroid injections

(DN) Dry Needling

(EMG) Electromyography

(EPI) Electrolysis Percutaneous Intratissue

(EPP) Endplate Potential

(EPT) Percutaneous Electrolysis Therapy

(EQ-5D) EuroQoL-5 dimensions

(ESWT) Extracorporeal Shockwave Therapy

(FAAM) Foot and Ankle Ability Measure

(FADI) Foot and Ankle Disability Index

(FFI) Foot Function Index

(FM) Fibromyalgia

(HLLT) High-level laser therapy

(HS) Heel Spur

(HTM) high-threshold mechanoreceptors

(INR) International Normalized ratio

(L-PRP) Leukocyte-PRP

(LLLT) Low-Level Laser Therapy

(LTR) Local Twitch Response

(LTrPs) Latent Trigger Points

(MCID) Minimum Clinically Important Difference

(MIO) Maximum Interincisal Opening

(MPS) Myofascial Pain Syndrome

(MSK) Musculoskeletal

(MTrPs) Myofascial Trigger Points

(NSAID's) Non-Steroidal Anti-Inflammatory

(P2X3) Purinoceptor 3

(PASS) Patient Acceptable Symptomatic State

(PBM) Photo Biomodulation

(PCS) Plantar Calcaneal Spur

(PEDro) Physiotherapy Evidence Database

(PF) Plantar Fasciitis

(PHP) Plantar Heel Pain

(PMN) Polymodal Nociceptors

(PNE) Percutaneous Needle Electrolysis

(PRISMA) Preferred Reporting System Items for Systematic Reviews and Meta-analyses

(PRP) Platelet-Rich Plasma

(QoL) Quality of Life

(ROM) Range of Motion

(SD) Standard Deviation

(SEA) Spontaneous Electrical Activity

(SP) Substance P

(SPIRIT) Standard Protocol Items: Recommendations for Interventional Trials

(SSHP) Self-Stretching Home Programs

(TPIs) Trigger Point Injections

(TRPV1) Transient Receptor Potential Vanilloid 1

(VAS) Visual Analog Scale

(VISA-P) Victorian Institute of Sport Assessment-Patella score

(WHOQOL-BREF) Quality of Life as Scored with the World Health Organization Quality of Life – Short Form

CHAPTER 1 BACKGROUND

1.1 SCIENCE OF PAIN

Pain is a sensation that people have long feared, as it typically signals that something is wrong. However, this perception of pain also forces us to seek medical care, thereby ironically protecting us. In many ways, this natural phenomenon was man's earliest warning system. Pain is a subjective measure, yet no equipment or device is able measure it. Individuals experience pain differently; some describe it as the worst thing they have ever experienced in their life, requiring analgesia for its relief, while others can tolerate it and even manage it using non-pharmacological methods such as meditation.

For many years, scientists have studied this normal physiological reaction that informs us of underlying pathology, in the hope of preventing or controlling pain. Pain occurs when our body and the nervous system alert our brain about actual or potential harm to the tissue. Musculoskeletal pain is one of the common causes of pain. It may involve any structure in the body, and for this reason, it can have a varied presentation and affect individual's lives in different ways.

Painful stimuli activate special receptors in the tissues called nociceptors, which then transduce this information into an electrical impulse carried by axons into the central nervous system (CNS). Nociceptors are the free nerve endings of nerve fibers. There are two main types: A-delta fibers, which are myelinated, and C fibers, which are unmyelinated. The types of pain and the speed at which pain is conducted along these fibers differ. These characteristics are summarized in **Table 1**, along with other properties of pain fibers.

Fiber type	***Að- fibers (myelinated)***	***C fibers (unmyelinated)***
Fiber diameter	*2-5 µm*	*< 2 µm*
Conducting velocity	*5-15 m/second*	*0.5-2 m/second*
Distribution	*Body surface, muscle, joint*	*Most tissue*
Pain sensation	*Rapid, pricking, well-localized*	*Slow, diffuse, dull, aching*
Position of synapses within the dorsal horn of the spinal cord	*Laminae I and V*	*Laminae II (substantia gelatinosa)*

Table 1. Type of fibers. Extracted from Charlotte E Steeds et al.2008 (1)

There are two types of nociceptors, high-threshold mechanoreceptors (HTM) and polymodal nociceptors (PMN), each of which respond to a different painful stimulus. HTM responds to a mechanical stimulus whereas PMN responds to various endogenous inflammatory mediators that immerse, activate and sensitize the nociceptors following different pathways. For instance, adenosine triphosphate (ATP) and protons (H+) bind to receptor molecules found in the membrane of the nerve ending, thereby activating them; ATP activates nociceptors by binding to purinoceptor 3 (P2X3) receptor molecule while H+ bind to both transient receptor potential vanilloid 1 (TRPV1) and acid-sensing ion channels (ASICs) (1, 2).

Chronic pain occurs due to an influx of nervous impulses from muscle nociceptors into the spinal cord, which increases the excitability of dorsal horn neurons to a greater extent than the input from cutaneous nociceptors. This spread of excitation is due, in part, to an overexcitability of sensory neurons of the spinal cord. The overexcitability of nociceptor neurons in the CNS is considered the leading cause of allodynia and hyperalgesia in patients with chronic muscle pain. Patients with chronic muscle pain are challenging to treat because the CNS's functional and structural changes require time to regress (2, 3). It is important to note that pain arising in muscles is more likely to cause referred pain patterns and be confused with dermatomal pain, which will affect diagnosis and treatment. Referred pain is pain that is not only felt at the site of origin but at another spot, which is sometimes distant from the site of pain (1-4). Patients will often complain of pain at one area although the origin of the pain is somewhere else; such is the case of patients who present with plantar heel pain (PHP), whereby treatment of the gastrocnemius, tibialis posterior, and other muscles leads to pain relief, according to Janet Travell (5). To quote one of the pioneers of musculoskeletal medicine, "he who treats the site of pain is lost" MD. Karel Lewit(6).

1.2 EPIDEMIOLOGY

The incidence and prevalence of PHP are uncertain, although it is the most common type of pain affecting the lower extremity treated by health care providers (7-9). However, it is estimated that 10% of the population may suffer from this condition (7, 10). Although there are few high-quality epidemiological studies available, a study conducted in the United States between 1995 and 2000 found that consultations for PHP equaled approximately one million visits to physicians per year (11). In the United States, PHP affects about 2 million Americans each year, and as much as 10% of the population will be affected throughout their lifetime (7, 8, 12). It is estimated that 7% of people aged over 65 years in the US report tenderness at the heel site (13).

1.3 PLANTAR HEEL PAIN DIAGNOSIS

Despite PHP being a common cause of pain and affecting a person's activities of daily living and thus the quality of life, muscles are poorly understood and often neglected as a potential source of pain. This situation translates to a limited number of treatment modalities available to patients. Suffering PHP can substantially affect a patient's quality of life (7, 8, 12-16). PHP is an umbrella term used to describe several clinical conditions with overlapping features (17, 18) and different diagnostic labels. One example is "plantar fasciitis," although there is a move away from this term towards "plantar fasciosis," which means degeneration of the plantar fascia, and "plantar fasciopathy," which simply means pathology of the plantar fascia. Current imaging studies demonstrate that the condition spreads beyond the fascia or the heel bone and surrounding tissue, therefore the more general term, PHP, is considered more appropriate (9, 19).

PHP causes tenderness and pain in the foot, sometimes extending to the medial arch of the foot (9) and in many cases, the only part of the foot that is affected is the heel. This condition affects both athletic and sedentary people and does not seem to be influenced by gender. The diagnosis is mainly clinical, as there are no definitive confirmatory studies available, and as such, it is based on the patient's history and physical examination, emphasizing pain during the first steps in the morning or after prolonged rest and pain during prolonged standing or walking (7, 12, 16). The proper identification of the cause of the pain can be difficult as it is often multifactorial (14). The similarities between the overlapping conditions and the lack of definitive investigations pose a diagnostic challenge.

There are some differences between the different diagnosed conditions, and it is crucial to be able to distinguish one from the other as it will have an impact on treatment:

- Plantar fasciitis (PF) and heel spur (HS)

Two conditions that are often confused and used interchangeably are PF and HS.

Some clinicians believe they are the same condition, while others believe they are a continuation of one another with a cause-and-effect relationship (9, 13, 19-22). PF is one of the most common causes of foot pain for which patients seek medical attention. One study has found that approximately 10% of the United States population visit the health system for this pain (12). PF is considered a degenerative inflammation of the plantar fascia, resulting from repeated trauma or microtrauma on the calcaneal bone (22). Some authors consider PF to be multifactorial; however, its etiology remains widely disputed. Some suggest that long-distance running causes the

inflammatory process, leading to fibrosis or degeneration, while others suggest the pain may be secondary to periosteal inflammation of the calcaneum. (22). Another condition which also contributes to heel pain is the HS. The plantar calcaneal spur (PCS) is a boney growth formed at the calcaneal tuberosity. It is caused by prolonged stress on the plantar fascia ligament and muscles of the foot, which cause the heel spur to appear at the attachment of the heel bone. However, some researchers believe the HS may not be the source of heel pain (20, 23). The PCS is typically described as bony outgrowths arising just anterior to the medial process of the calcaneal tuberosity. A review conducted by Kirkpatrick et al. noted that some authors define as a projection larger than 1 or 2 mm while others use microscopy or subjective assessments (23). According to ethnicity, the prevalence of the PCS varies with reported rates of 11% in India, 13% in Ireland, 15% in Zimbabwe, 17% in Thailand, 17% in Europe, and 21% in America. This rate increases with age, rising to 55% in those over 62 to 59-78% in those with current or previous heel pain and up to 81% in patients with osteoarthritis (23). According to the study by Ahmed et al. (20), the plantar heel spur is classified based on shape and size in patients with PF, with no significant correlation between the differences of the size or shape of the spur and patients' symptoms.

- Myofascial Pain Syndrome (MPS)

The most common pain in the musculoskeletal system is MPS. The conventional definition of MPS is a regional pain syndrome, originating from hyperirritable spots located within the taut bands of skeletal muscles, known as myofascial trigger points (MTrPs) (24). MTrPs are palpable nodules of taut bands within the muscle fibers. When these nodules are mechanically stimulated, local or referred pain is aggravated. This pain can be induced with a visible local twitch response

(LTR) (25, 26). Muscle trigger points can be either latent (LTrPs) or active trigger points (ATrPs), each having its own set of characteristics. LTrPs are well-known for their clinical characteristics: local tenderness with or without referred pain, restricted range of motion (ROM), muscle weakness, muscle fatigue, alternating muscle activation patterns, and ability to induce muscles cramps (27). ATrPs have the same clinical characteristics, furthermore, they provoke spontaneous referred pain. ATrPs can contribute to significant regional pain and neuromuscular dysfunction, and they are the main generator of peripheral pain, generalized musculoskeletal pain disorders such as fibromyalgia (FA) and whiplash (26, 27). LTrPs turn into an active trigger point when irritated.

The etiology of MTrPs is not well understood to date. Knowledge of the potential factors is essential to clinically understand the development of these MTrPs and limit recurrence. Several precipitating and perpetuating factors exist which involve MTrPs. There is general agreement that muscle trauma, whether direct or indirect, micro or macro trauma, overuse, repetitive low-level muscle contractions, maximal or submaximal concentric muscle contraction, muscle ischemia, muscle wasting can lead to their development. Also, non-muscular factors play a role in their development, such as anxiety, visceral pain, radiculopathy compression of the motor nerve, and climate-related factors (24, 28). According to the available evidence, the first step of trigger point formation is the development of contracted muscle fibers or a taut band, which may or may not be tender (29). The electrodiagnostic characteristic of a MTrP is the spontaneous electrical activity (SEA) or endplate noise, which is presented as a fast low-amplitude electrical activity (30). The electromyography studies available enable the identification of two types of independent electrical

potentials at MTrP sites; one of which is a low potential with an amplitude of 10μV to 80 μV, whereas the other finding is high potentials with an amplitude of approximately 100 μV to 600 μV with both normal and abnormal wave shapes (31). Evidence of increased frequency of low-voltage (50-100 microvolts) electrical activity was found at the point of maximum tenderness in the taut band of a human subject, localized to the neuromuscular junction of the endplate zone of the taut band. Also, an abnormally increased frequency of miniature endplate potentials has been observed in in vivo models and humans (32). The pathophysiology of the MTrPs appears principally located at the center of the muscles in its motor endplate zone, the zone where the motor nerve enters the muscle and divides into several branches with each of these having a terminal claw-like motor endplate embedded in the surface of a muscle fiber (24). The spontaneous electrical activity (SEA) is one of the characteristics of MTrPs, SEA originates from the dysfunctional extrafusal motor endplate potential (EPP), rather than the gamma motor units within the muscle spindle. The EPP, which is a local depolarization of the muscle fibers, spreads a short distance along the muscle fibers, with a decrement of approximately 50-75 percent per millimeter. Supposing the EPP exceeds a certain critical level, in this case, endplates spikes are initiated, which explains the clinical phenomenon of SEA associated with MTrPs, which is registered only at a localized spot in the muscle with an intramuscular needle (EMG) (26), leading to the assumption that the SEA is a combination of endplate noise and endplate spikes in action potentials generated by sufficient amount of released ACh. The perpetuating factor due to the excessive ACh release from the motor endplate combined with inhibition of acetylcholine esterase (AChE), an upregulation of nicotinic ACh receptors, leads to the hypothesis that sustained sarcomere contracture results in increased local metabolic demands and compression of capillary circulation, with reduced blood flow and

minimized source of adenosine triphosphate ATP. Therefore, muscle fibers become locked in a contracture without sufficient energy to return the Ca2+ to the sarcoplasmic reticulum to restore a polarized membrane potential. It is suggested that the extra leakage of Ach at the nerve ending triggers a failure in the motor endplate function. The excitation of the ACh receptors within the postsynaptic membrane produces a continuous local depolarization and prompts the sarcoplasmic reticulum to release a large amount of calcium. There is an increased concentration of serotonin, histamine, bradykinin, and substance P in the surroundings of contracted nodules, which is related to local ischemia and sensitization of the afferent nerves. This results in MTrP-related pain and local sympathetic symptoms; the pathological changes induce a feeling of local cold (vasoconstriction), anxiety, and mental stress (31, 33). The local hypoxia elicits the release of neuro-reactive and metabolic substances by sensitizing peripheral nociceptors (29, 33).

1.4 MISCELLANEOUS

Plantar heel pain can be associated with systemic diseases such as autoimmune, infectious, or neurological diseases. A detailed medical history, as well as clinical examination, can guide us to the proper diagnosis. Some of the most common causes are listed below.

1.4.1 ACHILLES TENDINOPATHY

This is a prevalent cause of disability. The inflammatory process within the Achilles tendon's tendinous insertion can be categorized and referred to as tenosynovitis, peritendinitis, paratenonitis (acute disease), tendinosis (chronic), and achillodynia. The acute phase is secondary to acute overexertion, blunt trauma, chronic overuse, and muscle (34). Tendon vascularity, gastrocnemius-soleus dysfunction, age, sex, body weight and height, pes cavus, and instability of the ankle are

common factors for the rise of tendinopathy (35). Tendinosis is a degenerative condition of the Achilles tendon, characterized by thickening of the tendon (34) due to damage at a cellular level, which is supposedly caused by microtears within the connective tissues in the tendon.

1.4.2 HAGLUND'S DEFORMITY (HEEL BUMP)

Haglund's deformity, first described by Patrick Haglund in 1927, is known as retrocalcaneal exostosis or Mullholland deformity. Despite being a common clinical condition, it is poorly understood. On clinical examination, there is localized pain at the superior posterior aspect of the calcaneus, which is hypothesized to be related to shoe wear. The soft tissues near the Achilles tendon become irritated when the boney enlargement rubs against the shoes, often leading to painful bursitis (34, 36, 37).

1.4.3 HEEL NEURITIS

Heel neuritis results from compression of a branch of the lateral plantar nerve, which causes tingling, numbness, and pain in the heel area. It usually appears after a micro or macro trauma, a sprain, or sometimes due to a varicose (swollen) vein near the heel (34)

1.4.4 HEEL BURSITIS

Bursitis is a swelling of the bursa. It is typically felt either deep inside the heel or behind the heel, and occasionally the Achilles tendon may swell (34).

1.5 MANAGEMENT AND TREATMENT

There is a lack of consensus regarding the ideal management approach for PHP (15, 38, 39). Clinical practice guidelines support the use of conservative treatment, such as joint and soft tissue mobilization or self-stretching home programs (SSHP) (7, 12). In particular, SSHP are effective for addressing PHP (7, 14, 40), although recent randomized clinical trials (RCTs) have shown that there is an additional effect in reducing the severity of pain when SSHP is combined with ischemic compression (41). In the case of failure of conservative treatments, minimally invasive therapies are often employed, and it is here where we find the lack of consensus and controversy. Many treatment modalities are categorized as minimally invasive therapies and can be used in the treatment of PHP. These vary from corticosteroid injections (CSI's) (42-44), platelet-rich plasma (PRP) (45-52), botulinum toxin (BOTOX) (53, 54), prolotherapy (55, 56), acupuncture (57-60) or dry needling (DN) (17, 61-63).

1.6 NON-INVASIVE TREATMENTS FOR PLANTAR HEEL PAIN

1.6.1 CONSERVATIVE THERAPY

Treatment usually follows a step-wise approach. Patients receive different types of medication, depending on the severity of the pain. Over-the-counter medications are initially used, although NSAIDs are the first line of treatment to decrease pain and inflammation. Medications are usually prescribed in conjunction with a rehabilitation plan, which is set depending on the clinician's preference. The rehabilitation program may involve using different modalities such as therapeutic ultrasound, electrotherapy, hot and cold packs, and exercises to strengthen the muscles or relieve tension (7).

1.6.2 MANUAL THERAPY: MOBILIZATION & MANIPULATION / ISCHEMIC COMPRESSION

Worldwide, manual therapy is provided by many professions such as osteopaths, chiropractors, physical therapists, or physicians. The difference lies in the technique each specialist uses and the force and velocity of the manipulation or adjustment. A recent study has shown that this type of treatment produces an overall improvement in the reduction of pain and disability and an increase in ankle dorsiflexion (64). A RCT conducted in Brazil showed a significant improvement in individuals who received ischemic compression and manual therapy compared to patients who received stretching exercises and a self-stretching protocol (41).

1.6.3 INSOLES & ORTHOTICS

Individuals with PHP have significantly greater difficulty with footwear comfort, fit, and choice than unaffected individuals. Pain level, age, BMI, foot and ankle ROM, strength, calf endurance,

foot contact with the surface during postural standing or walking are all critical factors (65). In an attempt to overcome these difficulties, some people use insoles and orthotics.

There are many varieties of insoles and orthotics. Some factors need to be considered when prescribing insoles and orthotics to patients with PHP. These include the material used and its stiffness, whether these are prefabricated or custom made, and the patient's weight and height. No studies to date have demonstrated the effectiveness of insoles or orthotics in decreasing pain. Moreover, the use of custom-made foot orthoses was found to be more effective than sham orthoses in improving function, although not for reducing pain (7).

1.6.4 NIGHT SPLINT

The use of the night splint is based on enabling extended stretching of the calf muscles. According to the American Association of Physical Therapy's clinical guidelines, the night splint should be considered for patients with symptoms of pain lasting over six months. The desired period for wearing the night splint is 1-3 months; furthermore, the design of the night splint did not affect the outcome (7).

One study recruited thirty-three patients who followed a program consisting of directed gastrocnemius stretching exercises, wearing a Strassburg Sock or night splint, and silicone heel insoles, as required. This study found a strong, statistically significant correlation between gastrocnemius tightness and the severity of heel pain in plantar fasciitis. (66)

1.6.5 TAPING

Many types of therapies exist involving taping, these include the use of Kinesiotape, low-dye tape and K-Tape. A recent study has demonstrated that calcaneal or low-dye taping can be used to provide short-term (7-10 days) pain relief. This study proved that taping could cause functional improvement. Calcaneal taping proved to be a more effective tool for PHP relief than a stretching protocol, sham taping, or a control group with no treatment (67). Clinicians are advised to use taping to improve foot function and avoid over-pronation leading to pain reduction. Also, they can use elastic tape on the gastrocnemius and plantar fascia for a short period of pain reduction lasting one week (7). Low-dye tape was an effective treatment despite minimal adverse events such as tape that was too tight or allergic reactions (68).

1.6.6 THERAPEUTIC EXERCISE AND NEUROMUSCULAR RE-EDUCATION

According to an expert opinion published in the clinical practice guidelines of the International Classification Functioning Disability and Health American Physical Therapy Association, therapeutic exercises are not recommended as a treatment for PHP. Nevertheless, clinicians may prescribe strengthening exercises and movement training for muscles that control pronation and which attenuate forces during weight-bearing activity (7)

1.6.7 EXTRACORPOREAL SHOCKWAVE THERAPY

Extracorporeal shockwave therapy (ESWT) was first introduced to treat urinary stones. It was a less invasive approach compared to the commonly used surgeries available at the time (69). Gradually, ESWT was employed in other areas of medicine, such as for musculoskeletal and orthopedic uses, the treatment of many painful disorders such as elbow epicondylitis,

calcifications, or plantar fasciitis, as well as the non-union of long bone fractures. A meta-analysis suggested that focused shockwave therapy (FSW) was associated with a higher success rate in pain reduction than sham therapy in chronic PF (70).

1.6.8 LIGHT AMPLIFICATION BY STIMULATED EMISSION OF RADIATION (LASER) THERAPY

LASER therapy has various uses in medicine, ranging from esthetic medicine targeting wrinkles and fine lines, for example, to tissue remodeling and bone repair and even in post-surgical stages or for radiotherapy management of breast cancer (71) (72). In addition to the various uses of LASER therapy in medicine, there are many types of LASER therapies, ranging from low-level LASER therapy (LLLT) to high-level laser therapy (HLLT) and photobiomodulation (PBM).

Currently, there is a vast amount of data to support the use of laser therapy for different medical conditions. Many studies and research are supporting the use of laser therapy (73-75). In a comparative study between LLLT and ESWT, used together with conventional treatment involving exercises and orthotic management, the results showed a significant improvement in reduction of pain levels after the third month in all groups, favoring the use of LLLT, which demonstrated an improvement of 79% compared with the ESWT group (61%) three months post-treatment (76).

A systematic review with meta-analysis was conducted to determine the parameters and effectiveness of PBM. Out of 3865 studies, seven were RCTs selected after the final review, and four articles were selected for meta-analysis. There was a significant difference between PBM and control for visual analog scale (VAS) (Chi^2=29.30; P <0.00001) with an I^2 value of 90% in favor

of PBM versus the control group. The overall score was statistically significant ($P < 0.02$) in favor of PBM. This meta-analysis provided evidence that PBM is an effective treatment modality to reduce pain and improve foot function in patients with chronic PF, and the ideal treatment parameters for PF need to be further elucidated (77).

1.7 MINIMALLY INVASIVE TREATMENTS FOR PLANTAR HEEL PAIN

1.7.1 CORTICOSTEROID INJECTIONS

Corticosteroids have been used worldwide for the treatment of different musculoskeletal ailments. They have been the most extensively studied, and their safety profile is widely known. Steroids have different compositions, which affect the duration of their effects, and the formulation used is mainly dependent on availability. Corticosteroids can be divided into short, intermediate, and long-acting medication. However, consensual guidelines regarding the use of corticosteroids in MSK health are lacking (78-83)

Despite PF being identified as a degenerative condition with an inflammatory component, corticosteroids, which are a type of anti-inflammatory medication, are commonly prescribed treatments. The current evidence shows that corticosteroid injections (CSIs) are more effective than placebo injections but not more than other types of therapies such as PRP (43). CSIs can provide relief for heel pain in the short term, as proven by a study which showed a statistically significant reduction of pain at one month ($p= 0.02$) in favor of steroids (84).

The recommendation of CSIs as an initial treatment option by the American College of Foot and Ankle Surgeons (ACFAS) was met with skepticism and raised specific controversial issues,

especially in recent years, with the rise of regenerative medicine. This made the treatment of PF more challenging for clinicians. There was a dispute about the superiority of the corticosteroid formulation and the anatomical approach used for CSIs (82).

A meta-analysis by Gaujoux-Viala et al. found no difference in efficacy between the different types of corticosteroids used. This author also concluded that there was no long-term effect of using CSIs (82, 85-87).

A comparative study of CSIs versus placebo and US-guided procedures versus non-guided procedures among 65 patients with inferior heel pain showed no difference in VAS scores following steroid injection between the US-guided and the non-guided groups at either time point. On the other hand, there was a significant decrease in plantar fascia thickness after injection in both active treatment groups (P=0.00) over six weeks, which was maintained at 12 weeks (88).

Some studies have reported that CSIs yield better results than other treatment modalities. However, the effect of CSIs in these studies was short-lived, lasting 4-12 weeks in duration. Furthermore, complications were noted, such as PF rupture, in 2.4% to 6.7% of cases, and heel fat pad atrophy. Also, diabetic patients may experience elevated blood sugar levels for up to two weeks post procedure. There were also certain practical aspects of CSIs that should not be neglected in patients taking oral anticoagulants. Patients taking warfarin should have their International Ratio (INR) checked before the procedure, aiming for INR < 1.5. Cessation of newer anticoagulants or antiplatelets such as rivaroxaban, dabigatran, apixaban, clopidogrel should occur 48 hours before CSIs, and resumed post-procedure (82, 85-87).

A systematic review showed that numerous varieties of corticosteroids can be categorized based on their duration of action, ranging from short-acting corticosteroids such as hydrocortisone, to intermediate-acting corticosteroids, such as methylprednisolone, prednisolone, and triamcinolone, and finally long-acting corticosteroids such as dexamethasone and betamethasone. However, there is no specific recommendation or guideline, or justification for the use of one type over the other. Furthermore, there are many different techniques that are used to inject the medications; some prefer the posterior approach over the medial approach while others use the peppering techniques of injection (82).

In recent times, many studies have been carried out or are underway to compare the effectiveness of cortisone therapy with other minimally invasive techniques such as PRP or Botox injections (guided or unguided), as well as with non-invasive techniques such as manual therapy, exercises, or shockwave therapy (89-96).

1.7.2 BOTULINUM TOXIN

Botulinum toxin, commonly known as BOTOX, is a neurotoxin produced by the bacterium Clostridium botulinum. It was initially used by an ophthalmologist to treat strabismus and rapidly other uses were reported by many medical specialties (97). There are several types of botulinum neurotoxins; type A (BoNT/A) is well established, especially in treating conditions characterized by hyperactivity of cholinergic neuromuscular fibers such as focal dystonia. It is also the most common type used for the treatment of pain related to musculoskeletal (MSK) origin and neurological conditions (98).

Many studies have evaluated the effect of BoNT/A on PHP and PF. A multicenter, double-blind, placebo-controlled study of 40 patients who were randomized to receive 200 units of BoNT-A injected directly into the calcaneal origin of the plantar fascia administered in a fan-shaped manner. The patients in the BoNT-A group achieved a response at week six (25% vs. 5% for placebo; p=0.18) There were no statistically significant differences between the groups on secondary outcome measures for pain. Furthermore, no adverse events were noted. There is a need for larger, prospective, long term effect studies (99).

Another double-blinded controlled study conducted in Taiwan using a US-guided procedure on a cohort of 50 patients with chronic unilateral plantar fasciitis. Participants were divided into an experimental group, who received 50 units of BoNT/A, and a control group, who received normal saline. Both groups received the respective treatment under ultrasound guidance. The outcome measure included a comparative VAS, changes in thickness of the PF and the fat pad, and gait assessment, including the maximal center of pressure velocity during the first step loading response. Visual analogue pain scale and plantar fascia thickness in the symptomatic foot decreased significantly, as noted at follow-up 3 weeks and 3 months after BoNT/A injections (p=0.001), whereas the fat pad remained unchanged. The center of pressure velocity during loading response increased three months post-injection (p=0.05), whereas the control group remained the same, concluding that BoNT/A was influential in treating foot pain without inducing fat pad atrophy (100).

Recently, a molecular mechanism has been found to underlie the neuromuscular block caused by the seven BoNT serotypes. The different BoNT serotypes may be useful when a specific immune

resistance related to BoNT/A has been proven. Serotype F was injected into the human muscle, however, its effects are shorter compared to BoNT/A, whereas BoNT serotype V (BoNT/B) is effective in humans only if injected at a very high dose. BoNT serotype C (BoNT/C) has a general profile action similar to BoNT/A, although there is no comparison between these types of BoNT in humans (97). A recent study conducted in Iran aimed to determine the effectiveness of injecting BoNT/A (the most common type used in MSK clinical practice) in the medial head of the gastrocnemius muscle on improvements in functions and disability in people with chronic PF. Thirty-two patients were randomly allocated to treatment and placebo groups and were followed up for one year, evaluating function and pain using the AOFAS and VAS, respectively. The results, determined at a 12-month follow-up, demonstrated a decrease in the mean VAS from 7.8 to 4 in the placebo group and from 8 to 0.33 in the BoNT/A group. The mean of AOFAS scores increased from 48.4 to 65.3 in the placebo group and from 45.5 to 90.6 in the BoNT/A group. The patients treated with BoNT/A showed improvements after one-year follow-up (101).

1.7.3 PLATELET-RICH PLASMA THERAPY

Platelet-rich plasma is a biological therapeutic modality that consists of the preparation of a concentration of platelet and plasma proteins. This treatment aims to improve the reparability of endogenous cells. It is based on the intraarticular delivery of autologous platelet-rich plasma preparations containing a large pool of growth factors and proteins in the alpha-granules of the platelets. These growth factors and proteins promote the induced healing of the damaged tissue. Numerous growth factors found in PRP stimulate the matrix synthesis and counteract the effect of

catabolic cytokines such as interleukin-1 and tumor necrosis factor-alpha. Basic scientific evidence supports the therapeutic potential of PRP (102).

