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Protocol

A randomised control trial comparing the use of prefabricated orthotics in combination with orthotic sandals versus the sole use of prefabricated orthotics for the treatment of plantar fasciitis

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ABSTRACT

Background: Plantar fasciitis is a painful and debilitating condition. There is currently no standard treatment for plantar fasciitis. Literature has shown that foot orthotics can help decrease pain and improve foot function in patients with plantar fasciitis. Orthotic sandals have also been shown to reduce symptoms of plantar fasciitis. These devices have only been used independently. This study will aim to take a novel approach to combine the orthotic and orthotic sandal to investigate the effect on plantar fasciitis symptoms.
Methods: A total of 104 participants will be randomised into two groups. Participants in group A, the test group, will be provided with prefabricated orthotics and indoor orthotic sandals, and participants in group B, the control group, will only be provided with prefabricated orthotics. Outcome data will be collected five times over a period of six months. The primary outcome measure of change in pain over time will be measured with the Visual analogue scale. The secondary outcome measures of changes in foot health status and overall health will be measured using the Foot health status questionnaire and Global rating scale of change, respectively.
Conclusions: The combined use of orthotics and orthotic sandals will increase the amount of time that the foot has adequate support. This novel research aims to provide evidence for an effective and easily implemented, standardised treatment for plantar fasciitis.
Trial Registration: This trial was registered in May 2021 (NCT04894383).

Keywords: Orthotics, Plantar fasciitis, Foot pain, Orthotic sandal, Foot health

INTRODUCTION

Plantar fasciitis is a self-limiting, chronic, and degenerative condition which involves inflammation or irritation of the plantar fascia. Plantar fasciitis can have a substantial effect on the quality of life of an individual. Current treatment methods for plantar fasciitis are not uniform and have discrepancies in reported effectiveness. With the use of home and over-the-counter treatments, one study reported 80% of plantar fasciitis cases improved within 12 months.[1] Another study, which looked at the use of at-home stretches and strengthening, found that after two years, more than 40% of the participants still suffered from symptoms.[2] These various reports of therapeutic modalities make it challenging to verify the 'gold-standard' intervention for plantar fasciitis.

Foot orthotics are a commonly used treatment modality for plantar fasciitis.[3] Improved arch support, even weight distribution and an increase in proprioception are a few of the benefits associated with foot orthotics.[4] The use of orthotics has been supported within the literature. Orthotics have been found to have a greater improvement in foot pain and function when compared to other non-surgical methods.[5] A review including 43 studies and 2837 patients found no negative outcomes associated with

orthotics.[6] However, literature concerning orthotics has been criticised often for being low in quality. One review found 45% of studies had a significantly high risk of bias, and so caution needs to be taken when interpreting the results.[3]

Another treatment method used for plantar fasciitis is orthotic sandals. Orthotic sandals follow the same principles of a foot orthotic. Both are contoured to the foot with additional arch support. A typical orthotic is worn inside one's shoes, meaning that, to provide constant pain relief, shoes would have to be worn for all waking hours of the day. The use of orthotic sandals may provide comfort during hours that shoes would not be typically worn, such as first thing in the morning, thereby helping to reduce first-step pain.

A study that compared the use of orthotics to orthotic sandals found no difference between the two.[7] However, there was a 60% improvement for both these devices when compared to a plain sandal.[7] The combined use of prefabricated orthotics and orthotic sandals, which should increase the amount of time that the foot is supported, should hence decrease the symptoms of plantar fasciitis more than the use of a single device independently.

Objectives

The primary objective of this study is to measure pain, specifically foot pain, in participants with Plantar Fasciitis. The secondary objectives include measurements of foot health and symptom changes. This study is a randomised control trial that is six months long and involves five incidences of data collection. Participants will be randomised into a group that will receive prefabricated orthotics and orthotic sandals or into a group that will receive prefabricated orthotics only. Parallel groups with an allocation ratio of 1:1 will be used. This study will follow a superiority framework and it is hypothesised that the combined use of orthotics and orthotic sandals will have a greater benefit than the sole use of prefabricated orthotics alone.

METHODS

Trial design

This study is six months long, with data collected at baseline, three weeks, six weeks, three months, and six months. This is a randomised control intervention trial involving the use of parallel groups.

The allocation ratio is 1:1 with the same number of participants in the control and intervention groups. The intervention group will receive prefabricated orthotics and orthotics sandals, and the control group will receive orthotics only. It is hypothesised that the combined use of prefabricated orthotics and orthotic sandals will have a greater benefit than the sole use of prefabricated orthotics, thereby following a superiority framework.

