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Physical interventions (orthoses, splints, exercise and manual therapy) for treating plantar heel pain (Protocol)

Rogers JA, Wilson A, Laslett LL, Winzenberg TM

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[Intervention Protocol]

Physical interventions (orthoses, splints, exercise and manual therapy) for treating plantar heel pain

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effects (benefits and harms) of physical interventions (orthoses, splints, exercise and manual therapy) for treating plantar heel pain.

BACKGROUND

Description of the condition

Plantar heel pain is a clinical diagnosis described by pain and tenderness under the heel. Individuals with plantar heel pain typically describe pain when standing for long periods, and with the 'first step' after a period of rest such as when getting out of bed in the morning (McPoil 2008).

The plantar fascia is often considered the primary source of pain in plantar heel pain. It is a tough, fibrous band connecting the underside of the heel to the bases of all five toes, and plays an important role in supporting the arch of the foot during weight bearing (Stecco 2013). However, the specific role of the plantar fascia in plantar heel pain remains uncertain, as inflammatory mechanisms of pain production are not well established (Lemont 2003). Degeneration of the plantar fascia is a common finding during surgery in older people being treated for chronic heel pain, but it is unclear if these findings apply to younger more athletic people with acute heel pain. The presence of imaging abnormalities in bone, nerve and other soft tissues about the heel (Van Leeuwen 2015) suggests that structures other than the plantar fascia also have a role to play in heel pain. This is recognised in the use of the umbrella term 'plantar heel pain'.

Plantar heel pain affects up to 10% of adults in their lifetime (Riddle 2004). It is common in both males and females, typically through the fourth and fifth decades of life (Irving 2007). It affects individuals in community, athletic, occupational and military settings (Hill 2008; Rome 2001; Scher 2009; Werner 2010). Community surveys report prevalence rates ranging from 3.6% to 11.1% (Dunn 2004; Hagedorn 2013). In a five-year study of running athletes, DiCaprio 2010 reported that 'plantar fasciitis' was the most common injury classification resulting in lost athletic time, affecting 31% of all athletes. Up to 20% of individuals with plantar heel pain develop it bilaterally; bilateral involvement is more common in those with chronic (30%) rather than acute

(13%) plantar heel pain (Klein 2012).

The clinical course of plantar heel pain generally appears to favour resolution, but the quality of evidence supporting this perception is low (Martin 1998; Wolgin 1994). There is, however, an important subgroup of at least 20% of individuals who demonstrate poorer progress or incomplete relief (Amis 1988; Taunton 2002; Wolgin 1994). When surveyed, compared with people without heel pain, people with plantar heel pain report a 40% reduction in foot-related physical function (Irving 2008). They also report lower levels of physical activity, vigour and social function compared to individuals without heel pain (Irving 2008). Higher levels of depression and stress have also been associated with decreased levels of foot function in individuals with plantar heel pain, particularly in females (Cotchett 2014). Plantar heel pain also frequently recurs; for example, 55% of participants in one trial reported a recurrence of heel pain over a six-year period (Wang 2006).

There are many treatment options available for plantar heel pain, which may be used singly or in combination. These include rest or activity modification, exercise (stretching and strengthening), manual therapies such as joint mobilisation and massage, and the application of physical devices such as orthoses, splints, socks, taping and braces. Other therapies include the use of: electromedical devices delivering heat, electricity, magnetic fields, or focused sound energy such as shockwave therapy; needling therapies such as acupuncture; and injectables such as corticosteroids or blood products. Conservative physical interventions typically precede the application of injectable or electrophysical agents such as shockwave therapy. Around 10% of individuals with chronic heel pain may go on to have surgery (Martin 1998).

Description of the intervention

The first approach in the management of plantar heel pain is usually conservative and often involves physical interventions (Martin 2014). This review will examine four commonly-used classes of physical interventions: the use of dynamic mechanical aids that facilitate movement such as orthoses; the use of static mechanical devices such as splints; exercise therapy and manual physical therapies, as follows.

