

# RESEARCH

## Ultrasound guided corticosteroid injection for plantar fasciitis: randomised controlled trial

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### Abstract

**Objective** To investigate the effectiveness of ultrasound guided corticosteroid injection in the treatment of plantar fasciitis.

**Design** Randomised, investigator and participant blinded, placebo controlled trial.

**Setting** University clinic in Melbourne, Australia.

**Participants** 82 people with a clinical and ultrasound diagnosis of plantar fasciitis unrelated to systemic inflammatory disease.

**Interventions** Participants were randomly allocated to ultrasound guided injection of the plantar fascia with either 1 mL of 4 mg/mL dexamethasone sodium phosphate (experimental group) or 1 mL normal saline (placebo). Before injection the participants were given an ultrasound guided posterior tibial nerve block with 2% lidocaine (lignocaine).

**Main outcome measures** Primary outcomes were pain, as measured by the foot health status questionnaire (0-100 point scale), and plantar fascia thickness, measured by ultrasound at 4, 8, and 12 weeks.

**Results** Reduction in pain at four weeks favoured the dexamethasone group by 10.9 points (95% confidence interval 1.4 to 20.4,  $P=0.03$ ). Between group differences for pain scores at eight and 12 weeks were not statistically significant. Plantar fascia thickness measured at four weeks favoured the dexamethasone group by  $-0.35$  mm (95% confidence interval  $-0.67$  to  $-0.03$ ,  $P=0.03$ ). At eight and 12 weeks, between group differences for plantar fascia thickness also favoured dexamethasone, at  $-0.39$  mm ( $-0.73$  to  $-0.05$ ,  $P=0.02$ ) and  $-0.43$  mm ( $-0.85$  to  $-0.01$ ,  $P=0.04$ ), respectively. The number needed to treat with dexamethasone for one successful outcome for pain at four weeks was 2.93 (95% confidence interval 2.76 to 3.12). There were no reported adverse events associated with the intervention.

**Conclusion** A single ultrasound guided dexamethasone injection is a safe and effective short term treatment for plantar fasciitis. It provides greater pain relief than placebo at four weeks and reduces abnormal swelling of the plantar fascia for up to three months. However, clinicians

offering this treatment should also note that significant pain relief did not continue beyond four weeks.

**Trial registration** Australian New Zealand Clinical Trials Registry ACTRN12610000239066.

### Introduction

Plantar fasciitis is the most commonly reported cause of inferior heel pain.<sup>1 2</sup> The condition is characterised by pain at the calcaneal origin of the plantar fascia, exacerbated by weight bearing after prolonged periods of rest.<sup>1</sup> The prevalence of heel pain in the general population is estimated to range from 3.6% to 7%,<sup>3 4</sup> and the disorder has been reported to account for about 8% of all running related injuries.<sup>5 6</sup> An estimated one million visits per year were made to office based physicians and hospital outpatient departments in the United States for the diagnosis and treatment of plantar fasciitis,<sup>7</sup> representing an important economic burden.<sup>8</sup>

The histological features of plantar fasciitis are poorly understood, although studies report a predominance of degenerative changes at the plantar fascia enthesis, including deterioration of collagen fibres, increased secretion of ground substance proteins, focal areas of fibroblast proliferation, and increased vascularity.<sup>9-12</sup> The presence of biochemical markers of inflammation such as cytokines and prostaglandins have not been well investigated, although, several studies report non-specific evidence of local inflammatory change.<sup>12-14</sup>

Plantar fasciitis is commonly described in the literature as a self limiting condition.<sup>1 2</sup> This view is supported by the findings of a systematic review, in which plantar heel pain, on average, resolved after 12 months regardless of treatment type (including placebo).<sup>15</sup> None the less, plantar fasciitis can be a painful and disabling condition, having a negative impact on health related quality of life.<sup>16</sup>

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Ultrasound guided posterior tibial nerve block

Ultrasound measurement location for plantar fascia thickness

Several interventions are used for the management of plantar fasciitis,<sup>17</sup> and corticosteroid injection is a common choice among clinicians. Surveys of American podiatrists<sup>18</sup> and orthopaedic surgeons<sup>19</sup> reported that about 75% of respondents used or recommended this intervention. Despite the widespread use of corticosteroid injection for plantar fasciitis, only two randomised controlled trials have evaluated the effect of this treatment compared with placebo.<sup>20 21</sup> One compared the effect of 25 mg prednisolone and lidocaine (lignocaine) with lidocaine alone (placebo) and found a significant difference in pain reduction favouring corticosteroid one month after treatment.<sup>21</sup> No significant differences between groups were detected three or six months after treatment. A large proportion of participants were, however, lost to follow-up, so the authors were unable to make conclusions about the efficacy of corticosteroid in the longer term. An earlier trial compared the effect of 25 mg hydrocortisone with normal saline (placebo) and found no significant difference in pain reduction between the groups two months after treatment.<sup>20</sup> This trial, however, had a small sample size (19 participants) and was therefore statistically underpowered to detect clinically worthwhile differences.

