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

Glen A. Whittaker [a, b, *], Shannon E. Munteanu [a, b], Hylton B. Menz [a, b], Ayman Elzarka [c], Karl B. Landorf [a, b]

[a] Discipline of Podiatry, School of Allied Health, La Trobe University, Bundoora, Victoria, 3086, Australia
[b] La Trobe Sport and Exercise Medicine Research Centre, La Trobe University, Bundoora, Victoria, 3086, Australia
[c] Southern Cross Medical Imaging, La Trobe Private Hospital, Bundoora, Victoria, 3083, Australia

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.
© 2016 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

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.

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
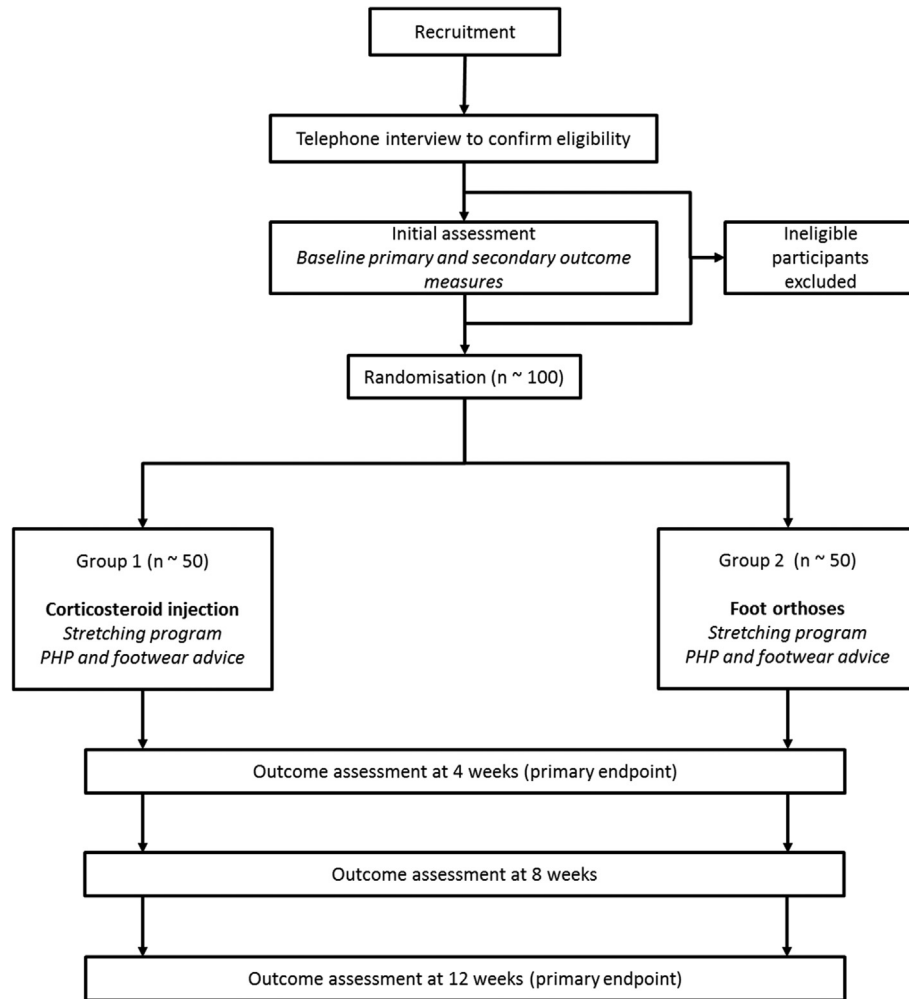
Fig. 1. Study flow diagram.

no knowledge of, or involvement with, any other part of the trial. All outcome assessments will be conducted by the primary investigator (GAW) who will be blind to group allocation. Prior to each outcome assessment, and to minimise the chance of the outcome assessor becoming unblinded, participants will be advised not to discuss their allocated intervention during the follow-up appointments.

2.3. Interventions

2.3.1. Ultrasound-guided corticosteroid injection

Participants randomised to Group 1 will receive a single ultrasound-guided corticosteroid injection from a qualified radiologist (AE). The injection technique will be based on the method used by Yucel et al. [15]. Participants will be placed in a prone position with their feet hanging from the end of the examination table. Following this, an ultrasound probe will be positioned to scan the fascia longitudinally and then a 25-gauge needle will be inserted through the medial heel approximately 1 cm above the weightbearing line of the skin (Fig. 2). A solution of 1 mL of a combination of betamethasone acetate and betamethasone sodium phosphate (Celestone® Chondrose) mixed with 1 mL of bupivacaine

(Marcaine® 0.5%) will be injected. Infiltration will be directed to the region surrounding the area of maximum plantar fascia thickening (i.e. there will be no infiltration into the plantar fascia itself) and aseptic technique will be maintained throughout the procedure. Prior to leaving the radiological clinic, participants will be advised to avoid running and high impact activities for two weeks. Participants with bilateral PHP will have both feet treated, and will receive the second injection the following day to ensure that there are no significant adverse events associated with the initial injection.