In recent years, there has been a surge in the demand of PRP, together with numerous studies for use of PRP in many medical branches such as aesthetic medicine, dermatology, orthopedics, regenerative medicine, and many other specialties. The most common one was in orthopedic medicine, and specifically for cartilage diseases and regeneration. One study found that chondrocytes treated in vitro with releasate from thrombin-clotted leukocyte-PRP (L-PRP), resulted in a significantly increased cell proliferation synthesis rate and accumulation of glycosaminoglycans and collagen type II (COL2), compared with the control group (103).

A Cochrane systematic review carried out in 2013 concluded that, overall, for individual clinical conditions, there is currently insufficient evidence to support the use of PRP for the treatment of soft tissue musculoskeletal injures. The researchers contemplating RCTs should consider the current ongoing trials when evaluating the need for future RCTs on each specific condition, bearing in mind that there is a need for standardization of PRP preparation methods. The available evidence is insufficient to indicate whether the effects of PRP will notably differ in individual clinical conditions (46).

A comparative RCT evaluated the efficacy of autologous conditioned plasma (ACP) with extracorporeal shockwave ESWT, and conventional treatment of stretching exercises and orthotics for the treatment of plantar fasciitis. Fifty-four patients (age range 29-71 years) with unilateral chronic plantar fasciitis with more than four months of symptoms participated. The primary outcome measure was VAS, AOFAS, and the ultrasound exam of plantar fascia thickness assessed

at baseline, before treatment, and at one month, three months, and six months post-treatment. The VAS and AOFAS scales, as well as plantar fascia thickness, improved in all groups. Pain also significantly improved in the ACP group compared to conventional treatment in the first month, and for the ESWT group, compared with conventional treatment at one, three, and six months. Significant improvements in plantar fascia thickness were seen in the ACP group at one month and three months when compared with conventional treatment, and at three months and six months when compared with ESWT. The study concluded a significant reduction in the ACP group compared to the ESWT, with no adverse events reported in this study (89).

A double-blind comparative study was also performed to analyze the effect of PRP versus corticosteroid and a control group who received a placebo (normal saline) for the treatment of chronic plantar fasciitis. The study was carried out with 75 randomly allocated patients who received one of the treatments and were assessed with VAS for pain and the AOFAS score prior to the injections and at a follow-up at three weeks and three months. The mean VAS score in both the PRP and Corticosteroid groups decreased from 7.44 and 7.72 pre-injection to 2.52 and 3.64 at final follow-up, respectively, whereas the mean AOFAS score in the PRP and Corticosteroid groups improved from 51.56 and 55.72 pre-injection to 88.24 and 81.32 at final follow-up, respectively. There was a significant improvement in both groups with no significant improvement in placebo. The study concluded that both PRP and corticosteroids were effective for the treatment of PHP (104).

Increasingly, a major question is whether PRP injection is more effective than steroid injection for the treatment of PF in the long term. Although steroids have proven to be a pain management

medication they do not promote tissue healing. Sixty patients diagnosed with heel pain for over six weeks after failed conservative treatment and with plantar fascia thickness greater than 4mm were included in a prospective, double-blind study. Patients were randomly divided into two groups, receiving PRP or steroid injections. They were all assessed with VAS and AOFAS scores. Assessments were performed at baseline, at six weeks, three months, and six months follow-up post injections. Plantar fascia thickness was assessed at baseline and six months after treatment using sonography. The mean VAS score in the PRP group decreased from 7.14 at baseline to 1.41 post injection, whereas in the corticosteroid group these values reduced from 7.21 at baseline to 1.93 post injection. The mean AOFAS score improved in the PRP group from 54 to 90.03 and in the corticosteroid group from 55.63 to 74.67 at the six-month follow-up. The improvements observed in the VAS and AOFAS scores were statistically significant; at six months, the plantar fascia thickness had reduced in both groups (5.78 mm to 3.35mm in the PRP group and 6.5 to 3.75 in the steroid group). The study concluded that PRP is an effective treatment compared with steroids, with a long-lasting beneficial effect (105).

There is a need for further research to determine the long-lasting effect of PRP and the effectiveness of the same. In another study, patients with chronic plantar fasciitis were allocated to receive a steroid injection or PRP. The primary outcome measure was the Foot Function Index (FFI) and the quality of life as scored with a short version of the World Health Organization Quality of Life (WHOQOL-BREF).

1.7.4 PERCUTANEOUS NEEDLE ELECTROLYSIS

Percutaneous Needle Electrolysis (PNE) is a novel minimally invasive approach that involves applying a minimal galvanic current directly through an acupuncture needle. Several devices are available for the administration of the current, with different brand names, such as EPI, EPT, EPTE, Physio Invasiva, etc. This technique provides an organic reaction that produces localized inflammation and microtrauma to the affected soft tissue structures. The needle is directed into the soft tissue under direct ultrasound guidance, stimulating a local inflammatory response which leads to increased cellular activity and the rapid regeneration of injured tissue (106, 107).

The effect of PNE was first analyzed in a prospective study of 33 athlete-patients consecutively treated for tendinopathy and followed up for two years. Functional assessments were performed at the baseline and three months (P<0.001). 78.8% of patients returned to the same level of activity as prior to the injury by the end of treatment, which increased to 100%(P<0.001) at two years (107).

Another study was conducted comparing the ultrasound-guided PNE technique vs. conventional electrophysical therapy to treat patellar tendinopathy. Sixty patients were randomized into two groups, and both groups received a program of eccentric exercises. All patients were assessed using the (VISA-P) Victorian Institute of Sport Assessment-Patella score. This study found that the best outcomes were obtained with a combination of ultrasound-guided PNE and eccentric exercise (108).

Percutaneous needle electrolysis was also used in a study of 73 patients who were randomly allocated to receive ultrasound-guided PNE vs. placebo for the treatment of patients with chronic

PHP; the primary outcome was an 11-point numerical scale for the assessment of pain, the secondary outcome was function and disability, measured by the 21-item activities of the daily living subscale of foot and ankle ability measure (FAAM) questionnaire, and fascia thickness was measured under US. All the above mentioned outcomes were measured at 1,12,24 weeks. There was a significant improvement of (P<0.01), in the numerical pain rating scale, FAAM activity subscale (P<0.002) and ultrasonography measurements of the plantar heel (P<0.002), furthermore, the PNE improved both pain and function (109).

A comparative study with a one-year follow-up for the treatment of plantar fasciosis using corticosteroid injection vs. PNE was carried out with 64 patients, including clinical and ultrasound assessments performed at baseline and at 3, 6, 12 months. Also, the VAS was used to measure pain and the Foot and Ankle Disability Index (FADI) was used to evaluate function. Both ultrasound-guided PNE and CI techniques were associated with significant clinical and sonographic improvements at 12 months post-treatment (P<.001) (110).

A double-blind RCT was performed comparing PNE vs. DN vs. sham needling for the management of temporomandibular myofascial pain syndrome, involving 60 patients allocated to receive one treatment session per week for three consecutive weeks. A clinical assessment was performed at baseline and at 28, 42, and 70 days post-treatment. Statistically significant differences (P<0.01) were found for the PNE and DN group concerning pain reduction at rest, during chewing, and maximum interincisal opening (MIO) with no adverse events observed for either technique (10).

A systematic review with meta-analysis found moderate evidence suggesting a large positive effect of PNE for the reduction of pain and for a large decrease in pain-related disability in MSK conditions in the short term, midterm and long term (111)

1.7.5 DRY NEEDLING

Dry needling is a technique that involves the insertion of a thin filiform needle into the trigger point for its release. The term DN is attributed to Dr. Janet Travell in her book "Myofascial pain and dysfunction: trigger point manual" (5). Karel Lewit first described this technique in 1979, which involved the insertion of the needle in the point of maximal tenderness at the trigger zone with immediate analgesia produced by the needle; he referred to this as "the needle effect" (112).

A Cochrane review concluded that "*DN appears to be a useful adjunct to other therapies for chronic low back pain*" (29). Although DN research is increasingly available, the exact mechanisms of action of direct needling in the deactivation of trigger points are still unclear. The most critical factors in deep DN are the depth of needle insertion, the amount and force of stimulation, and the elicitation of a "local twitch response" (LTR). LTR is the involuntary spinal reflex resulting from contraction of affected muscle fibers after being manually stimulated with the needle, injection, or even stretching with manual therapy. LTR are frequently triggered with DN compared to other methods, which affect the taut band and the blood flow of the targeted tissue and muscles (113).

The identification of MTrPs has been a challenge for many clinicians and researchers in the medical field. A novel preliminary study shows that US imaging techniques can be used to distinguish myofascial tissue containing MTrPs from normal myofascial tissue (lacking trigger

points), as it enables visualization of the LTR and some characterization of MTrPs and adjacent soft tissue (114). The identification of trigger points requires clinical skills and clinical applications to reach optimal results in the treatment of patients with plantar heel pain.

In 2011, a comparative RCT was conducted in Australia to evaluate the effectiveness of DN for the treatment of PHP, compared to a control group receiving sham needling. The study consisted of two parallel groups. Eighty-four patients were enrolled with pain of one-month duration. The treatment consisted of one session per week for six weeks and a 12-week follow-up. The primary outcome measure was first step-pain measured with a VAS scale, and foot pain and function using the (FHSQ). The primary endpoint for predicting the effectiveness of DN pain was six weeks. At the primary endpoint, significant effects favored real DN over sham DN for pain (adjusted mean difference: VAS first step-pain 14.4 mm, 95% confidence interval [95% CI] 23.5 to 5.5 FHSQ foot pain 10.0 points, 95% CI 1.0 to 19.1). The difference between groups was lower than the minimal important difference. The DN intervention provided a statistically significant reduction in plantar heel pain, however the limitation of this study was the inability to blind the clinician (therapist) (61, 115)

A comparative study for the treatment of plantar fasciitis using DN and corticosteroid injection was conducted in Iran to evaluate the superiority of each treatment; 60 patients were recruited to a single-blind clinical trial. Participants were allocated to receive 1 ml (40mg) of deop-Medrol (methylprednisolone acetate) or DN. They were followed up for 12 months. The mean VAS score at baseline was 6.96 ± 0.87 for the steroid group and 6.41 ± 0.83 for the DN group (P Values = 0.54). Patients who underwent DN reported lower VAS scores at the end of the follow-up

compared with the steroid group. In conclusion, the steroid injection group is able to palliate the plantar heel pain rapidly, however, DN can provide more satisfactory results for patients with plantar fasciitis in the long term (116)

CHAPTER 2 JUSTIFICATION

Despite its prevalence, the etiology of PHP is not well understood (8, 12) and there is a lack of consensus regarding the ideal management approach for PHP (15, 38, 39). Although PHP may be provoked by a tendinous injury affecting the plantar fascia, it is well known that myofascial trigger points MTrPs within the plantar and lower leg musculature may play an essential role in people with PHP (5). Clinical practice guidelines support the use of conservative treatment, such as joint and soft tissue mobilization or SSHP (8, 12). In particular, SSHP have been shown to address PHP effectively (7, 8, 12, 41, 117). In contrast, recent RCTs have shown that there is an additional effect for the reduction of pain severity when SSHP is combined with ischemic compression (41) and DN (63).

Physical therapy approaches continue to evolve, with minimal invasive techniques such as PNE, similar to DN but with the application of a galvanic electrolytic current through the needle to provoke a controlled local inflammatory process in the target tissue, which leads to phagocytosis and the subsequent regeneration of the affected tissue (107, 108).

At present, DN techniques have shown to be effective for the treatment of PHP (115, 118), PNE has also demonstrated its effectiveness for the treatment of tendinous pathologies (109, 119-122), however, to date there are no studies that have analyzed the effectiveness of PNE for the treatment of PHP, nor studies which have compared the effectiveness of PNE vs. DN.

CHAPTER 3 HYPOTHESIS AND OBJECTIVES

From a biological point of view, it seems reasonable to hypothesize that subjects can display improvements thanks to the mechanical effects of the needle and patients may benefit more when the electrolysis effect is added to the mechanical stimulus provided by the needle. Therefore, the main objective of this research was to analyze and compare the effectiveness of DN versus PNE for reducing the level of pain in patients suffering from PHP. In addition, the following secondary objectives were established:

1. To analyze the baseline characteristics of patients with PHP
2. To analyze the main muscles that contribute to PHP
3. To analyze the frequency of patient's compliance to the home stretching program and their progress in PHP.
4. To analyze the adverse effects associated to DN and PNE
5. To analyze the effectiveness of DN and PNE to reduce maximum and mean pain
6. To analyze the effectiveness of DN and PNE to improve foot function
7. To analyze the effectiveness of DN and PNE to improve Quality of life
8. To analyze the effectiveness of DN and PNE to improve general foot health
9. To analyze the patient's knowledge and limitations regarding proper shoe wear
10. To analyze whether participants can achieve an important improvement in their pain and whether this change is considered to be satisfactory.

CHAPTER 4 METHODS

A systematic review was conducted at the beginning of our research plan, from April 2016 to March 2017. The purpose of the review was to answer the following question: what is the effectiveness of minimally invasive non-surgical interventions, either applied on their own or combined, for the treatment of PF? The review was conducted in accordance with the Preferred Reporting System Items for Systematic Reviews and Meta-analyses (PRISMA) statement and was registered with PROSPERO (CRD42018083734) (83) (SEE ANNEX 1).

The search strategy aimed to identify all available experimental studies evaluating the invasive non-surgical management of PF. Searches of MEDLINE, Web of Science, Cochrane, and PEDro databases were conducted. The last search was performed in March 2017. The search strategy used was: ((Efficacy OR management OR effectiveness) AND (plantar OR fasciitis OR fasciosis OR fascitis OR heel) AND (dry need* OR intratissue percutaneous electrolysis or acupuncture or electroacupuncture or injection or injectabl* or puncture and infiltrat*)). These keywords were identified after preliminary literature searches. There was no restriction by date. The inclusion criteria were: 1) Randomized controlled clinical trials with a sample size of at least 20 subjects per study (10 per group); 2) Age of subjects: 18 years and older; 3) Diagnosis of plantar fasciitis (or equivalent terms such as fasciosis or fasciitis or heel pain); 4) Studies investigating the effectiveness of any invasive non-surgical treatment for PF (e.g., DN and/or injections, acupuncture, infiltration). The exclusion criteria were: 1) Any study including a surgical procedure or oral pharmacological agents or topical ointment; 2) Studies with animals 3) Trials whose sample of participants included any of the following terms: diabetes, spasticity, neuropathy, tumor,

fracture, hemophilia, stroke, amputation, artificial limbs, and rheumatoid arthritis; 4) Articles in which the full text was not in English; 5) RCTs not reaching a score of 5 in the PEDro scale. The evaluation of the eligibility of each study was carried out by three independent reviewers (ZA, ML, MA) who performed an initial screen by title, a second screen by abstract, and subsequently compared the results. In case of disagreements, a fourth reviewer was consulted (EG). Thereafter, the full text of the selected articles was read to verify whether they met the inclusion and exclusion criteria. Subsequently, the studies were evaluated using the PEDro scale, and those obtaining less than 5 points were excluded. For the data extraction, a table was generated containing all the results classified by the outcome measurements, which helped group the results and enabled a comparison amongst the different studies. This systematic review enabled us to evaluate all the recent RCTs involving minimally invasive therapies for the treatment of PHP, considering all the available evidence.

Based on the aforementioned systematic review, a protocol for a Randomized Clinical Trial was designed following the SPIRIT Guidelines. This protocol was published in the Journal of Orthopaedic Surgery and Research, (Volume (17) (SEE ANNEX 2). The study protocol was registered in clinical trials at Clinicaltrials.com, number NCT03236779 (Registered 2 August 2017). This study was conducted in compliance with the Helsinki Declaration of Human Rights. Ethical approval was obtained by the Medical Ethics Committee of the State of Kuwait Ministry of Health (19th September 2017), with reference number 642/2017. After registering the protocol, we started the recruitment for the study, and the RCT was reported in accordance with the CONSORT statement for non-pharmacological trials.

Patient recruitment commenced in January 2018 and was completed by October 2018. This study was a prospective, parallel-group RCT with blinded outcome assessments. Participants were recruited from Kuwait City, the State of Kuwait, and both the assessment and intervention were conducted at the Physical Medicine and Rehabilitation Hospital in Kuwait by a physician.

Participants who fulfilled the inclusion criteria received the standardized oral and written information, and, once they granted their consent to participate in the trial, they were randomized in a block system by blocks of 10 patients. Allocation to the groups was achieved using a computer program (Randomizer, https://www.randomizer.org/) with random patient file number sequences generated by a third person not involved in the study and based on their file number in Kuwait. This person was responsible for safekeeping the envelope with the information on the randomization. The envelopes were remained closed until the moment of the intervention to maintain the blinding. This professional also asked the patients for informed consent.

To be eligible for the study, participants had to meet the following inclusion criteria:

- A clinical diagnosis of PHP 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 (8, 12, 62, 63)
- Age 21 years or older at admission to the study, according to Kuwaiti law.
- History of PHP for over one month, showing no improvements with previous conservative treatment.
- Able to walk 50 meters without any support.

- The presence of MTrPs on plantar and calf muscles, based on initial physical examination carried out by a physiotherapist (MA) with experience and training in MTrPs.
- Accepting treatment from a male physiotherapist.
- The ability to understand the study and the informed consent, and signing the document.

The exclusion criteria for the study consisted of:

- Needle phobia.
- Needle allergy or hypersensitivity to metals.
- Presence of coagulopathy or use of anticoagulants according to medical criteria.
- Presence of peripheral artery disease.
- Pregnancy.
- Dermatological disease affecting the DN area.
- The presence of a chronic medical condition which might preclude participation in the study, such as malignancy, systematic inflammatory disorders (e.g., rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, septic arthritis), neurological diseases, polyneuropathy, mononeuropathy, and sciatica.
- Treatment of plantar heel pain with needling or acupuncture during the last four weeks.
- History of injection therapy in the heel over the previous three months.
- Previous history of foot surgery or fracture.

Participants were controlled by using the appropriate medication dosage as prescribed by the physiatrist (analgesics and non-steroidal anti-inflammatory medications) and were required to report any changes to the assessor during the evaluations, including the consumption of any

additional medication or undergoing any other treatment during the intervention. They were willing not to receive or implement any form of treatment for the plantar heel pain (taping, night splints, massage therapy, or footwear modifications) while they participated in the trial. The participants had the right to withdraw from the study at any time without providing any explanation.

In designing the study, the sample size was calculated, estimating that 94 participants with PHP were necessary. An initial prospective sample size calculation estimated that 39 participants per group would provide 80% power to detect a minimally significant difference of 13 points in the pain domain of the Foot Health Status Questionnaire (FHSQ) with a standard deviation of 20 points (123) and an alpha risk of 0.05, allowing 20% loss to follow-up (16 patients). Based on the initial data collection, the drop-out rate was recalculated to be 25% and the sample size was therefore increased to a total of 102 patients.

4.1 STUDY VARIABLES

4.1.1 BASELINE DATA

The baseline data were gender, age, height, weight, BMI, details regarding the affected side (right, left, or bilateral), duration of symptoms, medication, and previous treatments.

A blinded observer assessed all participants at baseline and at 4, 8, 12, 26, and 52 weeks post-treatment **[FIGURE 1].**

	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation					Close-out
TIMEPOINT	-3 to 0 days	0	Baseline	4 weeks	8 weeks	12 weeks	26 weeks	52 weeks
ENROLMENT:								
Eligibility screen	X							
Informed consent	X							
Allocation		X						
INTERVENTIONS:								
DN-G			◆—	—◆				
PNE-G			◆—	—◆				
ASSESSMENTS:								
Baseline demographic information	X							
FHSQ			X	X	X	X	X	X
VAS			X	X	X	X	X	X
EQ-5D			X	X	X	X	X	X

Figure 1. Schedule for enrolment and intervention. Extracted from Al-Boloushi et al 2019 (17) (SEE ANNEXE 2)

DN-G: DN group; PNE-G: Percutaneous needle electrolysis group. FHSQ: Foot Health Status Questionnaire; VAS: Visual Analog Scale; EQ-5D: EuroQol-5D

4.1.2 PRIMARY OUTCOME MEASURE

Participants completed the FHSQ questionnaire at baseline and at 4, 8, 12, 26, and 52 weeks post-treatment. The FHSQ consists of 13 questions reflecting four-foot health-related domains: pain (4 questions), function (4 questions), footwear (3 questions), and general foot health (2 questions). Individual item scores were then re-coded, tabulated, and finally transformed to a scale ranging from 0 to 100 for each of the four domains (124). Greater scores reflect better foot health and quality of life (125). The FHSQ has been validated (126) and has been used in similar trials that have evaluated the effectiveness of different interventions for plantar heel pain (62, 127, 128).

4.1.3 SECONDARY OUTCOME MEASURES

Participants completed the VAS at baseline and at the 4, 8, 12, 26, and 52-week assessments and, additionally, before each treatment session. The level of pain that patients have experienced during the previous 48 hours before starting the treatment session was recorded. Participants were asked about the mean and the highest level of pain that they had experienced in the past 48 hours. The exact wording of the questions was: 1) what is the level of pain, on average, that you have felt during the last 48 hours? and 2) what is the maximum level of pain you have felt during the last 48 hours? Additionally, after treatment, they were asked to score their current pain immediately upon standing up and walking a few steps. Participants were explained that a score of 0 indicates the absence of pain whereas a score of 10 represents the maximum tolerable pain. The VAS is widely used and is valid and reliable (129-131). Participants were also asked to indicate the areas

of perceived pain using an electronic body chart (Navigate pain, version 0.1.9.9, Aalborg, Denmark) (132).

Quality of Life (QoL) was assessed with the EuroQoL-5 dimensions (EQ-5D), completed by the patients at baseline and the 4, 8, 12, 26, and 52-week assessments. The EQ-5D self-report questionnaire is a descriptive system with five questions, each representing one dimension of the Health-related Quality of Life (HRQoL), i.e., mobility, self-care, daily activities, pain/discomfort, and depression/anxiety. Each dimension can be rated on three levels: no problems, some problems, and major problems, together, the results serve to classify people into 1 of 243 possible health states (133).

4.2 STATISTICAL ANALYSIS

The statistical analysis was performed via an intention-to-treat analysis. The variables are presented as the percentage, mean (standard deviation) or median (interquartile range), according to their distribution. Quantitative variables were analyzed using the Shapiro Wilk test in order to confirm their distribution and to determine the correct statistical tests according to these results. The outcomes were analyzed using mixed linear and logistic regression models, considering participants as a random effect and treatment group as fixed factors. Baseline characteristics were introduced in the model as covariance factors. The numbers needed to treat the index were also calculated. The primary aim of the analysis was to calculate the difference obtained in the FHSQ score after the intervention (final measurement - initial measurement). Finally, the magnitude of the effect of the result was calculated and, therefore, its clinical importance, by using the following formula: $r = \sqrt{[\boldsymbol{F}(\mathbf{1},\boldsymbol{dfR})]/[\boldsymbol{F}(\mathbf{1},\boldsymbol{dfR})+\boldsymbol{dfR}]}$. The significance level for statistical tests was set at

$p \leq 0.05$. The statistical analysis was performed using IBM SPSS Statistics (version 25, IBM, Chicago, IL) by intention to treat, with the last observation carried forward. The investigator who performed the analyses was masked to group allocation. The significance level for all statistical tests was set at $P \leq 0.05$. Chi-squared tests were used to analyze whether there were differences in categorical variables between groups at baseline. In addition, independent Student t-tests and Mann-Whitney U tests were used for parametric and nonparametric quantitative variables, respectively. Chi-squared tests were used to evaluate the compliance of the self-stretching protocol.

Following recommendations to estimate treatment effects in RCTs, mixed linear models adjusted for baseline values were used to test the mean effect of treatment interventions at the 4, 8, 12, 26 and 52-week follow-up, for the Foot Health Status Questionnaire and EQ-5D-5L measures. Linear mixed models adjusted for baseline values were used to test the mean effect of treatment interventions in the second session, third session, fourth session, and at the 4, 8, 12, 26, and 52-week follow-ups, for measures of VAS (average and maximum). Individual repeated measures (RM) ANOVAs were used to test time effects within each treatment group for primary and secondary outcomes. Cross-sectionally, at all linear mixed models and RM-ANOVAs, the Bonferroni correction was used to test between-group time point differences or within-group time changes, respectively. The Greenhouse-Geisser correction was applied for correcting against violations of sphericity, whereas eta-squared (η^2) was used to estimate the magnitude of the difference between both groups (0.01 small effect, 0.06 medium effect, and 0.14 large effect).

(134) Independent t-tests were used to determine any difference between groups for measures of the level of pain immediately after each treatment session.

4.3 INTERVENTIONS

To determine which muscles were treated, muscles fulfilled the following two criteria: a) muscles that typically refer pain to the heel (5) and b) muscles that can be directly palpated or needled with precision and safety without ultrasound guidance. The clinician performed a physical examination to find MTrPs following Travell and Simons criteria: 1) the presence of a taut band and 2) identification of exquisite spot tenderness in a nodule (5). Flat palpation or a pincer palpation technique was used to palpate the MTrPs, depending on the muscle being assessed. The muscles that were treated were: soleus, gastrocnemius, quadratus plantae, flexor digitorum brevis, and abductor hallucis. If a muscle contained more than one MTrP, the most sensitive MTrP was treated according to the patient's perceived pain upon palpation. If the patient had pain bilaterally, the clinician treated both sides. The patient's position was always lying down on the treatment table; however, the exact position was dependent on each muscle (supine, prone or side-lying position) and will be the same for the assessment as well as for the intervention (135).

During the first session, all participants were taught a self-stretching protocol (41), which had demonstrated to be effective for the management of PHP (7, 14, 41), and consisted of the following exercises: a) Self-stretching of the calf muscles: in standing, with the affected foot furthest away from the wall, the patient was instructed to lean forward, while keeping the heel on the floor. To focus the stretching on the soleus muscle, the affected knee was bent, whereas to focus on the

gastrocnemius muscle, the affected knee was kept in full extension. In this position, patients were taught to lean forward until they felt a stretch in the calf and Achilles region. All patients completed both versions of the stretch; b) Plantar fascia-specific self-stretching: in the sitting position, patients crossed the affected foot over the contralateral thigh. The patient placed his/her fingers over the base of the toes, grasped the base of the toes and pulled the toes back towards the shin until a stretch was felt in the plantar fascia (41). According to the evidence, we followed the same dosage for calf and plantar fascia-specific self-stretching exercises twice a day, using intermittent stretching lasting 20 seconds, followed by 20-second rest periods for a total of 3 minutes per stretch (41). The participants received four individual physiotherapy sessions once a week. The duration of the sessions was variable depending on the patient; however, these lasted approximately 30 minutes. The participants were treated by a physical therapist registered at the Kuwait Ministry of Health and trained in the protocol. The clinician had a minimum of 5 years of practical experience in DN and appropriate training.

4.3.1 INVASIVE INTERVENTIONAL GROUPS: DRY NEEDLING AND PERCUTANEOUS NEEDLE ELECTROLYSIS

Specific needles for DN were used during invasive treatments (Agu-punt, Spain). Needle lengths were determined by the location of the MTrP, and they ranged from 30 to 50 mm in length (or longer if necessary, according to the patients' characteristics). The needle diameter was 0.25 - 0.30 mm. If the participant was sensitive to needle insertion, the level of manipulation was reduced. If this measure was insufficient for reducing the painful stimulus, needle manipulation was ceased altogether, and the needle was left in situ (112, 135).

To maintain appropriate hygienic conditions during the invasive treatments, the clinician wore latex gloves and thoroughly cleaned the skin of the area to be needled with an antiseptic solution (70% Propan-2-ol, Skin-des). Upon removal of the needle, the area was firmly compressed for 10 seconds. The needle was discarded after every single use.

In both groups, the intervention was terminated in the following circumstances: in the event of severe adverse effects, if the participant did not wish to continue, or if there was an unapproved use of medication. Any adverse effects were duly reported.

4.3.2 DRY NEEDLING ARM

In the case of the DN intervention, once the clinician located the MTrP, the needle was inserted repeatedly, and a rapid needle entry was performed. The chosen technique for manipulating the needle was the technique described by Hong (136), which consists of a rapid needle entry and exit (fast in/fast out) in order to obtain a local twitch response (LTR), lasting 5 seconds and employing a rhythmic movement at approximately 1Hz/sec (5 entries). The number of LTRs was counted and registered.

4.3.3 PERCUTANEOUS NEEDLE ELECTROLYSIS ARM

The electrotherapy equipment used (Physio Invasiva, PRIM Fisioterapia, Spain), which produces a continuous galvanic current through the cathode (needle) while the patient holds a hand-held anode (106) was used to apply treatment in the PNE group. Once the needle reached the relevant treatment area, the procedure was carried out exactly in the same manner as in the DN group, with the only difference being that the needle was transmitting an electrical current with an intensity of 1.5 mA (intensity may be adapted to the characteristics of each patient, according to their pain

tolerance.

CHAPTER 5 RESULTS

5.1 SYSTEMATIC REVIEW RESULTS

Twenty-nine full-text articles of minimally invasive techniques were reviewed and included in this systematic review. These articles focused on corticosteroid injections, platelet rich plasma, botulinum toxin, dextrose injections, as well as comparative studies involving DN. The best results were obtained by combining several techniques **[FIGURE 2]**.

