Effectiveness of Trigger Point Dry Needling for Plantar Heel Pain: A Randomized Controlled Trial

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Background. Plantar heel pain can be managed with dry needling of myofascial trigger points; however, there is only poor-quality evidence supporting its use.

Objective. The purpose of this study was to evaluate the effectiveness of dry needling for plantar heel pain.

Design. The study was a parallel-group, participant-blinded, randomized controlled trial.

Setting. The study was conducted in a university health sciences clinic.

Patients. Study participants were 84 patients with plantar heel pain of at least 1 month's duration.

Intervention. Participants were randomly assigned to receive real or sham trigger point dry needling. The intervention consisted of 1 treatment per week for 6 weeks. Participants were followed for 12 weeks.

Measurements. Primary outcome measures included first-step pain, as measured with a visual analog scale (VAS), and foot pain, as measured with the pain subscale of the Foot Health Status Questionnaire (FHSQ). The primary end point for predicting the effectiveness of dry needling for plantar heel pain was 6 weeks.

Results. At the primary end point, significant effects favored 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), although the between-group difference was lower than the minimal important difference. The number needed to treat at 6 weeks was 4 (95% CI=2 to 12). The frequency of minor transitory adverse events was significantly greater in the real dry needling group (70 real dry needling appointments [32%] compared with only 1 sham dry needling appointment [<1%]).

Limitations. It was not possible to blind the therapist.

Conclusion. Dry needling provided statistically significant reductions in plantar heel pain, but the magnitude of this effect should be considered against the frequency of minor transitory adverse events.

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Plantar heel pain is a common source of pain and disability, with an estimated prevalence between 3.6% and 7.5%.[1–3] Between the years of 1995 and 2000 in the United States, it was estimated that approximately 1 million patient visits to office-based physicians and hospital outpatient departments per year were for plantar heel pain,[4] at a projected cost of between US$192 and US$376 million to third-party payers.[5] Plantar heel pain predominantly affects middle-aged as well as older adults[2] and is estimated to contribute 8.0% of all injuries related to running.[6]

Despite the high prevalence of plantar heel pain, the etiology remains controversial and is probably multifactorial. A number of factors have been associated with plantar heel pain including reduced ankle dorsiflexion, increased body mass index, and prolonged periods of standing.[7,8] Simons et al[9] proposed that the presence of myofascial trigger points (MTrPs), within the plantar intrinsic foot musculature and muscles proximal to the foot, might play an important role in people with plantar heel pain. A *myofascial trigger point* is defined as a "hyperirritable spot in skeletal muscle that is associated with a hypersensitive palpable nodule in a taut band. The spot is tender when pressed, and can give rise to characteristic referred pain, motor dysfunction, and autonomic phenomena."[9(p4)] Myofascial trigger points have been found to be prevalent in other musculoskeletal conditions, including chronic shoulder pain,[10] patellofemoral pain,[11] whiplash-associated disorders,[12] and neck pain.[13] There has been no rigorous research to evaluate the prevalence of MTrPs in people with plantar heel pain, although Imamura et al[14] found MTrPs within the soleus, gastrocnemius, tibialis posterior, popliteus, abductor hallucis, peroneus longus, and flexor digitorum brevis muscles were common in patients with plantar heel pain.

Numerous interventions are used to treat plantar heel pain; however, 2 systematic reviews have concluded that few interventions are supported by good evidence.[15,16] In addition to standard therapies, trigger point dry needling, which involves insertion of needles into an MTrP, is increasingly used by practitioners to manage pain associated with MTrPs within all parts of the body. Two systematic reviews provide evidence for the effectiveness of dry needling. Tough and White[17] found that dry needling of MTrPs, associated with neck, shoulder, low back, knee, and hamstring pain, was significantly better than sham and usual care for pain, whereas Kietrys et al[18] found that dry needling was superior to sham and placebo interventions in the short term for upper quarter myofascial pain.

We have previously evaluated the effectiveness of trigger point dry needling for plantar heel pain in a systematic review,[19] although our findings were not definitive due to the poor methodological quality of the included studies. Therefore, the aim of this study was to evaluate the effectiveness of trigger point dry needling for treatment of plantar heel pain.

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- eTable 1: Participant-Reported Use of Cointerventions and Pain-Relieving Medication During the Trial
- eTable 2: Assessments of Treatment Expectancy and Rationale Credibility Recorded After the First Treatment

Method

Study Design

We conducted a parallel-group, participant-blinded randomized controlled trial comparing the effectiveness of trigger point dry needling and sham dry needling.