2.3.2. Foot orthoses

Participants randomised to Group 2 will receive a pair (i.e. one for each foot) of Formthotics™ prefabricated foot orthoses (Fig. 3). The style of Formthotics™ provided will be full length, and manufactured from a dual-density polyethylene closed cell foam that has a firm-density bottom layer (Shore-A durometer 50), and a soft-density top layer (Shore-A durometer 25). Participants will receive the foot orthoses in accordance with the manufacturer's instructions. The foot orthoses are initially heated and then placed in the participants' footwear. Once positioned correctly, the participants will then be asked to stand on the orthoses in a 'corrected'
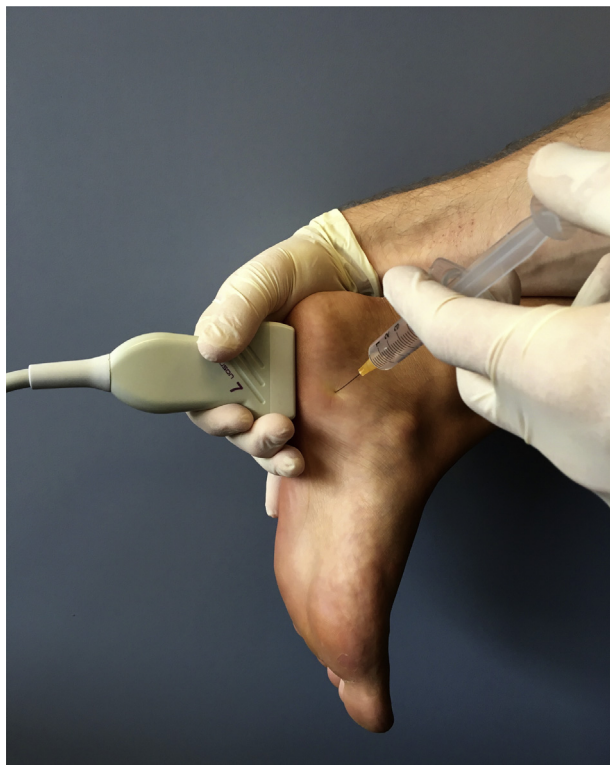
Fig. 2. Technique for administering the ultrasound-guided corticosteroid injection.

position (i.e. talo-navicular congruent position) to allow the orthoses to mould to the foot. This type of foot orthosis is an arch-contouring device that has been used in previous PHP research [12,22]. The foot orthoses will be fitted based on the participant's foot and shoe size. Any necessary adjustments to ensure correct fitting will be made during the treatment appointment.

2.3.3. Interventions provided to both groups

2.3.3.1. Stretching program. In addition to the experimental interventions provided (corticosteroid injection to Group 1 and foot orthoses to Group 2), participants in both groups will receive plantar fascia and calf stretches, which are regarded as 'usual care' and a common co-intervention in PHP research [17,23—27]. The stretching program will be based on the program evaluated by DiGiovanni et al. [28]. For the plantar fascia stretches, prior to

standing in the morning, the participant will cross their foot over their contralateral knee, dorsiflex their toes and ankle, and then hold the stretch (Fig. 4a). The calf stretches will be performed immediately after rising in the morning, and involve placing one foot directly behind the contralateral limb while leaning into a wall (Fig. 4b and c). Both the plantar fascia and calf stretches will be performed daily for a duration of 10 s and repeated 10 times.

2.3.3.2. Plantar heel pain and footwear education. Participants in both groups will receive education on PHP and wearing appropriate footwear (e.g. appropriately fitting footwear, suitable fixation, cushioning). Education will be provided verbally, and with a handout explaining PHP (Appendix A.1).

2.4. Outcome measures

Outcome measures will be obtained at baseline, 4, 8 and 12 weeks. The trial will have two primary endpoints at 4 and 12 weeks. Two primary endpoints (4 and 12 weeks) have been selected to ascertain if either of the interventions is more effective in the short-term or longer-term. To reduce the burden on participants in the trial, outcome measures will be either posted or emailed for the 8-week follow-up, and therefore, there will be no requirement for participants to attend in person. As a result, no ultrasound outcome measures will be reported at 8 weeks. Participants with bilateral PHP will be instructed to complete patient-reported outcome measures with respect to the most painful foot.
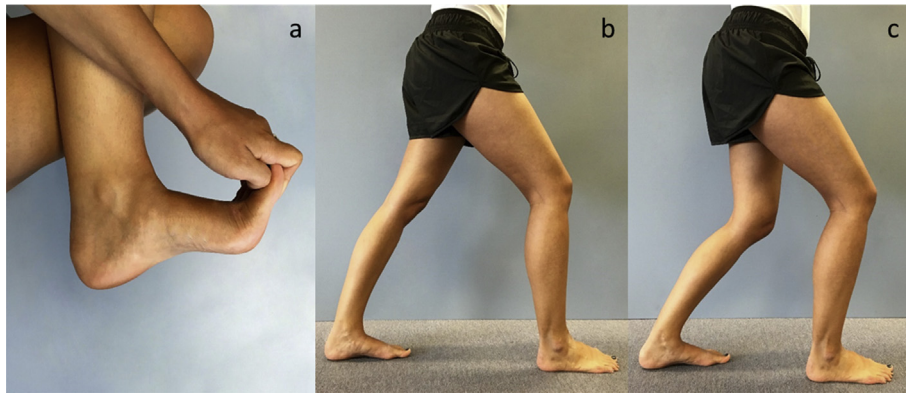
2.4.1. Primary outcome measure

The primary outcome measure will be the *foot pain* domain of the Foot Health Status Questionnaire (FHSQ) [29]. The FHSQ is a 13-item questionnaire used to evaluate foot-specific health-related quality of life. It has four domains or sub-scales (foot pain, foot function, footwear, and general foot health). The questionnaire uses a Likert scale format for participants to indicate their foot health from one (e.g. 'none') to five (e.g. 'severe'). The *foot pain* domain contains four questions that measure the type, frequency and intensity of pain over the previous week. The FHSQ has been shown to be valid (content, criterion and construct), have high test-retest reliability (intra-class correlation coefficients ranging from 0.74 to 0.92), and a high degree of internal consistency (Cronbach's α ranging from 0.85 to 0.88) [29]. In addition, the minimal important difference has been calculated for the *foot pain* domain in participants with PHP [30]. The FHSQ has been used in previous trials investigating interventions for PHP [12,17,21], and a recent review recommended its use in PHP research [8].
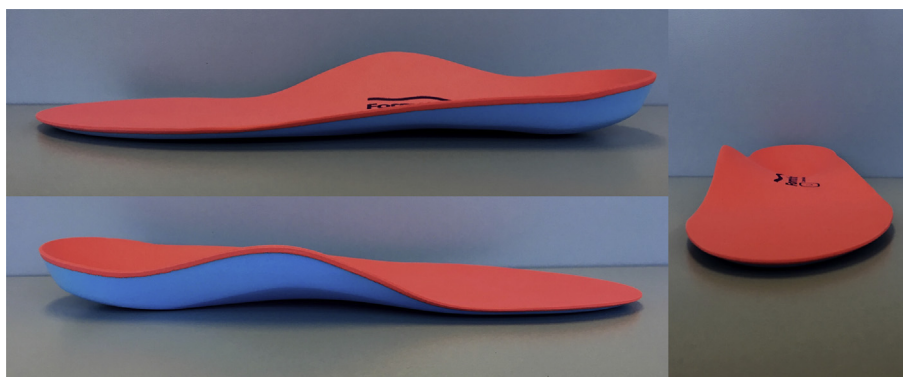
Fig. 3. Formthotics™ dual-density prefabricated foot orthosis.