The findings of existing clinical trials provide some support for the use of corticosteroid injection in the short term management of plantar fasciitis.<sup>1 15</sup> However, a recent systematic review concluded that the effectiveness of this treatment has not been sufficiently established,<sup>17</sup> indicating that further research is required. Therefore, we evaluated the effectiveness of ultrasound guided corticosteroid injection in the treatment of plantar fasciitis.

## Methods

We carried out a parallel group, blinded, randomised, placebo controlled trial. Eighty two participants were randomly assigned to an experimental group (corticosteroid injection) or placebo group (saline injection). Before enrolment in the trial, participants gave written informed consent. A methodological protocol was completed before the trial began and published in a peer reviewed journal.<sup>22</sup>

## Setting and eligibility criteria

We carried out the trial at the La Trobe University Health Sciences Clinic (Melbourne, Australia) between June 2010 and February 2011. Eighty two participants were recruited from the local community using several newspaper advertisements. Participants were required to have a history of inferior heel pain for at least eight weeks before enrolment and to report a minimum heel pain of 20 mm magnitude on a 100 mm visual analogue scale. Participants were also required on clinical examination to report pain on palpation of the medial calcaneal tubercle or the proximal plantar fascia. To confirm the diagnosis of plantar fasciitis we used diagnostic ultrasonography to measure the dorsoplantar thickness of the plantar fascia at a standard location where the fascia crosses the anterior aspect of the inferior calcaneal border. Participants were required to have a plantar fascia thickness of 4.0 mm or greater.<sup>23</sup>

We excluded potential recruits if they were pregnant or had received a corticosteroid injection for plantar fasciitis within the previous six months, had a known hypersensitivity to lidocaine (lignocaine) hydrochloride or corticosteroids, current skin or soft tissue infection near the injection site, posterior heel pain, systemic inflammatory disease, diabetes mellitus, previous local surgery, or a history of local trauma. Potential recruits were also excluded if they were unable to walk household distances without the use of an aid or if they had started any

treatment regimen for plantar fasciitis within four weeks before enrolment.

## Interventions

Participants were randomly allocated to ultrasound guided injection of the plantar fascia with either corticosteroid (experimental group) or normal saline (placebo group). To minimise pain during heel injection participants in both groups received an ultrasound guided posterior tibial nerve block with 2% lidocaine hydrochloride (see supplementary figure). Injections were carried out with a 25 gauge (38 mm) needle and a 1 mL Luer-lock syringe. Participants in the experimental group received an intrafascial injection with 1 mL of 4 mg/mL dexamethasone sodium phosphate and participants in the placebo group an intrafascial injection with 1 mL normal saline (0.9% sodium chloride). A podiatrist (AMcM) with two years' experience in regional anaesthesia carried out the injection procedure and received further clinical tuition on ultrasound guidance techniques. Before the start of the trial, the podiatrist tested the ultrasound guided techniques on several volunteers to ensure accuracy and standardisation throughout the trial.

The needle for heel injections was inserted with a medial oblique approach (perpendicular to the long axis of the ultrasound transducer) and advanced under continuous ultrasound guidance into the proximal plantar fascia (fig 1).<sup>24</sup> The plantar fascia was infiltrated near the calcaneal entheses, in the region of maximal fascia thickening ([www.youtube.com/watch?v=F5nsEMypmlg&feature=email](http://www.youtube.com/watch?v=F5nsEMypmlg&feature=email)). Both feet of participants with bilateral plantar fasciitis were treated with their allocated intervention during one appointment. We advised participants to avoid running and other high impact activities for a minimum of two weeks after treatment. A variable frequency (5-10 MHz) linear array transducer (Acuson Aspen; Siemens Medical Solutions, PA, USA) was used to carry out plantar fascia measurements and ultrasound guided injections. Sterile transmission gel and transducer covers were used throughout the injection procedures.

