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Corticosteroid injections compared to foot orthoses for plantar heel pain: protocol for the SOOTHE heel pain randomised trial

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ABSTRACT

Introduction: Corticosteroid injections and foot orthoses are common interventions for plantar heel pain. Previous clinical trials have found that the effectiveness of these interventions differs over time, with corticosteroid injections being more effective in the short-term (i.e. 0–4 weeks) and foot orthoses more effective in the longer-term (i.e. 5–12 weeks). However, some of these trials have methodological weaknesses that could have caused confounding and bias, which may have led to over- or under-estimation of the effectiveness of these interventions. As a result, there is a need to compare the effectiveness of corticosteroid injections and foot orthoses in a robust clinical trial with an appropriate follow-up time.

Methods: This article describes the protocol for a pragmatic, parallel-group assessor-blinded randomised trial (Steroid injection versus foot orthoses (SOOTHE) heel pain trial). One hundred participants with plantar heel pain will be randomly allocated (i.e. two groups of approximately 50) to receive either an ultrasound-guided corticosteroid injection or prefabricated foot orthoses. Outcome measures will be obtained at baseline, 4, 8 and 12 weeks, with two primary endpoints at 4 and 12 weeks to reflect the hypothesised temporal effects of each intervention. The primary outcome measure will be the *foot pain* domain of the Foot Health Status Questionnaire.

Trial registration: Australian and New Zealand Clinical Trials Registry number ACTRN12615001266550.

1. Introduction

Plantar heel pain (PHP) is one of the most common musculoskeletal conditions affecting the lower limb. The worldwide prevalence of PHP in the population is unknown, however it appears to be most common in middle-aged and older people, and in runners. In a sample of the general adult population in Australia who reported foot pain, 21% reported pain in the heel [1]. An investigation of an older sample in the United States found a PHP prevalence of 6.9% [2], and in the United Kingdom, PHP accounts for approximately 7.5% of all musculoskeletal foot and ankle general practice consultations [3]. In a North American study that collected injury data on runners who presented to a sports medicine clinic over a 2-year period, the incidence of PHP was 7.9% and it was the third most common running-related injury reported [4]. PHP causes significant mobility limitation [5,6], and individuals with PHP exhibit poorer health-related quality of life [6].

Corticosteroid injections and foot orthoses are common interventions used to treat PHP [7]. Clinical guidelines published by the *American Physical Therapy Association* [8] recommend foot orthoses as an initial treatment option, while the *American College of Foot and Ankle Surgeons* [9] recommend both corticosteroid injections and foot orthoses as initial treatment options. Previous research indicates that corticosteroid injections are more effective at reducing pain than placebo injections in the short-term (i.e. 4–6 weeks), but the effect is unclear in the longer-term (i.e. 8–12 weeks) [7]. In contrast, trials comparing foot orthoses to sham foot orthoses have reported inconsistent effects in the short-term (i.e.

Abbreviations: PHP, plantar heel pain.

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3–4 weeks) [10,11], but they have found foot orthoses are effective in the longer-term (i.e. at 12 weeks) [12,13]. Based on this research, corticosteroid injections may be more effective in the short-term, while foot orthoses may be more effective in the longer-term. At this stage, corticosteroid injections and foot orthoses have not been directly evaluated in robust randomised trials, and consequently, nor has the temporal difference between the two interventions.

Two randomised trials have compared the effectiveness of corticosteroid injections and foot orthoses, however the findings were inconsistent [14,15]. The trials had methodological shortcomings including high participant attrition [14], use of non-standardised outcome measures, and one trial had a relatively short follow-up period (i.e. 4 weeks) [15]. As a result, there is uncertainty regarding which intervention is more appropriate for health practitioners to recommend to individuals with PHP, or whether one should be recommended for short-term benefit, while the other recommended for longer-term benefit. Given corticosteroid injections and foot orthoses are both common interventions, it is important that health practitioners have robust evidence from which they can make decisions regarding treatment for PHP. Therefore, a high-quality randomised trial is needed to clarify inconsistencies in past research, and provide findings that can be readily adopted by health practitioners.

The primary aim of this study is to compare the effectiveness of corticosteroid injections to foot orthoses for PHP. Specifically, we seek to determine whether corticosteroid injections are more effective at reducing pain in the short-term (i.e. 0–4 weeks) and foot orthoses are more effective at reducing pain in the longer-term (i.e. 5–12 weeks). Our secondary aims are to investigate differences in 'first-step' pain, function, health-related quality of life, and fear-avoidance beliefs over time.