Sample size

This study will include 104 participants who meet the inclusion and exclusion criteria. The study sample size was determined based on the primary outcome of a change of one point in the VAS pain score. From previous studies, a standard deviation of 1.6 is accepted. For 80% power with a significance level of 5%, a sample size of 41 per group is required to identify the expected difference of one point on the VAS scale. To allow for a 20% dropout rate, the sample size is inflated to 52 participants in each group, totalling 104 participants for the entire study.

Recruitment

Participants will be recruited through a social media campaign. The study will be entirely in the participants environment, from the telephone consultation to the implementation of the intervention. Data will be collected from England, Wales, and Scotland only. The recruitment process began in August 2021 and aims to be completed at the end of July 2022. The study completion date, defined as the end of data collection, analysis and the writing up of the results, is the 31st of December 2022.

Eligibility criteria

Participants recruited for this study will have experienced symptoms of plantar fasciitis for at least two months and will be aged between 18 and 75 years. Plantar fasciitis is identified from pain located under the surface of the heel, which is the worst in the morning. Any prior operations on the foot and any treatment for plantar fasciitis within the previous twelve months, aside from analgesia, will exclude the participant from participating in this study. The last exclusion criterion for this study will be any congenital or acquired foot and ankle abnormalities that prevent the participant from wearing normal footwear.

Randomisation

This is a randomised control study with an allocation ratio of 1:1. There will be 104 participants in this study, with 52 in each group. Participants will be randomised with the use of sealed envelopes. Inside 52 sealed envelopes will be a label stating, 'group A' and inside another 52 sealed envelopes will be a label stating, 'group B'. All the envelopes will be shuffled together, and an individual independent of the research study will pick a blinded envelope at random. The label inside the envelope will assign the participant to a group. Following assignment to a group, blinding is not possible due to the nature of the study.

Objectives

The primary outcome of this study is pain. Pain will be reported on a Visual analogue scale (VAS) with a score between zero and ten, with zero representing 'no pain' and ten representing 'the worst imaginable pain'.

One of the secondary outcomes is foot health, and this will be measured on the Foot Health Status Questionnaire (FHSQ). Only two subsections of this questionnaire will be used, specifically foot pain and foot function. Another secondary outcome of this study is the change in symptoms. This will be measured using the Global rating scale of change (GROC). The GROC scale is an 11-point scale from +5 to -5 denotes 'completely recovered', 0 denotes 'no change', and -5 denotes 'very much worse'.

Intervention

Participants will have a consultation telephone call with our principal investigator in order to confirm eligibility and answer any questions. Following this, consent and baseline data will be collected. Consent is obtained using a secure website called legalesign.com. Baseline data collection will involve rating pain using the VAS and foot health using the FHSQ. Next the participants will be randomised into one of the two groups. Group A will receive a prefabricated orthotic (Aetrex L420 Compete Orthotics, Figure 1) and orthotic sandals (Aetrex L300 Orthotic Flips, Figure 2) whereas Group B will only receive the prefabricated orthotics.

Figure 1: An image showing Aetrex L420 compete orthotics. This orthotic is provided to participants in both group A and group B.

Figure 2: An image showing Aetrex L300 orthotic sandals. This sandal is provided only to participants in group A.

During the follow-up period, data will be collected on four instances and, in addition to measuring pain with a VAS and foot health using the FHSQ, it will also include measuring a change of symptoms using the GROC scale. The questionnaires will be available online, at smartsurvey.co.uk, or on paper through the postal service. Each participant can select their preferred method to complete and submit data.

For participants using the postal service, a pre-paid, stamped, self-addressed envelope will be provided to ensure that no cost is incurred. If the participant decides to submit the data online, they will be provided with a link via email. Online data will be collected through the secure website www.smartsurvey.

Analysis of outcomes

Once data is collected, it will be exported to Microsoft Excel and kept on a secure, password-protected server. Only the research team will have access to the server. All data will be collected and stored according to the data protection guidelines. Identifiable data will be kept until the study completion date (31/12/2022) when data will be anonymised. During dissemination, only anonymised data will be published and shared. All information regarding the collection and storage of data will be explained in the participation information sheet and consent form.

An independent statistician will perform the statistical analysis. This analysis will be conducted using a mixed Analysis of variance (ANOVA) to compare the mean differences between groups regarding various factors. The between-group analysis will compare the pain and function analyses between group A and group B. The within-group analysis will determine any difference in the symptoms of plantar fasciitis from the beginning to the end of the study within the same group.