During the initial eight weeks of the trial, participants were asked to complete a daily stretching programme shown to decrease pain associated with plantar fasciitis.<sup>25</sup> This was done to ensure appropriate ethical management of participants and so that the trial better represented normal clinical practice, where patients are likely to be advised to use a basic physical therapy routine.<sup>26</sup> Participants were asked to record their adherence to the stretching programme (frequency of stretching) on an individual log sheet.

## Randomisation, treatment allocation, and blinding

Treatment allocation was done according to a computer generated randomised number sequence. We used a simple randomisation procedure and randomised 100 allocations (50 experimental and 50 control) with the knowledge that fewer participants would be recruited. The investigator who generated the random number sequence (KBL) had no contact with participants throughout the trial. Allocation was concealed in a password protected computer file only accessible by investigators not involved in collecting data from participants (KBL and ADM). ADM also prepared the syringe before heel injection, thereby ensuring that the investigator (AMcM) who carried out injections, measured outcomes, and processed data was blinded throughout the trial. AMcM was the investigator responsible for screening and enrolling participants before the start of the trial. The contents of the syringe did not require

masking as both treatment solutions were clear liquids. This protocol also ensured that trial participants were blinded to their treatment allocation throughout enrolment.

## Primary outcomes

The primary outcomes were pain and plantar fascia thickness at 4, 8, and 12 weeks. Pain was measured by the foot pain domain of the foot health status questionnaire. This instrument has four domains (pain, function, footwear, and general foot health), with each scored on a 0-100 point scale, where 0 represents the worst foot health and 100 the best foot health. The foot health status questionnaire has been shown to have a high degree of internal consistency (Cronbach's  $\alpha=0.88$ ) and test-retest reliability (intraclass correlation coefficient=0.86).<sup>27</sup> We asked participants treated for bilateral plantar fasciitis to describe symptoms without reference to a specific foot, so that bilateral pain was evaluated as one independent sample. Plantar fascia thickness was measured by diagnostic ultrasonography at a standard location where the fascia crosses the anterior aspect of the inferior calcaneal border (see supplementary figure). This measurement technique has been shown to have good intrarater reliability, with the 95% limits of agreement ranging from -0.7 mm to 0.5 mm.<sup>28</sup> Thickness measurements were taken for each foot in participants treated for bilateral plantar fasciitis; however, to evaluate data as one independent sample we calculated the mean change in plantar fascia thickness for the two feet at each follow-up. One investigator (AMcM) who was blinded throughout the duration of the trial carried out all ultrasound measurements.

## Secondary outcomes

The secondary outcomes were function and "first step" pain at 4, 8, and 12 weeks. We measured function by the foot function domain of the foot health status questionnaire, which has been shown to have a high degree of internal consistency (Cronbach's  $\alpha=0.85$ ) and test-retest reliability (intraclass correlation coefficient=0.92).<sup>27</sup> We asked participants treated for bilateral plantar fasciitis to describe foot function without reference to a specific foot, so that bilateral function was evaluated as one independent sample. First step pain, experienced when initially getting out of bed in the morning, was measured on a 100 mm visual analogue scale. We asked participants treated for bilateral plantar fasciitis to indicate the magnitude of symptoms without reference to a specific foot so that bilateral pain was evaluated as one independent sample. We also recorded complications and adverse events associated with the intervention, such as nerve injury from needle penetration, post-injection flare, soft tissue infection, and rupture of the plantar fascia.

## Sample size

Prospective sample size calculation indicated that 40 participants per group would provide 80% power to detect a minimal important difference of 13 points<sup>29</sup> on the pain domain of the foot health status questionnaire (SD 20,  $\alpha=0.05$ , 5% loss to follow-up). When doing this calculation we conservatively ignored the extra precision provided by covariate analysis.<sup>30</sup> Although we did not prespecify a single time point for sample size calculation, we considered the four week follow-up as the most likely time point for clinical benefit, and therefore measured outcomes at eight and 12 weeks to obtain data for the duration of effect only. This expectation was based on the pharmacokinetics of a single corticosteroid injection (that is, decreasing effectiveness over time), and the findings of previous clinical research.<sup>21</sup>

## Data analysis

Statistical analyses were done on an intention to treat basis using IBM SPSS software (version 19). We explored continuous data for normality using standard tests to satisfy the assumptions of parametric statistics. A blinded investigator (AMcM) did the initial data manipulation and all hypothesis testing. Multiple imputation was used to replace missing data for primary and secondary outcomes at each follow-up, using five iterations, with baseline scores and group allocations as predictors.<sup>31 32</sup> We analysed continuous outcomes with a normal distribution using a linear regression technique with baseline outcome measurements adjusted for by the analysis of covariance model.<sup>33</sup> Results for key outcomes are expressed as estimates of the between group differences in the outcome at a time point and 95% confidence intervals to represent the precision of the estimate. We set the statistical significance for hypothesis tests at the conventional level of 0.05. To provide clinically meaningful data we also present the number needed to treat.