1. Dynamic mechanical aids that facilitate movement include custom-made or prefabricated orthoses (shoe inserts) that are typically either foam or thermoplastic in construction. Footwear, footwear modifications or orthopaedic boots, strapping, compression socks and heel cups also fit within this class.
2. Static mechanical devices that apply a sustained or fixed force across the foot or ankle include rigid (thermoplastic) splints worn at night, night socks and soft or hard plaster casts.
3. Exercise therapy includes the prescription of stretching and strengthening exercises for the foot, ankle and leg. It can also include exercise to improve proprioceptive (sensory awareness and balance) function, endurance, posture, and nerve mobility.
4. Manual therapies include 'hands-on' interventions applied by a health practitioner such as joint mobilisation, manipulation and soft tissue techniques such as massage and myofascial release.

Physical interventions from these different classes are often applied in combination, with individuals commonly receiving a mix of hands-on treatment, exercise and mechanical aids.

How the intervention might work

Collectively, physical interventions are thought to act through a combination of mechanical and nerve-mediated mechanisms. Mechanical devices that assist movement, such as orthoses, help by redirecting stresses, reducing pressure or cushioning forces at vulnerable tissue sites (McPoil 1995). Mechanical devices that provide a static force across the foot or ankle, such as a splint or cast, can stretch tight soft tissues or protect joint or soft tissue structures against external loads. Stretching exercises can increase joint or soft tissue range of motion. Strengthening exercises can improve the load-bearing capacity of supporting muscles, and graduated active exercise more generally stimulates cellular responses that condition connective tissues to adapt to load (Khan 2009). Manual therapies address range of motion impairments by decreasing joint and soft tissue stiffness and reducing muscle tone.

As well as these overt mechanical effects, physical interventions are also likely to provide important modulating effects that affect both local nerve sensitivity and how the central nervous system responds to, and perceives, pain (Hawke 2009). For example, manual therapies have been shown to have important effects on nerve function in the periphery, at spinal cord levels and higher up in the central nervous system, associated with anti-pain effects (Schmid 2008).

The harms associated with the physical interventions under consideration in this review are, overall, poorly documented, but have generally been mild (Landorf 2015). Orthoses have been associated with pressure complaints, local pain and blistering, and foot tiredness. Users of static splints report similar concerns, but also issues around sleep disturbance. Taping can produce skin reactions and discomfort due to tightness. Exercise has been associated with a short-term flare of muscle pain, and manual therapies similarly can result in transient discomfort during and after treatment (Landorf 2015).

Why it is important to do this review

Plantar heel pain is important because it is the most common reason why people with musculoskeletal foot pain consult a health professional. It accounts for at least one million physician visits a year in the US (Riddle 2004). This figure is an underestimate of the true health burden as it excludes visits to other healthcare providers (such as to physiotherapists), where plantar heel pain is the most commonly treated foot condition (McPoil 2008). In the

US, the direct costs of plantar heel pain to third party payers were estimated to be as high as $376 million in 2007, with indirect costs, such as lost productivity, unknown (Tong 2010). There is variation in practice and no standard of care has been established. A systematic review with a search date of November 2013 found the effectiveness of physical interventions such as orthoses and taping as 'likely beneficial' but others such as stretching exercise, heel cups and night splints of 'unknown effectiveness' (Landorf 2015). The effectiveness of strengthening exercises and manual therapy were not reported. Given these findings and the frequency with which orthoses, splints, manual therapy and exercise are used by a range of healthcare providers, this review seeks to clarify their effectiveness in the management of plantar heel pain.

OBJECTIVES

To assess the effects (benefits and harms) of physical interventions (orthoses, splints, exercise and manual therapy) for treating plantar heel pain.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) and quasi-randomised (method of allocating participants to a treatment which is not strictly random: e.g. by hospital number) controlled trials.

Types of participants

Adults with clinically-diagnosed plantar heel pain, preferably with explicit reference to pain on the underside of the heel that is "most noticeable with initial steps after a period of inactivity but also worse following prolonged weight bearing" (Martin 2014). Studies will be included regardless of the duration of symptoms.

