Effects of insoles adapted in flip-flop sandals for persistent heel pain: a protocol for a sham-controlled randomised trial

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ABSTRACT

Introduction Persistent heel pain is a prevalent complaint affecting up to 10% of the population. Insoles adapted in flip-flop sandals are an alternative treatment for pain and function of individuals with persistent heel pain, showing improvement within 12 weeks of treatment. Most studies considered foot posture and biomechanics to prescribe insoles for persistent heel pain, but few verified the effects of a 12-week treatment on pain catastrophising. This study will investigate the effects of insoles adapted in flip-flop sandals on pain intensity, function, functional walking capacity and pain catastrophising of individuals with persistent heel pain.

Methods and analysis This is a protocol for a sham-controlled randomised trial. Eighty individuals with persistent heel pain will be assessed and randomised into two intervention groups: insoles adapted in flip-flop sandals and flip-flop sandals with sham (ie, flat) insoles. Assessments will be conducted at baseline (T0), after 6 weeks (T6), 12 weeks post-intervention (T12) and after a 4-week follow-up (T16). The primary outcome will be the pain intensity, and secondary outcomes will be foot function, functional walking capacity and pain catastrophising. Analysis of variance with mixed design (if normal distribution) or Friedman's test (if not normal distribution) will verify intergroup and intragroup differences. Bonferroni post hoc tests will be performed in case of significant group or time interaction. Intent-to-treat analysis will be used, and a significance level of 5% and 95% CIs will be considered.

Ethics and dissemination This study was approved by the research ethics committee of the Federal University of Rio Grande do Norte (registry no. 4,018,821). Results will be disseminated to individuals, submitted to a peer-reviewed journal and disclosed in scientific meetings.

Trial registration number NCT04784598.

INTRODUCTION

Persistent heel pain affects approximately 2 million individuals annually and up to 10% of the population. Calcaneal spurs, inflammation, degeneration or injuries of the plantar fascia (eg, fasciopathy and plantar fasciitis), calcaneal fat pad disease and peripheral nerve injury are associated with heel pain. Studies also indicate that heel pain negatively influences the quality of life, social life, functional capacity and activities of daily living. Furthermore, heel pain is based on self-reported symptoms, including pain during palpation at the insertion of plantar fascia, morning pain at first steps or after a long period of inactivity and insidious feeling of pain.

Conservative treatments (eg, joint mobilisation, stretching, orthotics, manual therapy and low-level laser therapy) are effective for 90% of cases of persistent heel pain. The most recent clinical recommendations demonstrate strong evidence of extracorporeal shock wave therapies and custom orthoses to relieve persistent heel pain and moderate evidence of plantar fascia stretching and low dye tapping. Although shoes with customised insoles are an alternative orthosis to treat persistent heel pain in the short-term (up to 12 weeks), the medium-term effects (from 12 to 24 weeks) are still unclear.
Mechanical treatment may also relieve symptoms of persistent heel pain. However, divergences exist in literature about the relation between foot and ankle posture and persistent heel pain. Although a meta-analysis found that static pronation is not a risk factor for individuals with heel pain, the high heterogeneity of studies hindered the analysis of the relation between pain and dynamic pronation. Moreover, other studies indicated pronation as a risk factor for persistent heel pain.

Insoles are the most popular mechanical treatment, and interventions based on adequate biomechanics and foot posture support the clinical reasoning for prescribing insoles. However, these interventions must also consider psychosocial factors associated with persistent heel pain. A case series study observed pain catastrophising associated with persistent heel pain, indicating a psychological factor affecting these individuals.

Insole-type orthoses are generally restricted to closed footwear (e.g., shoes and sneakers), which may be an obstacle in hot climates. Thus, adapting insoles into flip-flop sandals may be a practical and comfortable alternative for individuals with persistent heel pain living in tropical regions. A recent clinical trial demonstrated that insoles adapted in flip-flop sandals (support or filling for plantar arches according to foot type) improved morning pain intensity of individuals with persistent heel pain after 12 weeks of intervention compared with flip-flop sandals with sham insoles (flat insole).

Another study using insole sandals with lateral wedges reported clinical improvement in pain intensity and...
function compared with flat sandals. However, these studies did not provide horseshoes or wedge pieces for heels according to foot type. Studies with pragmatic approaches are relevant because of their external validity for clinical implications and public health policies. Intervention time is another relevant aspect, and the effects of a 12-week treatment using insoles adapted to flip-flop sandals are still unknown.

Therefore, we present a protocol for a pragmatic study to investigate the short-term and medium-term effects of insoles adapted in flip-flop sandals on pain intensity, foot function, functional walking capacity and pain catastrophising of individuals with persistent heel pain. We hypothesise that insoles adapted in flip-flop sandals will reduce pain intensity and improve foot function, functional walking capacity and pain catastrophising in individuals with compared with sham insoles in individuals with persistent heel pain.