## Results

Of 188 applicants screened for eligibility, 82 were enrolled in the trial and randomised into two groups (fig 2). By chance the two groups were of equal size (41 dexamethasone and 41 placebo). Participant characteristics were similar between the groups (table 1), and mean differences for days to follow-up were not significant at any time point: four weeks (0.16 days, 95% confidence interval -1.67 to 1.35,  $P=0.84$ ), eight weeks (0.97 days, -2.16 to 4.11,  $P=0.54$ ), and 12 weeks (0.56 days, -4.93 to 3.80,  $P=0.80$ ). Cross tabulation showed that adherence to the stretching programme did not differ significantly between the groups ( $P=0.60$ ). One participant in the placebo group was lost to follow-up (before the four week assessment) therefore 81 participants completed the trial.

No adverse events were reported in association with the trial interventions. In particular, no cases of nerve injury (neuropathia), post-injection flare, soft tissue infection, or rupture of the plantar fascia were reported.

## Primary outcomes

Table 2 presents the results for the primary outcome of pain. The adjusted between group difference for pain scores at four weeks was significant, with the dexamethasone group showing greater improvement than the placebo group by 10.9 points (95% confidence interval 1.4 to 20.4,  $P=0.03$ ). The dexamethasone group continued to show greater improvement on pain scores throughout the duration of the trial (fig 3), although between group differences at eight weeks (5.6 points, 95% confidence interval -4.5 to 15.6) and 12 weeks (5.3 points, 95% confidence interval -5.7 to 16.3) were not significant ( $P=0.28$  and  $P=0.34$ , respectively).

Table 3 presents the results for the primary outcome of plantar fascia thickness (measured by ultrasound). Reduction in plantar fascia thickness was significantly greater for the dexamethasone group than placebo group at each follow-up interval (fig 4). The adjusted between group difference for plantar fascia thickness at four weeks was -0.35 mm (95% confidence interval -0.67 to -0.03,  $P=0.03$ ), favouring dexamethasone. Eight weeks after treatment, the adjusted between group difference for plantar fascia thickness increased to -0.39 mm (-0.73 to -0.05,  $P=0.02$ ), and at 12 weeks was further increased to -0.43 mm (-0.85 to -0.01,  $P=0.04$ ), favouring dexamethasone.

For the total sample ( $n=82$ ), there was a moderate correlation between improvement in pain (foot health status questionnaire)



and reduction in plantar fascia thickness at 12 weeks ( $r=-0.30$ ,  $P=0.007$ ). The negative correlation value results from differences in the direction of measurement between the two variables, where improvement in pain (as measured by the foot health status questionnaire) is shown by a positive value and reduction in plantar fascia thickness is shown by a negative value.

## Secondary outcomes

The adjusted between group difference for first step pain (measured by 100 mm visual analogue scale) at four weeks was significant, with the dexamethasone group showing greater improvement compared with placebo ( $-11.37$  mm, 95% confidence interval  $-20.94$  to  $-1.80$ ,  $P=0.02$ ). The dexamethasone group continued to show lower first step pain scores throughout the duration of the trial, although between group differences were not significant at eight weeks ( $-9.40$  mm,  $-20.42$  to  $1.63$ ) and 12 weeks ( $-7.34$  mm,  $-19.32$  to  $4.63$ ). The dexamethasone group also showed greater improvement in function than the placebo group over the duration of the trial. However, between group differences for function were not significant at any follow-up interval: four weeks (6.6 points, 95% confidence interval  $-2.2$  to  $15.4$ ), eight weeks (7.0 points,  $-1.6$  to  $15.6$ ), and 12 weeks (4.1 points,  $-3.8$  to  $11.9$ ).

## Discussion

A single ultrasound guided dexamethasone injection is a safe and effective short term treatment for plantar fasciitis, providing better pain relief than placebo at four weeks. The treatment also had a sustained biological effect on the plantar fascia tissue, leading to reduced fascial swelling, as observed by diagnostic ultrasound over a three month period.