Fig. 4. Plantar fascia and calf stretches: (a) plantar fascia stretch; (b) calf stretch with knee extended; (c) calf stretch with knee flexed.

2.4.2. Secondary outcome measures

Secondary outcome measures will be used to assess other issues related to pain, function (i.e. foot-related disability), and understand factors that may predict clinical outcome. These include:

(i) Severity of 'first step' pain and average pain over the last seven days, measured on a 100 mm visual analogue scale (VAS) at baseline, 4, 8 and 12 weeks;
(ii) Foot function measured on the *foot function* domain of the FHSQ [29] at baseline, 4, 8 and 12 weeks;
(iii) Plantar fascia thickness measured sonographically [17,18] at baseline, 4 and 12 weeks;
(iv) Plantar fascia hypoechogenicity measured sonographically [19] at baseline, 4 and 12 weeks;
(v) Generic health-related quality of life will be measured with the EQ-5D questionnaire [31] at baseline, 4, 8 and 12 weeks;
(vi) Generic health-related quality of life will also be measured with the Short Form 36® version 2 (SF-36) [32] at baseline, 4, 8 and 12 weeks;
(vii) Self-reported physical activity measured using the 7-day Physical Activity Recall Questionnaire [33] at baseline, 4, 8 and 12 weeks;
(viii) Fear-avoidance beliefs measured using the Fear-avoidance Components Scale (FACS) [34] measured at baseline, 4, 8 and 12 weeks;
(ix) Global perceived rating of change measured with a 15-point Likert scale at 4, 8 and 12 weeks;
(x) Days of work lost over the previous week due to PHP measured at baseline, 4, 8 and 12 weeks;
(xi) Sessions of sports or exercise lost over the previous week measured at baseline, 4, 8 and 12 weeks;
(xii) Use of co-interventions for foot pain measured at 4, 8 and 12 weeks;
(xiii) The participant's preference for treatment (i.e. corticosteroid injection, foot orthoses or no preference), which will be asked at baseline [35].

2.5. Participants

Participants will be adults aged 18 years or older, who are living independently in the community. Table 1 outlines the inclusion and exclusion criteria for the study. Participants will be recruited through advertisements in local newspapers and magazines, posters placed at universities, health clubs and senior citizen centres, web-based advertising on health noticeboards and forums,

and social media (e.g. Facebook, Twitter).

2.6. Ethical approval

Ethical approval will be obtained prior to the trial commencing from the La Trobe University Human Ethics Committee. The trial will adhere to the National Health and Medical Research Council's Statement on Ethical Conduct in Human Research [37], and all participants will sign informed consent prior to inclusion in the trial.

2.7. Adverse effects

Adverse effects at the time of the corticosteroid injection will be managed and recorded in line with standard medical practice by the radiologist administering the injection. Other adverse effects, such as additional foot pain due to wearing foot orthoses or pain related to the injection, will be recorded at each time-point (i.e. 4, 8 and 12 weeks). Participants will be asked to document the type of adverse effect, and the frequency or severity of the effect. If participants experience more significant adverse effects (e.g. infection) they will be advised to contact one investigator who is not involved in recruitment, allocation or data collection (SEM or KBL). Any adverse effects will be reported in the final manuscript.

2.8. Evaluation of adherence

The evaluation of adherence will be assessed during the outcome assessments at 4, 8 and 12 weeks. Adherence to the foot orthoses will be documented, with participants being asked how many days they have worn their foot orthoses over the last week, and for how many hours each day. Both groups will also be asked to document how many days over the last week they have performed the plantar fascia and calf stretches, and whether they have changed their footwear since their last outcome assessment.

2.9. Sample size

The sample size for the trial has been determined using an *a priori* power analysis based on the primary outcome measure, the *foot pain* domain of the Foot Health Status Questionnaire (FHSQ) [29] at week 12. The minimal important difference for this measure in individuals with PHP has previously been determined as 12.5 points [30]. Using a standard deviation derived from previous PHP research of 21 [17,38], a power level of 0.8, alpha level of 0.05, and a

Table 1
Inclusion and exclusion criteria.

Inclusion criteria
(i) Aged 18 years or older;
(ii) Have a clinical diagnosis of PHP in accordance with the clinical practice guidelines linked to the International Classification of Function, Disability and Health from the Orthopaedic Section of the American Physical Therapy Association [8], which includes:
a. Pain in the plantar medial heel region that is aggravated by weightbearing activities or worse in the morning and/or after a period of rest;
b. Pain upon palpation of the medial calcaneal tubercle;
(iii) A duration of PHP of at least 4 weeks;
(iv) Report their average pain over the last seven days as at least 30 mm on a 100 mm VAS [36];
(v) Be willing to regularly wear foot orthoses for the duration of the trial;
(vi) Be willing and have no contraindications to receive a corticosteroid injection in the plantar heel;
(vii) Be willing to attempt to not use any other forms of treatment during the trial (with the exception of paracetamol up to 4 g/day).

Exclusion criteria
(i) Unable to understand the English language;
(ii) Unable to walk household distances unaided;
(iii) Have received treatment for PHP in the last 4 weeks;
(iv) Have received a corticosteroid injection in the previous six months;
(v) Have regularly worn foot orthoses within the previous six months;
(vi) Have a history of surgery to the heel;
(vii) Have a systemic medical condition such as a connective tissue disease, degenerative neurological disorder or inflammatory disorder;
(viii) Currently pregnant or likely to become pregnant during the trial;
(ix) Unwilling to regularly wear footwear that can accommodate foot orthoses.

conservative drop-out rate of 10% (in our previous randomised trials for PHP, this has typically been <5%) [12,17,39,40], a sample size of 100 participants (i.e. approximately 50 per group) will be required for adequate statistical power. We have conservatively ignored the extra precision provided by covariate analysis when estimating the sample size. This sample size will also be sufficient to: (i) explain the variance in the *foot pain* domain of the FHSQ at baseline, and (ii) predict improvement in the *foot pain* domain of the FHSQ between baseline and 12 weeks.