2. Methods

This trial has been registered on the Australian and New Zealand Clinical Trial Registry (ACTRN12615001266550). All publications related to this trial will be reported in accordance with the CONSORT Guidelines for reporting randomised trials [16].

2.1. Design

This study will be a pragmatic, parallel-group assessor-blinded randomised trial. Due to the nature of the interventions, therapists and participants will not be blinded, however the assessor measuring outcomes will be blind to group allocation (i.e. there will be assessor blinding). Fig. 1 displays the flow of participants through the trial. Participants will be allocated to one of two groups:

Group 1 – corticosteroid injection: participants will receive a single ultrasound-guided corticosteroid injection into the affected heel(s) of 1 mL of betamethasone (Celestone®, Merck Sharp and Dohme, Macquarie Park, Australia) mixed with 1 mL of bupivacaine (Marcaine®, AstraZeneca, North Ryde, Australia), a long-acting local anaesthetic.

Group 2 – foot orthoses: participants will receive a pair of Formthotics™ (Footscience International, Christchurch, New Zealand) prefabricated foot orthoses.

Both groups will also be provided a stretching program, written and verbal advice regarding PHP and wearing suitable footwear. Accordingly, the only difference between the two groups is that Group 1 will receive a corticosteroid injection and Group 2 will receive foot orthoses.

2.1.1. Initial appointment

Prior to the initial appointment, potential participants will be screened via telephone to ensure they satisfy inclusion criteria (as outlined in Section 2.5) that can be provided verbally. At the initial appointment, potential participants will be further screened to ensure they satisfy all remaining inclusion criteria requiring assessment (as outlined in Section 2.5). All participants will be provided with a participant information statement and will give informed consent prior to being included into the trial. Following this, participant characteristics such as sex, height, weight, duration of symptoms, foot posture (measured using the Foot Posture Index – 6), medications and major medical conditions will be recorded. Ultrasonography will be performed to assess plantar fascia thickness and the presence of hypoechogenicity. To measure plantar fascia thickness, two measurements will be recorded. A longitudinal scan will measure (i) the maximum thickness in the proximal third of the plantar fascia, and (ii) the thickness of the plantar fascia as it crosses the anterior aspect of the inferior calcaneal border. The measurements will be performed with a variable frequency (5–10 MHz) linear array transducer (Acuson Aspen; Siemens Medical Solutions, PA, USA). Measuring plantar fascia thickness as it crosses the anterior aspect of the inferior calcaneal border has been used previously [17,18] and has good intra-rater reliability (intra-class correlation coefficient = 0.86 [95% CI, 0.77–0.92]) [19]. There is no accepted method of assessing hypoechogenicity, however previous studies have assessed hypoechogenicity as being either present or absent, which has been reported to have moderate intra-rater reliability (Cohen's Kappa ranging between 0.59 and 0.69) [19]. For bilateral cases, the most painful foot will be evaluated to satisfy the assumption of independent data [20]; this method has been used in previous heel pain research [21]. All remaining patient-reported outcome measures will be obtained at this appointment.

2.1.2. Intervention appointment

Following randomisation, participants will attend their second appointment where they will receive their allocated intervention. Participants randomised to the corticosteroid injection group will be referred to a radiologist at a medical imaging centre, who will perform a single ultrasound-guided corticosteroid injection into the affected heel. Participants randomised to the foot orthosis group will be referred to a podiatrist at the La Trobe University Health Sciences Clinic to have the orthoses fitted.

2.2. Randomisation, allocation concealment and blinding

Following the initial appointment for eligibility screening and inclusion into the trial, participants will be randomised to one of two groups. Randomisation and allocation to groups will be conducted using an interactive voice response telephone service provided by the National Health and Medical Research Council (NHMRC) Clinical Trials Centre at the University of Sydney, New South Wales, Australia. Adaptive stratification (i.e. minimisation) will be used to minimise baseline imbalance in the groups (factors to be included are sex, BMI and duration of symptoms), and permuted block randomisation with uneven random block sizes will be undertaken. Participants will be advised of their allocation by a secondary investigator who will not be involved with any other part of the trial. Following allocation, participants will contact one of two therapists (a radiologist for the corticosteroid injection or a podiatrist for the foot orthoses), who will arrange an appointment for the participant to receive the allocated intervention.

Given the nature of the interventions, it is not possible to blind the therapists and participants. However, the therapists will have