Although the mean difference in pain relief between groups at four weeks (11 points) was statistically significant, it only approached the minimal important difference for this outcome measure (13 points),<sup>29</sup> and therefore represents a suboptimal clinical change. For this reason, and to express results in a more clinically meaningful way, we dichotomised the pain data by considering that a reasonable improvement in pain from a patient's perspective occurred when pain levels were reduced by 19.5 points on the pain domain of the foot health status questionnaire, being 1.5 times the minimal important difference for this outcome.<sup>29</sup> According to this criterion, the number needed to treat with dexamethasone for one successful outcome regarding pain at four weeks was 2.93 (95% confidence interval 2.76 to 3.12).

## Explanation of results

In the treatment of musculoskeletal disorders, corticosteroid injection is typically used to inhibit synthesis of arachidonic acid from membrane phospholipids, thereby suppressing prostaglandin mediated inflammation and pain.<sup>34</sup> However, histological studies indicate that plantar fasciitis is predominantly a degenerative disorder, with limited involvement of chronic inflammatory processes.

Plantar fascia pathology may be similar to tendinopathy, and several alternatives to prostaglandin mediated pain have been suggested in relation to tendon models, including neurovascular in-growth,<sup>35</sup> up-regulation of excitatory neurotransmitters (for example, substance P, glutamate, and acetylcholine),<sup>35-38</sup> and increased presence of biochemical irritants, such as chondroitin sulphate.<sup>36</sup> The action of corticosteroids on these mechanisms is currently unclear<sup>39</sup>; however, corticosteroids have been shown to inhibit fibroblast proliferation and expression of ground

substance proteins.<sup>34-38</sup> It is possible that these known effects may be of benefit in the treatment of plantar fasciitis, as increased proliferation of fibroblasts and excessive secretion of proteoglycans are commonly reported features of the condition. Based on similar reasoning, corticosteroids have been suggested as potentially beneficial for treatment of early stage tendinopathy.<sup>38</sup>

Fusiform thickening of the plantar fascia is a well established feature of plantar fasciitis. According to a meta-analysis of diagnostic imaging studies,<sup>23</sup> people with plantar heel pain are over 100 times more likely to have an abnormally thickened ( $>4.0$  mm) plantar fascia than asymptomatic controls (odds ratio 105, 95% confidence interval 3 to 3577,  $P=0.01$ ). Abnormal thickening is also reported in the literature on tendinopathy and is thought to be the result of increased secretion of ground substance proteins such as proteoglycans and subsequent tissue oedema.<sup>38</sup> It is possible that the reduction in plantar fascia thickening observed in this trial resulted from the action of corticosteroids on fibroblast activity. The mean plantar fascia thickness values for the dexamethasone group had decreased sharply by the four week interval (see fig 4). This change could be related to the direct inhibiting effect of corticosteroids on expression of ground substance proteins, thereby reducing tissue oedema and the subsequent cross sectional area. In addition, the dexamethasone group showed a further reduction in plantar fascia thickness between the eight and 12 week intervals (see fig 4). This second phase of change could be related to reduced proliferation of fibroblasts, leading to a further reduction in overall ground substance protein, and subsequent tissue oedema, within the fascia.

The results of this trial, including findings on the correlation between pain and plantar fascia thickness, suggest that measuring plantar fascia thickness (with ultrasound) is a useful objective method for monitoring the progress of treatment. At an individual level, however, changes in plantar fascia thickness should be interpreted according to the accuracy of the measurement technique. The intrarater reliability of this measurement has not been investigated in detail; one study has reported the 95% limits of agreement to range from  $-0.7$  mm to  $0.5$  mm.<sup>28</sup> This suggests that a true decrease in plantar fascia thickness of  $0.5$  mm or less might not be detected, and that an observed decrease in plantar fascia thickness of  $0.7$  mm or less could result from an error in measurement. Therefore, when measuring plantar fascia thickness at an individual level, it is likely that observed thickness changes larger than  $-0.7$  mm represent true improvements in the underlying condition. To incorporate this value into the present trial results, we dichotomised the data on plantar fascia thickness by considering that a true improvement in plantar fascia thickness occurred when it was shown to have reduced by more than  $-0.7$  mm. According to this criterion, the number needed to treat with dexamethasone for one successful outcome with respect to plantar fascia thickness at four weeks was 3.15 (95% confidence interval 2.00 to 7.35).

## Choice of corticosteroid and injection technique

Selection of a particular corticosteroid agent for local injection varies across disciplines<sup>40</sup> and geographical regions,<sup>41</sup> with limited evidence available to assist in decision making. In relation to treatment outcomes, systematic reviews of data from randomised trials have shown no difference in clinical efficacy between various corticosteroid types.<sup>42-43</sup> None the less, when selecting a corticosteroid for treatment of soft tissue disorders, guidelines in the literature on rheumatology recommend use of

an agent with high tissue solubility<sup>39</sup> and avoidance of fluorinated compounds.<sup>44</sup> These recommendations are based on minimising the risk of unwanted localised side effects, such as post-injection flare and soft tissue atrophy.