2.10. Data analysis

Statistical analysis will be undertaken using SPSS version 22.0 (IBM Corp, NY, USA). All analyses will follow the intention-to-treat principle [16] for all randomised participants, and missing data will be accounted for using multiple imputation, with age, BMI, baseline scores and group allocation entered as predictors [41]. 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 PHP research [21]. Standard tests of the distribution of continuous data will be undertaken, and transformations applied to skewed data if appropriate. If data are not normally distributed and cannot be transformed, they will be handled non-parametrically.

The differences between the two groups for primary and secondary outcome measures will be analysed at 4, 8 and 12 weeks, with 4 and 12 weeks being the primary endpoints. The primary endpoints have been chosen to allow investigation of the primary aim of the trial; that is, that there may be temporal differences in the effectiveness of the two interventions. Continuous data will be analysed using a regression approach to analysis of covariance (ANCOVA) with the baseline score for each continuous outcome measure used as a covariate [42,43]. For example, for comparisons of pain at each of the time-points, adjustments will be made for pain at baseline. Dichotomous outcomes will be compared using risk ratios and number needed to treat where appropriate. All comparisons for outcome measures will be reported as point estimates with 95% confidence intervals and *p*-values.

3. Discussion

The primary aim of this randomised trial is to compare the effectiveness of corticosteroid injections to foot orthoses for individuals with PHP. This trial has been pragmatically designed to inform health practitioners about the effectiveness of the interventions in the short-term (i.e. 0—4 weeks) and longer-term (i.e. 5—12 weeks).

It is important to explore the effectiveness between corticosteroid injections and foot orthoses as they are both common interventions used to treat individuals with PHP, and previous trials comparing these interventions have reported inconsistent findings with respect to pain and function [14,15]. The first trial conducted by Lynch et al. [14], was a three group trial comparing: (i) a corticosteroid injection (dexamethasone acetate) plus an oral non-steroidal anti-inflammatory drug, (ii) customised foot orthoses plus taping, and (iii) a viscoelastic heel cup. The authors completed their final follow-up at 12 weeks and concluded that customised foot orthoses were more effective than either the corticosteroid injection or the viscoelastic heel cup. However, this trial exhibited substantial participant attrition, with only 57% of participants providing outcome data at 12 weeks, and the investigators did not employ an intention-to-treat analysis. In addition, it is unclear what specific effect the corticosteroid injection had on pain reduction as the corticosteroid injection was provided in conjunction with an oral non-steroidal anti-inflammatory drug that was not provided to participants in the other groups.

The second trial by Yucel et al. [15] compared a corticosteroid injection (reported as a combined betamethasone, trade-name Kenakort-A Retard® manufactured by Bristol-Myers Squibb) to a silicone prefabricated foot orthosis. The trial found a greater reduction in VAS pain, plantar fascia thickness, and Foot and Ankle Outcome Scores (FAOS) for *pain*, *sport and recreation*, and *activities of daily living* in the group receiving the corticosteroid injection. However, this trial's primary endpoint was 4 weeks (i.e. short-term only).

Four additional randomised trials [17,18,44,45] have evaluated corticosteroid injections against either a placebo or another type of injection. Similar to the Yucel et al. trial [15], three of these trials found a significant reduction in pain in the short-term (i.e. 4 weeks)

for individuals receiving a corticosteroid injection, but this reduction was not maintained after 4 weeks [17,44,45]. In contrast, the fourth trial by Ball et al. [18] found a sustained effect of a corticosteroid injection (methylprednisolone acetate) compared to placebo (saline) at both 6 and 12 weeks. The inconsistencies observed in these trials may have been due to the type of corticosteroid used, with acetates (e.g. methylprednisolone acetate) tending to have a longer duration of action than phosphates (e.g. betamethasone sodium phosphate) [46].

In addition to evaluating the effectiveness of these interventions reducing pain, previous trials have also evaluated the effectiveness of foot orthoses and corticosteroid injections at improving function. Three randomised trials have found improvements in function [11–13], and the most recent systematic review concluded customised foot orthoses are more effective than sham foot orthoses at improving function up to 12 months [7]. However, there has been limited research evaluating the effectiveness of corticosteroid injections to improve function. McMillan et al. [17] included function as a secondary outcome, finding no difference between a corticosteroid injection and a placebo injection. Two previous trials that compared corticosteroid injections to foot orthoses [14,15] included function as an outcome measure, but the findings were inconsistent between the trials. Lynch et al. [14] assessed the effect of corticosteroid injections and foot orthoses on *leisure*, *work*, and *exercise*, however no information was provided on how these were assessed and whether it was valid. They found no significant difference in these functional outcomes between the corticosteroid injection and foot orthosis groups at 12 weeks. In contrast, Yucel et al. [15] used the validated Foot and Ankle Outcome Score (FAOS) to assess function and health-related quality of life. After 4 weeks, FAOS *activities of daily living* and *sport and recreation* subscales improved more in the corticosteroid injection group than the foot orthosis group. Although, Yucel at al [15] used a validated outcome measure to assess function, the endpoint was 4 weeks, compared to the endpoint for Lynch et al. [14] trial being 12 weeks, which makes comparison between the two difficult. Given individuals with PHP report significant foot-related disability [5,6,47], it is important to better understand the influence of these interventions on function.

Regarding the experimental interventions that will be evaluated in this trial, an ultrasound-guided corticosteroid injection using betamethasone sodium phosphate combined with betamethasone acetate has been selected. There is no consensus for the most suitable corticosteroid to use for soft tissue injections, and differences in corticosteroid preference have been reported between practitioners [48]. Rheumatology guidelines published in Australia recommend two corticosteroids - betamethasone sodium phosphate combined with betamethasone acetate, or triamcinolone acetonide [49]. Betamethasone sodium phosphate combined with betamethasone acetate has been selected for use in this trial due to the combination of a long-acting acetate, which will increase potency, and a short-acting sodium phosphate which will increase solubility. This combination will balance the potency required for an anti-inflammatory action [46], against greater solubility which will decrease the likelihood of adverse effects such as plantar fascia rupture or fat pad atrophy [50]. An ultrasound-guided injection has been chosen as ultrasound-guided injections have been found to be more effective than palpation guided injections [51].