Setting and Participants

Participants were recruited through local and major metropolitan daily newspapers. Inclusion criteria were: aged 18 years or older; clinical diagnosis of plantar heel pain (plantar fasciitis) in accordance with the clinical guidelines linked to the *International Classification of Function, Disability and Health* from the Orthopaedic Section of the American Physical Therapy Association[20]; plantar heel pain for 1 month or longer; first-step pain during the previous week rated at least 20 mm on a 100-mm visual analog scale (VAS); and no previous history of acupuncture or dry needling. We excluded people with: potential contraindications to dry needling; more serious causes of heel pain (eg, fractures, infections, cancer); conditions that could have confounded the results (eg, systemic inflammatory disorders); and treatment for plantar heel pain in the previous 4 weeks. All treatments were conducted at the La Trobe University Health Sciences Clinic, Melbourne, Australia. All participants gave written informed consent.

Randomization

A simple block randomization procedure was used to allocate participants to the real or sham dry needling group. An external person not directly involved in the trial used a random number generator to create an allocation sequence containing 100 allocations (50 experimental and 50 control) under the knowledge that we would recruit fewer than this number of participants (see "Data Analysis" section). The allocation sequence was concealed from

the researcher (M.P.C.) enrolling and assessing participants; each participant's allocation was contained in sequentially numbered, sealed, and stapled opaque envelopes. Each envelope, containing the allocation, was opened immediately after all baseline measurements were recorded. This method has been used previously[21] and has been recommended by the CONSORT group.[22]

MTrP Diagnosis

Myofascial trigger points were identified using a list of essential criteria and a list of observations that help confirm the presence of an MTrP, including: (1) a tender point within a taut band of skeletal muscle, (2) a characteristic pattern of referred pain, (3) patient recognition of pain on sustained compression over the tender point, and (4) a local twitch response (LTR) elicited on dry needling of the taut band.[9] A flat palpation or pincer technique was used to palpate an MTrP depending on the muscle being assessed.

Interventions

The protocol, including needling details and treatment regimen, was formulated by general consensus[23] and was guided by the MTrP model (Tab. 1). Participants were treated by a registered podiatrist (M.P.C.) who had 12 years of clinical experience and 4 years of dry needling experience. The real and sham dry needling treatments consisted of 1 treatment per week, of 30 minutes' duration, for 6 weeks. Participants were followed for 12 weeks. To prevent participants from determining their allocation, a curtain was placed across the thoracic spine and cushions were positioned between their legs. If a participant's symptoms were bilateral, both limbs were treated.

Real dry needling. A detailed explanation of the real dry needling intervention, including treatment rationale, dry needling details, and treatment regimen, is outlined in Table 1.

Sham dry needling. Nonpenetrating sham acupuncture needles (50 × 0.30 mm) were prepared using a protocol outlined by Tough et al[24] and sterilized prior to each treatment. At the commencement of the treatment, a sham needle was removed from its packaging to simulate removal of a real acupuncture needle. Once the MTrP was identified by palpation, the sham needle, within its guide tube, was placed on the skin overlying the MTrP. The needle was tapped, to simulate needle insertion, and the guide tube immediately removed, while maintaining needle contact with the skin. The needle was subsequently manipulated, using an "up and down" motion, 6 or 7 times.[12] After 5 minutes, the chief investigator mimicked removal of the needle by placing a finger on either side of the point treated and pretended to remove the sham needle. A real acupuncture needle was disposed of in a sharps container, simulating the noise and effects associated with sharps disposal.

Outcome Measures

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

The primary outcome measures included: (1) first-step pain (pain when getting out of bed in the morning) over the previous week, as measured with a 100-mm VAS, and (2) foot pain, as measured using the pain subscale of the Foot Health Status Questionnaire (FHSQ),[25] a scale of 0 to 100 points, where 0 represents "worst foot health" and 100 represents "best foot health."

The Bottom Line

What do we already know about this topic?

Dry needling is increasingly used to manage musculoskeletal pain, although there is limited evidence for its effectiveness for plantar heel pain.

What new information does this study offer?

Real dry needling was found to be more effective than sham dry needling for reducing plantar heel pain. However, the size of the effect was slightly less than a value considered clinically meaningful.

If you're a patient, what might these findings mean for you?

Although effective in reducing plantar heel pain, dry needling also was associated with frequent adverse events. These were mild and transitory (mostly needle stick pain). Patients should be made aware of this when considering this intervention. Other effective interventions for plantar heel pain may have an additive benefit when combined with dry needling.