Accordingly, we considered two corticosteroids for use in this trial: methylprednisolone acetate (non-fluorinated, moderate acting) and dexamethasone sodium phosphate (fluorinated, shorter acting). As normal saline solution appears as a clear and colourless liquid, we considered use of an acetate compound problematic for blinding the investigator carrying out the injections. Therefore we regarded dexamethasone sodium phosphate as the most appropriate corticosteroid for use in the trial. We acknowledge that the results of this trial could have been altered (that is, a longer period of pain relief might have been detected) if a corticosteroid with longer duration of action had been selected. However, the lack of adverse events (for example, post injection flare and rupture of the plantar fascia) reported in this trial supports the use of dexamethasone as a safe treatment option, and that the same safety outcome may not have been achieved with acetate compounds. Future research in this area could investigate the comparative safety and effectiveness of different types of corticosteroids, as less soluble compounds might provide longer lasting pain relief, although with potentially greater side effects.

Clinician surveys have shown that combining corticosteroid and local anaesthetic solutions before soft tissue injection is a widely adopted practice.<sup>45</sup> Reported benefits of this include provision of temporary pain relief, dilution of potentially harmful corticosteroid crystals (acetates only), and confirmation of accurate solution deposit.<sup>46</sup> Despite this common practice, mixing of corticosteroid solution was not utilised in this trial as these reported benefits were addressed by other aspects of the trial protocol, such as provision of regional anaesthesia and use of continuous ultrasound guidance.

In comparison with a landmark based technique, use of ultrasound guidance during regional anaesthesia has been shown to reduce the occurrence of paraesthesia and inadvertent intravascular injection, while improving block onset time and success rates.<sup>47-49</sup> With this in mind, we chose to perform an ultrasound guided posterior tibial nerve block, and found this technique effective for reducing the high levels of pain otherwise experienced by patients during heel injection.

## Comparison with previous studies

Although to our knowledge this is the first randomised controlled trial testing the effect of ultrasound guided dexamethasone injection versus placebo in the treatment of plantar fasciitis, comparisons can be made with one previous trial that tested a similar intervention.<sup>21</sup> This trial tested a type of corticosteroid (prednisolone acetate) that has substantially lower tissue solubility than dexamethasone phosphate (a longer acting compound),<sup>39</sup> and injections were done without ultrasound guidance. Despite these differences, both trials reported pain relief at four weeks from a single corticosteroid injection. This suggests that injection of a more soluble (and arguably safer) corticosteroid under ultrasound guidance has equivalent efficacy to a less soluble corticosteroid injected with a conventional landmark based technique. In addition, the results for plantar fascia thickness reported in the present trial agree with findings from two observational studies, in which plantar fascia thickness was shown to significantly decrease as early as two weeks<sup>50</sup> and one month<sup>51</sup> after corticosteroid injection.

## Strengths and limitations of the study

The design of this trial was scientifically rigorous, incorporating adequate statistical power, random treatment allocation, placebo control, and blinding of the investigator carrying out the injection, the assessor, and the participant. The use of a standardised stretching programme was also undertaken to better represent normal clinical practice. However, it is possible that the recruitment method used (advertisements in major daily newspapers) produced a sample that does not fully represent the characteristics of patients seen in general practice for management of heel pain. This factor may limit the generalisability of the trial findings and should be considered by clinicians when interpreting the results. Notably, the sample in this trial contained a larger proportion of males than females (52% male), which is not typical compared with other samples for plantar fasciitis studies.<sup>23</sup> In addition to this, several other aspects of the trial intervention may limit external validity or generalisability to common clinical settings, and the findings might therefore be considered to have greater explanatory rather than pragmatic applications. Other factors limiting generalisability include provision of regional anaesthesia, use of an ultrasound guided injection technique, selection of a corticosteroid (dexamethasone) not often chosen by clinicians treating foot and ankle disorders,<sup>52</sup> and injection of plain corticosteroid solution (without mixing with a local anaesthetic). Any of these factors may introduce points of difference between the overall procedure tested in this trial and the techniques routinely used by clinicians such as general practitioners, podiatrists, rheumatologists, and radiologists. These points of difference should be considered carefully by clinicians when interpreting the trial findings, as variation in clinical techniques may lead to different patient outcomes. Nevertheless, we believe these limitations have been adequately dealt with by describing the rationale for important aspects of the trial protocol. Moreover, our protocol to administer the trial intervention was optimised to investigate the pharmacological effect of corticosteroids for treatment of plantar fasciitis, thereby meeting the aim of this study.