The type of foot orthoses selected for this trial are prefabricated arch-contouring devices rather than customised foot orthoses. Prefabricated foot orthoses have been demonstrated to have similar effectiveness to customised foot orthoses for PHP [52,53]. No research has investigated what features of foot orthoses are more effective for PHP, however a few studies have investigated kinetic (i.e. plantar pressure) changes using different foot orthoses. Arch-contouring devices have been shown to reduce peak plantar pressure and maximum force at the plantar heel [22,54], and there is some evidence to show that they reduce plantar fascia strain [55,56]. Based on this previous research, the Formthotics™ used in this trial, which are arch contouring devices, will serve to reduce both plantar fascia strain and vertical ground reaction forces at the plantar heel. In addition, the prefabricated foot orthosis selected has been used in previous PHP research [12,22,54].

The additional standard care interventions (i.e. stretching program) provided to both groups have been selected to reflect clinical practice, and allow the results to be generalisable. Plantar fascia and calf stretches are commonly provided by a wide variety of health practitioners, there is no associated cost, and they have been demonstrated to be effective for PHP [28,40,57]. A number of randomised trials investigating PHP have provided stretches to participants in both groups [17,23–27], and to reflect common clinical practice, these standard stretches will be provided to both groups in our trial.

4. Conclusions

This article outlines the protocol for an assessor-blinded, parallel-group randomised trial to compare the effectiveness of a single corticosteroid injection to foot orthoses for PHP. The trial has been designed to specifically investigate whether there are temporal differences between the interventions (e.g. a corticosteroid injection is more effective in the short-term and a foot orthosis is more effective in the longer-term). In addition, the trial will also assess variables that may predict clinical outcome. Finally, the pragmatic design of the trial, including a representative community-based recruitment process and commonly implemented interventions, will reflect everyday practice and ensure that the findings are generalisable.

Conflict of interest

The authors declare they have no actual or potential conflict of interest including financial, personal or other relationships that could influence or perceive to influence the conduct of this trial.

Appendix A

A.1 Heel pain handout

Plantar fascia and calf stretching

Stretching is one of the most important treatment strategies for plantar heel pain, and has been shown to be very effective.

Before standing in the morning, cross your foot over your leg, pull back your ankle and toes, and hold the stretch for 10 seconds. Repeat this 10 times before standing. Repeat this as many times throughout the day as you need.

To perform the calf stretches, place your hands on a wall in front of you, then take a step backward so your feet are straight ahead and both heels are on the ground.

Hold a stretch of your calf for 10 seconds, and repeat this 3 times. Do this 3 times per day.

You should do one stretch with your back knee straight (a), and one with your back knee bent (b).

a   b
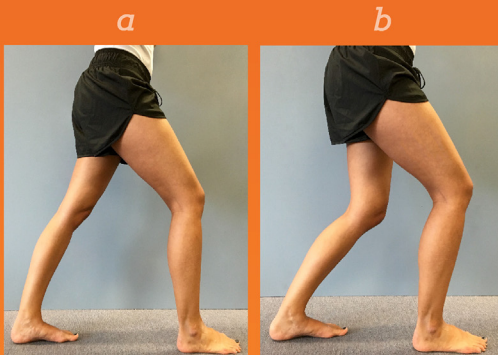
Suitable footwear

Suitable footwear to reduce plantar heel pain consists of shoes that are well-fitted, with suitable fastening (e.g. laces). Suitable fastening is important, and will prevent the toes from clawing in an attempt to stop loose fitting footwear from slipping off.

Avoid wearing low-heeled footwear such as flip flops, ballet flats or walking barefoot. Try to wear footwear with a mild heel lift (i.e. less than 2 cm) and footwear with some cushioning (i.e. runners). Try to avoid hard soled footwear.

This type of footwear will reduce the pressure on the sole of the heel and on the plantar fascia.

Reduce time spent standing and activity levels

Reducing activity levels and the amount of time you spend standing, especially standing on hard floors, will provide an opportunity for the tissue under your foot to heal. It is important that you maintain some activity level and continue exercising, however modifying your activity to reduce pressure on your heel will allow for faster recovery.

Try to avoid high impact activities such as running, jumping or squatting, and activities that require long periods of standing.

Modifying activity to include swimming, cycling or non-weightbearing weights, will allow for continued exercise.

Content provided by Glen Whittaker, La Trobe University
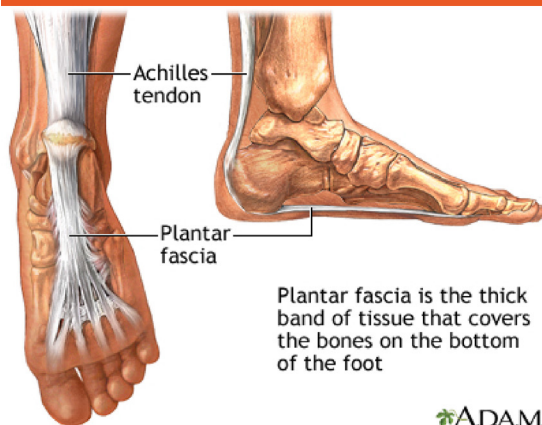
Illustration credit: A.D.A.M. Interactive Anatomy

LA TROBE UNIVERSITY

PLANTAR HEEL PAIN

SOOTHE Heel Pain Trial

LA TROBE UNIVERSITY

WHAT IS PLANTAR HEEL PAIN?

Achilles tendon

Plantar fascia

Plantar fascia is the thick band of tissue that covers the bones on the bottom of the foot

✿A.D.A.M.

Plantar heel pain refers to pain on the sole of the heel, that primarily involves a ligament-like structure that runs under the bottom of the foot called the plantar fascia. This condition is also known as plantar fasciitis or heel spurs. It is one of the most common conditions affecting the foot, and is more common in middle-aged people and athletes.