Table 1.
Details of the Trigger Point Dry Needling Intervention Implemented in the Trial Consistent With STRICTA Recommendations[a]

Variable	Description
Brand of acupuncture needle	Seirin J-type[b] or Hwa-To Ultraclean[c]
Muscles dry needled	Muscles assessed first included those harboring MTrPs that might have been responsible for the participant's pain, including the soleus, quadratus plantae, flexor digitorum brevis, and abductor halluces muscles. Synergists and antagonists of these muscles also were assessed for MTrPs. In addition, a search was undertaken for MTrPs in muscles, which might have influenced the participant's loading of the aforementioned muscles, as well as the piriformis, gluteus maximus, gluteus medius, gluteus minimus, tensor fascia latae, adductor longus, adductor magnus, adductor brevis, semitendinosus, semimembranosus, and biceps femoris muscles.
Needle length and diameter	Not prespecified, but needle length typically ranged from 30 to 75 mm, with a diameter of 0.30 mm
Needle insertions per muscle	The number of needle insertions per muscle depended on the number of MTrPs to be dry needled, participant's tolerance to needle insertion, responsiveness of the tissue to dry needling, and level of post-needle soreness for a specific muscle
Response elicited	Dry needling of a MTrP attempted to elicit sensations such as aching, soreness, and pressure and, if possible, a local twitch response
Manipulation of the acupuncture needle	Following insertion, the acupuncture needle was withdrawn partially and advanced repeatedly
Needle retention time	The needle remained in the muscle for as long as it took to produce an appropriate response and was tolerated by the participant; the needle then was left in situ for 5 min

[a] STRICTA=STandards for Reporting Interventions in Clinical Trials of Acupuncture, MTrP=myofascial trigger point.
[b] Seirin Corp, 13-7 Yokosuna-Nishicho, Shimizu-ku, Shizuoka City, Shizuoka 424-0036, Japan.
[c] Suzhou Medical Appliance Factory, 14 West Qi Lin Lance, Suzhou, China.

The secondary outcome measures included: (1) foot function and general foot health, as measured with the FHSQ[25]; (2) physical and mental health, as measured with the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), version 2[26]; (3) depression, anxiety, and stress, as measured with the 21-item short-form Depression Anxiety and Stress Scales (DASS-21),[27] which uses a 4-point severity/frequency scale, where a score of 0 indicates the symptom "did not apply to me at all" and a score of 3 indicates the symptom "applied to me very much, or most of the time" for each item; (4) self-reported magnitude of symptom change,[28] as measured on a 15-point Likert scale ranging from +7 ("A very great deal better") to −7 ("A very great deal worse"); and (5) foot posture, which was evaluated using the Foot Posture Index.[25]

Participants also completed the Credibility/Expectancy Questionnaire (CEQ),[29] after the first treatment only, to measure the perceived credibility and their expectations of the treatment. Participants also documented their level of activity in the previous week, at baseline, using the 7-day Physical Activity Recall (PAR) questionnaire.[30] Finally, participants were asked at each treatment and during the 12-week follow-up whether they had experienced any adverse events, used other cointerventions, taken pain-relieving medication for their heel pain, or developed any new medical conditions.

Data Analysis

To preserve baseline groups developed by randomization and to avoid overestimating the effectiveness of dry needling, all analyses were conducted on an intention-to-treat basis.[31] All participants were analyzed in the group to which they were randomly assigned regardless of: (1) the treatment actually received, (2) deviations from the trial protocol, and (3) withdrawal from the trial. To account for missing data (16/420 VAS measurements, 16/1,880 FHSQ pain measurements, 66/2,016 SF-36 measurements, 30/474 CEQ measurements, and 20/756 DASS-21 measurements), we used the multiple imputation method.[32] In total, 5 imputed datasets were created to avoid inaccuracy that might evolve from a single imputation.[33] Baseline measures and intervention group were included as variables predictive of missing values. All analyses were completed using SPSS version 19 (SPSS Inc, Chicago, Illinois), and we considered $P<.05$ to be statistically significant. The primary end point for predicting the effectiveness of dry needling for plantar heel pain (using the primary outcome measures) was 6 weeks. If a participant had bilateral symptoms, data from the most painful side was recorded and analyzed to satisfy the assumption of independent data.[34]

Continuous outcomes measured at 2, 4, 6, and 12 weeks were analyzed using an analysis of covariance (ANCOVA),[35] with baseline scores included as covariates.[36] Our decision to perform an ANCOVA, which was prespecified in the trial registration and protocol article,[37] was to account for regression to the mean, which may have occurred if there were chance differences in baseline scores.[38]

Prior to performing an ANCOVA, we tested for several assumptions, including linearity of the covariate, homogeneity of regression slopes, homoscedasticity and homogeneity of variances, normality, and the presence of outliers, to ensure validity of the analysis.[39] The results of the ANCOVA assumption testing revealed the absence of substantial violations. Cohen *d* was calculated to quantify the magnitude of the difference between groups at the primary end point.[40] To further estimate the interventions' effectiveness, we calculated: (1) the number needed to treat (NNT) for the primary outcome measures, which was based on the number of participants who changed greater than the prespecified minimal important difference (MID); (2) the number needed to harm (NNH) for the difference in frequency of adverse events between the 2 groups; and (3) the absolute risk reduction (ARR) for participant-reported use of cointerventions. Independent *t* tests were used to evaluate the difference between groups for each question relating to the assessment of treatment expectancy and rationale credibility and the level of activity in the previous week for each participant.