We will exclude trials focusing only on children because in that population heel pain is more likely to be related to abnormal bone growth (osteochondrosis). However, we will include trials with children (less than 16 years of age), provided the proportion of children in the trial is small (less than 10%) and the numbers are sufficiently balanced between treatment groups, or if separate data for adults are available.

We will also exclude studies that focus on individuals with a diagnosis of hindfoot or ankle arthritis, posterior heel pain such as Achilles tendinopathy or rheumatologic disease such as reactive arthritis; a primary diagnosis of nerve injury; post-operative pain or those with pain due to trauma such as foot fracture.

Types of interventions

The main categories of interventions to be tested in this review are:

- Mechanical aids to improve dynamic function such as custom and over-the-counter orthoses, footwear and strapping/taping
- Static mechanical aids such as night splints, night socks and casting
- Exercise (e.g. stretching, strengthening, any other directed functional or activity-based exercise intervention)
- Manual therapies (e.g. hands-on treatment including massage and manual joint mobilisation)

We plan to test the following comparisons.

1. Any of the above four intervention categories versus control, which can be placebo or sham (e.g. flat innersole), no treatment (e.g. wait-list controls) or advice only. Thus we aim to present four comparisons: exercise versus control; manual therapies versus control; dynamic mechanical aids versus control; and static mechanical aids versus control.
2. Any of the above four intervention categories versus another of the four categories. This would include, for example, exercise versus manual therapies. We would supplement these direct comparisons by indirect comparisons where data are available.
3. Any intervention versus any other intervention within the four main intervention categories. Examples include custom versus over-the-counter (on-the-shelf) orthoses, or night splints versus night socks. When deciding the 'control' group for each comparison, we will select the least intensive or complex intervention in the first instance.

For all of the above, studies in which co-interventions, such as non-steroidal anti-inflammatory drugs, with other physical therapies are given will be included, provided the co-intervention is given equally to the intervention and comparison groups. However, we will exclude trials with co-interventions consisting of injection or shockwave therapy, or surgery. We will also exclude trials involving the application of needling therapies such as acupuncture or dry needling, as this is the subject of another Cochrane Review (Lee 2013).

Types of outcome measures

We will include studies only if one or more of the outcomes listed below was, or was intended to be, measured.

Primary outcomes

1. Heel pain. Preference will be given to 'first step pain' assessed by validated questionnaire such as a visual analogue scale or numeric rating scale.
2. Foot function as assessed by any validated patient-reported outcome questionnaire: e.g. Foot Function Index, Foot and Ankle Ability Measure, Lower Extremity Functional Scale, Foot Health Status Questionnaire.
3. Treatment failure. This includes rare serious adverse events such as plantar fascia rupture and treatment failure necessitating further substantive intervention such as injection or surgery.

Secondary outcomes

1. Return to work, sports or previous levels of physical activity. (Preference will be given to previous levels of physical activity appropriate to the trial population).
2. Health-related quality of life, assessed via validated questionnaire such as the SF-36.
3. Less serious (minor) adverse effects such as post-treatment pain, swelling or bruising.
4. Recurrence, reported as the number of cases that relapse after a successful resolution.
5. Adherence (compliance) to allocated treatment.
6. Patient-reported rating of satisfaction with or improvement in outcome.

We will also collect data reported on intervention costs, resource use, days off work and other costs, as well as report on the results of any cost-effectiveness analyses associated with the included trials.

Timing of outcome measurement

The outcome measures will be grouped under three different time periods: short term (within one month of the intervention), medium term (one month to six months) or long term (more than six months).

Search methods for identification of studies

Electronic searches

We will search the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (to present), the Cochrane Central Register of Controlled Trials (CENTRAL) (current issue), MEDLINE (1946 to present), Embase (1974 to present), CINAHL (1982 to present) and the Physiotherapy Evidence Database (PEDRro) (1929 to present). We will also search ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform for ongoing and recently-completed trials. No language restrictions will be applied.