METHODS

Study design

This sham-controlled, randomised and single-blinded clinical trial study was approved by the research ethics committee of the Faculty of Health Sciences of Trairi, Federal University of Rio Grande do Norte (registry no. 4,018,821). This study will follow the Consolidated Standards of Reporting Trials guidelines, and the protocol will follow the Standard Protocol Items Recommendations for Intervventional Trials recommendations. The study flow chart is presented in figure 1.

Sample

Individuals will be recruited via social media, a waiting list at the Physical Therapy Outpatient Clinic of the Onofre Lopes University Hospital and dissemination in the Communication and Media Department of the hospital. The screening will be performed by one researcher using a telephone. If eligible, individuals will be informed about study aims and procedures and sign the informed consent form (online supplemental material). Personal information, anthropometric data, clinical history of the disease and foot posture will be collected. Personal data of individuals will be numerically encoded and stored in a database to ensure blinding.

Inclusion criteria

- Individuals of both sexes, aged from 18 to 65 years.
- Persistent heel pain for at least 3 months based on self-reported criteria: heel pain felt during first steps in the morning, after a period of inactivity or during prolonged weight-bearing.
- Pain intensity between 3 and 8 points, according to the Numerical Rating Pain Scale (NRPS).
- Individuals who can wear flip-flop sandals for at least 4 hours per day for 12 weeks.

Exclusion criteria

- Clinical diagnosis of neuropathic pain or neurodegenerative disorders, persistent heel pain due to rheumatic conditions or previous ankle or foot surgeries.
- Physical therapy treatment in the last 3 months.
- Corticosteroid injection into feet in the last 6 months.
- Perceived inability to answer study-related questionnaires.
- Individuals scheduled to travel in the next 6 months.

Research team

Five researchers will be responsible for different functions: (A) screening and blind assessment, (B) randomisation, (C) production and delivery of insoles adapted in flip-flop sandals, (D) tabulation of data collected and (E) statistical analysis (figure 2).

Randomisation

Researcher B will randomise (wwwsealedenvelope.com) the individuals selected in the screening and who agreed to participate in the study into two groups: (1) insoles adapted in flip-flop sandals with personalised foot...
elements; and (2) flip-flop sandals with sham insoles (ie, flat insoles without custom foot elements). Researcher B will not be involved in other study procedures.

Allocation
Opaque, sealed and sequentially numbered envelopes will be used to avoid allocation bias.

Blinding
Researcher A will identify the individuals by numbers and inform them about the study aims. Then, they will be assessed, and the results will be delivered to researcher C, who will produce the insole. The individuals will pick up the flip-flop sandals 5 days after the assessment at different times to avoid meetings or information exchange.

After the treatment, individuals will be asked which group they believe to be allocated to verify blinding effectiveness. However, groups will only be revealed after the follow-up assessment (T16), in which individuals can request to keep the personalised flip-flop sandals. After the last assessment, researcher D will tabulate and deliver the data to researcher E, who will conduct the statistical analysis.

Procedures and intervention
Assessments for prescription and production of insoles adapted in flip-flop sandals will be conducted at the Laboratory of Insoles and Rheumatology (Onofre Lopes university hospital). Data collection will start in April 2022 and end in October 2022. Data analysis will occur in November 2022, and we expect the manuscript is completed by December 2022.

Baseline assessment (T0) will comprise clinical and functional aspects of heel pain (ie, pain intensity, foot posture and function, pain catastrophising, expectation for treatment and functional walking capacity). Individuals will be informed on the importance of following recommendations for wearing sandals, possible risks and benefits of research and expectations with results. Also, individuals will sign the informed consent form.

Researcher C will define the foot element in the insole according to the Foot Posture Index (FPI-6), which classifies the foot as neutral, pronated or supinated (figure 3). This decision making will consider item three of this instrument—calcaneal frontal plane position.

Individuals with neutral feet allocated to the group insoles adapted in flip-flop sandals will receive flip-flop sandals with a horseshoe-type element on both feet to maintain limb symmetry, regardless of whether the problem is in only one foot (figure 4A). In contrast, individuals classified as pronated or supinated (item three of the FPI-6) will receive an insole adapted with an element for the painful foot, as the symmetry of the limb will not be altered. Individuals with a pronated foot will receive the medial wedge, and those with a supinated foot will receive a lateral wedge. The elements will have 3 mm of ethylene-vinyl acetate plastic (figure 4B). Finally, individuals from the sham group will receive flat flip-flop sandals without foot elements with the same coverage, regardless of FPI-6 assessment (figure 4C).

Insoles adapted to flip-flop sandals will be produced individually for each individual and delivered 5 days after assessment. They will be contacted to collect it and instructed about use, conservation and return to adjust if discomfort appears.

On delivery of the flip-flop sandals, the individuals will receive a diary to register the hours wearing the flip-flop sandals (minimum time of 4 hours a day). They will be instructed about how to fill the information in the diary and encouraged about the essential use of the instrument.

The second assessment will be conducted 6 weeks after delivery (T6). It will be performed using standardised commands via telephone by researcher A. At this stage, individuals will be encouraged to keep wearing the flip-flop sandals for at least 4 hours a day and register and control the daily hours of use in the diary.