We determined a sample size of 76 prior to commencement of the trial. This sample size provided 80% power to detect an MID of 13 points (SD=21) in the pain subscale of the FHSQ.[28] An alpha level .05 and a 5% dropout rate were factored into the calculation. This sample size also was sufficient to detect an MID of 19 mm (SD=28) for the other primary outcome measure (first-step pain, as measured with a VAS).[28]

Role of the Funding Source

This study was funded by the Australian Podiatry Education and Research Foundation (APERF).

Results

Study Recruitment and Follow-up

One hundred ninety-eight participants were screened for eligibility, and 84 participants were enrolled. The first and last enrollments occurred on February 8 and October 7, 2011, respectively. The flow of participants through the trial is illustrated in the Figure. In total, 81 participants (96.4%) completed the 6-week follow-up, and 79 participants (94.0%) completed the 12-week follow-up. For those individuals recruited into the trial, a total of 238 real dry needling visits (mean±SD=5.8±0.6 per participant) and 250 sham dry needling visits (mean±SD=5.8±0.8 per participant) were conducted over the course of the study. The mean time between treatments was 7.0 days (SD=0.3) for the real dry needling group and 6.9 days (SD=1.1) for the sham dry needling group.

Baseline Characteristics

Baseline characteristics of the study participants are listed in Table 2. Participants had a mean age of 56.1 years (SD=12.2), and 52% were male. The mean duration of plantar heel pain was 13.6 months (SD=12.2, range=1–95). All baseline characteristics were similar across groups. Although outcome measures for foot pain and function were slightly different, the ANCOVA model we used accounted for such confounding factors (ie, adjusted for baseline differences in outcome measures).

Primary Outcomes

Both groups showed decreased pain at the primary end point of 6 weeks; however, there were significant between-group effects that favored real dry needling over sham dry needling (Tab. 3). For first-step pain, the adjusted mean difference was −14.4 mm (95% CI=−23.5 to −5.2, *P*=.002). For foot pain measured with the FHSQ, the adjusted mean difference was 10.0 points (95% CI=1.0 to 19.1, *P*=.029). Even though the FHSQ finding was statistically significant, it did not quite reach the MID of 13 points. The Cohen *d* was −.49 for the effect of dry needling on first-step pain and .33 for the effect of dry needling on foot pain using the FHSQ. The NNT, based on the percentage of participants who met the MID for both primary outcomes, was 4 (95% CI=2 to 12) (ie, 4 patients would need to be administered the treatment in order for 1 patient to benefit).

Other than the primary end point of 6 weeks, there were few significant findings (Tab. 3). At 4 weeks, the adjusted mean difference for foot pain using the FHSQ was 11.6 points (95% CI=3.8 to 19.5, *P*=.004). At 12 weeks, the adjusted mean difference was −12.5 mm (95% CI=−21.6 to −3.4, *P*=.007) for first-step pain and 9.1 points (95% CI=1.1 to 17.0, *P*=.026) for foot pain using the FHSQ.

Secondary Outcomes

At 6 and 12 weeks, there were no significant differences in health-related quality of life between groups (Tab. 4). For level of depression, the adjusted mean difference was −2.0 (95% CI=−3.4 to −0.7, *P*<.001) at 6 weeks (Tab. 4). In relation to self-reported use of cointerventions, no significant differences were found between the real and sham dry needling groups at 6 weeks (5/41 [12.2%] versus 4/43 [9.3%]) or at 12 weeks (6/41 [14.6%] versus