In MEDLINE (Ovid Online), we will combine a topic-specific search strategy with the sensitivity-maximising version of the Cochrane Highly Sensitive Search Strategy for identifying RCTs (Lefebvre 2011). The search strategies developed for CENTRAL and MEDLINE are reported in Appendix 1. These strategies will be modified for use in the other databases.

Searching other resources

We will manually search the reference lists of key trial reports and review articles. We will handsearch the proceedings of key foot and ankle conference meetings from the disciplines of physiotherapy, podiatry and orthopaedics, and search online forums such as Podiatry Arena. We will also contact corresponding authors of included studies and known researchers in the field of plantar heel pain to help identify potentially-relevant published and unpublished studies.

Data collection and analysis

Selection of studies

Two authors (JR and AW) will independently screen the title and abstract of all search results. The full reports of potentially-eligible studies will be retrieved and study selection will be undertaken by the same two authors with the guidance of a standardised eligibility form. Any disagreements will be resolved by consulting a third author (TW). If eligibility is still unclear, we will contact the study authors for clarification.

Data extraction and management

Two review authors (AW and JR) will independently extract data based on the implementation of a standardised and piloted data extraction form. Disagreements will be resolved by consensus where possible, but a third review author (TW) will be consulted if consensus cannot be reached. Data entry into Review Manager will be by JR and AW (RevMan 2014).

Assessment of risk of bias in included studies

The assessment of the risk of bias in included studies will be based on the application of Cochrane's 'Risk of bias' tool (Higgins 2011a). Two review authors (JR and AW) will independently report on the following seven domains: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, the completeness of outcome data, the selective reporting of outcome data, and any other source of bias relevant but not reported in the previous domains. Separate assessment of risk of bias for both blinding domains and incomplete outcome assessment will be performed for outcome measures that are patient reported (e.g. pain and self-reported function) or objectively reported (e.g. numbers of adverse events and rate of

recurrence). We will categorise the risk of bias for each domain as low, unclear or high. A third review author (TW) will be consulted in the event that consensus cannot be reached.

It is difficult to blind the intervention provider when applying mechanical interventions. However there are valid ways to blind the participant for most physical interventions used in the treatment of heel pain: for instance, flat inner soles in the place of contoured orthoses, sham taping, or the prescription of exercise unrelated to the foot or ankle. Evidence of assessment of successful participant blinding is necessary to score a low risk of bias in the 'blinding of participants and personnel' section. Incomplete outcome assessment (due to attrition or exclusions) will be judged as high risk of bias if an intention-to-treat protocol has not been used.

Measures of treatment effect

For continuous outcomes (e.g. pain or function), we will use mean differences (MDs) and the corresponding 95% confidence intervals (CIs) to measure treatment effect. Where appropriate we will use final scores rather than change scores. Standardised mean differences (SMDs) will be used where different measurement scales are used; we will not pool final and changes scores for SMDs. The SMD will be back-translated to a typical scale (e.g. 0 to 10 for pain) by multiplying the SMD by a typical among-person standard deviation (e.g. the standard deviation of the control group at baseline from the most representative trial) (Schünemann 2011). For dichotomous outcomes such as adverse events, we will calculate risk ratios (RRs) and 95% CIs.

Unit of analysis issues

Unit of analysis issues might arise in studies that include participants with bilateral heel pain. Where the results are reported by feet and no adjustments are available, we will attempt to perform sensitivity analyses to assess the impact of including uncorrected data on the results. If the numbers with bilateral heel involvement are reported and high, we will first try to correct for this by adjusting the 'effective sample size' to account for the fact that the participant, and not the foot, has been treated as the randomised unit of analysis (Higgins 2011b). If this is not possible, we will explore the effects of excluding the trial from pooled analyses. We will analyse data from cross-over trials at the first time period in order to avoid sequencing or carry-over effects. Data presented at different time points within or across studies will be grouped for presentation according to the length of follow-up; short term (less than four weeks), medium term (four weeks to less than six months) and long term (greater than or equal to six months). If studies with multiple arms are identified, we will include the relevant arms as per our protocol. Where two comparisons with the same control group are pooled in the same meta-analysis, we will halve the control group in order to avoid double-counting.