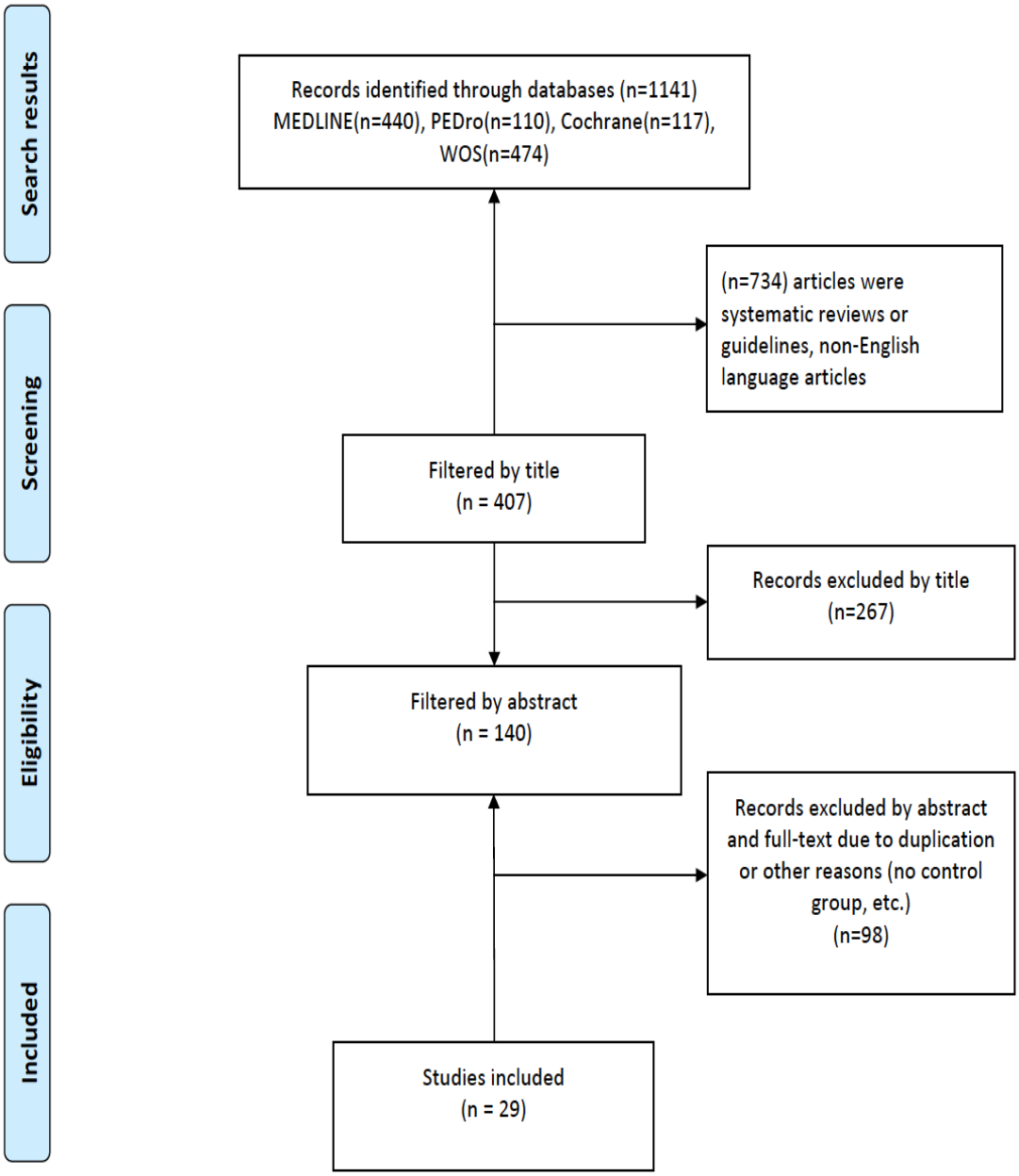

Figure 2. Flow diagram of studies through the different phases of the review. Extracted from Al-Boloushi et.al 2019 (83) (SEE ANNEXE 1)

Based on the findings of all the RCTs analysed, many authors consider that plantar fasciitis is a degenerative tissue condition rather than an inflammation at the site of origin of the plantar fascia at the medial calcaneal tuberosity. The histology of plantar fasciitis is the same as that of tendinopathies. This implies that degeneration can cause a micro tear within the fascia that does not heal, which can trigger inflammation. However, an interruption in the healing process due to poor circulation leads to degenerative changes in the connective tissues.The treatment of plantar fasciitis has dramatically improved in the past decade, with more minimally invasive techniques becoming increasingly available. The results demonstrate that the long term effects of minimally invasive (non-surgical) treatments such as shock wave therapy, botulinum toxin type-A injections, platelet-rich plasma injections, and intratissue percutaneous electrolysis DN show similar and sometimes better results when compared to corticosteroid injections. Most studies have used corticosteroids, which, as well as being associated with transient effects on pain and function, are associated with a number of complications, including infections, allergic contact dermatitis due to preservatives, skin atrophy, osteomyelitis of the calcaneus and rupture of the plantar fascia (137, 138). Furthermore, higher doses of corticosteroids can be contraindicated in certain patients (138). Corticosteroids, the current mainstay of plantar fasciitis treatment, are classified based on their duration of action and, as of yet, consensuated guidelines regarding corticosteroid use are lacking. In conclusion, definitive treatment guidelines for plantar fasciitis are still lacking.

5.2 RANDOMIZED CONTROLLED TRIAL RESULTS

One hundred and eighteen potential participants were screened for inclusion, and 102 participants were enrolled and randomly allocated to each of the treatment interventions. In total, 79 participants (78%) completed the four treatment sessions and were assessed at four weeks, 78 participants (77%) completed the eight-week follow-up, 76 (75%) participants completed the 12-week follow-up, 75 (74%) participants completed the 26-week follow-up and 68 (67%) participants completed the 52-week follow-up [**FIGURE 3**].

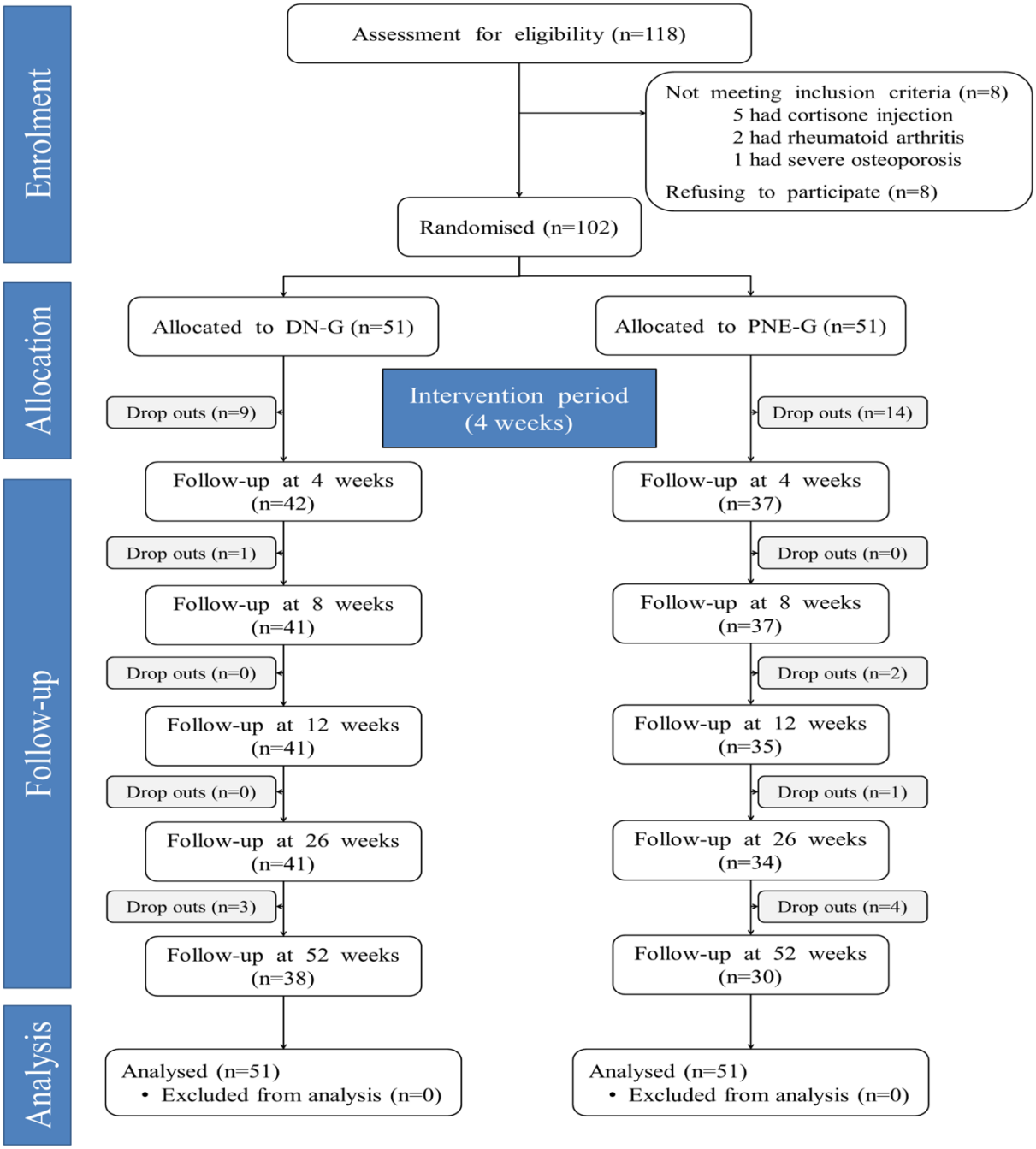

Figure 3. Participant flow chart. Abbreviations: DN, dry needling group; PNE, Percutaneous needle electrolysis group. Extracted from Al-Boloushi et.al 2020 (139)DN-G: Dry needling group; PNE-G: Percutaneous needle electrolysis group. (SEE ANNEX 3)

The mean time between each treatment session was 7.0 days (SD 1.1) for the DN group and 6.9 days (SD 1.2) for the PNE group.

The mean age of participants was 48.8 years (SD 8.8; range 24 to 60), and 71% were female. The mean duration of plantar heel pain was 7.9 months (SD 9.3; range 1 to 36). Both groups were similar for all baseline variables except for the consumption of medication for hypercholesterolemia (p=0.012) **[TABLE 2].**

TABLE 2. Baseline characteristics of participants by intervention group

	DN (n=51)	**PNE (n=51)**
Age, years	49.5 (8.9)	48.1 (8.8)
Sex, n (%), male	15 (29.4)	15 (29.4)
Height, cm	160.5 (8.2)	161.2 (7.9)
Weight, kg	87.5 (16.5)	90.8 (15.2)
BMI, kg/m^2	33.9 (5.5)	35.1 (6.4)
Duration of symptoms, months	6.0 (6.0)	9.9 (11.5)
Affected Side, n (%)		
Right	14 (27.5)	16 (31.4)
Left	13 (25.5)	20 (39.2)
Bilateral	24 (47.1)	15 (29.4)

Non-medicated, n (%)	11 (21.6)	15 (29.4)
Medications, n YES (%)		
Neuromodulators/antiepileptic	18 (35.3)	22 (43.1)
Painkillers	16 (31.4)	16 (31.4)
Anti-Inflammatory medication	16 (31.4)	17 (33.3)
Myorelaxant medication	9 (17.6)	8 (15.7)
Systemic medications, n YES (%)		
Hypercholesterolemia medication	12 (23.5)	3 (5.9)
Hypertension medication	14 (27.5)	8 (15.7)
Diabetes Mellitus medication	14 (27.5)	10 (19.6)
Osteoarthrosis medication	3 (5.9)	4 (7.8)
Lung disease medication	3 (5.9)	3 (5.9)
Hormonal therapy	5 (9.8)	7 (13.7)
Antidepressant medication	1 (2.0)	0 (0.0)
Diet supplements	8 (15.7)	13 (25.5)
Previous treatments, YES (%)		
Corticosteroid injections	4 (7.8)	10 (19.6)

ESWT	9 (17.6)	9 (17.6)
Exercise	4 (7.8)	6 (11.8)
Pain, FHSQ (100 - 0)	38.8 (18.8)	40.4 (21.9)
Function, FHSQ (100 - 0)	57.2 (34.9)	55.5 (36.3)
Shoe, FHSQ (100 - 0)	30.7 (35.3)	32.4 (35.9)
GFH, FHSQ (100 - 0)	14.3 (18.2)	19.2 (23.7)
VAS mean (0 -10)	6.0 (2.3)	5.9 (2.4)
VAS maximum (0 -10)	7.6 (2.0)	7.5 (2.3)

Abbreviations: DN, dry needling group; PNE, Percutaneous needle electrolysis group; BMI, Body Mass Index; ESWT, Extracorporeal Shock-Wave Therapy; FHSQ, Foot Health Status Questionnaire (0 corresponds to the worst foot health; 100, the best); GFH, General Foot Health; VAS, Visual Analog Scale (0 corresponds to absence of pain; 10, maximum tolerable pain). Values are expressed in mean (SD) unless stated. *P < 0.05, significant differences between groups.

Baseline characteristics of participants by intervention group Extracted from Al-Boloushi et.al 2020 (139) (SEE ANNEX 3)

There were two small hematomas in the PNE group and one in the DN group. No serious adverse events were reported. All withdrawals during the treatment period were due to an inability to withstand the pain related to needle insertion and stimulation of MTrPs. Nine withdrawals were registered during the follow-up, as these participants received other treatments during the study period (failure to comply to not receiving other treatments).

The frequencies of protocol compliance with self-stretching did not differ between groups ($\chi^2(4) = 1.13$, $P=0.890$) **[TABLE 3].**

TABLE 3. Frequencies of compliance with self-stretching protocol achieved in the dry needling and percutaneous needle electrolysis groups

	DN	PNE
Four full weeks complied	11 (22%)	10 (20%)
Three full weeks complied	6 (12%)	4 (8%)
Two full weeks complied	6 (12%)	9 (18%)
One full week complied	9 (18%)	10 (20%)
Any full week complied	19 (37%)	18 (35%)

Abbreviations: DN, dry needling group; PNE, Percutaneous needle electrolysis group.

Note: Values represent the number of participants (relative frequencies) for each compliance category of the four-weeks self-stretching protocol.

Frequencies of compliance with self-stretching protocol achieved in the dry needling and percutaneous needle electrolysis groups. Extracted from Al-Boloushi et.al 2020 (139) (SEE ANNEX 3)

Regarding the primary outcome measure, there was no *group* x *time* interaction for Foot Pain, although individual RM-ANOVA showed a significant effect of time in both groups, with lower scores at baseline than at follow-up for all time points in the DN group (P<0.001; 29.7 [17.8 to 41.5]) and the PNE group (P<0.001; 32.7 [18.3 to 47.0]) **[TABLE 4]**

TABLE 4. Mean scores, mean change within group and mean difference between groups for the Foot Health Status Questionnaire and EQ-5D-5L at baseline, week 4, week 8, week 12, week 26 and week 52.

Variable	DN mean (SD)	DN mean change from baseline (95% CI)	PNE mean (SD)	PNE mean change from baseline (95% CI)	Adjusted mean difference between groups (95% CI)	P-Value† (Effect Size)‡
Foot Pain, FHSQ (100 - 0)						
Baseline	38.8 (18.8)		40.4 (21.9)			
Week 4	73.4 (27.7)*	34.6 (21.7 to 47.5)	71.9 (25.7)*	31.5 (18.7 to 44.2)	-2.0 (-12.2 to 8.3)	0.707 (0.001)
Week 8	70.1 (28.4)*	31.4 (17.5 to 45.3)	67.4 (26.8)*	27.0 (13.9 to 40.1)	-3.1 (-13.8 to 7.6)	0.567 (0.003)
Week 12	66.8 (24.8)*	28.1 (16.2 to 39.9)	63.6 (26.1)*	23.1 (10.6 to 35.6)	-3.8 (-13.6 to 5.9)	0.437 (0.006)
Week 26	68.8 (25.3)*	30.0 (18.1 to 42.0)	67.1 (27.1)*	26.7 (12.0 to 41.3)	-2.0 (-12.3 to 8.3)	0.700 (0.002)

Week 52	68.4 (25.1)*	29.7 (17.8 to 41.5)	73.1 (29.0)*	32.7 (18.3 to 47.0)	4.3 (-6.3 to 14.8)	0.424 (0.006)
Main effect of time; P-Value	**< 0.001**		**< 0.001**			
Foot Function, FHSQ (100 - 0)						
Baseline	57.2 (34.9)		55.5 (36.3)			
Week 4	79.4 (31.2)*	22.2 (6.5 to 37.9)	71.7 (32.4)*	16,2 (0,5 to 31,8)	-7.1 (-18.4 to 4.3)	0.220 (0.015)
Week 8	72.7 (30.1)	15.4 (-1.3 to 32.2)	75.9 (29.7)*	20.3 (5.1 to 35.5)	3.7 (-7.5 to 14.7)	0.502 (0.005)
Week 12	65.7 (31.7)	8.5 (-8.6 to 25.5)	71.1 (29.8)	15.6 (-0.7 to 31.8)	5.9 (-5.6 to 17.3)	0.311 (0.010)
Week 26	70.2 (29.6)	13.0 (-4.5 to 30.4)	70.7 (28.8)	15.2 (-0.9 to 31.3)	0.9 (-10.1 to 11.9)	0.871 (0.001)
Week 52	69.8 (29.6)	12.6 (-4.9 to 30.1)	78.0 (30.2)*	22.5 (6.6 to 38.4)	8.6 (-2.6 to 19.9)	0.132 (0.023)

Main effect of time; P-Value	**< 0.001**		**< 0.001**			
Footwear, FHSQ (100 - 0)						
Baseline	30.7 (35.3)		32.4 (35.9)			
Week 4	35.0 (35.9)	4.2 (-10.5 to 19.0)	30.2 (33.9)	-2.1 (-16.1 to 11.9)	-5.6 (-17.1 to 5.9)	0.333 (0.009)
Week 8	37.6 (34.2)	6.9 (-7.3 to 21.0)	30.1 (35.4)	-2.3 (-18.9 to 14.3)	-8.3 (-20.3 to 3.7)	0.174(0.019)
Week 12	41.0 (32.1)	10.3 (-3.7 to 24.3)	35.8 (35.9)	3.4 (-13.0 to 19.9)	-6.0 (-17.8 to 5.8)	0.316 (0.010)
Week 26	43.3 (32.7)	12.6 (-1.9 to 27.0)	39.0 (35.8)	6.7 (-9.1 to 22.5)	-5.0 (-16.8 to 6.7)	0.397 (0.007)
Week 52	44.2 (31.3)	13.4 (-1.6 to 28.5)	55.9 (35.7)*	23.5 (8.9 to 38.1)	10.9 (-0.5 to 22.3)	0.061 (0.035)
Main effect of	**0.015**		**< 0.001**			

time; P-Value						
GFH, FHSQ (100 - 0)						
Baseline	14.3 (18.2)		19.2 (23.7)			
Week 4	59.9 (34.4)*	45.5 (30.4 to 60.7)	53.3 (37.0)*	34.1 (19.4 to 48.9)	-9.4 (-22.7 to 3.9)	0.165 (0.019)
Week 8	54.6 (34.4)*	40.2 (25.4 to 55.1)	51.6 (35.2)*	32.4 (16.5 to 48.2)	-5.2 (-18.5 to 8.2)	0.445 (0.006)
Week 12	49.5 (33.5)*	35.1 (21.3 to 49.0)	53.6 (34.4)*	34.4 (20.1 to 48.6)	1.1 (-11.4 to 13.6)	0.860 (0.001)
Week 26	54.7 (34.3)*	40.4 (26.0 to 54.8)	58.7 (34.9)*	39.5 (23.3 to 55.6)	1.8 (-11.4 to 15.1)	0.785 (0.001)
Week 52	54.7 (34.3)*	40.4 (26.0 to 54.8)	66.4 (38.6)*	47.2 (30.1 to 64.2)	9.2 (-4.7 to 23.2)	0.190 (0.017)
Main effect of time; P-Value	**< 0.001**		**< 0.001**			
EQ-5D-5L (1 - 0)						

Baseline	0.63 (0.23)		0.67 (0.22)			
Week 4	0.78 (0.22)*	0.15 (0.05 to 0.25)	0.76 (0.24)*	0.09 (0.01 to 0.17)	-0.04 (-0.12 to 0.03)	0.265 (0.013)
Week 8	0.72 (0.23)	0.09 (-0.03 to 0.21)	0.74 (0.23)*	0.07 (0.01 to 0.13)	-0.01 (-0.08 to 0.07)	0.889 (0.001)
Week 12	0.64 (0.30)	0.02 (-0.11 to 0.15)	0.70 (0.26)	0.03 (-0.05 to 0.11)	0.03 (-0.07 to 0.12)	0.587 (0.003)
Week 26	0.65 (0.29)	0.02 (-0.10 to 0.14)	0.73 (0.27)	0.06 (-0.03 to 0.14)	0.05 (-0.04 to 0.14)	0.276 (0.012)
Week 52	0.66 (0.27)	0.02 (-0.10 to 0.14)	0.77 (0.25)*	0.10 (0.02 to 0.18)	0.10 (0.01 to 0.18)	**0.032 (0.045)§**
Main effect of time; P-Value	**0.002**		**0.002**			

Abbreviations: CI, confidence intervals; DN, dry needling group; PNE, Percutaneous needle electrolysis group; FHSQ, Foot Health Status Questionnaire (0 corresponds to the worst foot health; 100, the best); GFH, General Foot Health; EQ-5D-5L (0 corresponds to the worst quality of life; 1, the best).

Positive between group differences represent greater change [improvement] in the PNE group compared to the DN group.

*P < 0.05 after Bonferroni's correction comparing follow-up against baseline scores within group.

§P < 0.05, significant differences between groups.

†P-value after Bonferroni's correction between group.

‡Eta-squared (η^2); between groups effect size.

Mean scores, mean change within group and mean difference between groups for Foot Health Status Questionnaire and EQ-5D-5L at baseline, week 4, week 8, week 12, week 26 and week 52.Extracted from Al-Boloushi et.al 2020 (139) (SEE ANNEX 3)

Individual RM-ANOVAs also showed a significant effect of time in both groups for Foot Function DN: *P*<0.001; PNE: *P*<0.001), Footwear DN: *P*=0.031; PNE: *P*<0.001), General Foot Health DN: *P*<0.001; PNE: *P*<0.001), EQ-5D-5L DN: *P*=0.002; PNE: *P*=0.002), VAS-mean DN: *P*<0.001; PNE: *P*<0.001) and VAS-maximum DN: *P*<0.001; PNE: *P*<0.001) **[TABLE 4]**.

Regarding the different timelines for the secondary outcome measurements, Foot Function improved in the PNE group at eight weeks (*P*=0.002; 20.3 [5.1 to 35.5]) and 52 weeks (*P*=0.001; 22.5 [6.6 to 38.4]), although without differences between groups. Footwear scores also improved significantly at 52 weeks in the PNE group (*P*<0.001; 23.5 [8.9 to 38.1]), without differences between groups. Regarding Quality of Life, there was a significant improvement at eight weeks (*P*=0.035; 0.07 [0.01 to 0.13]) and 52 weeks (*P*=0.003; 0.10 [0.02 to 0.18]) in the PNE group, with differences between groups in favor of the PNE group only at 52 weeks (P=0.032; 0.10 [0.01 to 0.18]) **[TABLE 4]**.

Regarding pain, the DN intervention provided a benefit over PNE for the mean VAS (*P*=0.009; -1.36 [-2.37 to 0.35]) and VAS Maximum (*P*=0.043; -1.28 [-2.53 to -0.04]) at four weeks **[TABLE 5]**

TABLE 5. Mean scores, mean change within group and mean difference between groups for Visual Analog Scale at baseline/1st session, 2nd session, 3rd session, 4th session, week 4, week 8, week 12, week 26 and week 52.

Variable	DN mean (SD)	DN mean change from baseline (95% CI)	PNE mean (SD)	PNE mean change from baseline (95% CI)	Adjusted mean difference between groups (95% CI)	P-Value† (Effect Size)‡
VAS average						
Baseline/1st session	6.0 (2.3)		5.9 (2.4)			
2nd session	4.6 (2.2)*	-1.4 (-2.5 to -0.3)	4.4 (2.7)*	-1.5 (-2.5 to -0.5)	0.14 (-0.64 to 0.92)	0.725 (0.001)
3rd session	4.0 (2.4)*	-2.0 (-3.3 to -0.7)	4.1 (2.8)*	-1.8 (-3.1 to -0.5)	0.16 (-1.11 to 0.79)	0.743 (0.001)
4th session	3.5 (2.5)*	-2.6 (-3.9 to -1.2)	3.4 (2.7)*	-2.5 (-3.8 to -1.1)	0.01 (-0.95 to 0.97)	0.984 (0.001)
Week 4	2.6 (2.5)*	-3.5 (-4.9 to -2.0)	3.8 (3.0)*	-2.0 (-3.2 to -0.8)	-1.36 (-2.37 to 0.35)	**0.009 (0.067)§**
Week 8	3.3 (2.8)*	-2.7 (-4.2 to -1.2)	3.8 (2.7)*	-2.1 (-3.4 to -0.8)	-0.54 (-1.57 to 0.49)	0.298 (0.011)

Week 12	3.3 (2.7)*	-2.7 (-4.2 to -1.2)	3.7 (2.8)*	-2.1 (-3.6 to -0.7)	-0.46 (-1.51 to 0.58)	0.381 (0.008
Week 26	3.4 (2.8)*	-2.6 (-4.0 to -1.2)	3.4 (2.7)*	-2.5 (-3.8 to -1.1)	-0.06 (-0.97 to 1.09)	0.911 (0.001)
Week 52	3.4 (2.8)*	-2.6 (-4.0 to -1.2)	2.8 (3.0)*	-3.0 (-4.5 to -1.6)	0.508 (-0.57 to 1.58)	0.351 (0.009)
Main effect of time; P-Value	< **0.001**		< **0.001**			
VAS maximum						
Baseline/1st session	7.6 (2.0)		7.5 (2.3)			
2nd session	6.2 (2.3)*	-1.3 (-2.3 to -0.3)	5.5 (2.9)*	-2.0 (-3.0 to -0.9)	0.66 (-0.18 to 1.50)	0.122 (0.024)
3rd session	5.4 (2.6)*	-2.2 (-3.6 to -0.8)	5.3 (3.1)*	-2.2 (-3.6 to -0.8)	0.05 (-1.03 to 1.13)	0.926 (0.001)
4th session	4.9 (2.9)*	-2.7 (-4.1 to -1.3)	4.5 (3.0)*	-3.0 (-4.4 to -1.6)	0.31 (-0.76 to 1.39)	0.563 (0.003)
Week 4	3.6 (3.2)*	-3.9 (-5.5 to -2.3)	4.9 (3.5)*	-2.6 (-4.1 to -1.1)	-1.28 (-2.53 to -0.04)	**0.043 (0.041)**§

Week 8	4.7 (3.4)*	-2.8 (-4.5 to -1.2)	5.0 (3.1)*	-2.5 (-3.8 to -1.2)	-0.32 (-1.50 to 0.87)	0.599 (0.003)
Week 12	4.7 (3.3)*	-2.9 (-4.5 to -1.3)	5.1 (3.1)*	-2.4 (-3.9 to -1.0)	-0.42 (-1.63 to 0.78)	0.487 (0.005)
Week 26	4.5 (3.2)*	-3.0 (-4.6 to -1.4)	4.6 (3.1)*	-2.9 (-4.5 to -1.2)	-0.13 (-1.34 to 1.09)	0.838 (0.001)
Week 52	4.5 (3.2)*	-3.0 (-4.6 to -1.4)	4.1 (3.4)*	-3.4 (-5.1 to -1.8)	0.45 (-0.80 to 1.70)	0.480 (0.005)
Main effect of time; P-Value	< **0.001**		< **0.001**			

Abbreviations: CI, confidence intervals; DN, dry needling group; PNE, Percutaneous needle electrolysis group; VAS, Visual Analog Scale (0 corresponds to absence of pain; 10, maximum tolerable pain).

Positive between group differences represent greater change [improvement] in the PNE group compared to the DN group.

*P < 0.05 after Bonferroni's correction comparing follow-up against baseline scores within group.

§P < 0.05, significant differences between groups.

†P-value after Bonferroni's correction between group.

‡Eta-squared (η^2); between groups effect size.

Mean scores, mean change within group and mean difference between groups for Visual Analog Scale at baseline/1st session, 2nd session, 3rd session, 4th session, week 4, week 8, week 12, week 26 and week 52. Extracted from Al-Boloushi et.al 2020 (139) (SEE ANNEX 3)

TABLE 6 shows the most frequently treated muscles.

TABLE 6. Localization and frequency of myofascial trigger points needled in the dry needling and percutaneous needle electrolysis groups

Muscles	***DN***	**PNE**
Gastrocnemius	178	168
Soleus	176	162
Quadratus plantae	122	105
Flexor digitorum brevis	106	92
Abductor hallucis	102	93

Abbreviations: DN, dry needling group; PNE, Percutaneous needle electrolysis group.

Note: Values represent the number of myofascial trigger points needled per muscle over the course of the study.

Localization and frequency of myofascial trigger points needled in the dry needling and percutaneous needle electrolysis groups Extracted from Al-Boloushi et.al 2020 (139) (SEE ANNEX 3)

The level of pain immediately after each treatment session, according to the VAS, did not differ between groups **[TABLE 7]**

TABLE 7. Mean scores for the visual analog scale, immediately after each treatment session.

VAS	DN mean (SD)	PNE mean (SD)	P-Value†
1st session	3.1 (2.9)	3.5 (2.6)	0.459
2nd session	3.1 (2.8)	3.1 (2.6)	0.968
3rd session	2.9 (2.6)	3.3 (3.2)	0.419
4th session	2.2 (2.7)	2.4 (2.6)	0.792

Abbreviations: DN, dry needling group; PNE, Percutaneous needle electrolysis group; VAS, Visual Analog Scale (0 corresponds to absence of pain; 10, maximum tolerable pain).

†P-value after Independent T test.

Mean scores for the visual analog scale immediately after each treatment session. Extracted from Al-Boloushi et.al 2020 (139) (SEE ANNEX 3)

CHAPTER 6 DISCUSSION

Plantar heel pain is a common cause of foot pain and discomfort affecting the health and quality of life of patients, with a high tendency for relapse and chronicity (140). Previous studies have demonstrated the positive effect of conservative treatment in reducing painful conditions associated with PHP (41, 141), whereas other RCTs show that DN probably has a higher potential benefit over more traditional approaches (63). Nevertheless, according to our findings, new high-quality RCTs are needed to provide evidence regarding the effectiveness of DN for symptomatic management in PHP (142). Even though the plantar fascia can be a source of pain in itself (143) and other studies performing invasive treatments have considered needling applications at the insertion of the plantar fascia (144), our hypothesis is restricted to evaluating the contribution of MTrPs towards PHP.