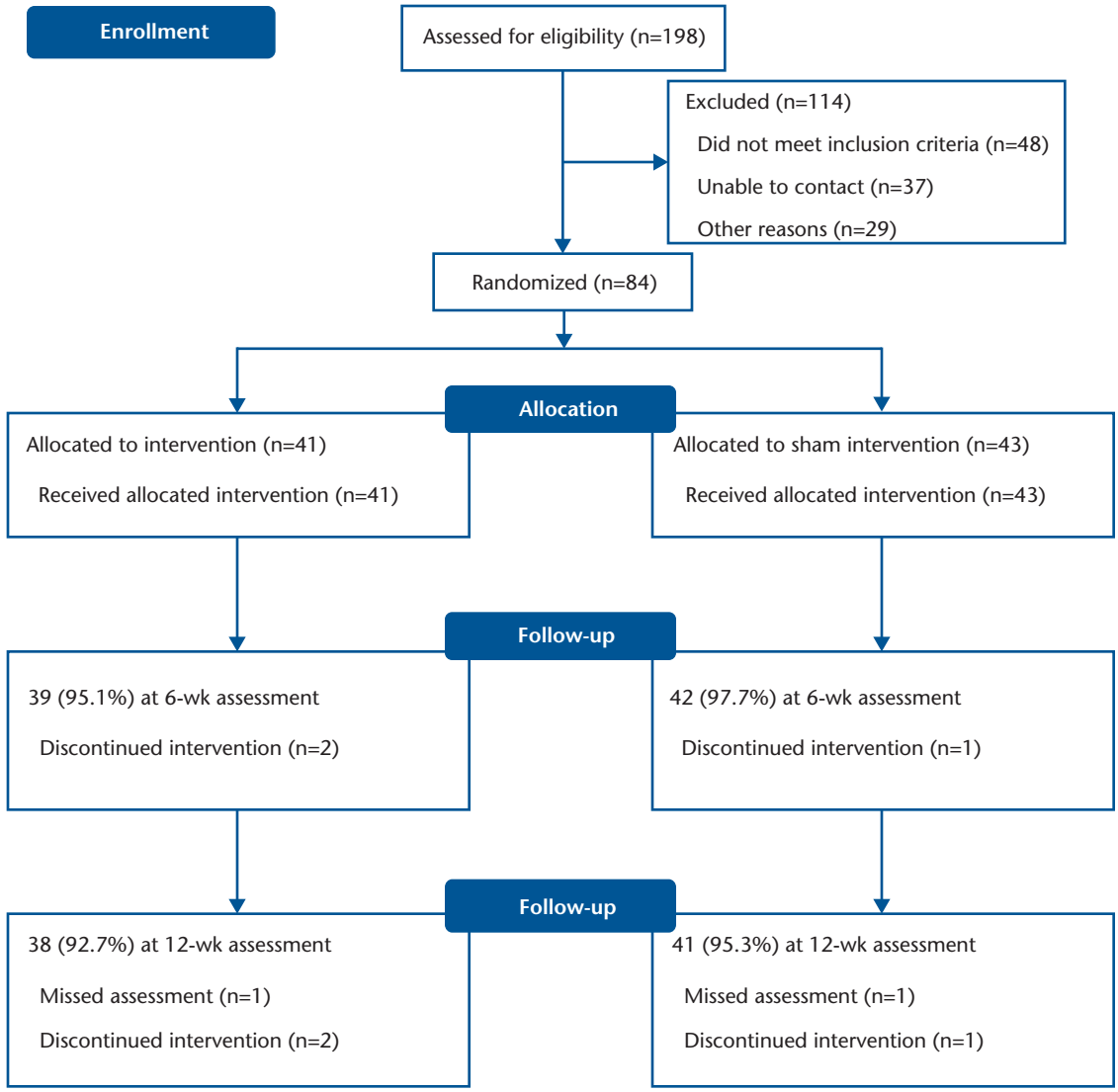

Figure.
Study participant flow diagram.

11/43 [25.6%]) (eTab. 1, available at ptjournal.apta.org).

All cases of immediate adverse events related to needle site pain and were transient in nature. Minor, transitory adverse events were reported at 70 real dry needling appointments (32%) compared with 1 appointment (<1%) in the sham dry needling group. This difference in frequency of adverse events between the 2 groups equates to an absolute risk ratio (ARI) of 29% (95% CI=23% to 35%) and an NNH of 3 (95% CI=1 to 5). The most common delayed adverse event (ie, adverse events occurring between 1 and 7 days posttreatment) was bruising, followed by an exacerbation of symptoms. Delayed adverse events in the real dry needling group were reported at 8 real dry needling appointments (3%) compared with 1 case (<1%) in the sham dry needling group. This difference in frequency of adverse events between the 2 groups equates to an ARI of 3% (95% CI=−0.5% to 6%) and an NNH of 33 (95% CI=18.6 to 184.7). No serious adverse events (eg, leading to days off work or hospital admission) were reported.

After the first treatment, there was no significant difference between the 2 groups in their expectations of improvement in plantar heel pain. There was also no significant difference between groups regarding how believable, convincing, and logical the treatment appeared (eTab. 2, available at ptjournal.apta.org).

Details of Needling

The most frequently treated muscles were the soleus, gastrocnemius, quadratus plantae, flexor digitorum brevis, and abductor hallucis (Tab. 5). Less frequently needled muscles included the abductor digiti minimi and flexor hallucis longus. Treatments averaged 4 needles per session (range=2–8), each retained for 5 minutes.