Those suffering plantar heel pain will have a sharp pain upon first standing in the morning or after a period or rest, which will reduce with continued walking. This pain may return at the end of the day, especially after being very active.

CAUSES AND RISKS

The cause of plantar heel pain is unknown, but there are two main theories. The first is that increased pressure from the ground compresses the tissues under the heel, causing pain. The second is that there is increased stress on the plantar fascia, and this causes pain at the spot where it inserts on the heel bone.

Despite the unknown cause, there are certain known risk factors for getting plantar heel pain, which include:

- Being overweight;
- Increased number of hours spent standing;
- Decreased ankle joint range of motion;

Some people will experience plantar heel pain that is not caused by problems with the plantar fascia. These may include:

- Nerve impingement;
- Injury to the fat pad under the heel;
- Thickened tissue called a plantar fibroma;
- Inflammatory conditions such as rheumatoid arthritis.

TREATMENT

Treatment involves a step-wise progression through treatment options, starting with simple non-invasive treatment and progressing to complex invasive treatment such as surgery. Most people will find simple treatments are sufficient to reduce their pain.

If you visit a health practitioner, they may provide treatment such as taping, foot orthoses, extracorporeal shockwave therapy, night splints or corticosteroid injections.

Self-care is equally, if not more important than the treatment provided by a health practitioner. Self-care treatment includes:

- **Weight reduction;**
- **Plantar fascia and calf stretching;**
- **Wearing suitable footwear;**
- **Reducing time spent standing and activity levels.**

Weight reduction

People often experience plantar heel pain after an increase in weight, and those who are overweight are at greater risk of having plantar heel pain. Reducing weight can help alleviate the pressure on the bottom of the heel, which will aid in healing and reduce pain. It can be difficult for some people to reduce their weight, so speaking with a General Practitioner, Dietitian or Exercise Physiologist may be helpful to get proper advice .

References

[1] C.L. Hill, T.K. Gill, H.B. Menz, A.W. Taylor, Prevalence and correlates of foot pain in a population-based study: the North west Adelaide health study, J. Foot Ankle Res. 1 (2008) 1–7, http://dx.doi.org/10.1186/1757-1146-1-2.

[2] J. Dunn, C. Link, D. Felson, M. Crincoli, J. Keysor, J. McKinlay, Prevalence of foot and ankle conditions in a multiethnic community sample of older adults, Am. J. Epidemiol. 159 (2004) 491–498, http://dx.doi.org/10.1093/aje/kwh071.

[3] H.B. Menz, K.P. Jordan, E. Roddy, P.R. Croft, Characteristics of primary care consultations for musculoskeletal foot and ankle problems in the UK, Rheumatol. Oxf. 49 (2010) 1391–1398, http://dx.doi.org/10.1093/rheumatology/keq092.

[4] J.E. Taunton, M.B. Ryan, D. Clement, D.C. McKenzie, D. Lloyd-Smith, B. Zumbo, A retrospective case-control analysis of 2002 running injuries, Br. J. Sports Med. 36 (2002) 95–101, http://dx.doi.org/10.1136/bjsm.36.2.95.

[5] D.L. Riddle, M. Pulisic, K. Sparrow, Impact of demographic and impairment-related variables on disability associated with plantar fasciitis, Foot Ankle Int. 25 (2004) 311–317, http://dx.doi.org/10.1177/107110070402500506.

[6] D.B. Irving, J.L. Cook, M.A. Young, H.B. Menz, Impact of chronic plantar heel pain on health-related quality of life, J. Am. Podiatr. Med. Assoc. 98 (2008) 283–289, http://dx.doi.org/10.7547/0980283.

[7] K.B. Landorf, Plantar heel pain and plantar fasciitis. Systematic review 1111, BMJ Clin. Evid. (2015/11/27) ed2015, http://clinicalevidence.bmj.com/x/systematic-review/1111/overview.html.

[8] R.L. Martin, T.E. Davenport, S.F. Reischl, T.G. McPoil, J.W. Matheson, D.K. Wukich, et al., Heel pain-plantar fasciitis: revision 2014, J. Orthop. Sports Phys. Ther. 44 (2014) A1–A33, http://dx.doi.org/10.2519/jospt.2014.0303.

[9] J.L. Thomas, J.C. Christensen, S.R. Kravitz, R.W. Mendicino, J.M. Schuberth, J.V. Vanore, et al., The diagnosis and treatment of heel pain: a clinical practice guideline-revision 2010, J. Foot Ankle Surg. 49 (2010) S1–S19, http://dx.doi.org/10.1053/j.jfas.2010.01.001.

[10] M. Walther, B. Kratschmer, J. Verschl, C. Volkering, S. Altenberger, S. Kriegelstein, et al., Effect of different orthotic concepts as first line treatment of plantar fasciitis, J. Foot Ankle Surg. 19 (2013) 103–107, http://dx.doi.org/10.1016/j.fas.2012.12.008.

[11] J.S. Wrobel, A. Fleischer, R.T. Crews, B. Jarrett, B. Najafi, A randomized controlled trial of custom foot orthoses for the treatment of plantar heel pain, J. Am. Podiatr. Med. Assoc. 104 (2015) 281–294, http://dx.doi.org/10.7547/13-122.1.

[12] K.B. Landorf, A.-M. Keenan, R.D. Herbert, Effectiveness of foot orthoses to treat plantar fasciitis: a randomized trial, Arch. Intern Med. 166 (2006) 1305–1310.

[13] H.A. Oliveira, A. Jones, E. Moreira, F. Jennings, J. Natour, Effectiveness of total contact insoles in patients with plantar fasciitis, J. Rheumatol. 42 (2015) 870–878, http://dx.doi.org/10.3899/jrheum.140429.

[14] D.M. Lynch, W. Goforth, J. Martin, R. Odom, C. Preece, M. Kotter, Conservative treatment of plantar fasciitis. A prospective study, J. Am. Podiatr. Med. Assoc. 88 (1998) 375–380, http://dx.doi.org/10.7547/87507315-88-8-375.