If any future plans to update the protocol and guidelines for the treatment of PHP should consider the treatment protocols with an emphasis on first- and second-line treatments. Consideration should be placed on beginning with non-invasive techniques and lack of improvement following these techniques should cause the clinician to proceed towards minimally invasive techniques.

As an innovative treatment modality, PNE is increasingly used in order to promote the regeneration of injured tendons (106-108, 145) and is being gradually recognized as a cornerstone for invasive approaches in physiotherapy. However, even though its use is increasing based on an additional effect to DN alone, there is no scientific evidence to support the use of this technique in clinical practice. Therefore, we aim to research whether PNE can offer an additional effect to DN for PHP management. To our knowledge, this is the first study to compare two invasive treatments for MTrPs associated with PHP. This study contributes not only to research regarding the possible

additional effects of PNE but also by analyzing differences in pain perception after therapy, which is a common patient complaint. Furthermore, cost-effectiveness was measured with the EQ-5D, thus providing a valuable economic variable to studies involving physiotherapy techniques.

In this RCT important clinical improvements were observed in both groups (146) for the Foot Pain and General Foot Health domains of the Foot Health Status Questionnaire at all time points. However, Foot Function and Quality of Life did not follow the same pattern as the aforementioned domains. Thus, clinically significant improvements were observed at four weeks in both groups; however, at eight weeks and 52 weeks, improvements were only observed in the PNE group. Furthermore, at 52 weeks, differences between groups were only found for Quality of Life. These findings suggest a trend in the group receiving PNE, producing longer-lasting effects regarding Foot Function and Quality of Life compared to DN. Although there were statistically significant differences in Quality of Life, there is no consensus of what the minimum clinically important difference (MCID) is, which ranges from 0.03 to 0.54 (147)

Patients allocated to both groups also had clinically important improvements in their mean and maximum level of pain since week one and during the 52 weeks of follow-up.(148) There were differences between groups after four weeks of treatment in favor of the DN group; however, this difference was not maintained over time. Both groups had similar results to those reported by Cotchett et al(115) at four weeks. However, at 12 weeks, although significant improvements were found in both groups, these findings differed from the aforementioned study, which we believe may be due to a higher number of drop-outs.

Both PNE and DN were effective for PHP management, with long-lasting effects (52 weeks) for Foot Pain and the General Foot Health scores, without differences between groups. Besides, both treatments were found to be effective for reducing mean and maximum pain since the first treatment session, with differences between groups in favor of the DN group at four weeks only. Although Foot Function and Quality of Life also improved at four weeks for both intervention groups, the PNE group showed improvements at eight weeks and 52-weeks, with significant differences between groups in the case of Quality of Life at 52 weeks.

6.1 CLINICAL IMPLICATIONS

Clinical implications may vary as it is possible that this study was underpowered and the sample size necessary to avoid this was a total of 78 patients at the end of the study. Therefore, once we realized that the drop-out rate was higher than initially estimated, we increased the recruited patients from 94 (considering a 20% of drop-outs) to 102 (considering a 25% of drop-outs). Despite this, in week 12 and the following weeks, the number of patients was lower than necessary to avoid underpowering, which could result in not detecting the treatment effect in week 12 or later. For this reason, we carried out a per-protocol analysis and compared the results with the intention to treat analysis, which was more conservative, revealing similar results for both analyses. In addition, we analyzed whether there were any results in week eight that were not maintained, which was observed in Foot Function and Quality of Life, revealing significant improvements at week eight and week 52 for the percutaneous electrolysis group. Although it is speculative, underpowering of the intention to treat analysis may explain the inconsistency of the results in the percutaneous electrolysis group, possibly leading to significant results in weeks 12 and 26.

From a clinical point of view, both groups reported similar levels of pain after the treatment; therefore, both treatment options should be considered to be equal in terms of pain tolerance or sensitization after treatment. Besides the minimal clinically important difference, it is also essential to consider the patient acceptable symptomatic state (PASS), which provides the basis for determining whether the treatment enabled patients to achieve a satisfactory state and a clinically relevant treatment target. In our study, we found that in both groups, the mean pain scores, measured using the VAS was five points lower since the first session, which fulfills the PASS values determined in populations with similar sociocultural characteristics,(149) even though this value was found to be unexpectedly high (50 mm) when compared to other populations.

The 118 initially selected patients presented MTrPs on plantar and calf muscles, as this was part of our inclusion criteria, meaning that MTrPs could be directly or indirectly contributing to PHP. However, we were unable to find any previous study on the prevalence of MTrPs in patients with PHP. Therefore, future studies should consider following this line of research.

6.2 STRENGTHS AND LIMITATIONS

This study presents several strengths and limitations. One of the strengths is that this is the first RCT that has analyzed the effectiveness of PNE and compared it with DN for PHP caused by MTrPs, with a large sample size and an extended follow-up. Several limitations should be noted. First, other sources of pain were not considered, as the study was designed to analyze the contribution of MTrPs in PHP. Furthermore, we did not measure the number of local twitch responses, which is a controversial factor, potentially affecting the treatment effectiveness of MTrPs.(150) Besides, 23 patients (22.5%) dropped out of the study during the intervention as they were unable to tolerate pain, which is a higher drop-out rate compared to other studies.(10, 115, 151, 152) After the intervention period, drop-outs increased progressively throughout the follow-up to 24 at 8-weeks (23.5%), 26 at 12-weeks (25.5%), 27 at 26-weeks (26.5%) and 34 at 52-weeks (33.3%), which is similar to the study published by Tasoglu et al(152), with 27.7% of drop-outs at 12 weeks. However, these rates differ from other previously mentioned studies.(10, 115, 151) These differences may be due to the cultural behaviors towards pain in the region, which constitutes a limitation and a critical challenge that must be addressed by clinicians. It is important to note that both treatments were safe with minimal side effects, such as hematoma or bruising, which is in line with other published studies revealing a low incidence of adverse effects.(153)

CHAPTER 7 CONCLUSIONS

7.1 SYSTEMATIC REVIEW CONCLUSIONS

1- Many authors consider that plantar fasciitis is a degenerative tissue condition rather than an inflammation at the site of origin of the plantar fascia at the medial calcaneal tuberosity.

2- Plantar fasciitis treatment has dramatically improved in the past decade, with minimally invasive techniques increasingly available.

3- Corticosteroid injections have been associated with several complications, including infections, allergic contact dermatitis due to preservatives, skin atrophy, osteomyelitis of the calcaneus, and rupture of the plantar fascia.

7.2 RANDOMIZED CLINICAL TRIAL CONCLUSIONS

1. Both groups were similar in terms of all baseline variables, except for the consumption of medication for hypercholesterolemia ($p=0.012$) where female participants had a higher intake.
2. The most frequent muscles containing MTrPs in the participants were medial and lateral gastrocnemius, soleus, quadratus plantae, flexor digitorum brevis and abductor hallucis.
3. The frequencies of protocol compliance with self-stretching did not differ between groups.
4. Both treatments were safe with no serious adverse effects during the clinical trial. A total of three minor adverse effects were recorded (2 patients from the PNE group and 1 patient from the DN group had a hematoma).
5. PNE and DN are equally effective for reducing mean and maximum pain from the first treatment session and during 52 weeks follow-up, although DN was found to be more effective at four weeks.

6. PNE and DN are equally effective to improve Foot Function at 4 weeks, although PNE was more effective than DN at 8 weeks and 52 weeks.
7. PNE and DN were equally effective for improving the Quality of life at four weeks, although PNE was more effective than DN in the case of QoL at 52 weeks.
8. PNE and DN were equally effective for improving the General Foot Health at four weeks, although PNE was more effective than DN in the case of general foot health, producing long-lasting effects at 52 weeks.
9. Footwear scores were significantly improved at 52 weeks in the PNE group, without differences between groups.
10. Both groups had clinically significant changes in their pain and the level of improvement was greater than the Patient Acceptable Symptom State (PASS).

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ANNEX I

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FASCIA SCIENCE AND CLINICAL APPLICATIONS: SYSTEMATIC REVIEW

Minimally invasive non-surgical management of plantar fasciitis: A systematic review

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ABSTRACT

Background: Minimally invasive non-surgical techniques have been widely used worldwide to treat musculoskeletal injuries. Of these techniques, injectable pharmaceutical agents are the most commonly employed treatments, with corticosteroids being the most widely used drugs. The aim of this article is to review current scientific evidence as well as the effectiveness of minimally invasive non-surgical techniques, either alone or combined, for the treatment of plantar fasciitis.
Methods: This systematic review was conducted from April 2016 until March 2017, in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement and was registered with PROSPERO. Randomized controlled trials (RCTs) of adult patients diagnosed with plantar fasciitis were included as well as intervention studies, with a minimal sample size of 20 subjects per study (10 per group). Assessment of study eligibility was developed by three reviewers independently in an unblinded standardized manner. The physiotherapy evidence database (PEDro) scale was used to analyse the methodological quality of studies.
Results: Twenty-nine full-text articles on minimally invasive techniques were reviewed. These articles focused on corticosteroid injections, platelet-rich plasma, Botox, dextrose injections, as well as comparative studies with dry needling vs sham needling.
Conclusion: The treatment of plantar fasciitis has dramatically improved in the past decade with minimally invasive techniques becoming increasingly available. Research findings have shown that the long term effects of minimally invasive (non-surgical) treatments such as shock wave therapy, botulinum toxin type-A injections, platelet-rich plasma injections and intratissue percutaneous electrolysis dry needling show similar and sometimes better results when compared to only corticosteroid injections. The latter have been the mainstay of treatment for many years despite their associated side effects both locally and systemically. To date, there is no definitive treatment guideline for plantar fasciitis, however the findings of this literature review may help inform practitioners and clinicians who use invasive methods for the treatment of plantar fasciitis regarding the levels of evidence for the different treatment modalities available.

1. Introduction

Plantar heel pain (PHP) is one of the main sources of complaint in the general population, affecting approximately 2 million Americans each year and as much as 10% of the population over the course of a life-time (Martin et al., 2014; McPoil et al., 2008). Plantar heel pain may include different sources of pain, and involves different diagnoses such as myofascial pain syndrome, plantar fasciitis or neuritis, amongst others. Although there are few high quality epidemiological studies available, one study conducted in the United States between 1995 and 2000 found that consultations for PHP equalled approximately one million patient visits to physicians per year (Riddle and Schappert, 2004).

Plantar fasciitis (PF) is the most common cause of chronic pain

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beneath the heel in adults and may be treated using different therapeutic strategies (Martin et al., 2014; McPoil et al., 2008). Conservative treatments have always been the first approach for treating PF, as recommended by the APTA (Martin et al., 2014; McPoil et al., 2008). However, in some cases, minimally invasive therapies such as corticosteroid injections (Grice et al., 2017; Karls et al., 2016; Yucel et al., 2009), platelet-rich plasma (Ragab and Othman, 2012; Sharma, 2013; van Egmond et al., 2015; Moraes et al., 2013; Franceschi et al., 2014; Lee, 2013; Monto, 2013, 2014b), botulinum toxin (Venancio Rde and Zamperini, 2009; Diaz-Llopis et al., 2013), acupuncture (Zhang et al., 2011; Tough et al., 2009; Barbagli and Ceccherelli, 2003; Abbasoğlu et al., 2015), dry needling (Cotchett et al., 2014a, 2014b; Cotchett and Landorf, 2014; Eftekharsadat et al., 2016) and prolotherapy (Kim and Lee, 2014; Demir et al., 2015) have been used. Also, a recent meta-analysis was published on the effect of dry needling on the treatment of PHP (He and Ma, 2017).

The aim of this study was to review the current scientific evidence regarding minimally invasive non-surgical techniques for PF.

2. Methods

This systematic review was conducted from April 2016 to March 2017. Its purpose was to answer the following question: what is the effectiveness of minimally invasive non-surgical interventions, either alone or combined for the treatment of plantar fasciitis? The review was conducted in accordance with the Preferred Reporting System Items for Systematic Reviews and Meta-analyses (PRISMA) statement, and was registered with PROSPERO (CRD42018083734).

2.1. Design

A systematic review of scientific studies was conducted for the treatment of plantar fasciitis using minimally invasive non-surgical interventions.

2.2. Search strategy

Our literature search aimed to identify all available experimental studies evaluating the invasive non-surgical management of PF. Searches of MEDLINE, Web of Science, Cochrane, and PEDro databases were conducted. The last search was performed in March 2017. The search strategy was: ((Efficacy OR management OR effectiveness) AND (plantar OR fasciitis OR fasciosis OR fascitis OR heel) AND (dry need* OR intratissue percutaneous electrolysis or acupuncture or electroacupuncture or injection or injectabl* or puncture and infiltrat*)). These keywords were identified after preliminary literature searches. There was no restriction by date. The inclusion criteria were: 1) Randomized controlled clinical trials with a sample size of at least 20 subjects per study (10 per group); 2) Age of subjects: 18 years and older; 3) Diagnosis of plantar fasciitis (or equivalent terms such as fasciosis or fascitis or heel pain); 4) Studies investigating the effectiveness of any invasive non-surgical treatment for PF (e.g. dry needling and/or injections, acupuncture, infiltration). The exclusion criteria were: 1) Any study including a surgical procedure or pharmacological oral agents or topical ointment; 2) Studies with animals 3) Trials whose sample or participants included any of the following terms: diabetes, spasticity, neuropathy, tumour, fracture, haemophilia, stroke, amputation, artificial limbs and rheumatoid arthritis; 4) Articles for which the full text was not in English; 5) RCTs not reaching a score of 5 in the PEDro scale (Fig. 1). The evaluation of the eligibility of the studies was carried out by three independent reviewers (ZA, ML, MA) who did an initial filter by title, a second filter by abstract and subsequently compared the results. In case of disagreements, a fourth reviewer was consulted (EG). Thereafter, the full text of selected articles was read to verify whether they met the inclusion and exclusion criteria. Subsequently, they were evaluated with the PEDro scale and those obtaining less than 5 points were excluded. For the data extraction, a table was generated containing all the results classified by the outcome measurements, which helped to group the results and enabled a comparison amongst the different studies.

2.3. Evaluation of risk of bias

We evaluated articles using the Physiotherapy Evidence Database (PEDro) Scale checklist (https://www.pedro.org.au/wp-content/uploads/PEDro_scale.pdf) for RCTs (Fig. 2). In the PEDro checklists, each article is scored as “high quality, low risk of bias,” “acceptable quality, moderate risk of bias,” “low quality, high risk of bias,” or “unacceptable quality” which resulted in rejection. We defined each level based on scoring the checklists by assigning a value of 0 or 1 for each “no” or “yes” response, respectively.

For RCTs, checklists had 10 items and quality scores were assigned as follows: high quality, low risk of bias, 9–10; acceptable quality, moderate risk of bias, 6–8; low quality, high risk of bias, 3–5; unacceptable (reject), 0–2 (Fig. 3).

At least three investigators evaluated each article. If there was disagreement between reviewers, a fourth investigator reviewed the paper and the majority rating was used after discussion among reviewers. Studies of unacceptable quality were excluded from the evidence tables.

2.4. Data extraction

Data were extracted from all included studies by at least three investigators, with one serving as the primary extractor and the second and third verifying the data. Disagreements were resolved by discussion, including a fourth reviewer if necessary. The extracted data were entered into a Microsoft Word table grouped by the condition as outlined in the included studies (Table 1). Items included on the data extraction form were as follows: *study identification* (first author); *participants* (dosage, gender, age, number of treatment sessions over period); *comparator* (age, dosage, number of treatment sessions over period); pain and functional outcome measures used; *results* (in terms of pain and functional outcomes); *conclusions*, (possible side effects).

A total of 1141 studies were identified from the databases. Following inspection of the articles, 734 articles were excluded due to the language or other exclusion criteria. Studies following the inclusion criteria were filtered by title (n = 407) and then by abstracts (n = 140). Further analysis of the remaining text yielded 29 articles which fulfilled the inclusion criteria (Fig. 3).

We scored the 29 articles using the PEDro scale and excluded studies that obtained less than 6 points (n = 1). All the trials included had a score of more than 5 in the PEDro scale (Tables 2 and 3).

3. Results

Twenty-nine full-text articles of minimally invasive techniques were reviewed and included in this systemic review. These articles focused on corticosteroid injections, platelet rich plasma, botulinum toxin, dextrose injections, as well as comparative studies with dry needling. Each intervention claims that the patients improved, and that the pain was decreased. There is no superior treatment but rather a choice of interventions, as each treatment shows some significant improvement.

Inclusion	Exclusion
• ***Published in a peer-reviewed journal between January 2000 and March 2017***	• Interventions delivered only to hospitalized patients
• ***Human subjects aged 18 or older presenting to ambulatory care***	• Commentaries/editorials/letters
• ***English language***	• Non-peer-reviewed publications
• ***Treatment of non-acute (≥ 4 weeks duration) heel pain/condition***	• Conference abstracts
• ***Intervention included at least one group with only nondrug, nonsurgical treatment(s)***	• Case reports/series
• ***Randomized controlled trial***	• Pilot RCTs not designed or powered to assess effectiveness
	• No treatment outcomes
	• Non-clinical studies
	• Oral or topical medications/surgery used in all treatment groups
	• Systematic review & Meta- analyses

Fig. 1. Inclusion and exclusion criteria.

1. **Eligibility criteria were specified**
2. **Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)**
3. **Allocation was concealed**
4. **The groups were similar at baseline regarding the most important prognostic indicators**
5. **There was blinding of all subjects**
6. **There was blinding of all therapists who administered the therapy**
7. **There was blinding of all assessors who measured at least one key outcome**
8. **Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups**
9. **All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case data for at least one key outcome was analysed by "intention to treat".**
10. **The results of between- group statistical comparisons are reported for at least one outcome.**
11. **The study provided point measure for both point measure and measures variability for at least one key outcome.**

Fig. 2. Randomized controlled trial checklist (PEDro scale).

3.1. Corticosteroids

The most common treatment that has been employed over the past decades is corticosteroid injections. Our literature search of invasive methods retrieved 26 RCTs investigating the use of different types of corticosteroids for the treatment of plantar fasciitis. Some studies used long-acting corticosteroids such as dexamethasone (Ryan et al., 2014), and betamethasone (Li et al., 2014a), while other studies employed intermediate-acting corticosteroids such as methylprednisolone (Eslamian et al., 2016b; Celik et al., 2016; Canyilmaz et al., 2015; Ball et al., 2012; Guner et al., 2013b; Mahindra et al., 2016; Kiter et al., 2006a), prednisolone (Jain et al., 2015a), dopomedrol (Jain et al., 2015a) and tenoxicam (Guner et al., 2013b). There was no significant criteria or protocol used for choosing the type of corticosteroid. A meta-analysis conducted by Gaujoux-Viala et al. (Gaujoux-Viala et al., 2009) found no difference between the various types of corticosteroid used. In addition, the technique and application of the medication differed between the studies; some studies used a medial approach to inject the patients, while others used either a posterior approach or through the plantar aspect of the heel pad. The approach used also depended on whether the study was conducted using the palpation intervention approach or under ultrasound guidance.

3.2. Botulinum toxin Type-A

Traditionally, botulinum toxin has been used in the treatment of spasticity and nerve blocks. Only recently has it found its way into musculoskeletal medicine. Three RCTs compared the effect of botulinum toxin type-A (BTA) on heel pain with steroids (Huang et al., 2010a; Peterlein et al., 2012a; Díaz-Llopis et al., 2012). The studies reported significant improvements with BTA. Furthermore, patients with plantar fasciitis who received BTA had significantly longer lasting relief of dysfunction and pain than those who received placebo. Further comparative studies are needed with larger sample sizes (Ahmad et al., 2017).

3.3. Autologous platelet-rich plasma therapy

Platelet-rich plasma (PRP) therapy showed significant improvements in the 3-month follow-up. The use of PRP improves blood flow at the site of injection, which aids in the regeneration at the site of pain and inflammation, and the boost that occurs after the injections help the regeneration of the site of pain and inflammation. In chronic plantar fasciitis, local autologous whole blood (AWB) injections were superior to conservative treatment and comparable to corticosteroids, however the effects of AWB last longer than those of corticosteroids and either can be used as a second-line treatment, although the use of corticosteroids is associated with a slightly higher risk of complications (Jain et al., 2015b; Karimzadeh et al., 2017). This approach has been studied in nine

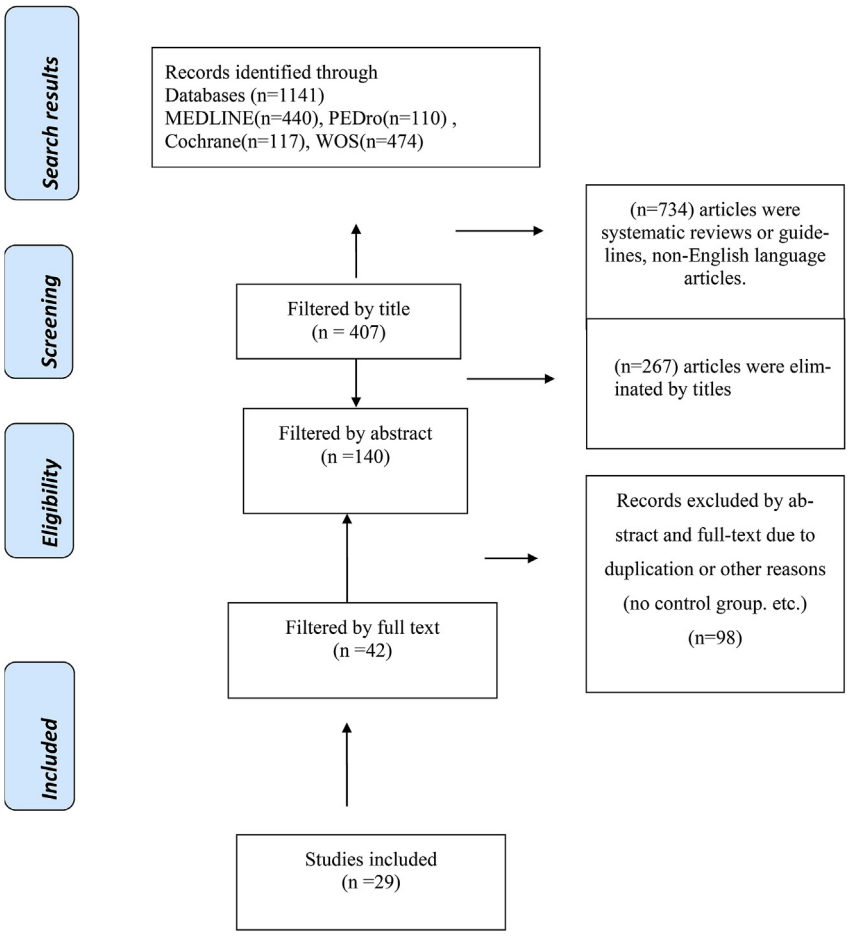

Fig. 3. Flow diagram of studies through the different phases of the review.

RCTs for plantar heel pain showing that PRP injections are as effective as corticosteroids and, in most cases, superior to the use of corticosteroids. Some of the papers reviewed compared PRP with corticosteroid injections, and some with other treatment modalities.

3.4. Polydeoxyribonucleotide (PDRN) injections

Polydeoxyribonucleotide injections have clinical efficacy with no notable complications and were associated with symptomatic improvement in refractory plantar fasciitis. Two main pharmacological effects of PDRN are hypothesized: the stimulation of VEGF and a decrease in inflammatory cytokines, such as TNF-α and IL-6, and an increase in the anti-inflammatory cytokine IL-10, which could result in the treatment effect on plantar fasciitis (Kim and Chung, 2015).

3.5. Acupuncture

Acupuncture has been used in Chinese medicine for hundreds of years however few RCTs were available in English. We retrieved two articles that used acupuncture for the relief of heel pain with high significant outcome, however these were based on small samples and were lacking evidence supporting the use of the acupuncture (Kumnerddee and Pattapong, 2012; Zhang et al., 2011).

3.6. Dry needling

Dry needling is a more recent minimally invasive technique. Considerable research has been conducted in the past few years to prove the effectiveness of this technique, which shows promising results with fewer side effects. The theory behind dry needling is the release of the myofascial trigger point (MTrP), which is a hyperirritable spot in the skeletal muscle tissue. The reasons for trigger point production are multifactorial and include micro-tears, smoking, or a lack of oxygenated blood at the site of trigger point which decreases the pH level and renders the site more acidic and vulnerable to changes at the cytoskeletal level as well the cellular level, and thus produces pain. To date, there are few studies supporting the use of dry needling and its effects. Recently, two RCTs have reported a good outcome for these patients with minimal side effects. Over recent years, the use of dry needling is gaining popularity within the medical field [23, 24].

4. Discussion

If any future plans to update the protocol and guidelines for the treatment of plantar fasciitis are to be undertaken, treatment protocols should be put in place with emphasis on first- and second-line treatments. The concept of referred pain to the heel, which can originate from a myofascial trigger point, has been neglected. A more in-depth assessment of patients must be considered before prescribing any treatments. The needle effect was described by Lewit in 1979, who emphasized that the trigger point can be the

Table 1
Characteristics of the included studies.

Author	Participants	Comparator	Outcome	Results	Conclusion
Eslamian, F (Eslamian et al., 2016b)	*(n = 40) Age 18–65 years. Chronic plantar fasciitis.* **Group 1:** (n = 20) ESWT with (41.45 ± 8.05) years, 18 (90%) female. 2000 shock waves/session of 0.2 mJ/mm (2) for 15 min, 5 sessions in 3 days intervals. Only Acetaminophen was recommended during the trail.	**Group 2:** (n = 20) local methylprednisolone injection with the age of (42.85 ± 8.62) years, 15 (75%) females **Corticosteroid injection** 40 mg local methylprednisolone, 1% lidocaine on palpation at the most tender point, medial plantar or inferior calcaneal area.	Outcome measures: pre-treatment 4 weeks, and post treatment 8 weeks. **Pain:** (VAS) **Functional:** (FFI)	*[FFI decreased to 19.65 ± 21.26 points (67.4% improvement) in ESWT vs 31.50 ± 20.53 points (47.7%) in injection group at week 8, P = 0.072)]* *The inter-group differences were not significant, FFI was enhanced more with ESWT and patients were more satisfied with ESWT.*	The shockwave therapy seems a safe alternative for management of chronic plantar fasciitis.
Mardani-Kivi, M (Mardani-Kivi et al., 2015)	(n = 68) Acute plantar fasciitis >18 years. **Group 1:** (n = 43) CSI *(44.68 ± 9.20) years, (28) female and (6) Male* 40 mg of methyl prednisolone acetate plus 1 mL of lidocaine 2% was injected into maximal tenderness point at the infra medial calcaneal tuberosity.	**Group 2:** (n = 41) ESWT *(43.91 ± 7.96), (29) females and (5) males* ESWT 2000 impulses with energy of 0.15 mJ/mm, total energy flux density of 900 mJ/mm for consecutive 3 sessions at 1 week intervals 3 times weekly intervals, at the maximum tender point marked with a skin marker with an US gel applied as a medium. No anaesthesia or narcotics applied.	**Pain:** VAS-3,6,12 weeks follow-up.	*The pain reduction in CSI group was significantly in those in the ESWT group (p < .0001).* *In the ESWT and CSI groups, 19 (55.9%) and 5 (14.7%) patients experienced treatment failure, respectively. Age, gender, body mass index, and recurrence rate were similar between the two groups (p > .05)* *The patient were 4 times more irresponsive to ESWT than CSI*	ESWT and CSI can be used as a primary treatment option for treating patients with acute plantar fasciitis; however, the CSI technique had better therapeutic outcomes.
Canyilmaz, E (Canyilmaz et al., 2015)	(n = 128) Chronic Fasciitis> 6 months of evolution, have calcaneal spur and are over 40, no previous pharmacological treatment is restricted. **Group 1:** (n = 64) Receive radiation therapy mean ± SD, years 52.6 (40–74) years, 46 (76.7%) female 14 (23,3%) in male. (A total dose of 6.0 Gy applied in 6 fractions of 1.0 Gy three times a week).	**Group 2:** (n = 64) PG-Steroid injection mean ± SD, years 54.7 (40–74) years, 51 (79.7%) female 13 (20.3%) Local corticosteroid injections; A 22-gauge 1.5-inch needle with 40 mg of methylprednisolone (1 mL) mixed with 0.5 mL of 1% lidocaine. The painful area and medial tubercle of calcaneus were determined by palpation.	**Pain:** VAS **Functionality**: a modified von Pannewitz scale, and a 5-level function score. Post treatment is: 3 months Follow-up period of up to 6 months. *The patient underwent the radiation therapy; the median follow-up was 13 months* *(PG) steroid injection arm, it was 12.1 months;*	*The pre-treatment VAS score was higher in radiation therapy:* ***VAS**: 7.6 in radiation* *6.9 in PG-Steroid* *After three months, results in the radiation therapy arm were significantly superior to those in the PG steroid injection arm (VAS P < .001; modified von Pannewitz scale, P < .001; 5-level function score, P < .001). Requirements for a second treatment was not significant. The time intervals for the second treatment was significantly shorter in the PG-Steroid groups (p = .045)*	This study confirms the better analgesic effect of radiation therapy compared to mean Palpation Guided steroid injection on plantar fasciitis for at least six months after treatment
Monto, RR (Monto, 2014b)	(n = 40) Unilateral chronic PF whom did not respond to minimum 4 months of standardized non-operative treatment modalities, no pharmacological treatment's. **Group 1**: (n = 20) 9 males, 11 females 59 years average of age range (24–74 years); 40 mg DepoMedrol cortisone Both group used 2% of chlorhexidine, gluconate/70% isopropyl alcohol and then local anaesthesia. Insertion of the injection at the medial calcaneal tubercle. Patients were placed into calm walker for 2 weeks, allowed to return to activity as tolerated with daily home eccentric exercises and calf stretch	**Group 2**: (n = 20); 51 average age (21–67 years) 8 male and 12 females. single guided US PRP Both group used 2% of chlorhexidine, gluconate/70% isopropyl alcohol and then local anaesthesia. Insertion of the injection at the medial calcaneal tubercle. Patients were placed into calm walker for 2 weeks, allowed to return to activity as tolerated with daily home eccentric exercises and calf stretch PRP = 27 cc venous blood sample mixed with 3 cc of anticoagulation citrate dextrose solution formula to prevent clotting of the sample, then centrifuged at 2400 rpm/12 min using a soft spin	**Pain:** VAS **Functionally:** (AOFAS) (pre-treatment = time 0) and at 3, 6, 12, and 24 months following injection treatment. Baseline pre-treatment radiographs and MRI studies were obtained in all cases to confirm the diagnosis.	*The cortisone group had AOFAS: score of 52 pre-treatments, which initially improved to 81 at three months post treatment but decreased to 74 at six months, suddenly dropped to near baseline levels of 58 at 12 months and proceeded to decline to a final score of 56 at 24 months.* *The PRP group began with an average pre-treatment AOFAS score of 37, which increased to 95 at three months, remained elevated at 94 at 6 and 12 months, and had a final score of 92 at 24 months.*	PRP was more efficient and durable than cortisone injection for the treatment of chronic cases of plantar fasciitis.
Kim, E (Kim and Lee, 2014)	(n = 21) with unilateral foot pain for more than 6 months with chronic PF confirmed	**Group 1:** (n = 10) PRP 36.2 (20–57 years), 6 females & 4 males	**Functionally**: FFI **Follow-up:** Data	An improvement in the mean FFI total scores from 132.5 ± 31.1 at baseline to	Both treatments seem to be effective for chronic recalcitrant PF, but after 2 month.