Discussion

The aim of this trial was to evaluate the effectiveness of dry needling for plantar heel pain. At the primary end point of 6 weeks, statistically significant differences in first-step pain (measured on a VAS) and foot pain (measured on the FHSQ) were found in favor of real dry needling. However, these results did not quite reach the previously calculated MIDs used in our sample size calculation. Nonetheless, the 95% CIs included the values of the MID for first-step pain and the pain domain of the FHSQ, indicating that dry needling for plantar heel pain might have clinical importance. In an attempt to explore this finding further, we calculated effect sizes (Cohen *d*), which were medium in magnitude.[40] In addition, the NNT at 6 weeks was 4 (ie, 4 patients would need to be treated with dry needling to achieve 1 beneficial outcome). When assessing the secondary outcomes, we found significant reductions in first-step pain and foot pain at 12 weeks favoring real dry needling, although again these findings did not reach the prespecified MIDs. Differences in foot pain between groups at 2 and 4 weeks were less convincing. Accordingly, dry needling appears to reach its peak effect after 6 weeks of treatment and beyond.

The main strengths of this trial were: it had an appropriate sample size, it had high adherence, it had a 3-month follow-up, the participants were blinded, the interventions were found to be credible, and we used a dry needling treatment developed by consensus.

However, there were some limitations that need to be considered as well. First, the practitioner implementing the treatment (M.P.C.) was not blinded to the intervention, which might have contributed to bias, although the results of the Credibility/Expectancy Questionnaire

Table 2.
Baseline Characteristics of Participants for Intervention Groups[a]

Variable	Real Dry Needling Group (n=41)	Sham Dry Needling Group (n=43)
Age (y)	54.4 (12.4)	57.8 (12.0)
Sex (male), n (%)	17 (41.4)	27 (62.8)
Height (cm)	168.2 (10.7)	171.1 (8.8)
Weight (kg)	86.6 (22.6)	82.9 (13.2)
Body mass index (kg/m^2)	30.3 (5.7)	28.4 (4.4)
Foot Posture Index	3.1 (1.4)	2.8 (1.5)
Duration of symptoms (mo)	13.4 (14.1)	13.7 (17.3)
Medical conditions,[b] n (%)		
Heart disease	1 (2.6)	2 (4.3)
Hypertension	13 (28.9)	8 (21.7)
Hypercholesterolemia	13 (31.6)	10 (23.9)
Lung disease	4 (10.5)	0 (0.0)
Osteoarthritis	4 (10.5)	5 (10.9)
Thyroid disease	1 (2.6)	2 (4.3)
Depression	2 (5.3)	2 (4.3)
Anxiety	0 (0.0)	1 (2.2)
Education (y)	14.9 (2.8)	15.8 (3.2)
First-step pain (VAS[c])	67.7 (20.9)	58.5 (19.5)
Pain (FHSQ[d])	32.9 (22.1)	40.2 (19.7)
Foot function (FHSQ)	45.4 (26.0)	52.6 (22.1)
General foot health (FHSQ)	46.2 (31.8)	42.4 (29.0)
Health-related quality of life (SF-36[e] physical component)	43.4 (9.0)	44.5 (8.7)
Health-related quality of life (SF-36 mental component)	49.3 (10.7)	49.9 (8.3)
Depression (DASS-21[f])	6.4 (7.9)	6.5 (7.0)
Anxiety (DASS-21)	3.8 (4.5)	3.8 (4.5)
Stress (DASS-21)	10.9 (10.0)	8.5 (8.0)
Level of activity in the previous week (PAR[g])	290.5 (54.1)	303.9 (90.1)

[a] Values are mean (SD) unless stated otherwise.
[b] A comorbidity was defined as any medical condition reported by a participant for which he or she was taking medication.
[c] VAS=visual analog scale (higher values indicate greater levels of heel pain when getting out of bed in the morning).
[d] FHSQ=Foot Health Status Questionnaire (0="worst foot health," 100="best foot health").
[e] SF-36=36-Item Short-Form Health Survey (0="worst quality of life," 100="best quality of life").
[f] DASS-21= 21-item short-form Depression, Anxiety and Stress Scale (higher scores indicate more symptoms).
[g] PAR=Physical Activity Recall Questionnaire (values correspond to total weekly energy expenditure in kcal/kg/wk).

Table 3.
Mean Scores and Mean Difference Between Groups for Primary Outcome Measures[a]

Variable	Real Dry Needling Group	Sham Dry Needling Group	Adjusted Mean Difference (95% CI)	*P*	Cohen *d*
First-step pain (VAS[b])					
Baseline	67.7 (20.9)	58.5 (19.5)			
2 wk	51.6 (22.0)	52.7 (23.8)	−8.3 (−15.6 to −1.0)	.026*	
4 wk	38.1 (23.0)	42.6 (24.1)	−9.2 (−18.7 to 0.3)	.058	
6 wk	**28.6 (19.0)**	**38.3 (25.0)**	**−14.4 (−23.5 to −5.2)**	**.002***	**−.49**
12 wk	20.9 (19.4)	29.9 (23.3)	−12.5 (−21.6 to −3.4)	.007	
Pain (FHSQ[c])					
Baseline	32.9 (22.1)	40.2 (19.7)			
2 wk	47.7 (21.0)	47.1 (19.2)	5.0 (−2.0 to 12.0)	.158	
4 wk	60.7 (20.6)	52.7 (20.7)	11.6 (3.8 to 19.5)	.004*	
6 wk	**63.0 (20.5)**	**55.7 (23.4)**	**10.0 (1.0 to 19.1)**	**.029***	**.33**
12 wk	72.2 (18.9)	65.7 (20.5)	9.1 (1.1 to 17.0)	.026*	