[15] U. Yucel, S. Kucuksen, H.T. Cingoz, E. Anliacik, O. Ozbek, A. Salli, et al., Full-length silicone insoles versus ultrasound-guided corticosteroid injection in the management of plantar fasciitis: a randomized clinical trial, Prosthet. Orthot. Int. 37 (2013) 471–476, http://dx.doi.org/10.1177/0309364613478328.

[16] K.F. Schulz, D.G. Altman, D. Moher, CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials, BMJ 340 (2010), http://dx.doi.org/10.1136/bmj.c332.

[17] A.M. McMillan, K.B. Landorf, M.F. Gilheany, A.R. Bird, A.D. Morrow, H.B. Menz, Ultrasound guided corticosteroid injection for plantar fasciitis: randomised controlled trial, BMJ 344 (2012) e3260, http://dx.doi.org/10.1136/bmj.e3260.

[18] E.M. Ball, H.M. McKeeman, C. Patterson, J. Burns, W.H. Yau, O.A. Moore, et al., Steroid injection for inferior heel pain: a randomised controlled trial, Ann. Rheum. Dis. 72 (2013) 996–1002, http://dx.doi.org/10.1136/annrheumdis-2012-201508.

[19] J.-W. Cheng, W.-C. Tsai, T.-Y. Yu, K.-Y. Huang, Reproducibility of sonographic measurement of thickness and echogenicity of the plantar fascia, J. Clin. Ultrasound 40 (2012) 14–19, http://dx.doi.org/10.1002/jcu.20903.

[20] H.B. Menz, Two feet, or one person? Problems associated with statistical analysis of paired data in foot and ankle medicine, Foot Edinb. 14 (2004) 2–5, http://dx.doi.org/10.1016/S0958-2592(03)00047-6.

[21] M.P. Cotchett, S.E. Munteanu, K.B. Landorf, Effectiveness of trigger point dry needling for plantar heel pain: a randomized controlled trial, Phys. Ther. 94 (2014) 1083–1094, http://dx.doi.org/10.2522/ptj.20130255.

[22] D.R. Bonanno, K.B. Landorf, H.B. Menz, Pressure-relieving properties of various shoe inserts in older people with plantar heel pain, Gait Posture 33 (2011) 385–389, http://dx.doi.org/10.1016/j.gaitpost.2010.12.009.

[23] G. Pfeffer, P. Bacchetti, J. Deland, A. Lewis, R. Anderson, W. Davis, et al., Comparison of custom and prefabricated orthoses in the initial treatment of proximal plantar fasciitis, Foot Ankle Int. 20 (1999) 214–221, http://dx.doi.org/10.1177/107110079902000402.

[24] E.S. Dimou, J.W. Brantingham, T. Wood, A randomized, controlled trial (with blinded observer) of chiropractic manipulation and achilles stretching vs. orthotics for the treatment of plantar fasciitis, J. Am. Chiropr. Assoc. 41 (2004) 32–42.

[25] T.G. Lee, T.S. Ahmad, Intralesional autologous blood injection compared to corticosteroid injection for treatment of chronic plantar fasciitis. A prospective, randomized, controlled trial, Foot Ankle Int. (28) (2007) 984–990, http://dx.doi.org/10.3113/FAI.2007.0984.

[26] M. Ryan, J. Hartwell, S. Fraser, R. Newsham-West, J. Taunton, Comparison of a physiotherapy program versus dexamethasone injections for plantar fasciopathy in prolonged standing workers: a randomized clinical trial, Clin. J. Sport Med. 24 (2014) 211–217, http://dx.doi.org/10.1097/JSM.0000000000000021.

[27] J.M. Greve, M.V. Grecco, P.R. Santos-Silva, Comparison of radial shockwaves and conventional physiotherapy for treating plantar fasciitis, Clin. Sao Paulo 64 (2009) 97–103, http://dx.doi.org/10.1590/S1807-59322009000200006.

[28] B.F. DiGiovanni, D.A. Nawoczenski, M.E. Lintal, E.A. Moore, J.C. Murray, G.E. Wilding, et al., Tissue-specific plantar fascia-stretching exercise enhances outcomes in patients with chronic heel pain: a prospective, randomized study, J. Bone Jt. Surg. Am. 85A (2003) 1270–1277.

[29] P.J. Bennett, C. Patterson, S. Wearing, T. Baglioni, Development and validation of a questionnaire designed to measure foot-health status, J. Am. Podiatr. Med. Assoc. 88 (1998) 419–428, http://dx.doi.org/10.7547/87507315-88-9-419.

[30] K.B. Landorf, J.A. Radford, S. Hudson, Minimal Important Difference (MID) of two commonly used outcome measures for foot problems, J. Foot Ankle Res. 3 (2010) 1–6, http://dx.doi.org/10.1186/1757-1146-3-7.

[31] R. Rabin, Fd Charro, EQ-SD: a measure of health status from the EuroQol Group, Ann. Med. 33 (2001) 337–343, http://dx.doi.org/10.3109/07853890109002087.

[32] C.A. McHorney, J.E. Ware Jr., A.E. Raczek, The MOS 36-item short-form health survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs, Med. Care 31 (1993) 247–263, http://dx.doi.org/10.1097/00005650-199303000-00006.

[33] J.F. Sallis, W.L. Haskell, P.D. Wood, S.P. Fortmann, T. Rogers, S.N. Blair, et al., Physical activity assessment methodology in the Five-City Project, Am. J. Epidemiol. 121 (1985) 91–106.

[34] R. Neblett, T.G. Mayer, M.M. Hartzell, M.J. Williams, R.J. Gatchel, The Fear-avoidance Components Scale (FACS): development and psychometric evaluation of a new measure of pain-related fear avoidance, Pain Pract. (2015), http://dx.doi.org/10.1111/papr.12333 epub 31 Jul 2015.

[35] D.J. Torgerson, J. Klaber-Moffett, I.T. Russell, Patient preferences in randomised trials: threat or opportunity? J. Health Serv. Res. Policy 1 (1996) 194–197, http://dx.doi.org/10.1177/135581969600100403.