Dealing with missing data

We will attempt to contact the trial authors to obtain missing data and information. Where possible, we will attempt to analyse the available data using intention-to-treat principles. Where possible, we will calculate missing standard deviations (SDs) from other statistics such as standard errors, confidence intervals or P values, according to methods recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). We will not impute missing SDs from other sources. Where possible, we will conduct sensitivity analyses to explore the effects of missing binary data where these are in excess of 10% of the trial population.

Assessment of heterogeneity

Statistical heterogeneity will be assessed by visual inspection of the forest plot, and by consideration of the Chi^2 statistic at a significance level of $P < 0.10$. The level of inconsistency across trials will be defined by the I^2 statistic and will be interpreted as follows: 0% to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity; 75% to 100% considerable heterogeneity (Deeks 2011).

Assessment of reporting biases

Where sufficient numbers of trials (more than 10 trials) contribute to an analysis of a primary outcome, we will generate a funnel plot to explore possible small study biases. In interpreting funnel plots, we will examine the different possible reasons for funnel plot asymmetry as outlined in section 10.4 of the *Handbook* (Sterne 2011).

To assess outcome reporting bias, we will check trial protocols against published reports. For studies published after 1 July 2005 we will screen the Clinical Trial Register at the International Clinical Trials Registry Platform of the World Health Organisation for the trial protocol. Where it is apparent that the a priori stated outcomes (e.g. in a trial protocol) have not been, or are, selectively reported, we will note this in the 'Risk of bias' table.

Data synthesis

When considered appropriate, we will pool results of comparable groups of trials using both the fixed-effect and the random-effects models. Our choice of the model to report will be guided by careful consideration of the extent of heterogeneity and whether it can be explained, in addition to other factors, such as the number and size of included studies. We will use 95% CIs throughout. We will consider not pooling data where there is considerable heterogeneity ($I^2 > 75\%$) that cannot be explained by the diversity of methodological or clinical features among trials. Where it is inappropriate to pool data, we will still present trial data in the analyses or tables for illustrative purposes and will report these in the text.

Subgroup analysis and investigation of heterogeneity

Where data allow, we plan to conduct the following subgroup analyses:

1. Age (less than 40; 40 to 60; more than 60 years)
2. Gender
3. Body mass index (less than 25 kg/m²; more than 25 kg/m²)
4. Disease duration (less than three months; greater than or equal to three months)
5. Level of physical activity (athletes or high levels of physical activity; non-athletes or sedentary)

The above subgroups will be analysed at the primary time points (less than one month, one month to less than six months, and six months or greater) for each type of intervention. In addition, for the following interventions we will perform specific subgroup analyses:

- Exercise by stretching versus strengthening
- Manual therapy by joint mobilisation versus massage
- Orthoses by custom made versus prefabricated/over the counter

We will investigate whether the results of subgroups are significantly different by inspecting the overlap of CIs and performing the test for subgroup differences available in RevMan 2014.

Sensitivity analysis

If there are sufficient data, we will conduct sensitivity analyses on various aspects of trial and review methodology. These will include sensitivity analyses to explore:

1. the effects on primary outcomes of excluding trials at high or unclear risk of selection bias (thus restricting the analysis to studies with low risk of selection bias due to the use of adequate methods of allocation concealment);
2. the effects of excluding trials reported only in conference proceedings or other short reports;
3. the effects on primary outcomes of comparing studies with smaller (less than 50 cases in each group) versus larger sample sizes;
4. the effect of including bilateral heel pain cases as a unit of analysis issue;
5. the effects of missing binary data; and
6. the choice of statistical model for pooling data (fixed-effect versus random-effects).

