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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

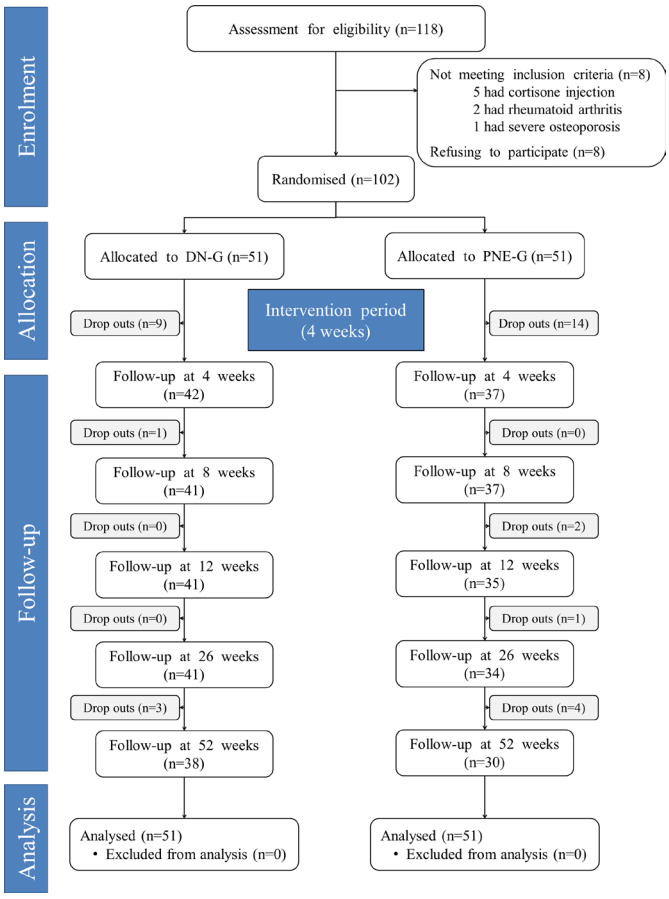

Figure 1 Participant flow chart. DN, dry needling; PNE, percutaneous needle electrolysis.

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).

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).

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.

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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Patient consent for publication Not required.

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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Data availability statement Data are available upon reasonable request. All the anonymised data related to the different clinical outcomes may be obtained from the corresponding author on reasonable request in an excel/SPSS format for secondary analysis (ie, meta-analysis). Study protocol is publicly available at: 10.1186/s13018-019-1066-4.

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