The results of the statistical analysis will be illustrated in the form of tables and graphs, which will be further supplemented with a comprehensive statistical analysis.

Monitoring

A DMC has the function of ensuring that data is legitimate and reliable. This research study will include the use of a DMC composed of a member of the public, an independent doctor who is not part of the research team, and an independent statistician. A discussion will be undertaken involving the collection of the data and the progress of the study at various time points. The DMC will reserve the right to recommend study stoppage on the grounds of ethical violation or study feasibility.

Any comments, particularly negative ones, made by participants about the effects of the orthotics or orthotic sandals will be noted. These comments will be presented within the final publication of the study. Negative comments will be discussed with the DMC to ensure participant safety.

Ethics

This research received ethical approval on the 14th of April 2021 by the Wales Research Ethics Committee 5 (REC

reference: 21/WA/0099). To ensure informed consent, participants will be provided with an information sheet that details the study process. Additionally, the participants will be supplied with a flowchart that shows the timeline of the study.

During the telephone consultation, the participants will be given a chance to ask any questions, and during the entire study period, the participants can contact the research team for any advice. During every data collection event, the participant will be required to provide ongoing informed consent.

Data and personal information collected during the consent, survey, and the data collection questionnaires and during the course of the study will be kept on a secure, password-protected server, and any personal, identifiable data will be deleted at the end of the study.

Dissemination

Plans to disseminate the results of this study include publication in peer-reviewed journals and presentations at relevant conferences. The study participants will receive a write-up of the results in lay terms but can also request a copy of the final publication.

The protocol is currently available to the public on clinical trials.

DISCUSSION

Plantar Fasciitis is an inflammation or irritation of the plantar fascia. This is a self-limiting, chronic, degenerative condition that affects 10% of the general population.[8] The aim of this study is to conduct a high-quality randomised control trial to investigate the combined use of orthotic sandals and orthotics in the treatment of plantar fasciitis. The proposed method includes two groups. The test group will be provided with both the orthotics and the orthotic sandals, whilst the control group will be provided with the prefabricated orthotics only. The study will run for a period of six months, and data will be collected a total of five times. The outcome measures of this study include foot pain, foot health and symptom change. The prevalence and debilitating nature of plantar fasciitis, along with the lack of a common first treatment technique, provides cause for undertaking this research.

Previously, research has found that both orthotics and orthotic sandals are useful for the treatment of plantar fasciitis. These tools have only been considered when used independently. Orthotics have been found to have no adverse effects and have been shown to be more successful in the treatment of plantar fasciitis than other non-surgical options.[5-6] Furthermore, a recent systematic review that compared orthotics with sham orthotics found favourable evidence for the use of orthotics as a treatment for plantar fasciitis.[9] However, the quality of the research analysed was questioned, meaning caution is needed when suggesting the clinical relevance of the study. A randomised, double-blinded trial that compared orthotic sandals to plain sandals found that orthotic sandals were far superior in improving foot pain and function in participants with plantar fasciitis over a twelve-week period.[10] When orthotics were compared to orthotic sandals, no difference was identified between the two, but both had a significant improvement when compared to placebo sandals.[7] This shows that both devices are useful treatment methods for plantar fasciitis.

CONCLUSION

The current study aims to build upon the statement that both orthotics and orthotic sandals are effective treatment tools for plantar fasciitis. However, this study aims to take a novel approach to combine and use the two in unison, rather than using these tools independently. A limitation of prefabricated orthotics usage is that they are worn in shoes. Therefore, the amount of time in which they can be effective as a treatment can be limited. On the other hand, orthotic sandals can be worn at times in which one wouldn't wear orthotics, like around the house. Therefore, a combination of these devices will theoretically provide a longer time in which the foot is adequately supported, potentially resulting in a further improvement in symptoms of plantar fasciitis. This proposal is a novel and unique research study that may have clinical implications, potentially providing evidence in support of an effective, easily implemented, and reliable treatment option for patients with plantar fasciitis.

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Conflict of interest: George Ampat, Samantha Rhodes and Jonathan Sims are employees of Talita Cumi Ltd, which is the sponsor of the study. Talita Cumi Ltd has a commercial relationship with Aetrex Worldwide, Inc. 414 Alfred Avenue Teaneck, NJ 07666, USA. Jaida Chacko Madathilethu has no conflict of interest
Ethical approval: The study was approved by the Wales Research Committee 5 Bangor, Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB

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