Assessing the quality of the evidence and 'Summary of findings' tables

We will use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to assess the quality of the body of evidence for each outcome listed in Types of outcome measures (Schünemann 2011). The quality rating 'high' is reserved for a body of evidence based on RCTs. We may downgrade the quality rating to 'moderate', 'low' or 'very low' depending on the presence and extent of five factors: study limitations, inconsistency of effect, imprecision, indirectness and publication bias.

Where there is sufficient evidence, we will prepare 'Summary of findings' tables for each comparison using the available evidence for the three primary outcomes. We plan to present the results for heel pain and foot function at the three stated time periods (short, medium and long term).

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Search strategies

CENTRAL (Cochrane Register of Studies Online)

#1 MESH DESCRIPTOR Fasciitis, Plantar
#2 MESH DESCRIPTOR Fasciitis EXPLODE ALL TREES
#3 MESH DESCRIPTOR foot diseases EXPLODE ALL TREES
#4 #2 AND #3
#5 (plantar adj3 fasci*):TI,AB,KY
#6 ((plantar or heel* or foot or arch*) adj3 (pain* or inflam*)):TI,AB,KY
#7 (calcaneodynia or calcaneal periostitis or enthesopathy or heel spur or joggers heel or policemans heel or heel bruise or subcalcaneal bursitis or Baxters neuropathy):TI,AB,KY
#8 #1 OR #4 OR #5 OR #6 OR #7
#9 MESH DESCRIPTOR exercise EXPLODE ALL TREES
#10 MESH DESCRIPTOR Physical Therapy Modalities EXPLODE ALL TREES
#11 (joint adj3 mobil*):TI,AB,KY
#12 ((joint or soft tissue) adj3 manipulat*):TI,AB,KY

#13 ((manual or physical or manipulat*) adj3 therap*):TI,AB,KY
#14 physiotherapy:TI,AB,KY
#15 MESH DESCRIPTOR Orthotic Devices EXPLODE ALL TREES7
#16 orthos#s or orthotic* or insert* or arch support* or heel cup* or heel pad*
#17 MESH DESCRIPTOR splints EXPLODE ALL TREES
#18 splint*:TI,AB,KY
#19 MESH DESCRIPTOR Athletic Tape
#20 (taping or tape* or strap*):TI,AB,KY
#21 #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20
#22 #8 AND #21

MEDLINE *(Ovid* Online)

1. FASCIITIS, PLANTAR/
2. exp FASCIITIS/
3. exp FOOT DISEASES/
4. 2 and 3
5. (plantar adj3 fasci$).tw.
6. ((plantar or heel$ or foot or arch$) adj3 (pain$ or inflam$)).tw.
7. (calcaneodynia or calcaneal periostitis or enthesopathy or heel spur or joggers heel or policemans heel or heel bruise or subcalcaneal bursitis or Baxters neuropathy).tw.
8. or/1,4-7
9. exp EXERCISE/
10. exp PHYSICAL THERAPY MODALITIES/
11. (joint adj3 mobil$).tw.
12. ((joint or soft tissue) adj3 manipulat$).tw.
13. ((manual or physical or manipulat$) adj3 therap$).tw.
14. physiotherapy.tw.
15. exp ORTHOTIC DEVICES/
16. (orthos#s or orthotic$ or insert$ or arch support$ or heel cup$ or heel pad$).tw.
17. SPLINTS/
18. splint$.tw.
19. ATHLETIC TAPE/
20. (taping or tape$ or strap$).tw.
21. or/9-20
22. Randomized Controlled Trial.pt.
23. Controlled Clinical Trial.pt.
24. randomized.ab.
25. placebo.ab.
26. randomly.ab.
27. trial.ab.
28. groups.ab.
29. or/22-28
30. exp Animals/ not Humans/
31. 29 not 30
32. 8 and 21 and 31

CONTRIBUTIONS OF AUTHORS

The protocol was drafted by Jason Rogers with support from Tania Winzenberg, Laura Laslett and Anitra Wilson. Jason Rogers is the guarantor of the protocol.

DECLARATIONS OF INTEREST

None known.