[a] Values are mean (SD) unless stated otherwise. 95% CI=95% confidence interval. Primary end-point results, nominated prior to the commencement of the trial, are highlighted in bold type. *Statistically significant at $P<.05$.
[b] VAS=visual analog scale (higher values indicate greater levels of heel pain when getting out of bed in the morning).
[c] FHSQ=Foot Health Status Questionnaire (0="worst foot health," 100="best foot health").

suggest we treated both groups equally. Second, the number and duration of treatments were restricted, which would not normally occur in clinical practice, although in our previous consensus study,[23] 30 experts worldwide agreed upon this protocol. Third, the statistical analysis included an evaluation of only between-group effects and did not include a model that evaluated a group × time interaction. Fourth, the dry needling technique conducted in the study was performed by only a single podiatrist, which might affect the generalizability of the findings. Fifth, the participants recruited into the trial might not be entirely representative of people with plantar heel pain, as there might be systematic differences between those people who are willing to participate in an experiment and those who elect not to participate.[41] Sixth, it might be expected that with a significant reduction in pain, there might also be an improvement in foot function. However, our study was not powered to detect changes in foot function that might be considered clinically worthwhile.[28] Finally, the unique criteria used in this study to diagnose MTrPs have proven to be challenging from a clinical trial perspective, as the criteria has limited reproducibility and validity.[42] Nevertheless, we used MTrP diagnostic criteria that clinicians implement in everyday practice, and any issue with the reproducibility of the criteria would largely be negated, as both groups were assessed in a similar manner.

The results of our study are consistent with a meta-analysis that showed acupuncture was superior to sham treatment for chronic pain[43] and with 2 meta-analyses that established dry needling of MTrPs was significantly better than sham treatment and usual care for pain.[17,18] Our findings are also similar to those of other studies that evaluated the effectiveness of MTrP needling for plantar heel pain.[44,45] Tillu and Gupta[44] found significant improvement in 18 adults with plantar heel pain (68% improvement) with 2 weeks (1 treatment per week) of dry needling of the calf and heel regions, following a 4-week period of Chinese acupuncture. Perez-Millan and Foster[45] also demonstrated a significant reduction in pain (46% improvement) in 18 participants with plantar heel pain with a 6-week (1 treatment per week) program of Chinese medicine acupuncture and dry needling of the heel and arch. However, these trials were case series of poor methodological quality,[19] which lacked control groups. Therefore, the effects of the MTrP treatment are likely to have been overestimated due to confounding and possible bias.

The effect of dry needling for plantar heel pain found in this trial might be explained by nonspecific and specific elements of the treatment.[46] It is widely recognized that nonspecific components of an acupuncture treatment, such as time spent in the consultation, patient expectations, the practitioner/patient alliance, and credibility of the intervention, might affect the outcome.[47] The extent to which these factors contributed to

Table 4.
Mean Scores and Mean Difference Between Groups for Secondary Outcome Measures at 6 and 12 Weeks[a]

Variable	Real Dry Needling Group	Sham Dry Needling Group	Adjusted Mean Difference (95% CI)	*P*
Foot function (FHSQ[b])				
Baseline	45.4 (26.0)	52.6 (22.1)		
6 wk	65.6 (24.8)	69.3 (25.7)	−0.7 (−9.8 to 8.3)	.875
12 wk	77.2 (21.7)	79.5 (18.1)	−0.5 (−7.8 to 6.8)	.889
General foot health (FHSQ)				
Baseline	46.2 (31.8)	42.4 (29.0)		
6 wk	48.2 (29.2)	43.6 (27.5)	4.2 (−6.8 to 15.1)	.457
12 wk	52.4 (26.0)	57.9 (24.0)	−7.4 (−17.3 to 2.5)	.141
Health-related quality of life (SF-36[c] physical component)				
Baseline	43.4 (9.0)	44.5 (8.7)		
6 wk	45.9 (8.3)	46.4 (9.0)	−0.3 (−2.9 to 2.3)	.837
12 wk	46.3 (8.8)	48.3 (7.3)	−1.3 (−4.1 to 1.4)	.344
Health-related quality of life (SF-36 mental component)				
Baseline	49.3 (10.7)	49.9 (8.3)		
6 wk	52.5 (8.1)	51.8 (11.0)	1.3 (−1.3 to 3.9)	.323
12 wk	52.1 (8.0)	54.6 (7.9)	−2.1 (−4.9 to 1.7)	.136
Depression (DASS-21[d])				
Baseline	6.4 (7.9)	6.5 (7.0)		
6 wk	3.8 (5.7)	5.7 (6.9)	−2.0 (−3.4 to −0.7)	<.001*
12 wk	4.5 (6.3)	3.0 (4.3)	1.4 (−0.4 to 3.2)	.154
Anxiety (DASS-21)				
Baseline	3.8 (4.5)	3.8 (4.5)		
6 wk	2.4 (3.5)	2.8 (5.1)	−0.3 (−2.2 to 1.6)	.722
12 wk	3.2 (5.3)	2.3 (3.1)	0.7 (−1.2 to 2.6)	.420
Stress (DASS-21)				
Baseline	10.9 (10.0)	8.5 (8.0)		
6 wk	7.8 (8.5)	6.9 (7.6)	1.0 (−0.9 to 2.9)	.315
12 wk	7.3 (8.4)	4.7 (5.4)	1.5 (−0.9 to 4.0)	.394