## Conclusion

Our findings show that a single ultrasound guided dexamethasone injection is a safe and effective short term treatment for plantar fasciitis, providing better pain relief than placebo at four weeks. The treatment also reduces abnormal swelling of the plantar fascia soon after treatment, and continuously for several months. These findings are important for clinical practice as they indicate that an appropriately administered dexamethasone injection is efficacious in the short term for plantar fasciitis and that such an injection may lead to beneficial longer term physiological changes to the affected plantar fascia. Clinicians offering this treatment should also note that significant pain relief did not continue beyond four weeks.

Contributors: AMcM and KBL designed the trial protocol and obtained project funding. MFG, ARB, and HBM assisted in designing the trial protocol. AMcM screened participants (including ultrasound examination), carried out ultrasound guided injection procedures, measured treatment outcomes, analysed data, and drafted the manuscript. KBL assisted with data analysis and drafting of the manuscript. MFG provided clinical supervision and ADM assisted with clinical procedures. MFG, ARB, ADM, and HBM commented on the manuscript. All authors read and approved the final manuscript before submission. AMcM and KBL accept full responsibility for this work and act as guarantors for the study.

**What is already known on this topic**

Plantar fasciitis is the most common cause of inferior heel pain

This condition is often managed by corticosteroid injection, although the effectiveness of such treatment is unclear

**What this study adds**

A single ultrasound guided dexamethasone injection is a safe and effective short term treatment for plantar fasciitis

It provides significantly greater pain relief than placebo at four weeks, and reduces abnormal swelling of the plantar fascia for up to three months

Significant pain relief did not, however, continue beyond four weeks

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**Competing interests:** All authors have completed the ICMJE uniform disclosure form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) (available on request from the corresponding author) and declare that AMcM, KBL, MFG, ARB, ADM, and HBM have no relationships with companies that might have an interest in the submitted work in the previous three years; and AMcM, KBL, MFG, ARB, ADM, and HBM have no non-financial interests that may be relevant to the submitted work.

**Ethical approval:** This study was approved by the La Trobe University human ethics committee.

**Data sharing:** The dataset is available from the corresponding author at [a.mcmillan@latrobe.edu.au](mailto:a.mcmillan@latrobe.edu.au).

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## Tables

**Table 1** | Baseline characteristics of participants with plantar fasciitis allocated to ultrasound guided dexamethasone or placebo. Values are means (SDs) unless otherwise stated

| Variable  | Dexamethasone group (n=41) | Placebo group (n=41) |
|---|----------------------------|----------------------|
| Age in years  | 51.7 (11.9)                | 53.6 (9.0)           |
| No (%) of women   | 22 (53.7)                  | 17 (41.5)            |
| Body mass index   | 31.4 (5.5)                 | 30.9 (5.4)           |
| Median (interquartile range) duration of symptoms in months | 9.0 (8.0)                  | 12.0 (11.5)          |
| No (%) of bilateral cases                                   | 12 (29.3)                  | 12 (29.3)            |
| Foot health status questionnaire:                           |                            |                      |
| Pain score at baseline                                      | 36.8 (19.9)                | 35.8 (20.4)          |
| Function score at baseline                                  | 53.4 (25.5)                | 60.2 (25.3)          |
| Plantar fascia thickness in mm at baseline                  | 6.67 (1.53)                | 6.29 (1.20)          |
| First step pain in mm at baseline                           | 62.2 (20.6)                | 60.5 (22.7)          |



**Table 2| Foot pain scores on foot health status questionnaire for participants with plantar fasciitis treated with dexamethasone or placebo**

| Time points | Mean (SD) score     |               | Mean (95% CI) adjusted between group difference* | SE  | P value |
|-------------|---------------------|---------------|--|-----|---------|
|             | Dexamethasone group | Placebo group |  |     |         |
| Baseline    | 36.8 (19.9)         | 35.8 (20.4)   | —  | —   | —       |
| 4 weeks     | 58.9 (24.8)         | 47.5 (24.8)   | 10.9 (1.4 to 20.4)                               | 4.8 | 0.03    |
| 8 weeks     | 62.3 (24.5)         | 56.3 (24.2)   | 5.6 (−4.5 to 15.6)                               | 5.1 | 0.28    |
| 12 weeks    | 65.4 (27.7)         | 59.7 (25.4)   | 5.3 (−5.7 to 16.3)                               | 5.6 | 0.34    |

\*Adjusted for baseline values by the analysis of covariance model.