[36] D.R. Bonanno, G.S. Murley, S.E. Munteanu, K.B. Landorf, H.B. Menz, Foot orthoses for the prevention of lower limb overuse injuries in naval recruits: study protocol for a randomised controlled trial, J. Foot Ankle Res. 8 (2015), http://dx.doi.org/10.1186/s13047-015-0109-2.

[37] National Health and Medical Research Council, National Statement on Ethical Conduct in Human Research - Updated March 2014, Commonwealth of Australia, Canberra, 2007.

[38] K.B. Landorf, A.M. Keenan, R.D. Herbert, Effectiveness of foot orthoses to treat plantar fasciitis: a randomized trial, Arch. Intern Med. 166 (2006) 1305–1310, http://dx.doi.org/10.1001/archinte.166.12.1305.

[39] J.A. Radford, K.B. Landorf, R. Buchbinder, C. Cook, Effectiveness of low-Dye taping for the short-term treatment of plantar heel pain: a randomised trial, BMC Musculoskelet. Disord. 7 (2006), http://dx.doi.org/10.1186/1471-2474-7-64.

[40] J.A. Radford, K.B. Landorf, R. Buchbinder, C. Cook, Effectiveness of calf muscle stretching for the short-term treatment of plantar heel pain: a randomised trial, BMC Musculoskelet. Disord. 8 (2007), http://dx.doi.org/10.1186/1471-2474-8-36.

[41] J.A.C. Sterne, I.R. White, J.B. Carlin, M. Spratt, P. Royston, M.G. Kenward, et al., Multiple imputation for missing data in epidemiological and clinical research: potential and pitfalls, BMJ 338 (2009), http://dx.doi.org/10.1136/bmj.b2393.

[42] J. Twisk, K. Proper, Evaluation of the results of a randomized controlled trial: how to define changes between baseline and follow-up, J. Clin. Epidemiol. 57 (2004) 223–228, http://dx.doi.org/10.1016/j.jclinepi.2003.07.009.

[43] G.M. Raab, S. Day, J. Sales, How to select covariates to include in the analysis of a clinical trial, Control Clin. Trials 21 (2000) 330–342, http://dx.doi.org/10.1016/S0197-2456(00)00061-1.

[44] F. Crawford, D. Atkins, P. Young, J. Edwards, Steroid injection for heel pain: evidence of short-term effectiveness. A randomized controlled trial, Rheumatol. Oxf. 38 (1999) 974–977, http://dx.doi.org/10.1093/rheumatology/38.10.974.

[45] J. Elizondo-Rodriguez, Y. Araujo-Lopez, J.A. Moreno-Gonzalez, E. Cardenas-Estrada, O. Mendoza-Lemus, C. Acosta-Olivo, A comparison of botulinum toxin A and intralesional steroids for the treatment of plantar fasciitis: a randomized, double-blinded study, Foot Ankle Int. 34 (2013) 8–14, http://dx.doi.org/10.1177/1071100712460215.

[46] C.A. Speed, Injection therapies for soft-tissue disorders, Best. Pract. Res. Clin. Rheumatol. 17 (2003) 167–181, http://dx.doi.org/10.1016/S1521-6942(02)00122-5.

[47] F. Badlissi, J.E. Dunn, C.L. Link, J.J. Keysor, J.B. McKinlay, D.T. Felson, Foot musculoskeletal disorders, pain, and foot-related functional limitation in older persons, J. Am. Geriatr. Soc. 53 (2005) 1029–1033, http://dx.doi.org/10.1111/j.1532-5415.2005.53315.x.

[48] J.G. Skedros, K.J. Hunt, T.C. Pitts, Variations in corticosteroid/anesthetic injections for painful shoulder conditions: comparisons among orthopaedic surgeons, rheumatologists, and physical medicine and primary-care physicians, BMC Musculoskelet. Disord. 8 (2007), http://dx.doi.org/10.1186/1471-2474-8-63.

[49] Rheumatology Expert Group, Therapeutic Guidelines: Rheumatology. Version 2, Therapeutic Guidelines Limited, Melbourne, 2010.

[50] D.A. Cardone, A.F. Tallia, Joint and soft tissue injection, Am. Fam. Physician 66 (2002) 283—288.

[51] Z. Li, C. Xia, A. Yu, B. Qi, Ultrasound-versus palpation-guided injection of corticosteroid for plantar fasciitis: a meta-analysis, Plos One 9 (3) (2014) e92671, http://dx.doi.org/10.1371/journal.pone.0092671.

[52] S.Y. Lee, P. McKeon, J. Hertel, Does the use of orthoses improve self-reported pain and function measures in patients with plantar fasciitis? A meta-analysis, Phys. Ther. Sport 10 (2009) 12—18, http://dx.doi.org/10.1016/j.ptsp.2008.09.002.

[53] F. Hawke, J. Burns, J. Radford, V. du Toit, Custom-made foot orthoses for the treatment of foot pain, Cochrane Database Syst. Rev. 3 (2008), http://dx.doi.org/10.1002/14651858.CD006801.pub2.

[54] J.K.K. Chia, S. Suresh, A. Kuah, J.L.J. Ong, J.M.T. Phua, A.L. Seah, Comparative trial of the foot pressure patterns between corrective orthotics, formthotics, bone spur pads and flat insoles in patients with chronic plantar fasciitis, Ann. Acad. Med. Singap. 38 (2009) 869—875.

[55] R. Ferber, B. Benson, Changes in multi-segment foot biomechanics with a heat-mouldable semi-custom foot orthotic device, J. Foot Ankle Res. 4 (2011), http://dx.doi.org/10.1186/1757-1146-4-18.

[56] G. Kogler, S. Solomonidis, J. Paul, Biomechanics of longitudinal arch support mechanisms in foot orthoses and their effect on plantar aponeurosis strain, Clin. Biomech. Bristol Avon 11 (1996) 243—252, http://dx.doi.org/10.1016/0268-0033(96)00019-8.

[57] J.D. Rompe, A. Cacchio, L. Weil Jr., J.P. Furia, J. Haist, V. Reiners, et al., Plantar fascia-specific stretching versus radial shock-wave therapy as initial treatment of plantar fasciopathy, J. Bone Jt. Surg. Am. 92 (2010) 2514—2522, http://dx.doi.org/10.2106/JBJS.I.01651.