	with an US (thickness >4 mm) It is chronic fasciitis that has failed conservative treatment even with corticosteroid injections before 6 months prior to the study, no pharmacological Treatment. **Group 2**: (n = 11) DP 37.8 (19–51 years), DP 4 females & 7 males Dextrose Prolotherapy, 1.5 mL of 20% dextrose and 0.5 mL of 0.5% lidocaine, resulting in a 15% dextrose solution, within a 2.5-mL syringe.	Whole blood (20 mL) was collected from the antecubital fossa into a 25-mL syringe that contained 2 mL of anticoagulant (Huons ACD-soln; sodium citrate 22 mg, citric acid 7.3 mg, glucose monohydrate 24.5 mg). *Injection was given in both group 2 times. 2 weeks and then after the next 2 weeks the second injection* *Patients were kept sitting position for 30 min. They were sent home with instructions (allowing only indoor activities of daily living) for approximately 72 h & to use acetaminophen for pain. The use of nonsteroidal anti-inflammatory drugs and any type of foot orthoses was not allowed.*	collected before the first injection at 2 weeks and at 2- and 6th month	123.7 ± 47.4 (3.8% improvement) at 10 weeks and to 97.7 ± 52.5 (15.1% improvement) at 28 weeks' follow-up was achieved in the DP group. *The main FFI improves were greater in PPR group compared with DP (30.4% vs.15.1%)* *Pain: 29.7% vs.17.1%* *Disability: 26.6% vs.14.5%* *Activity limitation: 28.0% vs 12.4%*	Improvement achieved over time with no adverse events accept of the pain after injections. PRP also may lead better initial improvements in function compare with DP.
Yucel, U (Yucel et al., 2013)	(n = 67) with unilateral Chronic plantar fasciitis of 3 months' duration, exclude those who previously had shock waves and corticosteroid injections. **Group 1:** (n = 22) Full length silicone insole 45.6 ± 9.3, 16 (80%) were female. A prefabricated full-length silicone insole daily lives for 1 month both indoors and outdoors as possible, (acetaminophen) was allowed if necessary, except last 24 h before evaluations.	**Group 2:** (n = 22) 47.4 ± 7.9, 16 (80%) were female Guided corticosteroid injections To injection group, A 4-cm 21-gauge needle was positioned in a caudo-cranial oblique manner into the area of maximal ultrasound abnormality, 1 mL of betamethasone dipropionate (6.43 mg/mL) and betamethasone sodium phosphate (2.63 mg/mL) combination. Plus 1 mL lidocaine HCL. (20mg/2 mL)	**Pain:** first step heel pain via VAS & heel tenderness **Functionally:** (FAOS) And ultrasonographic thickness of PF in both groups.	*Both groups showed significant change in VAS at one month from baseline* ***Injection group:*** *6.45 ± 1.23 to 3.70 ± 1.45* ***Insole group***: *6.95 ± 0.94 to 4.65 ± 1.34* *VAS scores were **significantly better** in injection group than in insole group (p < 0.05)*	Both ultrasound-guided corticosteroid injection and wearing full-length silicone insole were effective in the conservative treatment of PF. The study recommends the use of silicone insole as the first line of treatment for persons with plantar fasciitis. No adverse events occurred
Chew, KTL (Chew et al., 2013)	(n = 54) with unilateral chronic plantar fasciitis with more than 4 months of symptoms. excluding those who have injection with corticosteroids or another injection 4 months before the study, did not exclude those who had physiotherapeutic treatment or splints, all carry conventional treatment 3 Groups **Group 3:** (n = 16) 47.5 (41–53 years) 8 Male/8 Females to conventional treatment alone. Conventional treatment included stretching exercises and orthotics if indicated.	**Group 1: ACP** (n = 19) age 46 years (38 –51), 10 males/9 females. 10 mL of peripheral blood drawn and centrifuged at 1500 rpm for 5 min No buffer or preservative was added, per manufacturer's protocol. 23-gauge, 1.5-inch needle at a single peri-fascial target at the site of plantar fascia thickening and tenderness at the medial calcaneal tubercle. **Group 2:** (n = 19) 45 (37–53 years) 11 Male/8 Female to **ESWT**: 2000 shockwaves with energy levels progressing gradually from 0.02 mJ/mm3 to 0.42 mJ/mm3. The total treatment duration was 10 min. No local anaesthetic was administered.	**Pain:** VAS **Functionally:** AOFAS US thickness assessed at baseline and 1,3,6 months	*ACP Group: significant VAS pain score improvements compared with the conventional treatment at month 1 (p = .037)* *The AOFAS ankle-hind foot scale improved in ACP at third month and sixth month (p = 0.04 and p = .013)* *PF thickness was seen in the ACP at 1st and three months (p = .015 and p = .14)* ESWT: 1,3,6 months (p = 017, p = 0.22, p = 0.42) The AOFAS ankle-hind foot scale improved in ESWT at the first month and third month (p = 0.11 and p = .003) PF thickness was seen in the ACP at 1st, and three months (p = .019 and p = .027) *PF thickness improved in all groups.* There was no significant difference between ACP & ESWT regarding VAS & AOFAS ankle-hind foot scale improvements, although the ACP group showed a greater reduction in PF thickness.	ACP treatment resulted in greater decreases in ultrasound plantar fascia thickness than ESWT, The ACP treatment group displayed better objective improvements, when compared with the conventional treatment group at the 6-month follow-up. with an overall median decrease of ultrasound plantar fascia thickness by 1.3 mm at the 6-month follow-up. Changes in plantar fascia thickness more than 0.6 mm are considered changes in thickness not due to measurement error *No adverse events occurs.*
Kumnerddee, W (Kumnerddee and Pattapong, 2012)	(n = 30) Chronic Fasciitis of 6 months of evolution that does not work conservative treatment, excluding those who have received injection of corticosteroids in less than 6 month.	**Group 2:** (n = 15) (52.4 ± 10.5) years, (12) females, 3 males. same conventional plus 10 sessions of electro-acupuncture twice weekly. **Acupuncture group:** Topical 5% lidocaine/	**Pain:** VAS **Function:** FFI Endpoints included a success rate determined	VAS decreased significantly from 6.00 ± 1.69 to 1.89 ± 1.59 and from 6.27 ± 2.34 to 5.40 ± 2.26 in acupuncture and control group (p < 0.05) acupuncture group had higher success rate than the	Electro-acupuncture coupled with conventional treatment provide success rate of 80% in chronic PF which was more effective than conventional treatment

(*continued on next page*)

Table 1 (*continued*)

Author	Participants	Comparator	Outcome	Results	Conclusion
	Group 1: (n = 15) (52.4 ± 10.5) years, 12 females conventional treatment stretching exercise, shoe modification and rescue analgesics	prilocaine cream (Emla) was applied 30 min prior treatment 2–6 needles were inserted at the most tender spot over anteromedial aspect no manipulation or twisting applied only a stimulated for 30 min using the SDZ- II nerve and muscle stimulator	by a minimum of a 50% decrease (VAS) and (FFI).	control group (80% and 13.3% respectively) FFI was in acupuncture group was better than those control group (<0.001) Six week follow up acupuncture group showed a better FFI and success rate for pain during the day than those in control group ($p < 0.05$)	alone, the effect lasted for at least six weeks.
Huang, YC (Huang et al., 2010b)	(n = 50) unilateral chronic plantar fasciitis, double blind **Group 1**: (n = 25) (54.4 SD 9.6), 6:19 male to female. 50 units of botulinum toxin type A	**Group 2:** (N = 25) (51.5 5.5 years) Normal saline under US. 1 mL normal saline, by injection into the plantar fascia under ultrasonographic guidance us- ing a 25-gauge, 1.5 inch needle. Subjects in the control group were injected with 1 mL normal saline into the plantar fascia under ultrasonographic guidance.	**Pain**: VAS Measuring the fat pad of thickness. **Functionally:** Gait assessment including maximal centre of pressure during the first loading step.	*Follow up three weeks and three months after Botox-A injection ($p < 0.001$).* *The fat pad thickness remained unchanged, the centre of pressure velocity during loading response increased three months after injection ($p < 0.05$) outcome measure of the control group remained unchanged.*	BTX- A is effective in the treatment of foot pain associated with PF and increases the centre of pressure velocity during loading response without inducing fat pad atrophy.
Kalaci, A (Kalaci et al., 2009)	(n = 100) with PF using four different methods of local injection, patients were blinded to the treatment given. Exclusion were if previous 6 months any surgery was done, or an abnormal erythrocyte sedimentation rate or C-reactive protein level, previous injections for plantar fasciitis were not included. **Group A**: (n = 25) Age (52.88 ± 11.11), 6 males were treated with 2 mL of autologous blood alone **Group B**: (n = 25) Age (49.92 ± 10.8), 7 males an anaesthetic (2 mL of lidocaine) combined with peppering	**Group C**: (n = 25) age (49.87 ± 9.36), 8 males a corticosteroid (2 mL of triamcinolone) alone **Group D**: (n = 25) age 52.22 ± 8.49, 9 males, a corticosteroid (2 mL of triamcinolone) combined with peppering. *No additional medication was given, and no restriction of activity was advised. Patients were evaluated by re- viewers who were blinded to the study method.*	**Pain:** 10-cm VAS and modified criteria of the Roles and Maudsley score. **Follow-up:** in 3 weeks and 6 months after the injection and compared with the pre-treatment condition.	*Successful results in all the groups post-treatment were higher than those in the pre-treatment condition ($P = .000$).* *In both C and D groups, in which local corticosteroid injections used, excellent results were obtained, with excellent effect in the group in which peppering was used ($P < .05$).*	The treatment of PF, combined corticosteroid injections and peppering is efficient and produces better clinical results.
Porter, MD (Porter and Shadbolt, 2005)	(n = 132) unilateral with manifest of 6 weeks PF. Exclusion of Previous surgery, CSI, or ESWT for heel pain. , Clinical features suggestive of seronegative spondyloarthropathy, Clinical features suggestive of regional pain syndrome. **Group C:** (n = 19) age 38.1 (21–61) 6 males. non-randomized patients who performed stretching program only *All patients standardized a stretching program of the soleus, gastrocnemius, and plantar fascia each stretch consists of 2 min/4 times a day, ice massage and continuing the ADL with tolerance to pain.*	**Group A:** (n = 64) age 39.9 (21–80 years) 20 males single CSI. One millilitre betamethasone (5.7 mg) and 2 mL of lignocaine 1% were injected into the site of maximal tenderness. The medial calcaneal tuberosity was infiltrated until the patient declared that his/her tenderness and symptoms had gone. Patients were instructed not to take part in any running or impact activities for at least 10 days following the injection. **Group B:** (n = 61) age 38.6 (18–81 years) 22 males Low dose of ESWT 3 treatments over 3 weeks. Patients randomized to group B each received 3 applications of 1000 pulses of an energy flux density of 0.08/mm2. 1000 impulses were applied 3 times at weekly intervals. Neither local anaesthesia nor sedation was used.	**Pain:** VAS, PPT **Follow-up:** baseline, 3 –12 months.	VAS pain scores, values for the CSI (1.48; 0 –7) were significantly lower than both ESWT (3.69; 0–8), and controls (3.58; 2–5) at 3 months. At 12 months, VAS scores for CSI (0.84; 0–7) and ESWT (0.84; 0–4) were both significantly lower than controls (2.42; 1–4). The tenderness values at 3 months were significantly higher for CSI (9.42; 7–11) than both ESWT (6.72; 4–11) and controls (7.63; 6–9). $P < 0.05$ was used throughout	Corticosteroid injection is more efficient and more cost-effective than ESWT in the treatment of plantar fasciitis that has been symptomatic for more than six weeks. *Of the 64 heels that received CSI, there were no infections and no cases of rupture of the plantar fascia. There were 8 cases of post-injection pain that required analgesia and/or ice application*
Demir G, (Demir et al., 2015)	(n = 150) **Group 1:** received Dextrose Prolotherapy **Group 2:** corticosteroid injection as a single		Pain: VAS, THI Functionally: FFI and FAOS, SF-36	*The analysis demonstrated statistically significant improvements in all parameters from baseline to 1 and three months*	Prolotherapy, corticosteroid, and phonophorosis therapies were well tolerated and appeared to provide the

	dose. **Group 3:** phonophoresis All patients were given exercises program.		Measurements at baseline, 1,3-month follow-up. Besides PF thickness was measured with US.	*(p < 0.05). There was no significant difference between groups regarding the efficacy of treatment (p > 0.05).* *The plantar fascial thickness between the baseline and final measurements revealed a mean decrease in thickness, statistically significant difference (p < 0.05) in three groups. Between groups before treatment, 1 and three months after treatment in terms of plantar fascia thickness there was no statistically significant difference (p > 0.05)*	benefit of patients with PF. As a result, Prolotherapy can be an effective way to treat PF. *Aside from injection-associated pain, no adverse reactions were reported.*
Li S, Shen T (Li et al., 2014a)	(n = 61) after 6 months of filed conservative treatments. patients were excluded if they had fracture or arthritis of the ankle and knee, previous foot surgery or trauma, nerve injury, a severe systemic disease, contralateral heel pain, or a history of MSN release treatment or local steroid injection age (54.74 ± 10.16), 10 males, 19 females) **Group 1**: **MSN** (n = 31) age (54.74 ± 10.16), 10 males, 19 females) 2 mL of 2% lidocaine. then, the MSN(diameter 0.80 mm, length 50 mm), inserted into the tender point vertically with the direction of the MSN parallel to the long axis of the foot. the release of plantar fasciitis was performed by moving the MSN up and down 3–5 times without rotation, the MSN was withdrawn, and pressure was applied to the wound for 2 min to avoid bleeding the hole was covered with a simple adhesive bandage for 2 days.	**Group 2**: **CSI** (n = 30) age (56.93 ± 9.25, 7 males, 25 females) steroid injection 2 mL of 2% lidocaine plus 2 mL triamcinolone acetonide (20 mg) was injected into the most painful tender point. After treatment, the patients in both groups were observed for 30min to record any adverse reaction. All patients were asked to avoid bearing weight on the heel pad for 2 days.	**Pain**: morning pain, (VAS) 0-10 **Follow-up:** 1,6,12 month follow up	*In the MSN group, the VAS scores for morning pain, and overall pain were significantly improved at 1, 6, and 12 months after intervention compared to the baseline scores (< 0.01).* *There were no statistical differences in the VAS scores observed between 1, 6, and but no significant improvement in pain was experienced at 6 or 12 months after intervention compared to the baseline levels (> 0.05)*	The study suggests that the MSN release treatment is safe and has a significant benefit for PF compared to steroid injection. *No severe side effects were observed with MSN treatment. The study suggests that MSN release treatment is safe and has a significant benefit for plantar fasciitis compared to steroid injection.*
Mahindra P (Mahindra et al., 2016)	(n = 75) Patients had not responded to at least 3 months of conservative therapy, including physical therapy, NSAIDs, bracing, and orthotics. Treatment with NSAIDs was discontinued 1 week before injection. **Group C (Normal saline):** age (35.48 ± 9.54) 11 males. assigned to receive normal saline.	**Group A (PRP):** (n = 25) age (30.72 ± 7.42) 8 males was assigned to receive platelet-rich plasma 27 mL of blood was withdrawn placed in a glass tube containing 3 mL of citrate dextrose solution. Citrate dextrose solution was used to prevent clotting. The blood was centrifuged at 3200 rpm for 12 min, and 2.5–3 mL of platelet-rich plasma was obtained by this method. No activating agents were used. **Group B** (**CSI):** age (33.92 ± 8.61) 12 males was assigned to receive corticosteroid 2 mL of 40 mg of methylprednisolone was used for injection Injection was given at the point of maximum tenderness in the heel with a 22-g needle using a peppering technique	**Outcome measure:** VAS and AOFAS **Follow-up at** 3 weeks and 3 months by a blinded observer.	Mean VAS and AOFAS scores improved over time after injection in groups A and B. In group A, VAS score decreased significantly from the pre-injection level at follow-up of three weeks (P = 0) and 3 months (P = 0). Compared with the pre-injection level, AOFAS score improved significantly at follow-up of three weeks (P = 0) and 3 months (P = 0). Similarly, in group B, VAS score decreased significantly from pre-injection level at follow-up of three weeks (P = 0) and 3 months (P = 0). The AOFAS score improved significantly at follow-up of three weeks (P = 0) and 3 months (P = 0) in group B. In group C, no significant difference was observed in VAS score pre, and post injections score at three weeks (P = .11); at three months (P = .41). There were no significant difference observed between pre-injection AOFAS score and the score at three weeks (P = .06); at three months (P = .39)	PRP is as effective or more than corticosteroid injection in treating PF

(*continued on next page*)

Table 1 (*continued*)

Author	Participants	Comparator	Outcome	Results	Conclusion
Crawford F, Atkins D (Crawford et al., 1999)	(n = 106) patients, above the age of 18 and pain from 1 to 120 months. Median duration 6 months (±20.6) excluding patient who received corticosteroid in less than 6 months. 69 female and 37 males mean age was 57 year (±12.9). **Group 1:** (n = 27), Mean: (53.69), SD: (14.28); 1 ml of 25 mg/ml of prednisolone acetate with 1 mL of 2% lignocaine; **Group 2:** (n = 26), Mean (56.88) SD: (13.02); 1 mL of 25 mg/mL of prednisolone acetate with 1 mL of 2% lignocaine given after a tibial nerve block	**Group 3:** (n = 27) Mean (59.41), SD (11.84); 2 mL of 1% lignocaine hydrochloride **Group 4:** (n = 26) Mean (58.81) SD: (12.48); 2 mL of 1% lignocaine hydrochloride given after a After a tibial nerve block.	**Pain:** 10 cm VAS. **Follow-up:** 1,3,6 months	*There was a statistical difference between the groups in favour of treatment with steroid at one month (p = 0.02)* No statistically significant difference in pain reduction could be detected between the injected sub- stances for pain outcomes taken at 3 and 6 months; the *P* values were 0.9 and 0.8, respectively. No statistical difference existed in the numbers of patients lost to follow-up between the four groups (*P* = 0.7) *Mean VAS score at one month (p = 0.02) There was no statistically significant difference in pain reduction among the groups for pain outcomes taken at three months (p = 0.9) and six months (p = 0.8)* but thereafter no differences could be detected. Patient comfort was not significantly affected by anaesthesia of the heel (P = 0.5)	A steroid injection can provide relief from heel pain in the short term; there appears to be no increase in patients comfort from anesthetizing using tibial nerve block prior heel infiltrations. No adverse event mentioned
Kiter E (Kiter et al., 2006b)	(n = 45) PHP in 3 groups, patients who received CSI last year they were excluded, average duration of heel pain was 19.3 months (range, 6–180 months). **Age and Gender:** 31 Females and 14 Males. The mean patient age was 50.7 years (range, 26–70 years) **Group 1:**(n = 15) patients underwent the peppering technique **Group 2:** (n = 15) underwent autologous blood injection, a mixture of 2 mL of autologous blood drawn from the ipsilateral or contralateral upper extremity and 1 mL of 2% prilocaine was infiltrated. **Group 3:** (n = 15) underwent corticosteroid injection. 40 mg of methylprednisolone acetate mixed with 1 mL of 2% prilocaine was injected. 3 injections were given to all groups	**Peppering group:** In the peppering technique group, after infiltration of 1 mL of 2% prilocaine the needle was inserted, withdrawn, slightly redirected, and reinserted 10 to 15 times with- out emerging from the skin. During injection, a sensation similar to crepitation due to dissection of the fascia or degenerative tissue was felt	**Pain:** 10 cm VAS, Rear foot score of AOFAS 0 −100 (100-best score) **Follow-up**: 6 months.	*At six-months assessment, statistically significant improvement found in all groups (VAS and rear foot scores) there was no significant difference among the three groups.* Rear foot score in 6-months: Peppering group: (P .018) Autologous blood injection: (P .025) Corticosteroid injection: (P .30) VAS score in 6-months: Peppering group: (P < .001) Autologous blood injection:(P < .001) Corticosteroid injection: (P < .001) Mean ± SD visual analogue scale scores in the peppering technique, autologous blood injection, and corticosteroid injection groups improved from 6.4 ± 1.1, 7.6 ± 1.3, and 7.28 ± 1.2 to 2.0 ± 2.2 (P < .001), 2.4 ± 1.8 (P < .001), and 2.57 ± 2.9 (P < .001), respectively. Mean ± SD rear foot scores in the same groups improved from 64.1 ± 15.1, 71.6 ± 1, and 65.7 ± 12.7 to 78.2 ± 12.4 (P = .018), 80.9 ± 13.9 (P = .025), and 80.07 ± 17.5 (P = .030), respectively. There were no statistically significant differences among the groups.	The curative mechanisms of both injection modalities based on a hypothesis, they seem to be great alternatives to corticosteroid injection for the treatment of plantar heel pain *No adverse events mentioned*
Zhang SP (Zhang et al., 2011)	(n = 89) onset of heel pain <3 months. Excluding needle phobic, fractures, pregnant and breast feeding. **Control group:** (n = 25) age *(50.0 ± 2.0, 6 males & 19 females)* The control group received needling at the acupoint Hegu (LI 4), which has analgesic properties	**Treatment group:** (n = 28): *(47.0 ± 2.2, Males 8 & 20 females)* needling at the acupoint PC 7, which is purported to have a specific effect for heel pain	**Pain**: VAS, PPT **Follow-up:** 1,3,6 months	*There was a significant difference in reduction in pain scores, favouring the treatment group. At one month for morning pain (22.6 ± 4.0 versus 12.0 ± 3.0, mean ± SEM). Overall pain (20.3 ± 3.7 versus 9.5 ± 3.6) PPT (145.5 ± 32.9 versus -15.5 ± 39.4)*	The study provided that acupuncture can cause a pain relief to the patient with PF, The PC 7 point is a relatively specific acupoint for heel pain. *No serious adverse event noted in either group*
Yucel I, (Yucel et al., 2010)	(n = 60) < 6 month of pain with previously field treatments, excluding previous CSI, surgery. Patients were allowed to continue	**Group A:** (n = 33), age (44.7 ± 9.20, 5 males, 8 females) CSI A 22- gauge, 1.5-inch needle was	**Pain:** 100-mm VAS and a physician-assessed heel	The mean visual analogue scale score changes were 4.0 for group A and 5.3 for group B (P < .05 for both). Both groups	ESWT and corticosteroid injection provided significant improvements in VAS and HTI scores.

	their heel cup. **Group B:** (n = 27), age (42.9 ± 7.08 13 males and 14 females) ESWT A fivefold nerve block (posterior tibial, superficial and deep peroneal, sural, and saphenous nerves) was applied to each operative ankle with 20 mL of prilocaine hydrochloride, 2%. Patients received a single application of 3000 shockwaves using an electrohydraulic shockwave generator. Com- mon ultrasound gel was used as a contact medium no additional treatment was permitted during the study period, including night splints, nonsteroidal anti-inflammatory drugs, and physical therapy.	connected to a 2-mL syringe filled with 0.5 mL of combined betamethasone dipropionate (6.43 mg/mL) and betamethasone sodium phosphate (2.63 mg/mL) (Diprospan; and 0.5 mL of prilocaine hydrochloride, 2% (20 mg/mL) The injections were performed from the medial side of the heel. The most painful area over the medial calcaneal tuberosity was determined by palpation, and the injection was performed at this spot. Care was taken to avoid the fat pad and injection into the skin or subcutaneous tissues. Patients were instructed to refrain from running and impact activities for 10 days.	tenderness index. Follow-up: 3-months.	showed significant improvement in visual analogue scale scores, but there were no significant differences in scores between the groups 3 months after treatment (P > .05). Results of the visual analogue scale and heel tender- ness index scores between patients with and without a spur in groups A and B were not significantly different (P > .05). Eleven of the 13 patients (84.6%) in group A and 10 of the 12 patients (83.3%) in group B responded to therapy.	All of the patients in group A had pain during injection. The pain lasted an average of 5 days, 4 patients required analgesia. No infections or other major complications occurred in group A. None of the patients experienced pain during the ESWT protocol. Two patients had a mild throbbing sensation that lasted an average of 5 days, but did not require analgesia. Two patients had mild erythema.
Celik D (Celik et al., 2016)	(n = 46) with unilateral PF **Group 1:** (n = 22) age (45.4 ± 9.3), 6 male and 14 females. Joint Mobilization & Stretching.	**Group 2**: (n = 21) age (45.6 ± 7.9), 5 males & 14 females. Stretching & mobilizations + one CSI 1 mL of corticosteroids (40 mg methylprednisolone acetate) or 4 mL of 2% (prilocaine HCL) using 22-guage at the heel around the PF ***(no stretching was performed)***	**Pain**: VAS **Functionally:** FAAM **Follow-up:** at baseline and at 3-week, 6-week, 12-week, and 1-year.	*Significantly improvement in VAS & FAAM pain and functional outcome in only 12 weeks and 1 year in group 1 (P = .002)* *Both groups were statistically significant for both FAAM (P = .001; F = 7.0) and VAS (P = .001; F = 8.3) scores* *At 3 weeks,-6 weeks and -12 weeks.* *Between-group differences in VAS & FAAM favoured the SI group at the 3-week (P = .001, P = .001), 6-week (P = .002, P = .001), and 12-week (P = .008, P = .001).*	The Steroid Injection group exhibited better outcomes at all 3-time points. The noted improvements continued group 1 in 12-weeks to one year.
Jain K (Jain et al., 2015a)	(n = 46) heels with intractable plantar fasciitis who had failed conservative treatments for 12 months (ESE, cushioned insole, physical therapy) 14 patients were treated bilateral heel, 19 left heel 31 right heel. **Age & Gender:** (mean 55.6 years) 31–79 years, 16 male **Group 2:** (n =)Steroid injection. Triamcinolone (Kenalog) 40 mg and Levobupivacaine hydrochloride (Chirocaine) injection	**Group 1:** (n =)PRP injections 6 underwent bilateral heel injection 27 (ml) of blood was withdrawn from the patient and added to 3 ml of sodium citrate (anticoagulant). then centrifuge and spun for 15 min at 3200 rpm. The plasma portion of the centrifuged mixture was discarded. Since the anticoagulant introduced to the whole blood used to produce the platelet concentrate is acidic, the PRP portion harvested is buffered with 8.4% sodium bicarbonate, to increase the Ph to normal physiological levels.	**Pain:** VAS, RM **Functionally:** AOFAS **Follow-up:** pre-treatment, at 3, 6 and 12 months.	*Pre-injection, the two groups were well matched with no statistically significant difference. At three months, all three outcome scores had significantly improved from their pre-treatment level in both groups.* *At 12 months, the RM, VAS and AOFAS scores in the PRP arm (1.9, 3.3 and 88.5) were significantly better than the Steroid arm (2.6, 5.3 and 75) with P values of .013, .028 and .033, respectively.*	PRP is significantly more efficient than Steroid, making it better and more durable than cortisone injection. PRP is doesn't wear off with time. At 12 months, PRP is significantly more effective.
Kim JK (Kim and Chung, 2015)	(n = 40) Patients with PF, excluding patients underwent injections within 6 months. **Group 2:** (n = 20) age 55 (42–71 years n 4 male & 16 females) Placebo injected with normal saline. Injections were performed weekly for three weeks.	**Group 1:** (n = 20) age was 52 (34–68 years, 7 male & 13 female) injection (PDRN) In the PDRN group, a half vial of PDRN (1.5 mL, was injected into the tender region of the heel, medial to the insertion of the plantar fascia. In the placebo group, the same volume of nor- mal saline was injected at the same site.	**Pain:** (VAS) **Functionally:** (MOXFQ) **Follow-up:** Done at baseline and 4,12 weeks after treatment began. *P value represent pairs t-test with values of initial status*	*The PDRN group show a significant improvement in VAS and MOXFQ scores at four weeks' post-treatment, and this continued until 12 weeks' post-treatment. The placebo group did not achieve a significant improvement in the VAS or MOXFQ scored at four or 12 weeks.*	PDRN is an efficient and safe treatment option and may be considered for PF treatment. We noticed no injection-related complications, such as itching, urticaria, redness or infection signs around the injection site in either group.
Cotchett MP (Cotchett et al., 2011)	(n = 84) patients with plantar heel pain of at least one month's duration. **Age:** 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 1–95).	**Group 1:** (n = 42) Real Dry needling The most frequently treated muscles were soleus, gastrocnemius, quadratus plantae, flexor digitorum brevis and abductor halluces. Less frequently needled muscles included abductor digiti minimi, and flexor	**Pain**: first step in the morning (VAS), FHSQ **Follow-up:** 2,4,6,12 weeks	*Significant results favoured real dry needling over sham dry needling for pain (adjusted mean difference: VAS first-step pain = -14.4 mm, 95% confidence interval [95% CI] = -23.5 to -5.2; FHSQ foot pain = 10.0 points, 95% CI = 1.0 to 19.1)*	Dry needling provided statistically significant reduction in PHP. *However, the magnitude of this effect should be studied against the frequency of minor transitory adverse events.*