[a] Data are expressed as mean (SD) unless stated otherwise. *Statistically significant at $P<.05$.
[b] FHSQ=Foot Health Status Questionnaire (0="worst foot health," 100= "best foot health").
[c] SF-36=36-Item Short-Form Health Survey (0="worst quality of life," 100="best quality of life").
[d] DASS-21=21-item short-form Depression, Anxiety and Stress Scale (higher scores indicate more symptoms).

the effect found in our trial is unclear. However, we believe the difference between groups for pain scores was due to the specific effect of the acupuncture needle, as we controlled for nonspecific treatment effects using rigorous randomized controlled trial methods. This argument is supported by the findings of our Credibility/Expectancy Questionnaire, where there was no difference between the 2 groups.

A number of mechanisms might help explain the effect of dry needling over sham dry needling in this trial, although the current physiological mechanisms to explain the effects of dry needling are largely derived from research involving traditional acupuncture. Nevertheless, dry needling has been proposed to influence pain by affecting the biochemical environment and local blood flow surrounding an MTrP, and ultimately the central nervous system. Shah et al[48] found that dry needling significantly reduced the concentration of substance P and calcitonin gene-related peptide surrounding an MTrP

Table 5.
Localization and Frequency of Myofascial Trigger Points Dry Needled in the Real and Sham Dry Needling Groups[a]

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

[a] Values represent the number of myofascial trigger points needled per muscle over the course of the study.

following the elicitation of a local twitch response, albeit only temporarily, in participants with myofascial pain of the neck. In an animal model, Hsieh et al[49] found that levels of substance P were reduced following a single dry needling intervention of the biceps femoris muscle, which was accompanied by a short-term increase in β-endorphin in local tissue and serum, suggesting a short-term analgesic effect for dry needling. Cagnie et al[50] found that a single dry needling intervention of an MTrP within the upper trapezius muscle increased blood flow and oxygen saturation in the immediate vicinity of the MTrP for 15 minutes after removal of the needle. It has been proposed that increased blood flow to the region might aid the removal of pain-inducing substances.[48]

In addition to local effects, dry needling is proposed to produce analgesia by influencing neural mechanisms.[51] In a recent meta-analysis of changes in brain activity associated with acupuncture needle insertion, Chae et al[52] found that the insertion of an acupuncture needle activated and deactivated areas of the brain involved in the sensory, cognitive, and affective dimensions of pain. Following control tactile stimulation, which included the use of nonpenetrating sham needles similar to those used in our trial, changes in the activity levels of structures linked to these areas were significantly lower than that produced by needle insertion. Hence, the small, specific effect of needling found in our study, beyond that of the sham comparison, might be explained by differences in the extent to which the pain matrix of the brain was influenced.

Although the results of our trial showed that real dry needling produced medium (Cohen *d* effect size) reductions in foot pain beneath the heel, its value also must be considered in the context of the inconvenience of the intervention. It was clear from our trial that real dry needling frequently generates immediate adverse events, such as needle site pain. We estimated that for every 3 people with plantar heel pain treated with dry needling, 1 person will experience an immediate adverse event. Although these adverse events were relatively mild and transitory, patients need to be informed about the possibility of such adverse events prior to treatment so they can weigh the benefits of dry needling against them.

In summary, our findings are important for the treatment of plantar heel pain, as they demonstrate that dry needling has some beneficial effect on the pain associated with this condition. However, therapists must consider whether this effect outweighs the elevated risk of immediate adverse events, even though these are mild and transitory. It also is possible that dry needling may have larger effects when combined with other treatments. Therefore, future work could add to this study by evaluating the effectiveness of this intervention when used in a multimodal approach.

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Ethics approval for the study was obtained from the La Trobe University's Faculty Human Ethics Committee (No. 10–015).

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