**Table 3| Plantar fascia thickness in participants with plantar fasciitis treated with dexamethasone or placebo**

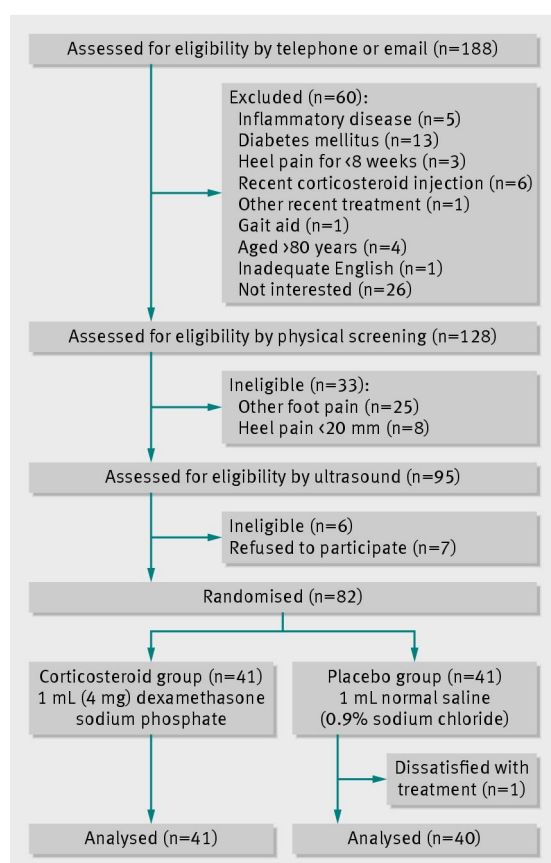
| Time points | Mean (SD) thickness (mm) |               | Mean (95% CI) adjusted between group difference* | SE   | P value |
|-------------|--------------------------|---------------|--|------|---------|
|             | Dexamethasone group      | Placebo group |  |      |         |
| Baseline    | 6.67 (1.53)              | 6.29 (1.20)   | —  | —    | —       |
| 4 weeks     | 6.00 (1.31)              | 6.05 (1.29)   | −0.35 (−0.67 to −0.03)                           | 0.16 | 0.03    |
| 8 weeks     | 5.96 (1.18)              | 6.05 (1.39)   | −0.39 (−0.73 to −0.05)                           | 0.17 | 0.02    |
| 12 weeks    | 5.74 (1.14)              | 5.94 (1.34)   | −0.43 (−0.85 to −0.01)                           | 0.21 | 0.04    |

\*Adjusted for baseline values by the analysis of covariance model.

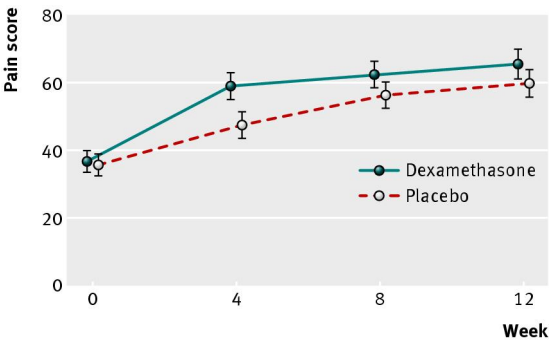
## Figures



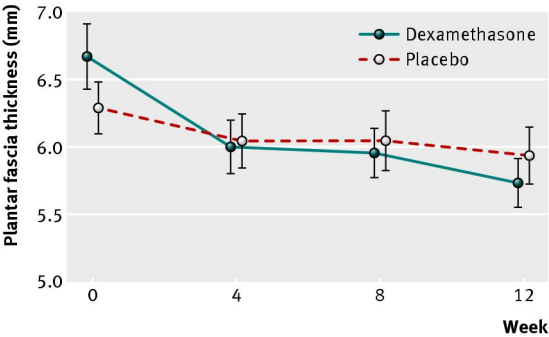
**Fig 1** Ultrasound guided heel injection with medial oblique approach



**Fig 2** Flow of participants through study



**Fig 3** Mean (SE) scores for pain on foot health status questionnaire (0-100 points) in participants with plantar fasciitis treated with corticosteroid (dexamethasone) or placebo (normal saline). High values represent better pain, low values represent worse pain



**Fig 4** Mean (SE) plantar fascia thickness in participants with plantar fasciitis treated with corticosteroid (dexamethasone) or placebo (normal saline)