(*continued on next page*)

Table 1 (*continued*)

Author	Participants	Comparator	Outcome	Results	Conclusion
	Group 1: (n = 42) Real Dry needling **Group 2:** (n = 42) Sham Dry needling Patients received dry needling once per week for six weeks	hallucis longus. Treatments averaged four needles per session (range 2–8), each retained for 5 min.			
Ryan M (Ryan et al., 2014)	(n = 56) workers required to stand for greater than 5 h/day with chronic plantar fasciopathy took part. Duration of heel pain at least 12 months no mention of prior treatment **Group 1**: Physiotherapy-lead exercises 7 different exercises. **Group 2**: Dexamethasone Injection with routine calf stretch.	The steroid injection procedure has been described previously in the literature. A 22-guage, 1.5″ needle and 3 cm^3 syringe filled with 1 ml of dexamethasone mixed with 0.5 ml of 1% lidocaine was prepared.	**Primary outcome measure:** FADI (0–136, 136 = no disability) **Secondary outcome:** 100 mm VAS for patients **Follow up:** 6 and 12 weeks	*The follow-up showed significant improvement in FADI & VAS compared with baseline scores (P < 0.001).* *There were no significant between-group differences.* *No significant changes to PF thickness reported at the 6- and 12-week follow-up point.* *Both improved significantly in the PHYSIO (P = 0.003) and INJECTION (P < 0.001) groups at 12-week follow-up.*	The study showed that prolong standing period workers experienced the same short-term therapeutic effect. With a physiotherapy-led exercise program compared with an injection of corticosteroid with stretching.
Guner S (Guner et al., 2013a)	(n = 69) participants **Gender**: 47 (77%) women and 14 (23%) men) Mean age of 41.4 12.23 years (range, 18–60 years). A total of 28 (45.9%) left, and 33 (54.1%) right feet were studied. *Single injection for both groups* **Group 1:** (n = 31) Tenoxicam group treated with local injection of 1 mL of Tenoxicam (20 mg/2 mL) and one mL of 2% lidocaine.	**Group 2:** (n = 30) Steroid injection The steroid group using a local 1-mL injection containing 40 mg of methylprednisolone acetate and one mL of 2% lidocaine.	**Pain:** VAS **Follow-up:** 12 months.	Mean VAS reduction from pre-treatment to 12 month post-treatment was statistically significant for both groups ***Mean VAS scores of tenoxicam group:*** *8.26 (pre) → 2.94 (12 month) (p < 0.05)* ***Steroid group:*** *7.97 (pre) → 3.17 (12 month) (p < 0.05)* No significant difference was found between the steroid and tenoxicam groups in terms of VAS	Tenoxicam is an effective treatment for PF. *No complications attribute to either injection was observed.*
Peterlein CD (Peterlein et al., 2012a)	(n = 40) the pain >4 months, had at least two previous non-successful treatments of non-operative therapy strategy. **Age:** 51.54 (28–77) years old **Gender:** 80% women's **Group 2:** Normal saline injection ***Weakness side****: Concomitant treatment such as the application of ice, iontophoresis, ESWT, heel cups and orthosis, activity modification, or stretching/strengthening programs, which were prescribed before study start****, was not interrupted.*** *Medication changes were not recommended.*	**Group 1:** BoNT-A injection Botox (200 units) in 2 mL 0.9% saline solution or same volume in placebo with saline solution's.	**Pain**: VAS **Follow-up:** 2,6,10,14,18 weeks.	*The participants in the BoNT-A group achieved a response at the 6th week (25% vs. 5% for placebo; P = 0.18).* *Differences between treatments were for BoNT-A on secondary measures of pain but did not reach statistical significance.* *Most of the participants in the BoNT-A group achieved a response at week 6 (25% vs. 5% for placebo; P = 0.18).* *The difference was favouring the BoNT-A on secondary measures of pain but did not reach statistical significance. In the BoNT-A group, 52.7% (vs. 40% for placebo) assessed their condition as slightly/significantly improved at week 6*	BoNT-A achieved a good response a large prospective long-term should is recommended. *(The author did not stop other intervention which can be causing some effects of the treatments, if not the control group the placebo shall have some results which affect the final findings).* *No adverse events occur or was noticed.*
Ball EM (Ball et al., 2012)	(n = 65) PHP failed to response to 8 weeks of conservative therapy, excluding previous injection in heel pad. **Group 3:** (n = 22) age [50.1 (10.6) 11 males, (52%)] ultrasound guided placebo; 1 mL of 0.9% saline (placebo group) was injected along the superficial border of the plantar fascia enthesis under direct ultrasound guidance. *All patients were asked to avoid weight bearing on the heel pad for 48 h and could continue with their usual analgesia.*	**Group 1:** (n = 22) age [49.0 (12.9) male 10, (45%)] patient received ultrasound guided steroid injections A 21-gauge needle was inserted parallel to the heel pad in line with the long axis of the transducer, Either 0.5 mL (20 mg) of methylprednisolone acetate +0.5 mL of 0.9% saline (ultrasound guided steroid group) or **Group 2:** (n = 21) age [49.1 (10.7), males 8 (36%)]patients given steroid under palpations	**Pain**: VAS (100) at 6, 12. Change in the PF thickness by US. **Follow-up:** 6,12 weeks' post-injections.	*The difference significantly in VAS scores between the groups at 6 and 12 weeks (p = 0.018 and p = 0.004, respectively).* *19.7 (95% CI 2.5 to 37.0) difference in mean VAS scores at six weeks between the US-guided steroid group, & the placebo group.* *24.0 (95% CI 6.6 to 41.3) difference between the unguided steroid group & the placebo group at six weeks.* *At the 12 weeks, the mean difference was 25.1 (95% CI 6.5 to 43.6) and 28.4 (95% CI 11.1 to 45.7) respectively between both steroid injection groups and the placebo group.*	Although both ultrasound-guided corticosteroid injection and wearing a full-length silicone insole were effective in the conservative treatment of plantar fasciitis, we recommend the use of silicone insoles as the first line of treatment for persons with plantar fasciitis. *There were no adverse events.* Any patient who failed to respond clinically to injection at 12 weeks was then offered an ultrasound guided steroid injection outside the trial

		A 21-gauge needle was inserted parallel to the heel pad in the direction of the medial tubercle of the calcaneus. An amount of 0.5 mL (20 mg) of methylprednisolone acetate and 0.5 mL of 0.9% saline was injected once the needle had been inserted to the hilt.		*No difference in VAS scores following steroid injection within the US-guided & the unguided groups at either time point.* *PF thickness significantly reduced after injection in both active treatment groups ($p = 0.00$).* *Patients in both injection groups showed a* ***statistically significant reduction*** *in VAS pain scores compared with the placebo group* *There were* ***no significant differences*** *between the steroid groups at either time point ($p = 0.58$)* ***VAS score difference.***	
Díaz-Llopis IV (Díaz−Llopis et al., 2012)	(n = 56) patient who undergo for 6 month of conservative treatment's for PF. all patients were initially treated with stretching, with revision after several weeks patients with injections in the last 6 months were excluded. **Group 1:** (n = 28) received Botox injection [BTX, SD 51.50 (14.79), 9 males (32.14%)] 100 U of botulinum toxin type A were diluted in 1 mL of normal saline and 70 U were injected: 40 U in the tender region of the heel medial to the insertion of the plantar fascia and 30U in the area between one inch (2.5 cm) distal to the talar insertion of the plantar fascia and the midpoint of the plantar arch **Group 2**: (n = 28) [CS, SD 56.36 (14.71), 10 males (35.7%)] receive corticosteroid injection corticosteroid (2 mL of betamethasone 6 mg/mL (as acetate and disodium phosphate)) plus local anaesthetic (0.5 mL of 1% mepivacaine) in the same area of the calcaneal tuberosity. In addition, a small sub- cutaneous injection of placebo (normal saline) was performed in the middle of the medial side of the fascia to make the injections	two different phases; patients with therapeutic failure after the 1st intervention crosses to the comparator group (after one month) duration of heel pain at least six months; prior conservative treatment (NSAIDs, heel pads, insoles, night splints) for at least 6 months without succeeding **Phase 1** **BTX group** Injection of 40 units in tender region of heel medial to insertion of plantar fascia and **Unguided steroid injection group** 2 mL (12 mg) betamethasone acetate + 0.5 mL 1% mepivacaine (LA) in the same tender region of the heel and a subcutaneous injection of placebo (normal saline) in the middle of the medial side of the fascia	**Functionally and Pain:** (FHSQ 4 items) foot pain, foot function, foot shoe, and general foot health. **Follow-up:** 1, 6 months	At 1 month, there was **significant improvement** in all the item scores of both groups compared to baseline, except in item 3 (shoe) in the steroid injection group **Change at 1 month from baseline FSHQ1** BTX-A: 34.24 (21.10), p < 0.001 CS: 22.12 (27.42), p < 0.001 **FSHQ2** BTX-A: 27.45 (20.58), p < 0.001 C S: 21.43 (24.85), p < 0.001	BoTX-A should be considered for the treatment of chronic PF, the change found by one month, in particularly at six months, when this treatment clearly has better results than corticosteroid injections. *There were no early or late adverse effects related* *to either of the two treatments administered*
Lee TG (Lee and Ahmad, 2007)	(n = 61) PF for 6 weeks, excluding previous surgery. **Group 2:** (n = 31) age (49.2 ± 11.1) (29−66) 2 males 29 females. received corticosteroid group. A combination of 20 mg (0.5 mL of a 40 mg/	**Group 1:** (n = 30) age (48.3 ± 10.5), range (28−65) 4 males 28 females received autologous blood group For autologous blood injection, 1.5 mL of autologous blood obtained from the antecubital vein, and this was combined	**Pain**: VAS, TT **Follow-up:** 6-weeks,3-months, 6-months.	Before treatment, both the autologous blood group and corticosteroid group had similarly high levels of pain ($p = 0.306$). Over the 6-month follow-up, a significant reduction in pain levels was noted in both groups ($p < 0.0001$). *Significant difference was noticed in VAS in*	Intralesional autologous blood injection is efficacious in lowering pain and tenderness in chronic plantar fasciitis, but corticosteroid is more superior concerning speed and probably extent of improvement *There was no fat pad atrophy, infection or*

(*continued on next page*)

Table 1 (*continued*)

Author	Participants	Comparator	Outcome	Results	Conclusion
	mL solution) of Triamcinolone Acetonide with 2 mL of Lignocaine HCL 1% was used. All patients could walk but were advised to avoid impact-loading activities, such as running or jumping, for at least 10 days. Nonsteroidal anti-inflammatory drugs were prescribed for not more than 3 days, and ice packs were allowed for post-injection pain. Elevation of the foot was advised for swelling	with 1 mL of Lignocaine HCL 2%. Thus, for both groups, there was an equal volume of injection solution as well as an equal amount of Lignocaine HCL used.		*CSI* *6-week p = 0.011* *3-month p = 0.005* *6-month p = 0.094*	*rupture of the plantar fascia* *All patients found the injection painful*
Eftekharsadat (Eftekharsadat et al., 2016)	(n = 20) patients with chronic plantar fasciitis, Refuse needling and routine physical therapy (e.g., cooling, stretch, massage therapy and/or footwear modifications),; diagnosis of coagulopathy or taking anticoagulants except for acetylsalicylic acid at dosages up to 325 mg/day **Case Group** 1: (n = 10) Age [Mean SD (50.3 ± 8.9) 3 male & 7 females] **Control Group** 2: (n = 10) [4 male & 6 females (50.9 ± 8.9)] Control group 50 mg diclofenac sodium/12 h and orthostatic plantar pad were prescribed for all patients. All patients were trained to do cold ice massage and self-stretching for four weeks	**DN:** dry needling of MTPs one session per week for four consecutive weeks. Diagnosis of MTPs was based on detecting a tender spot or nodule in a taut band of skeletal muscle. Dry needling was based on calf muscles trigger points, especially four trigger points of gastrocnemius muscle using a dry needle with the length of 30 −50 mm and diameter of 0.6 mm. Treatment was conducted within a 30-min timeframe.	**Pain**: VAS (0−10 cm), FFI **Functionally**: Range of motion of ankle joint in dorsi- flexion (ROMDF) and plantar extension (ROMPE) was measured at baseline	DN effect was evaluated at three-time points of baseline, 4 weeks after intervention and 4 weeks after withdrawing treatment. Based on paired *t*-test, the mean VAS scores were significantly decreased after four weeks of intervention ($p < 0.001$) and four weeks of cessation period ($p < 0.001$). ROMDF of ankle joint was significantly increased both after four weeks of intervention ($p < 0.001$) and four weeks of cessation period ($p < 0.001$). ROMPE of ankle joint was not significant after four weeks of intervention ($p = 0.34$), the mean ROMPE of ankle joint was significantly increased after four weeks of cessation period ($p < 0.04$).	There was an insignificant effect on ROMDF and ROMPE, trigger point dry needling. dry needling and/or injection of therapeutic medications (local anaesthetics, steroids, botulinum toxin A) have been studied for plantar fasciitis treatment. Of these treatment options, steroid injections are more commonly used in treating acute and chronic plantar fasciitis, especially when more conservative managements are unsuccessful.

Abbreviations; VAS: visual analogue scale SFMPQ: AOFAS: American Orthopedic Foot and Ankle Society, FFI: Foot Function Index,ESWT: Extracorporeal Shock Wave Therapy, ESE: Eccentric stretching exercises. Gy: is a derived unit of ionizing radiation dose in the International System of Units, PG: Palpation Guide, PF: Plantar Fasciitis PHP: plantar heel pain. ISI: Intralesional Steroid Injection, AVBI: Autologous Venous Blood Injection, AOFAS: American orthopedic foot ankle society, PRP: Platelet Rich Plasma Therapy, FAOS: Foot & Ankle outcome score, FHSQ: Foot Health status questioner, TT: Tenderness Threshold, HTI: Heel Tenderness Index, US: Ultrasonography, MSN: Miniscalpel needle, PPT: Pain Pressure Threshold, ACP: Autologous condition plasma, FAAM: Foot Ankle Ability Measure, MOXFQ: Manchester Oxford Foot Questioner, PDRN: Polydeoxyribonucleotide, FADI: Foot Ankle Disability Index, BoNT-A: Botulinum toxin type-A, BTX: Botox, ROMDF: range of motion in dorsiflexion,ROMPE: range of motion in plantar extension, DN: dry needling, RM: Roles-Maudsley.

Table 2
Summary of PEDro scale scores.

PEDro Scale Score	Number of articles Found
5/10	(n = 1) article
6/10	(n = 4) articles
7/10	(n = 12) articles
8/10	(n = 3) articles
9/10	(n = 9) articles
10/10	(n = 0) articles

source of the pain.

Clinicians should consider starting treatment with non-invasive techniques and lack of improvement following these techniques should indicate the need to proceed towards minimally invasive techniques (Fig. 4).

First line treatment should include exercise therapy and one additional treatment modality, either shockwave therapy or manual therapy, to treat the trigger points. As a second-line treatment, dry needling techniques should be employed initially as these are non-pharmacological and show promising results. However, this technique should be investigated further on a bigger sample group with a longer follow-up period (Eslamian et al., 2016a).

The use of intratissue percutaneous electrolysis has been widely used in Europe, mainly in Spain, however, to date, there are no published studies comparing its effectiveness for the treatment of plantar fasciitis. Preliminary studies with prolotherapy are promising and this technique can be used if dry needling fails. Also, prolotherapy has a better side effect profile compared to steroid injections. Injectable corticosteroids have been the mainstay of treatment for many years despite their associated side effects both locally and systemically (Cole and Schumacher, 2005). Despite this, there are no specific guidelines for the use of steroids indicating the dosage, type or frequency of injections.

Radiation therapy is another treatment approach that has been employed for pain relief of plantar fasciitis. Its mechanism of action is unknown, however, it is thought to have anti-inflammatory properties in low doses which may be attributed to the pain relief seen when used in treatment of plantar fasciitis. Fractional doses of 0.5–1.0 Gy and total doses of 3–6 Gy are employed in the treatment of plantar fasciitis. It is important to note that radiation therapy is carcinogenic and patient selection is crucial as well as their informed consent (Canyilmaz et al., 2015).

Table 3
PEDro scale scores.

	Author	Random Allocation	Concealed Allocation	No Bassline Capability	Blind Subject	Blind Clinician	Blind Assessor	Adequate Follow Up	Intention-To Treat Analysis	Between Group Comparison	Point Estimate & Variability	TOTAL
1	Eslamian, F (Eslamian et al., 2016b)	1	1	0	1	0	0	1	1	1	1	**7/10**
2	Mardani-Kivi, M (Mardani-Kivi et al., 2015)	1	1	1	1	0	0	0	1	1	1	**7/10**
3	Canyilmaz, E (Canyilmaz et al., 2015)	1	1	1	0	0	0	1	1	1	1	**7/10**
4	Monto, RR (Monto, 2014b)	1	1	1	0	0	0	1	1	1	1	**7/10**
5	Kim, E (Kim and Lee, 2014)	1	1	1	1	1	0	1	1	1	1	**9/10**
6	Yucel, U (Yucel et al., 2013)	1	1	1	0	0	1	1	1	1	1	**7/10**
7	Chew, KTL (Chew et al., 2013)	1	1	1	1	0	0	1	0	0	1	**6/10**
8	Kumnerddee, W (Kumnerddee and Pattapong, 2012)	1	1	1	1	0	0	0	1	0	1	**6/10**
9	Huang, YC (Huang et al., 2010b)	1	1	1	1	0	1	1	1	1	1	**9/10**
10	Kalaci, A (Kalaci et al., 2009)	1	1	1	1	0	1	1	1	1	1	**9/10**
11	Porter, MD (Porter and Shadbolt, 2005)	1	1	1	1	0	0	1	0	1	1	**7/10**
12	Demir G, (Demir et al., 2015)	1	1	1	1	0	1	1	1	1	1	**9/10**
13	Li S, Shen T (Li et al., 2014; Monto, 2014a)	1	1	1	1	0	1	1	1	1	1	**9/10**
14	Mahindra P (Mahindra et al., 2016)	1	1	1	0	0	0	1	1	1	1	**7/10**
15	Crawford F, Atkins D (Crawford et al., 1999)	1	1	1	1	0	1	1	1	1	1	**9/10**
16	Kiter E (Kiter et al., 2006b)	1	1	0	1	0	1	1	1	1	1	**8/10**
17	Zhang SP (Zhang et al., 2011)	1	1	1	1	0	0	1	0	0	1	**6/10**
18	Yucel I, (Yucel et al., 2010)	1	1	1	1	0	0	0	1	1	1	**7/10**
19	Celik D (Celik et al., 2016)	1	1	1	1	0	0	0	1	1	1	**7/10**
20	Jain K (Jain et al., 2015a)	1	1	0	0	0	0	1	1	1	0	**5/10**
21	Kim JK (Kim and Chung, 2015)	1	1	1	1	0	1	1	1	1	1	**9/10**
22	Cotchett MP (Cotchett et al., 2011)	1	1	0	1	0	0	0	1	1	1	**6/10**
23	Ryan M (Ryan et al., 2014)	1	1	1	1	1	1	1	1	0	0	**8/10**
24	Guner S (Guner et al., 2013a)	1	1	1	1	1	1	0	1	0	0	**7/10**
25	Peterlein CD (Peterlein et al., 2012b)	1	1	1	1	0	1	1	1	1	1	**9/10**
26	Ball EM (Ball et al., 2012)	1	1	1	1	0	0	1	1	0	1	**7/10**
27	Díaz-Llopis IV (Díaz–Llopis et al., 2012)	1	1	1	1	1	1	0	1	0	0	**7/10**
28	Lee TG (Lee and Ahmad, 2007)	1	1	1	1	0	1	1	1	1	1	**9/10**
29	Eftekharsadat (Eftekharsadat et al., 2016)	1	1	1	0	0	1	1	1	1	1	**8/10**

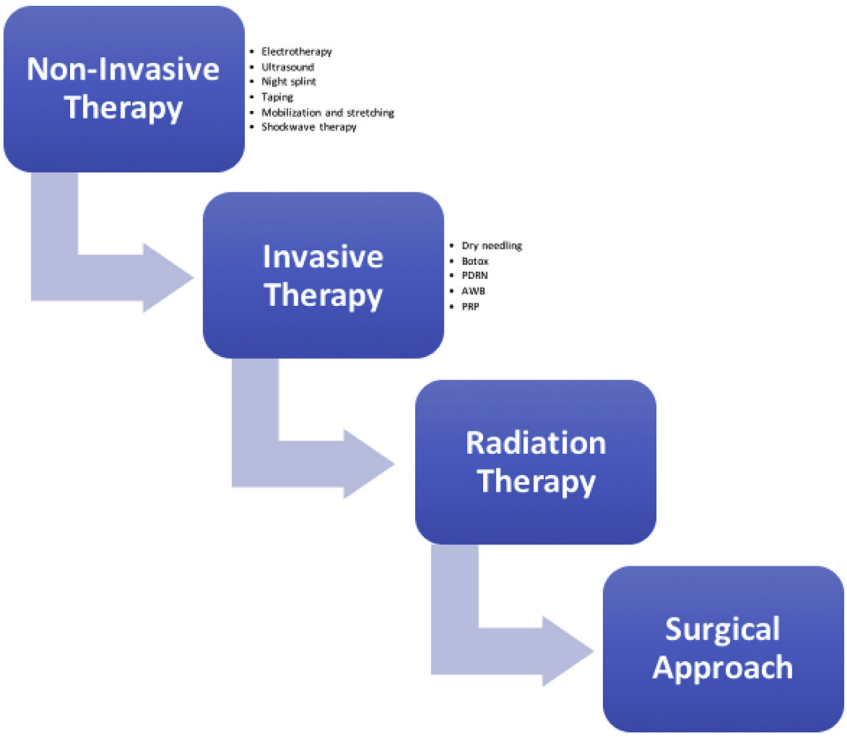

Fig. 4. Schematic diagram to demonstrate the approach to treatment.

4.1. Conclusion

Based on the findings of all the RCTs analysed, many authors consider that plantar fasciitis is a degenerative tissue condition rather than an inflammation at the site of origin of the plantar fascia at the medial calcaneal tuberosity. The histology of plantar fasciitis is the same as that of tendinopathies. This implies that degeneration can cause a micro tear within the fascia that does not heal, which can trigger inflammation. However an interruption in the healing process due to poor circulation leads to degenerative changes in the connective tissues.

The treatment of plantar fasciitis has dramatically improved in the past decade with more minimally invasive techniques becoming increasingly available. The results demonstrate that the long term effects of minimally invasive (non-surgical) treatments such as shock wave therapy, botulinum toxin type-A injections, platelet-rich plasma injections and intratissue percutaneous electrolysis dry needling show similar and sometimes better results when compared to corticosteroid injections. Most studies have been using corticosteroids which, as well as being associated with transient effects on pain and function, are associated with a number of complications, including infections, contact allergic dermatitis due to preservatives, skin atrophy, osteomyelitis of the calcaneus and rupture of the plantar fascia (Canyilmaz et al., 2015; Karimzadeh et al., 2017). Furthermore, higher doses of corticosteroids can be contraindicated in certain patients (Karimzadeh et al., 2017). Corticosteroids, the current mainstay of plantar fasciitis treatment, are divided based on their duration of action and, as of yet, consensuated guidelines regarding corticosteroid use are lacking. In conclusion, definitive treatment guidelines for plantar fasciitis are still lacking. The best results were obtained by combining several techniques with minimal invasive therapy such as stretching or exercises in additional to the treatment that been prescribed.

The findings of this literature review may help inform practitioners and clinicians who use invasive methods for the treatment of plantar fasciitis regarding the levels of evidence for the different treatment modalities available.

4.2. Limitations and future study recommendations

We have identified 29 relevant RCTs, which covered a wide variety of interventions and several procedural approaches that can be employed to establish treatment protocols for plantar heel pain. However, a wide range of dosages were used in some of the treatments (number of treatments and interval of care), making it difficult to draw exact conclusions about optimal dosage. Studies should clearly describe treatment protocols, including frequency, intensity and duration in order to reach optimal management. Further research is needed to investigate the value of single and combined modalities. Additionally, it is possible that some studies were missed, despite the formal literature search.

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No conflict of interest was reported for this study.

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ANNEX II

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STUDY PROTOCOL Open Access

Comparing two dry needling interventions for plantar heel pain: a protocol for a randomized controlled trial

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Abstract

Background: Both manual therapy techniques and dry needling have shown to be effective treatment options for the treatment of plantar heel pain; however, in recent years, other techniques based on dry needling (DN), such as percutaneous needle electrolysis (PNE), have also emerged. Currently, PNE is being used in clinical practice to manage myofascial trigger points, despite the lack of studies comparing the effects of this technique over dry needling. Therefore, the aim of this randomized controlled study is to compare the effectiveness of DN versus PNE for improving the level of pain experienced by patients suffering from plantar heel pain provoked by myofascial trigger points.

Methods: A randomized controlled trial will be conducted with blinded participants and outcome assessors. A sample of 94 patients with a medical diagnosis of plantar heel pain will be recruited and divided into two treatment groups. Eligible participants will be randomly allocated to either (a) treatment group with DN and a self-stretching home program or (b) treatment group with PNE and a self-stretching home program. Each group will receive one treatment session per week over a period of 4 weeks. The primary outcome measure will be the pain subscale of the Foot Health Status Questionnaire. The secondary outcome measures will be a visual analogue scale for pain (average and highest level of pain experienced during the previous 48 h; level of pain immediately after the treatment session) and health-related quality of life (assessed using the EuroQoL-5 dimensions). Cost-effectiveness data will be extracted based on the EuroQoL-5 dimensions. Follow-up measurements will take place at baseline and at 4, 8, 12, 26, and 52 weeks.

Discussion: The justification for this trial is the need to improve current understanding regarding the effectiveness of treatments targeting the rehabilitation of plantar heel pain. This study will be the first randomized controlled trial to directly compare the effectiveness of DN and PNE combined with a specific stretching program for the treatment of plantar heel pain provoked by myofascial trigger points.

Trial registration: Clinical Trials NCT03236779. Registered at clinicaltrials.gov 2 August 2017.

Keywords: Plantar heel pain, Myofascial trigger points, Dry needling, Percutaneous needle electrolysis, Self-stretching protocol, Cost-effectiveness

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Background

Plantar heel pain (PHP) is one of the main sources of pain in the foot, causing soreness or tenderness in the sole of the foot, under the heel, and which sometimes extends into the medial arch [1, 2]. This condition affects both athletic and sedentary individuals and does not seem to be influenced by gender [2]. The incidence and prevalence of plantar heel pain is uncertain; however, it is estimated that over the course of a lifetime, 10% of the population may suffer this condition [3, 4]. Furthermore, results from a high-quality epidemiological study in the USA from the 1990s found that approximately one million patient visits to physicians per year were due to PHP [5], with an associated annual cost of around $300 million [6].

Plantar heel pain may include different sources of pain, involving various diagnoses, such as myofascial pain syndrome, plantar fasciitis, or heel spur, among others [7]. The diagnosis is usually made based on the patient's history and physical examination, including pain during the first steps in the morning or after prolonged rest, as well as pain during prolonged standing or walking [3, 4, 6]; more in-depth examinations are used only to rule out other disorders causing inferior heel pain, such as tumors, infections, and neuropathic pain (including tarsal tunnel syndrome) [8, 9]. The proper identification of the main cause of pain can be difficult as, usually, this may be multifactorial [10]. Current heel pain guidelines identify risk factors that include limited ankle dorsiflexion ROM, high body mass index (BMI) in nonathletic individuals, running, and work-related weight-bearing activities [3, 4].

There is a lack of consensus regarding the ideal management approach for PHP [11–13]. Clinical practice guidelines support the use of conservative treatment, such as joint and soft tissue mobilization or self-stretching home programs (SSHP) [3, 4]. In particular, SSHP has shown to be effective for addressing PHP [3, 10, 14], while recent randomized clinical trials (RCTs) have shown that there is an additional effect reducing the severity of pain when SSHP is combined with ischemic compression [15] and with dry needling (DN) [16].

Despite its prevalence, the etiology of PHP is not well understood [3, 4]. Although PHP may be provoked by a tendinous injury affecting the plantar fascia, it is well known that the presence of myofascial trigger points (MTrPs) within the plantar and lower leg musculature may play an important role in people with PHP [17], and recent studies have based their hypothesis on this assumption [15, 16, 18, 19]. Some of these have demonstrated the effectiveness of manual therapy techniques (i.e., ischemic compression) [15, 19] while others have also demonstrated the effectiveness of DN [16, 18].

Physical therapy approaches continue to evolve and include the combination of DN and electrolysis, known as percutaneous needle electrolysis (PNE), with promising results for the treatment of tendon pathologies [20–22]. The PNE technique is a minimally invasive treatment that consists of the application of a galvanic electrolytic current that causes a controlled local inflammatory process in the target tissue. This promotes phagocytosis and the subsequent regeneration of the affected tissue [20, 21]. Nowadays, PNE is being used in clinical practice to manage MTrPs; however, there are no studies supporting any additional beneficial effects over DN. Furthermore, there are cost variations between these techniques, which affect the healthcare system. A cost-effectiveness comparison will determine which treatment intervention is the most efficient.

From a biological point of view, it seems reasonable to hypothesize that subjects can display improvements thanks to the mechanical effects of the needle and that patients may benefit more when the electrolysis effect is added to the mechanical stimulus provided by the needle. Therefore, the aim of this randomized controlled study is to compare the effectiveness of DN versus PNE for reducing the level of pain in patients suffering from PHP.

Methods

Sample

The study subjects will be adults of both genders who have been admitted to the Physical Medicine and Rehabilitation Department in a Kuwait City hospital by a medical registered doctor from the Ministry of Health. To be eligible for the study, participants will have to meet the following inclusion criteria:

- Clinical diagnosis of PHP 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 [3, 4, 16, 18]
- Age between 21 and 60 years at admission to the study, according to the Kuwaiti law
- History of plantar heel pain for over 1 month, showing no improvements with previous conservative treatment
- Able to walk 50 m without any support
- The presence of MTrPs on plantar and calf muscles, based on initial physical examination carried out by a physiotherapist (MA) with experience and training in MTrPs
- Accepting treatment from a male physiotherapist
- The ability to understand the study and the informed consent, as well as having signed the document

Exclusion criteria for the study will be based on:

- Needle phobia
- Needle allergy or hypersensitivity to metals
- Presence of coagulopathy or use of anticoagulants according to medical criteria
- Presence of peripheral arterial vascular disease
- Pregnancy
- Dermatological disease affecting the dry needling area
- The presence of a chronic medical condition which might preclude participation in the study, such as malignancy, systemic inflammatory disorders (e.g., rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, septic arthritis), neurological diseases, polyneuropathy, mononeuropathy, and sciatica
- Treatment of plantar heel pain with needling or acupuncture during the last 4 weeks
- A history of injection therapy in the heel over the previous 3 months
- Previous history of foot surgery or fracture

Participants will be controlled by using the appropriate medication dosage as prescribed by the physiatrist (analgesics and non-steroidal anti-inflammatory medications) and will be required to report any changes to the assessor during the evaluations if they take any additional medication or undergo any treatment during the intervention. They must be willing not to receive or implement any form of treatment for the plantar heel pain (taping, night splints, massage therapy, or footwear modifications) while they participate in the trial. The participants will have the right to withdraw from the study at any time without having to provide any explanation.

Regarding sample size, 94 participants with PHP will be recruited. An initial prospective sample size calculation estimated that 39 participants per group will provide 80% power to detect a minimally important difference of 13 points in the pain domain of the Foot Health Status Questionnaire (FHSQ) with a standard deviation of 20 points [23] and an alpha risk at 0.05, allowing 20% loss to follow-up (16 patients).

Study design

Both the assessment and intervention will take place at the Physical Medicine and Rehabilitation Hospital in Kuwait.

This study is a prospective, two parallel groups (participant) randomized controlled trial with blinded outcome assessment at baseline and at 4, 8, 12, 26, and 52 weeks. The study flow chart shown in Fig. 1 conforms to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines for nonpharmacological studies [24].

Participants who fulfill the inclusion criteria will receive the standardized oral and written information and, once they consent to participate in the trial, will be randomized in a block system by blocks of 10 patients. Allocation to the groups will be achieved using a computer program (Randomizer, https://www.randomizer.org/) with random patient file number sequences generated by a third person not involved in the study, and based on their file number in Kuwait. This person will be responsible for safekeeping the envelope with the information of the randomization. The envelopes will remain closed until the moment of the intervention in order to maintain the blinding. This professional will also ask the patients for informed consent. This research study was approved by the Medical Ethics Committee of the State of Kuwait Ministry of Health, with reference number 642/2017.

Interventions

To determine what muscles will be treated, muscles fulfilling the following two criteria will be selected: (a) muscles that typically refer pain to the heel [17] and (b) muscles that can be directly palpated or that can be needled with precision and safety without ultrasound guidance. The clinician will perform a physical examination to find MTrPs following Travell and Simons' criteria: (1) the presence of a taut band and (2) identification of an exquisite spot tenderness or a nodule [17]. A flat palpation or pincer palpation technique will be used to palpate the MTrPs, depending on the muscle being assessed. The muscles to be treated will be the soleus, gastrocnemius, quadratus plantae, flexor digitorum brevis, and abductor hallucis. If a muscle contains more than one MTrP, the most sensitive MTrP will be treated, according to the patient's perceived pain upon palpation. If the patient has pain bilaterally, the clinician will treat both sides. The position of the patient will always be lying; however, it depends on each muscle (supine, prone, or lateral decubitus position), and will be the same for the assessment as well as for the intervention [25].

During the first session, all participants will be taught a self-stretching protocol [15] which has demonstrated to be effective for the management of PHP [10, 15, 26] and will consist of the following exercises: (a) Self-stretching of the calf muscles: in standing, with the affected foot furthest away from the wall, the patient will be instructed to lean forward, while keeping the heel on the floor. To focus the stretching on the soleus muscle, the affected knee will be bent, whereas to focus on the gastrocnemius muscle, the affected knee will be kept in full extension. In this position, patients will be taught to lean forward until they feel a stretch in the calf and/or Achilles region. All patients will complete both versions

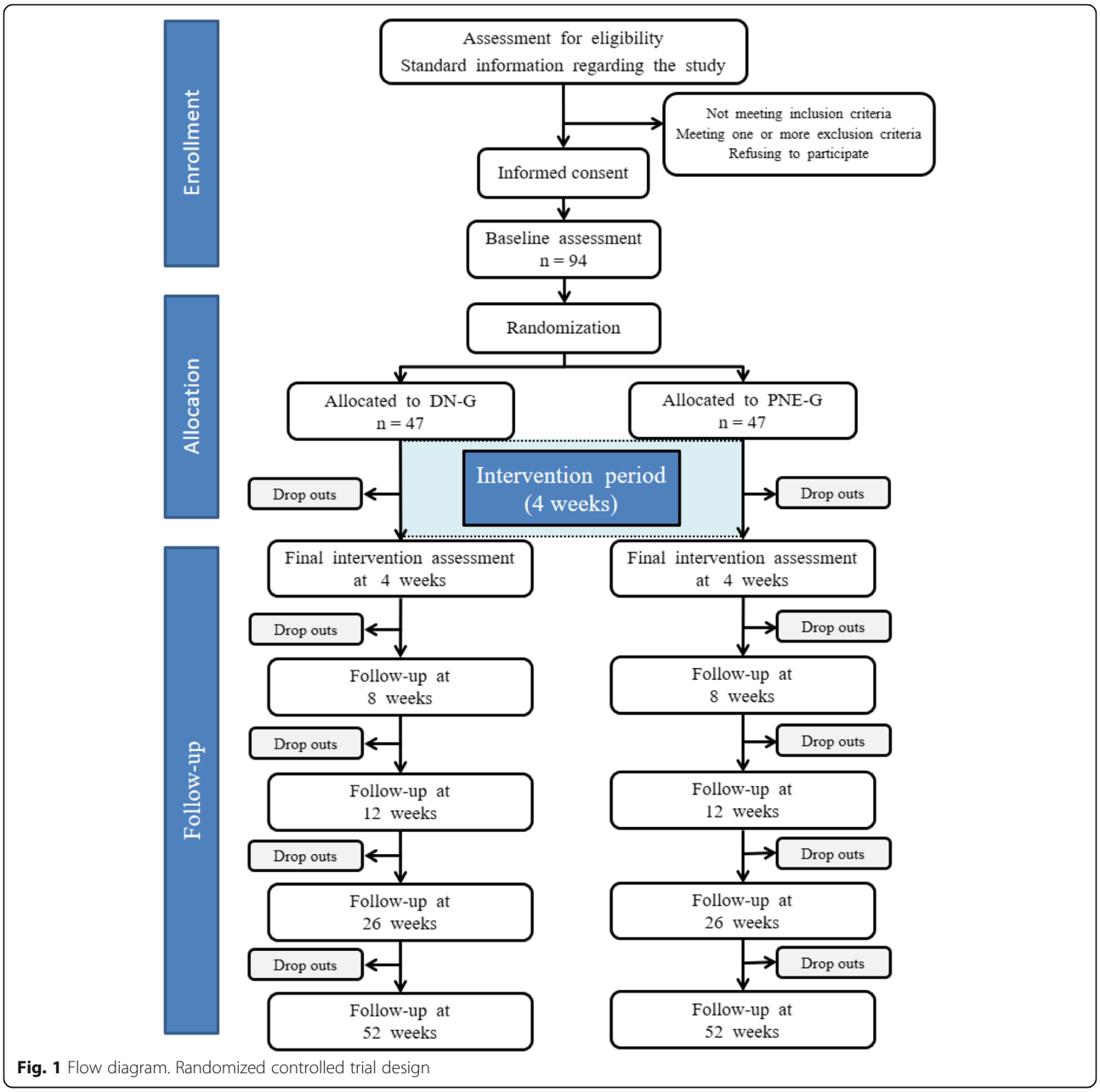

Fig. 1 Flow diagram. Randomized controlled trial design

of the stretch. (b) Plantar fascia-specific self-stretching: in the sitting position, patients will cross the affected foot over the contralateral thigh. The patient will place his/her fingers over the base of the toes, grasp the base of the toes, and pull the toes back towards the shin, until a stretch is felt in the plantar fascia [15]. According to the evidence, we will follow the same dosage for calf and plantar fascia-specific self-stretching exercises, twice a day, using intermittent stretching lasting 20 s, followed by 20-s rest periods for a total of 3 min per stretch [15].

Participants will receive four individual physiotherapy sessions, once a week. The duration of the sessions may change depending on the patient; however, these will last approximately 30 min. Participants will be treated by a physical therapist registered at the Kuwait Ministry of Health and trained in the protocol. The clinician will have a minimum of 5 years practical experience in the field of dry needling and appropriate training.

Invasive interventional groups: dry needling and percutaneous needle electrolysis

Specific needles for dry needling will be used during invasive treatments (Agu-punt, Spain). Needle length will be determined by the location of the MTrP and will

range from 30 to 50 mm in length (or longer if necessary according to patients' characteristics). The diameter of the needle will be 0.25–0.30 mm. If the participant is sensitive to the needle insertion, the level of manipulation will be reduced. If this measure proves insufficient for reducing the painful stimulus, manipulation of the needle will cease altogether and the needle will be left in situ [25, 27].

To maintain appropriate hygienic conditions during the invasive treatments, the clinician will wear latex gloves and thoroughly clean the skin of the area to be needled with an antiseptic solution (70% Propan-2-ol, Skin-des). Upon removal of the needle, the area will be firmly compressed for 10 s. The needle will be discarded after each single use.

In both groups, the intervention will be terminated in the case of severe adverse effects, if the participant does not wish to continue, and if there is an unapproved use of medication. Any adverse effects will be duly reported.

Dry needling arm

Once the clinician locates the MTrP, the needle will be inserted over the same and a rapid needle entry will be performed. The chosen technique for manipulating the needle will be the technique described by Hong [28], which consists of a rapid needle entry and exit (fast in/fast out), in order to obtain a local twitch response (LTR), lasting 5 s employing a rhythmic movement at approximately 1 Hz/sec (five entries). The number of LTRs will be counted and registered.

Percutaneous needle electrolysis arm

The electrotherapy equipment used (Physio Invasiva, PRIM Fisioterapia, Spain) produces a continuous galvanic current through the cathode while the patient holds a hand-held anode [22]. Once the needle reaches the relevant treatment area, this will be needled in exactly the same manner as in the DN group, with the only difference being that the needle will be transmitting an electrical current with an intensity of 1.5 mA (intensity may be adapted to patient's characteristics according to their pain's tolerance).

Study variables

Baseline data

Baseline data will include gender, age, height, weight, BMI, details regarding the affected side (right, left, or bilateral), duration of symptoms, medication, and previous treatments.

A blinded observer will assess all participants at baseline and at 4, 8, 12, 26, and 52 weeks post-treatment (Fig. 2).

Primary outcome measure

Participants will complete the FHSQ at baseline and at 4, 8, 12, 26, and 52 weeks post-treatment. The FHSQ consists of 13 questions reflecting four foot health-related domains: pain (4 questions), function (4 questions), footwear (3 questions), and general foot health (2 questions). Individual item scores will then be re-coded, tabulated, and finally transformed to a scale ranging from 0 to 100 for each of the four domains [29]. Greater scores reflect better foot health and quality of life [30]. The FHSQ has been validated [31] and has been used in similar trials that have evaluated the effectiveness of different interventions for plantar heel pain [18, 32, 33].

Secondary outcome measures

Participants will complete the visual analogue scale (VAS) at baseline and at the 4-, 8-, 12-, 26-, and 52-week assessments and additionally before each treatment session. The level of pain that patients have experienced during the previous 48 h prior to starting the treatment session will be recorded. Participants will be asked about the mean and the highest level of pain they have experienced. The exact wording of the questions will be: (1) what is the level of pain, on average, that you have felt during the last 48 h? and (2) what is the maximum level of pain you have felt during the last 48 h? Additionally, after treatment, they will be asked to score their current pain immediately upon standing up and walking a few steps. Participants will be explained that a score of 0 indicates the absence of pain, whereas a score of 10 represents the maximum tolerable pain. The VAS is widely used and is valid and reliable [34–36]. They will also indicate the areas of perceived pain on an electronic body chart (Navigate pain, version 0.1.9.9, Aalborg, Denmark) [37].

Quality of life (QoL) will be assessed with the EuroQoL-5 dimensions (EQ-5D), which will be filled out by the patients at baseline and at the 4-, 8-, 12-, 26-, and 52-week assessments. The EQ-5D self-report questionnaire is a descriptive system with five questions, each representing one dimension of health-related quality of life (HRQoL), i.e., mobility, self-care, daily activities, pain/discomfort, and depression/anxiety. Each dimension can be rated on three levels: no problems, some problems, and major problems, and together, the results serve to classify people into 1 of 243 possible health states [38].

Cost analysis

Costs will be collected from the healthcare viewpoint. Direct healthcare costs are the costs of manual therapy, physiotherapy or general practitioner care, additional visits to other healthcare providers, drugs, and hospitalization. Cost-effectiveness and cost-utility analyses will be carried out with quality-adjusted life-year, estimated from EQ-5D scores.

	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation					Close-out
TIMEPOINT	-3 to 0 days	0	Baseline	4 weeks	8 weeks	12 weeks	26 weeks	52 weeks
ENROLMENT:								
Eligibility screen	X							
Informed consent	X							
Allocation		X						
INTERVENTIONS:								
DN-G			◆	———	◆			
PNE-G			◆	———	◆			
ASSESSMENTS:								
Baseline demographic information	X							
FHSQ			X	X	X	X	X	X
VAS			X	X	X	X	X	X
EQ-5D			X	X	X	X	X	X

Fig. 2 Schedule for enrolment and intervention

Statistical analysis

The statistical analysis will be performed via an intention-to-treat analysis. Variables will be described in number (percentage) and average (standard deviation) or median (interquartile range), according to their distribution. Quantitative variables will be analyzed with the Shapiro Wilk test in order to confirm their distribution and to determine the correct statistical tests according to these results.

The outcomes will be analyzed using mixed linear and logistic regression models considering participants as a random effect and treatment group as fixed factors.

Baseline characteristics will be introduced in the model as covariance factors. The numbers needed to treat index will also be calculated. The primary aim of the analysis will be to calculate the difference obtained in the FHSQ score after the intervention (final measurement – initial measurement). Finally, the magnitude of the effect of the result will be calculated and, therefore, its clinical importance, by using the following formula: $r = \sqrt{[F(1,dfR)]/[F(1,dfR)+dfR]}$.

The significance level for statistical tests will be set at $p \leq 0.05$.

Ethics and dissemination

The study design, procedures, and informed consent procedure were approved by the Ministry of Health in the state of Kuwait on 19 September 2017, and the study will be conducted in compliance with the Helsinki Declaration of Human Rights. The registration number provided by ClinicalTrials.gov is NCT03236779 (registered 2 August 2017). Participants will be requested to provide informed written consent before randomization. The software used to assemble the papers included in this review will be EndNote X7 v17.0.1. The participant data obtained in this ongoing research will not to be used for other purposes. All the personal information collected such as the informed consent form and the physical examination findings will be stored by category in a specific filing cabinet before, during, and after the trial, in order to protect confidentiality. After completing the data analysis, and regardless of the findings, we plan to disseminate all the trial results via conferences and publications.

Discussion

Plantar heel pain is a common cause of foot pain and discomfort affecting the health and quality of life of patients, with a high tendency for relapse and chronicity [8]. Previous studies have demonstrated the positive effect of conservative treatment in reducing painful conditions associated to PHP [15, 19], while other RCTs show that DN probably has a higher potential benefit over more conservative approaches [16]. Nevertheless, according to systematic reviews, new high-quality RCTs are needed on which to base the evidence regarding the effectiveness of DN for symptoms management in PHP [39]. Despite the fact that the plantar fascia can be a

source of pain in itself [40] and that other studies performing invasive treatments have considered needling upon the insertion of the plantar fascia [41], our hypothesis is restricted to evaluating the contribution of MTrPs towards PHP.

As an innovative treatment modality, PNE is being increasingly used in order to promote the regeneration of injured tendons [20–22, 42] and is being gradually recognized as a cornerstone for invasive approaches in physiotherapy. However, despite the fact that its use is increasing based on an apparently additional effect to only DN, there is no scientific evidence to support the use of this technique in clinical practice. Due to this fact, our aim is to research whether PNE can offer an additional effect to DN for PHP management. To our knowledge, this will be the first study to compare two invasive treatments for MTrPs associated with PHP. Not only this study will contribute to research regarding the possible additional effects of PNE, but also by analyzing differences in pain perception after therapy, it will address a common patient complaint. Furthermore, cost-effectiveness data will be extracted based on the EQ-5D, thus providing a valuable economic variable to studies involving physiotherapy techniques.

Abbreviations

BMI: Body mass index; DN: Dry needling; DN-G: Dry needling group; EQ-5D: EuroQol-5D; FHSQ: Foot Health Status Questionnaire; HRQoL: Health-related quality of life; LTR: Local twitch response; MTrP: Myofascial trigger point; PHP: Plantar heel pain; PNE: Percutaneous needle electrolysis; PNE-G: Percutaneous needle electrolysis group; QoL: Quality of life; RCT: Randomized clinical trials; ROM: Range of motion; SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials; SSHP: Self-stretching home program; VAS: Visual analogue scale

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

ZA, EMG, MLR, PBL, and PH conceived of the idea. ZA developed the intervention. ZA, EMG, MLR, PBL, DF, and PH developed the design of the trial and wrote the article. DF developed the cost-effectiveness part of the protocol. All authors have read and approved the final manuscript.

Ethics approval and consent to participate

The study design, procedures and informed consent procedure were approved by the Ministry of Health in the state of Kuwait. Consent to participate will be obtained from the participants.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

Publisher's Note

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ANNEX III

BMJ Open

Comparing two dry needling interventions for plantar heel pain: a randomised controlled trial

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ABSTRACT

Objectives To compare the effectiveness of dry needling (DN) versus percutaneous needle electrolysis (PNE) for improving the level of pain, function and quality of life (QoL) of patients suffering from plantar heel pain (PHP) provoked by myofascial trigger points.

Design A prospective, parallel-group, randomised controlled trial with blinded outcome assessment.

Setting A single treatment facility in the State of Kuwait.

Participants 118 participants were screened for eligibility. Of these, 102 participants were enrolled (30 men (49.5±8.9 years) and 72 women (48.1±8.8 years)) and 68 of them completed the trial.

Interventions Two parallel groups, one study arm received DN and a stretching protocol whereas the other arm received percutaneous needling electrolysis with a stretching protocol.

Primary and secondary outcome measures The primary outcome measure was the Foot Pain domain of the Foot Health Status Questionnaire, with 13 questions related to foot health-related domains. Secondary outcome measures included the 0–10 numerical rating scale pain visual analogue scale (VAS) scores, performed before and after each treatment session. In addition, QoL was measured using the EuroQoL-5 dimensions. All measurements were taken at baseline, at 4, 8, 12, 26 and 52 weeks.

Results Foot Pain domain improved at all time points for DN group (p<0.001; 29.7 (17.8 to 41.5)) and percutaneous needling electrolysis group (p<0.001; 32.7 (18.3 to 47.0)), without significant differences between groups. Pain VAS scores decreased at all time points for both DN (p<0.001; −2.6 (−4.0 to −1.2)) and percutaneous needling electrolysis group (p<0.001; −3.0 (−4.5 to −1.6)). QoL improved at 4 weeks for both DN (p<0.01; 0.15 (0.5 to 0.25)) and percutaneous needling electrolysis group (p<0.01; 0.09 (0.01 to 0.17)) and at 8 and 52 weeks for the PNE group (p<0.01; 0.10 (0.02 to 0.18)), with significant differences between groups for the QoL at 52 weeks (p<0.05; 0.10 (0.01 to 0.18)). There were two small haematomas in the PNE group and one in the DN group. No serious adverse events were reported.

Conclusions Both PNE and DN were effective for PHP management, reducing mean and maximum pain since the first treatment session, with long lasting effects (52 weeks) and significant differences between groups in the case of QoL at 52 weeks in favour of the PNE group.

Trial registration number NCT03236779.

Strengths and limitations of this study

- This is the first randomised controlled trial comparing the effectiveness of percutaneous needle electrolysis with dry needling for plantar heel pain (PHP) provoked by myofascial trigger points (MTrPs), involving a large sample and a long follow-up period.
- The assessor was blinded to group allocation for all assessments; however, neither the therapist nor the participants were blinded due to the difficulty of blinding investigators and participants when applying invasive treatment techniques.
- Due to the different potential causes of PHP, the results of this study are only valid if this is provoked by MTrPs.
- This is a single centre trial and results may not be generalisable.
- Due to the large number of drop-outs, our study had the limitation of being underpowered to report a difference between the two groups.

INTRODUCTION

Plantar heel pain (PHP) is a common problem affecting the foot, causing soreness or tenderness in the sole of the foot, and under the heel, sometimes extending into the medial arch.[1] The frequency and incidence of PHP is uncertain; however, it is estimated that over the course of a lifetime 10% of the population may suffer from this condition.[2 3] Several pathologies may cause PHP, such as myofascial pain syndrome, plantar fasciitis or heel spur, among others.[4] The clinical diagnosis is usually established based on the patient's history and physical examination, including pain during the first steps in the morning or after prolonged rest, as well as pain during prolonged standing or walking.[2 3 5] The identification of the main cause of pain can be challenging as this is often multifactorial,[6] and despite its prevalence, the aetiology of PHP is not well understood.[2 3] The presence of myofascial trigger points (MTrPs) within the muscles of the foot and lower leg may play an important role in people in PHP,[7] an

implicit assumption underlying many recent studies.[8–11] In addition, there is a lack of consensus regarding the ideal management approach for PHP.[12–14]

Clinical practice guidelines support the use of conservative treatment, such as joint and soft tissue mobilisation or self-stretching home programmes.[2 3] In particular, self-stretching home programmes have shown to be effective for addressing PHP.[2 6 15] Furthermore, recent randomised clinical trials (RCTs) have shown that there is an additional effect of reduction of pain severity when self-stretching home programmes are combined with ischaemic compression[11] and with dry needling (DN).[9] Physical therapy approaches continue to evolve and include the combination of DN and electrolysis, known as percutaneous needle electrolysis (PNE), with promising results for the treatment of tendon pathologies.[16–18] The PNE technique is a minimally invasive treatment that consists of the application of a galvanic electrolytic current that causes a controlled local inflammatory process in the target tissue. This promotes phagocytosis and the subsequent regeneration of the affected tissue.[16 17] Currently, PNE is being used in clinical practice to manage MTrPs; however, there are no studies supporting any additional beneficial effects of the same over DN.

From a biological point of view, it seems reasonable to hypothesise that subjects may display improvements thanks to the mechanical effects of the needle, and that patients may experience superior benefits when the electrolysis effect is added to the mechanical stimulus provided by the needle. Therefore, the aim of this RCT was to compare the effectiveness of DN versus PNE for improving the level of pain, function and quality of life (QoL) of patients suffering from PHP caused by MTrPs.

METHODS

Design

This study was a prospective, parallel-group RCT with blinded outcome assessment. Participants were recruited from Kuwait City, Kuwait, and both the assessment and intervention were conducted at the Physical Medicine and Rehabilitation Hospital in Kuwait. The study protocol has been previously published[19] and the trial is registered at Clinicaltrials.com. This RCT was reported in accordance with the Consolidated Standards of Reporting Trials statement for non-pharmacological trials.

Participants

The study subjects were men and women, enrolled at the Physical Therapy Department of the Physical Medicine and Rehabilitation Hospital in Kuwait City. Participants were included if they fulfilled the following criteria: (1) diagnosed of PHP 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[2 3 8 9]; (2) aged 21–60 years at admission to the study, according to the Kuwaiti Ethical Committee; (3) a history of PHP for over 1 month, showing no improvements with previous conservative treatment; (4) the ability to walk 50 m without any support; (5) the presence of MTrPs on plantar and calf muscles based on an initial physical examination carried out by a physiotherapist (MA) with experience and training in MTrPs; (6) accepting treatment from a male physiotherapist; (7) the ability to understand the study and the informed consent, as well as having signed the consent form.

The exclusion criteria were: (1) needle phobia; (2) needle allergy or hypersensitivity to metals; (3) the presence of coagulopathy or use of anticoagulants according to medical criteria; (4) the presence of peripheral arterial vascular disease; (5) pregnancy; (6) dermatological disease affecting the DN area; (7) the presence of any chronic medical condition which might preclude participation in the study, such as: malignancy, systemic inflammatory disorders (eg, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, septic arthritis), neurological diseases, polyneuropathy, mononeuropathy and sciatica; (8) treatment of PHP with needling or acupuncture during the last 4 weeks; (9) history of injection therapy in the heel over the previous 3 months; and (10) history of foot surgery or fracture. Receiving or implementing any form of treatment for the PHP (taping, night splints, massage therapy or footwear modifications) during the trial was considered withdrawal criteria.

The sample-size calculation initially estimated that 39 participants per group would provide 80% power to detect a minimally important difference of 13 points in the pain domain of the Foot Health Status Questionnaire (FHSQ) with a SD of 20 points[20] and an alpha risk at 0.05. Allowing for a 20% loss to follow-up, a minimum of 47 participants was required in each group, equalling 94 participants in total. Based on initial data collection, the drop-out rate was recalculated to be 25% and the sample size was therefore increased to a total of 102 patients.

Patient and public involvement

No patients were involved in the design, recruitment or conduction of this study and the burden of the intervention was not assessed by patients themselves neither.

Randomisation

Participants who fulfilled the inclusion criteria received standardised oral and written information, and, after consenting to participate in the trial, they were randomised using block randomisation by blocks of 10 patients. Allocation was randomly assigned using a computer program (Randomizer, https://www.randomizer.org/) with random patient file number sequences generated by a third person not involved in the study.

Procedure and interventions

Two study groups were randomly formed. The first was treated with DN whereas the second group was treated with PNE. In both groups, during the first session, all participants were taught a self-stretching protocol[11] which

has been demonstrated to be effective for the management of PHP,[2 6 11] consisting of self-stretching of the calf muscles and specific self-stretching for the plantar fascia.[19] The frequency of calf and plantar fascia-specific self-stretching exercises was two times a day, using intermittent stretching lasting 20 s, followed by 20 s rest periods, for a total of 3 min per stretch.[11] Compliance with the self-stretching protocol was registered before each treatment session and at the 4-week follow-up.

The muscles considered for invasive physical therapy treatment were the soleus, gastrocnemius, quadratus plantae, flexor digitorum brevis and abductor hallucis. These muscles typically refer pain to the heel and are muscles than can be directly palpated or that can be needled precisely and safely without ultrasound guidance. The clinician performed a physical exam to find MTrPs following the criteria by Travell and Simons: (1) the presence of a taut band and (2) identification of an exquisite spot tenderness or a nodule.[7] A flat palpation or pincer palpation technique was used to palpate the MTrPs, depending on the muscle being assessed. If a muscle contained more than one MTrP, the most sensitive MTrP was treated, according to the patient's perceived pain on palpation. If the patient presented bilateral pain, the clinician treated both sides. The patient's position (supine, prone or lateral decubitus position) depended on each muscle examined and was the same for the assessment as well as for the intervention.

Each participant received four individual physical therapy sessions, once a week. Participants was treated by one physical therapist registered at the Kuwait Ministry of Health (ZA) with 5 years of practical experience in the field of DN and appropriate training in the protocol. The duration of each session was approximately 30 min.

Participants were instructed to use the appropriate dose of medication as prescribed by their Physical Medicine and Rehabilitation physician (analgesics and non-steroidal anti-inflammatory medications) and were required to report any changes to the assessor during the evaluations if they took any additional medication or underwent any treatment during the intervention.

Invasive intervention groups: DN and PNE

Specific needles for DN were used during invasive treatments (Agu-punt, Spain). Needle length was determined by the location of the MTrP and ranged from 30 to 75 mm in length (or longer if necessary, according to the patients' characteristics). The diameter of the needle was 0.25–0.30 mm. If the participant was sensitive to the needle insertion, the level of manipulation was reduced. If this measure proved insufficient for reducing the painful stimulus, needle manipulation ceased altogether and the needle was left in situ.[21 22]

To maintain appropriate hygienic conditions during the invasive treatments, the clinician wore latex gloves and thoroughly cleaned the skin of the area to be needled with an antiseptic solution (70% Propan-2-ol, Skin-des). On removal of the needle, the area was firmly compressed for 10 s. The needle was discarded after each single use. In both groups, the intervention was terminated in the case of severe adverse effects and if the participant did not wish to continue.

DN arm

Once the clinician located the MTrP, the needle was inserted over the same and a rapid needle entry was performed. The chosen technique for manipulating the needle was the technique described by Hong, which consists of a rapid needle entry and exit (fast in/fast out), in order to obtain a local twitch response, lasting 5 s employing a rhythmic movement at approximately 1 Hz/s (five entries).

PNE arm

The electrotherapy equipment used (Physio Invasiva, PRIM Fisioterapia, Spain) produced a continuous galvanic current through the cathode while the patient held a hand-held anode.[18] Once the needle reached the relevant treatment area, this was needled in exactly the same manner as in the DN group, with the only difference being that the needle was transmitting an electrical current with an intensity of 1.5 mA (intensity was adapted to patient's characteristics according to their pain tolerance).

Study variables

An independent assessor (MA) blinded to treatment group allocation conducted all assessments at baseline, and at the 4, 8, 12, 26 and 52-week follow-up. Demographic and disease data were collected at baseline.

The primary outcome was the Foot Pain domain of the FHSQ, a validated measure of foot-health status[23] that has been used in similar trials, which evaluated the effectiveness of different interventions for PHP.[8 24 25] Individual item scores were inserted into a computer program (FHSQ V.1.03) which, after data transformation, provides a score ranging from 0 to 100 for each domain,[26] with greater scores reflecting a better condition.[27]

Secondary outcomes were the Foot Function, Footwear and General Foot Health (GFH) domains of the FHSQ, as well as the average and maximum level of pain over the past 48 hours using the visual analogue scale (VAS). Participants were explained that a score of 0 indicated the absence of pain whereas a score of 10 represented the maximum tolerable pain. Additionally, before each treatment session, they were asked to complete the VAS and after each treatment session, participants were asked to score their current pain immediately on standing up and walking a few steps. The VAS is widely used and is both valid and reliable.[28–30]

Quality of life (QoL) was assessed with the EQ-5D-5L, which was completed by the participants at baseline and at the 4, 8, 12, 26 and 52-week assessments. The EQ-5D-5L self-report questionnaire is a descriptive system with five questions, each representing one dimension of health-related QoL, that is, mobility, self-care, daily activities,

pain/discomfort and depression/anxiety. Each dimension can be rated on five levels: no problems, slight problems, moderate problems, severe problems and extreme problems. Together, the results serve to classify people into 1 of 3125 possible health states.[31] These health states are subsequently transformed to QoL values with the EQ-5D-5L crosswalk value sets.[32]

Statistical analysis

The statistical analysis was performed using IBM SPSS Statistics (V.25, IBM) by intention to treat, with the last observation carried forward. The investigator who performed the analyses was masked to group allocation. The significance level for all statistical tests was set at $p \leq 0.05$.

χ^2 tests were used to analyse if there were differences in categorical variables between groups at baseline. In addition, independent Student's t-tests and Mann-Whitney U tests were used for parametric and non-parametric quantitative variables, respectively. χ^2 tests were used to evaluate the compliance of the self-stretching protocol.

Following recommendations to estimate treatment effects in RCTs, linear mixed models adjusted for baseline values were used to test the mean effect of treatment interventions at the follow-up at the 4, 8, 12, 26 and 52 weeks, for the FHSQ and EQ-5D-5L measures. Linear mixed models adjusted for baseline values were used to test the mean effect of treatment interventions at the second session, third session, fourth session, and at the 4, 8, 12, 26 and 52-week follow-ups, for measures of VAS (average and maximum). Individual repeated measures (RM) ANOVAs were used to test time effects within each treatment group for primary and secondary outcomes. Cross-sectionally, at all linear mixed models and RM-ANOVAs, the Bonferroni correction was used to test between-group time point differences or within-group time changes, respectively. The Greenhouse-Geisser correction was applied for correcting against violations of sphericity, whereas eta-squared (η^2) was used to estimate the magnitude of the difference between both groups (0.01 small effect, 0.06 medium effect and 0.14 large effect).[33] Independent t-tests were used to determine any difference between groups for measures of level of pain immediately after each treatment session.

RESULTS

Recruitment commenced in January 2018 and was completed by October 2018. One hundred and eighteen potential participants were screened for inclusion and 102 participants were enrolled and randomly allocated to each of the treatment interventions. In total, 79 participants (78%) completed the four treatment sessions and were assessed at 4 weeks, 78 participants (77%) completed the 8-week follow-up, 76 (75%) participants completed the 12-week follow-up, 75 (74%) participants completed the 26-week follow-up and 68 (67%) participants completed the 52-week follow-up (figure 1). The mean time between

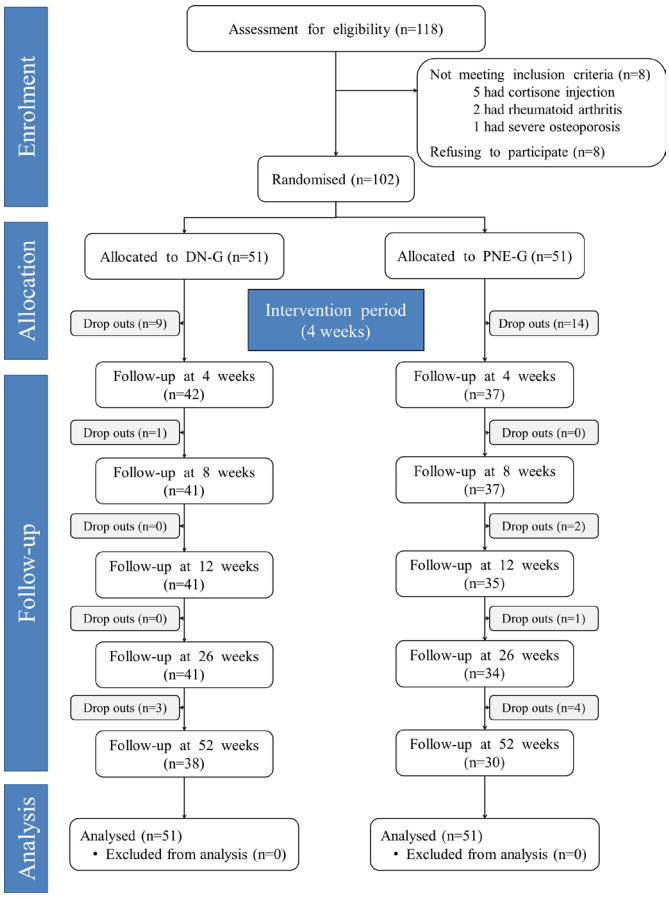

Figure 1 Participant flow chart. DN, dry needling; PNE, percutaneous needle electrolysis.

each treatment session was 7.0 days (SD 1.1) for the DN group and 6.9 days (SD 1.2) for the PNE group.

The mean age of participants was 48.8 years (SD 8.8; range 24–60) and 71% were women. The mean duration of PHP was 7.9 months (SD 9.3; range 1–36). Both groups were similar for all baseline variables except for the consumption of medication for hypercholesterolaemia (p=0.012) (table 1).

There were two small haematomas in the PNE group and one in the DN group. No serious adverse events were reported. All withdrawals during the treatment period were due to an inability to withstand the pain related to needle insertion and stimulation of MTrPs. Nine withdrawals were registered during the follow-up, as these participants received other treatments during the study period (non-compliance of receiving other treatment).

The frequencies of protocol compliance with self-stretching did not differ between groups ($\chi^2(4)=1.13$, p=0.890) (table 2).

Regarding the primary outcome measure, there was no *group×time* interaction for Foot Pain, although individual RM-ANOVA showed a significant effect of time in both groups, with lower scores at baseline than at follow-up for all time points in the DN group (p<0.001; 29.7 (17.8 to 41.5)) and the PNE group (p<0.001; 32.7 (18.3 to 47.0)) (table 3).

Table 1 Baseline characteristics of participants by intervention group

	DN (n=51)	PNE (n=51)
Age, years	49.5 (8.9)	48.1 (8.8)
Sex, n (%), male	15 (29.4)	15 (29.4)
Height, cm	160.5 (8.2)	161.2 (7.9)
Weight, kg	87.5 (16.5)	90.8 (15.2)
BMI, kg/m^2	33.9 (5.5)	35.1 (6.4)
Duration of symptoms, months	6.0 (6.0)	9.9 (11.5)
Affected side, n (%)		
Right	14 (27.5)	16 (31.4)
Left	13 (25.5)	20 (39.2)
Bilateral	24 (47.1)	15 (29.4)
Non-medicated, n (%)	11 (21.6)	15 (29.4)
Medications, n yes (%)		
Neuromodulators/antiepileptic	18 (35.3)	22 (43.1)
Painkillers	16 (31.4)	16 (31.4)
Anti-inflammatory medication	16 (31.4)	17 (33.3)
Myorelaxant medication	9 (17.6)	8 (15.7)
Systemic medications, n yes (%)		
Hypercholesterolaemia medication	12 (23.5)	3 (5.9)
Hypertension medication	14 (27.5)	8 (15.7)
Diabetes mellitus medication	14 (27.5)	10 (19.6)
Osteoarthrosis medication	3 (5.9)	4 (7.8)
Lung disease medication	3 (5.9)	3 (5.9)
Hormonal therapy	5 (9.8)	7 (13.7)
Antidepressant medication	1 (2.0)	0 (0.0)
Diet supplements	8 (15.7)	13 (25.5)
Previous treatments, yes (%)		
Corticosteroid injections	4 (7.8)	10 (19.6)
ESWT	9 (17.6)	9 (17.6)
Exercise	4 (7.8)	6 (11.8)
Pain, FHSQ (100–0)	38.8 (18.8)	40.4 (21.9)
Function, FHSQ (100–0)	57.2 (34.9)	55.5 (36.3)
Shoe, FHSQ (100–0)	30.7 (35.3)	32.4 (35.9)
GFH, FHSQ (100–0)	14.3 (18.2)	19.2 (23.7)
VAS mean (0–10)	6.0 (2.3)	5.9 (2.4)
VAS maximum (0–10)	7.6 (2.0)	7.5 (2.3)

Values are expressed in mean (SD) unless stated.
*P<0.05, significant differences between groups.
BMI, body mass index; DN, dry needling; ESWT, extracorporeal shock-wave therapy; FHSQ, Foot Health Status Questionnaire (0 corresponds to the worst foot health; 100, the best); GFH, General Foot Health; PNE, percutaneous needle electrolysis; VAS, visual analogue scale (0 corresponds to absence of pain; 10, maximum tolerable pain).

Table 2 Frequencies of compliance with self-stretching protocol achieved in the DN and PNE groups

	DN	PNE
Four full weeks complied	11 (22%)	10 (20%)
Three full weeks complied	6 (12%)	4 (8%)
Two full weeks complied	6 (12%)	9 (18%)
One full week complied	9 (18%)	10 (20%)
Any full week complied	19 (37%)	18 (35%)

Values represent the number of participants (relative frequencies) for each compliance category of the 4 weeks self-stretching protocol.
DN, dry needling; PNE, percutaneous needle electrolysis.

Individual RM-ANOVAs also showed a significant effect of time in both groups for Foot Function (DN: p<0.001; PNE: p<0.001), Footwear (DN: p=0.031; PNE: p<0.001), GFH (DN: p<0.001; PNE: p<0.001), EQ-5D-5L (DN: p=0.002; PNE: p=0.002), VAS-average (DN: p<0.001; PNE: p<0.001) and VAS-maximum (DN: p<0.001; PNE: p<0.001) (table 3).

Regarding the different timelines for the secondary outcome measurements, Foot Function improved in the PNE group at 8 weeks (p=0.002; 20.3 (5.1 to 35.5)) and at 52 weeks (p=0.001; 22.5 (6.6 to 38.4)), although without differences between groups. Footwear scores also had a significant improvement at 52 weeks in the PNE group (p<0.001; 23.5 (8.9 to 38.1)), without differences between groups. Regarding the QoL, there was a significant improvement at 8 weeks (p=0.035; 0.07 (0.01 to 0.13)) and 52 weeks (p=0.003; 0.10 (0.02 to 0.18)) in the PNE group, with differences between groups in favour of the PNE group only at 52 weeks (p=0.032; 0.10 (0.01 to 0.18)) (table 3).

Regarding pain, the DN intervention provided a benefit over PNE for VAS average (p=0.009; −1.36 (−2.37 to 0.35)) and VAS maximum (p=0.043; −1.28 (−2.53 to −0.04)) at 4 weeks (table 4).

Table 5 shows the most frequently treated muscles. The level of pain just after each treatment session according to the VAS did not differ between groups (table 6).

DISCUSSION

Important clinical improvements were observed in both groups[20] for the Foot Pain and GFH domains of the FHSQ at all time points. However, Foot Function and QoL did not follow the same pattern as the aforementioned domains. Thus, clinically significant improvements were observed at 4 weeks in both groups; however, at 8 weeks and 52 weeks, improvements were only observed in the PNE group. Furthermore, at 52 weeks, differences between groups were only found for QoL. These findings suggest a trend in the group receiving PNE, producing longer lasting effects regarding Foot Function and QoL compared with DN. Although there were statistically significant differences in QoL, there is no consensus of what the minimum clinically important difference is, which ranges from 0.03 to 0.54[34]

Table 3 Mean scores, mean change within group and mean difference between groups for FHSQ and EQ-5D-5L at baseline, week 4, week 8, week 12, week 26 and week 52

Variable	DN mean (SD)	DN mean change from baseline (95% CI)	PNE mean (SD)	PNE mean change from baseline (95% CI)	Adjusted mean difference between groups (95% CI)	P value* (effect size)†
Foot Pain, FHSQ (100–0)						
Baseline	38.8 (18.8)		40.4 (21.9)			
Week 4	73.4 (27.7)‡	34.6 (21.7 to 47.5)	71.9 (25.7)‡	31.5 (18.7 to 44.2)	−2.0 (−12.2 to 8.3)	0.707 (0.001)
Week 8	70.1 (28.4)‡	31.4 (17.5 to 45.3)	67.4 (26.8)‡	27.0 (13.9 to 40.1)	−3.1 (−13.8 to 7.6)	0.567 (0.003)
Week 12	66.8 (24.8)‡	28.1 (16.2 to 39.9)	63.6 (26.1)‡	23.1 (10.6 to 35.6)	−3.8 (−13.6 to 5.9)	0.437 (0.006)
Week 26	68.8 (25.3)‡	30.0 (18.1 to 42.0)	67.1 (27.1)‡	26.7 (12.0 to 41.3)	−2.0 (−12.3 to 8.3)	0.700 (0.002)
Week 52	68.4 (25.1)‡	29.7 (17.8 to 41.5)	73.1 (29.0)‡	32.7 (18.3 to 47.0)	4.3 (−6.3 to 14.8)	0.424 (0.006)
Main effect of time; p value	<0.001		<0.001			
Foot Function, FHSQ (100–0)						
Baseline	57.2 (34.9)		55.5 (36.3)			
Week 4	79.4 (31.2)‡	22.2 (6.5 to 37.9)	71.7 (32.4)‡	16,2 (0,5 to 31,8)	−7.1 (−18.4 to 4.3)	0.220 (0.015)
Week 8	72.7 (30.1)	15.4 (−1.3 to 32.2)	75.9 (29.7)‡	20.3 (5.1 to 35.5)	3.7 (−7.5 to 14.7)	0.502 (0.005)
Week 12	65.7 (31.7)	8.5 (−8.6 to 25.5)	71.1 (29.8)	15.6 (−0.7 to 31.8)	5.9 (−5.6 to 17.3)	0.311 (0.010)
Week 26	70.2 (29.6)	13.0 (−4.5 to 30.4)	70.7 (28.8)	15.2 (−0.9 to 31.3)	0.9 (−10.1 to 11.9)	0.871 (0.001)
Week 52	69.8 (29.6)	12.6 (−4.9 to 30.1)	78.0 (30.2)‡	22.5 (6.6 to 38.4)	8.6 (−2.6 to 19.9)	0.132 (0.023)
Main effect of time; p value	<0.001		<0.001			
Footwear, FHSQ (100–0)						
Baseline	30.7 (35.3)		32.4 (35.9)			
Week 4	35.0 (35.9)	4.2 (−10.5 to 19.0)	30.2 (33.9)	−2.1 (−16.1 to 11.9)	−5.6 (−17.1 to 5.9)	0.333 (0.009)
Week 8	37.6 (34.2)	6.9 (−7.3 to 21.0)	30.1 (35.4)	−2.3 (−18.9 to 14.3)	−8.3 (−20.3 to 3.7)	0.174 (0.019)
Week 12	41.0 (32.1)	10.3 (−3.7 to 24.3)	35.8 (35.9)	3.4 (−13.0 to 19.9)	−6.0 (−17.8 to 5.8)	0.316 (0.010)
Week 26	43.3 (32.7)	12.6 (−1.9 to 27.0)	39.0 (35.8)	6.7 (−9.1 to 22.5)	−5.0 (−16.8 to 6.7)	0.397 (0.007)
Week 52	44.2 (31.3)	13.4 (−1.6 to 28.5)	55.9 (35.7)‡	23.5 (8.9 to 38.1)	10.9 (−0.5 to 22.3)	0.061 (0.035)
Main effect of time; p value	0.015		<0.001			
GFH, FHSQ (100–0)						
Baseline	14.3 (18.2)		19.2 (23.7)			
Week 4	59.9 (34.4)‡	45.5 (30.4 to 60.7)	53.3 (37.0)‡	34.1 (19.4 to 48.9)	−9.4 (−22.7 to 3.9)	0.165 (0.019)
Week 8	54.6 (34.4)‡	40.2 (25.4 to 55.1)	51.6 (35.2)‡	32.4 (16.5 to 48.2)	−5.2 (−18.5 to 8.2)	0.445 (0.006)
Week 12	49.5 (33.5)‡	35.1 (21.3 to 49.0)	53.6 (34.4)‡	34.4 (20.1 to 48.6)	1.1 (−11.4 to 13.6)	0.860 (0.001)
Week 26	54.7 (34.3)‡	40.4 (26.0 to 54.8)	58.7 (34.9)‡	39.5 (23.3 to 55.6)	1.8 (−11.4 to 15.1)	0.785 (0.001)
Week 52	54.7 (34.3)‡	40.4 (26.0 to 54.8)	66.4 (38.6)‡	47.2 (30.1 to 64.2)	9.2 (−4.7 to 23.2)	0.190 (0.017)
Main effect of time; p value	<0.001		<0.001			
EQ-5D-5L (1–0)						
Baseline	0.63 (0.23)		0.67 (0.22)			
Week 4	0.78 (0.22)‡	0.15 (0.05 to 0.25)	0.76 (0.24)‡	0.09 (0.01 to 0.17)	−0.04 (−0.12 to 0.03)	0.265 (0.013)
Week 8	0.72 (0.23)	0.09 (−0.03 to 0.21)	0.74 (0.23)‡	0.07 (0.01 to 0.13)	−0.01 (−0.08 to 0.07)	0.889 (0.001)
Week 12	0.64 (0.30)	0.02 (−0.11 to 0.15)	0.70 (0.26)	0.03 (−0.05 to 0.11)	0.03 (−0.07 to 0.12)	0.587 (0.003)
Week 26	0.65 (0.29)	0.02 (−0.10 to 0.14)	0.73 (0.27)	0.06 (−0.03 to 0.14)	0.05 (−0.04 to 0.14)	0.276 (0.012)
Week 52	0.66 (0.27)	0.02 (−0.10 to 0.14)	0.77 (0.25)‡	0.10 (0.02 to 0.18)	0.10 (0.01 to 0.18)	0.032 (0.045)§
Main effect of time; p value	0.002		0.002			

Continued

Table 3 Continued

Variable	DN mean (SD)	DN mean change from baseline (95% CI)	PNE mean (SD)	PNE mean change from baseline (95% CI)	Adjusted mean difference between groups (95% CI)	P value* (effect size)†

Positive between group differences represent greater change (improvement) in the PNE group compared with the DN group.
*P value after Bonferroni's correction between group.
†Eta-squared (η^2); between groups effect size.
‡P<0.05 after Bonferroni's correction comparing follow-up against baseline scores within group.
§P<0.05, significant differences between groups.
DN, dry needling; EQ-5D-5L, 0 corresponds to the worst quality of life; 1, the best; FHSQ, Foot Health Status Questionnaire (0 corresponds to the worst foot health; 100, the best); GFH, General Foot Health; PNE, percutaneous needle electrolysis.

Table 4 Mean scores, mean change within group and mean difference between groups for VAS at baseline/1st session, 2nd session, 3rd session, 4th session, week 4, week 8, week 12, week 26 and week 52

Variable	DN mean (SD)	DN mean change from baseline (95% CI)	PNE mean (SD)	PNE mean change from baseline (95% CI)	Adjusted mean difference between groups (95% CI)	P value* (effect size)†
VAS average						
Baseline/1st session	6.0 (2.3)		5.9 (2.4)			
2nd session	4.6 (2.2)‡	−1.4 (−2.5 to −0.3)	4.4 (2.7)‡	−1.5 (−2.5 to −0.5)	0.14 (−0.64 to 0.92)	0.725 (0.001)
3rd session	4.0 (2.4)‡	−2.0 (−3.3 to −0.7)	4.1 (2.8)‡	−1.8 (−3.1 to −0.5)	0.16 (−1.11 to 0.79)	0.743 (0.001)
4th session	3.5 (2.5)‡	−2.6 (−3.9 to −1.2)	3.4 (2.7)‡	−2.5 (−3.8 to −1.1)	0.01 (−0.95 to 0.97)	0.984 (0.001)
Week 4	2.6 (2.5)‡	−3.5 (−4.9 to −2.0)	3.8 (3.0)‡	−2.0 (−3.2 to −0.8)	−1.36 (−2.37 to 0.35)	0.009 (0.067)§
Week 8	3.3 (2.8)‡	−2.7 (−4.2 to −1.2)	3.8 (2.7)‡	−2.1 (−3.4 to −0.8)	−0.54 (−1.57 to 0.49)	0.298 (0.011)
Week 12	3.3 (2.7)‡	−2.7 (−4.2 to −1.2)	3.7 (2.8)‡	−2.1 (−3.6 to −0.7)	−0.46 (−1.51 to 0.58)	0.381 (0.008
Week 26	3.4 (2.8)‡	−2.6 (−4.0 to −1.2)	3.4 (2.7)‡	−2.5 (−3.8 to −1.1)	−0.06 (−0.97 to 1.09)	0.911 (0.001)
Week 52	3.4 (2.8)‡	−2.6 (−4.0 to −1.2)	2.8 (3.0)‡	−3.0 (−4.5 to −1.6)	0.508 (−0.57 to 1.58)	0.351 (0.009)
Main effect of time; p value	<0.001		<0.001			
VAS maximum						
Baseline/1st session	7.6 (2.0)		7.5 (2.3)			
2nd session	6.2 (2.3)‡	−1.3 (−2.3 to −0.3)	5.5 (2.9)‡	−2.0 (−3.0 to −0.9)	0.66 (−0.18 to 1.50)	0.122 (0.024)
3rd session	5.4 (2.6)‡	−2.2 (−3.6 to −0.8)	5.3 (3.1)‡	−2.2 (−3.6 to −0.8)	0.05 (−1.03 to 1.13)	0.926 (0.001)
4th session	4.9 (2.9)‡	−2.7 (−4.1 to −1.3)	4.5 (3.0)‡	−3.0 (−4.4 to −1.6)	0.31 (−0.76 to 1.39)	0.563 (0.003)
Week 4	3.6 (3.2)‡	−3.9 (−5.5 to −2.3)	4.9 (3.5)‡	−2.6 (−4.1 to −1.1)	−1.28 (−2.53 to −0.04)	0.043 (0.041)§
Week 8	4.7 (3.4)‡	−2.8 (−4.5 to −1.2)	5.0 (3.1)‡	−2.5 (−3.8 to −1.2)	−0.32 (−1.50 to 0.87)	0.599 (0.003)
Week 12	4.7 (3.3)‡	−2.9 (−4.5 to −1.3)	5.1 (3.1)‡	−2.4 (−3.9 to −1.0)	−0.42 (−1.63 to 0.78)	0.487 (0.005)
Week 26	4.5 (3.2)‡	−3.0 (−4.6 to −1.4)	4.6 (3.1)‡	−2.9 (−4.5 to −1.2)	−0.13 (−1.34 to 1.09)	0.838 (0.001)
Week 52	4.5 (3.2)‡	−3.0 (−4.6 to −1.4)	4.1 (3.4)‡	−3.4 (−5.1 to −1.8)	0.45 (−0.80 to 1.70)	0.480 (0.005)
Main effect of time; p value	<0.001		<0.001			

Positive between group differences represent greater change (improvement) in the PNE group compared with the DN group.
*P value after Bonferroni's correction between group.
†Eta-squared (η^2); between groups effect size.
‡P<0.05 after Bonferroni's correction comparing follow-up against baseline scores within group.
§P<0.05, significant differences between groups.
DN, dry needling; PNE, percutaneous needle electrolysis; VAS, visual analogue scale (0 corresponds to absence of pain; 10, maximum tolerable pain).;

Table 5 Localisation and frequency of myofascial trigger points dry needled in the DN and PNE groups

Muscles	DN	PNE
Gastrocnemius	178	168
Soleus	176	162
Quadratus plantae	122	105
Flexor digitorum brevis	106	92
Abductor hallucis	102	93

Values represent the number of myofascial trigger points needled per muscle over the course of the study.
DN, dry needling; PNE, percutaneous needle electrolysis.

Patients allocated to both groups also had clinically important improvements in their mean and maximum level of pain since week 1 and during the 52 weeks of follow-up.[35] There were differences between groups after 4 weeks of treatment in favour of the DN group; however, this difference was not maintained over the time. Both groups had similar results to those reported by Cotchett *et al*[8] at 4 weeks. However, at 12 weeks, although significant improvements were found in both groups, these findings differed from the aforementioned study, which we believe may be due to a higher number of drop-outs.

Clinical implications

Clinical implications may vary as it is possible that this study was underpowered. The sample size necessary to avoid this was a total of 78 patients at the end of the study, therefore, once we realised that the drop-out rate was higher than initially estimated, we increased the recruited patients from 94 (considering a 20% of drop-outs) to 102 (considering a 25% of drop-outs). Despite this, in week 12 and the following weeks, the number of patients were lower than the necessary to avoid underpowering, which could result in not detecting the treatment effect in week 12 or later. For this reason, we carried out a per-protocol analysis and compared the results with the intention to treat analysis, which was more conservative, revealing similar results for both analyses. In addition, we analysed whether there were any results in week 8 that were not maintained, which was observed in Foot Function and QoL, revealing significant improvements at week 8 and week 52 for the percutaneous electrolysis group. Although it is speculative, either underpowering or the intention to treat analysis may explain the inconsistency of the results in the percutaneous electrolysis group, possibly leading to significant results in weeks 12 and 26.

Table 6 Mean scores for the VAS immediately after each treatment session

VAS	DN mean (SD)	PNE mean (SD)	P value*
1st session	3.1 (2.9)	3.5 (2.6)	0.459
2nd session	3.1 (2.8)	3.1 (2.6)	0.968
3rd session	2.9 (2.6)	3.3 (3.2)	0.419
4th session	2.2 (2.7)	2.4 (2.6)	0.792

*P value after independent t-test.
DN, dry needling; PNE, percutaneous needle electrolysis; VAS, visual analogue scale (0 corresponds to absence of pain; 10, maximum tolerable pain).

From a clinical point of view, both groups reported similar levels of pain after the treatment, therefore, both treatment options should be considered to be equal in terms of pain tolerance or sensitisation after treatment. Apart from the minimal clinically important difference, it is also important to consider the patient acceptable symptomatic state (PASS) which provides the basis for determining whether the treatment enabled patients to achieve a satisfactory state and which may be a clinically relevant treatment target. In our study, we found that in both groups the average pain, measured using the VAS was 5 below points since the first session, which fulfils the PASS values determined in populations with similar sociocultural characteristics,[36] despite the fact that this value was found to be unexpectedly high (50 mm) when compared with other populations.

The 118 initially selected patients presented MTrPs on plantar and calf muscles, as this was part of our inclusion criteria, meaning that MTrPs could be directly or indirectly contributing to PHP. However, we were unable to find any previous study on the prevalence of MTrPs in patients with PHP. Therefore, future studies should consider following this line of research.

Strengths and limitations

This study presents several strengths and limitations. One of the strengths is that this is the first RCT to analyse the effectiveness of PNE and to compare it with DN for PHP caused by MTrPs, with a large sample size and a long follow-up. Several limitations should be noted. First, other sources of pain were not considered, as the study was designed to analyse the contribution of MTrPs in PHP. Furthermore, we did not measure the number of local twitch responses, which is a controversial factor, potentially affecting the treatment effectiveness of MTrPs.[37] Besides, 23 patients (22.5%) dropped out of the study during the intervention as they were unable to tolerate pain, which is a higher drop-out rate compared with other studies.[8 38–40] After the intervention period, drop-outs increased progressively to 24 at 8 weeks (23.5%), 26 at 12 weeks (25.5%), 27 at 26 weeks (26.5%) and 34 at 52 weeks (33.3%) of follow-up, which is similar to the study published by Taşoğlu *et al*,[40] with 27.7% of drop-outs at 12 weeks. However, these rates differ with other previously mentioned studies.[8 38 39] These differences may be due to the cultural behaviours towards pain in the region, which constitutes a limitation and an important challenge that must be addressed by clinicians. It is important to note that both treatments were safe with minimal side effects, such as haematoma or bruising, which is in line with other published studies revealing a low incidence of adverse effects.[41]

CONCLUSIONS

Both PNE and DN were effective for PHP management, with long lasting effects (52 weeks) for Foot Pain and the GFH scores, without differences between groups. Besides, both treatments were found to be effective for reducing mean and maximum pain since the first treatment session, with differences between groups in favour of DN group at 4 weeks only.

Although Foot Function and QoL also improved at 4 weeks for both intervention groups, the PNE group showed improvements at 8 weeks and 52 weeks, with significant differences between groups in the case of QoL at 52 weeks.

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Contributors ZA-B, EMG-T, PB-L and PH conceived of the idea and developed the design of the trial. ZA-B and MA developed the intervention and collected data. ZA-B, EMG-T, PB-L, DF and PH were involved in development of the statistical analysis of the trial. All authors contributed to writing the article and have read and approved the final manuscript.

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Ethics approval The study was conducted in compliance with the Declaration of Helsinki of Human Rights and ethical approval was obtained by the Medical Ethics Committee of the State of Kuwait Ministry of Health, with reference number 642/2017.

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