For the third assessment (T12), pain intensity, foot function, functional walking capacity, blinding and self-assessment of treatment will be collected. At this stage, the individuals will be informed about the end of the treatment.

A follow-up assessment (T16) will be performed 4 weeks after treatment by researcher A via telephone. Standardised commands will be used to collect foot pain intensity, function and self-assessment of treatment.

Before each assessment, individuals will be asked not to use any therapeutic resources to control heel pain or general pain (eg, analgesic or anti-inflammatory drugs, ice, heat or any non-pharmacological and analgesic aid).

Assessments
Pain intensity, function, functional walking capacity and pain catastrophising will determine baseline data. Age, educational level, anthropometric data (height, body weight, body mass index and foot posture) and clinical
data (eg, disease history and time onset of symptoms) of individuals will be collected to characterise the sample.

FPI-6: this questionnaire will classify foot posture according to six clinical criteria: (1) talar head palpation; (2) supra and inframalleolar curvature; (3) calcaneal frontal plane position; (4) talonavicular prominence; (5) medial longitudinal arch congruence; and (6) abduction or adduction of the forefoot on the heel. Criteria are graded as 0 (neutral), +1 or +2 (pronated) or −1 or −2 (supinated). Values will result in a global foot posture index (results between +6 and +9 indicate a pronated foot; between +10 and +12, highly pronated; between −1 and −4, supinated foot; between −5 and −12, highly supinated; and between 0 and +5, neutral foot).22 Item 3 (calcaneal frontal plane position) will define the type of insole offered in the intervention. However, the characterisation of the sample will be based on FPI-6 total score.

Primary outcome
Pain intensity at first steps in the morning
NRPS: this 11-point scale will assess pain intensity at first steps in the morning and throughout the day, after walking. It ranges from 0 (absence of pain) to 10 (worst imaginable pain). The individuals will rate the mean heel pain felt in the last week.26 27

Secondary outcomes
Foot function
Foot Function Index (FFI) - Portuguese version: this questionnaire assesses foot function in individuals with musculoskeletal injuries and pain interference in daily activities, according to three sessions: pain, difficulty and functional limitation. The result (from 0% to 100%) will be the mean value of all domains (ie, the sum of values divided by three); higher values indicate greater functional loss.28

Functional walking capacity
6 min walking test: individuals must walk as fast as possible without running for 6 min on a flat corridor of 30 m; the researcher will provide verbal encouragement. Resting will be allowed during the trial without stopping the timer. The total distance (m) will be registered at the end of 6 min.29

Pain catastrophising
Pain Catastrophizing Scale – Portuguese version: a self-reported questionnaire composed of 13 items on a 5-point Likert scale about the degree of thought or feeling of each item. The instrument has three subscales (hopelessness, magnification and rumination); the total score (from 0 to 52 points) is obtained by the sum of items. Higher values indicate a greater level of catastrophising.30 31

Expectation for treatment
Expectation for treatment: this scale assesses the expectations of individuals at the beginning of the study regarding the treatment they will receive. This scale will be applied only at baseline (T0) assessment.15 The question will be ‘Do you think that with flip-flop sandals, you will: (1) get very worse, (2) get a little worse, (3) neither improve nor get worse, (4) improve a little, or (5) improve a lot’.

Self-assessment of treatment
Self-assessment of treatment: the scale will assess perceptions of the individual about the effects of the treatment using the following question: ‘After using flip-flop sandals with insoles, are you feeling: (1) much worse, (2) a little
worse, (3) neither better nor worse, (4) a little better, or (5) much better.23

Blinding
Blinding questionnaire: the individuals must respond to which group they believe to be allocated: intervention with adapted insoles in flip-flop sandals or flip-flop sandals with sham insoles. This questionnaire is recommended at the end of clinical trials to test whether blinding was effective.32

Daily hours of use
Diary for adapted insoles in flip-flop sandals: the individuals will be instructed to wear the flip-flop sandals as much as possible (a minimum of 4 hours daily). To ensure proper use, the individuals will receive a diary to register the using hours. In the T6 assessment, the individuals will be asked about their usage and reinforced to register daily use. In the T12 assessment, the diary will be returned to the researcher. This strategy ensures that individuals will not wear the sandals for less than 4 hours.15

Use of other analgesic modality
Register of usage of other analgesic modalities: before each assessment, individuals will be asked about the use of therapeutic resources for heel pain control (eg, ice or heat packs, massage) or any analgesic medication they might have used the day before the assessment, either for heel pain or general pain.

Figure 5 presents primary and secondary outcomes and instruments used at each assessment (T0 - baseline, T6, T12 and T16).

| TIMEPOINT | Screening | Baseline | Post- allocation |
|-----------|-----------|----------|-----------------|
| ENROLMENT: | -T1 | T0 | 6 weeks | 12 weeks | 16 weeks |
| Eligibility screen | | | | | |
| Informed consent | X | | | | |
| Allocation | X | | | | |
| INTERVENTIONS: | | | | | |
| Insoles adapted in flip-flop sandals group | | | | | |
| Flip-flop sandals with sham insoles group | | | | | |
| ASSESSMENTS: | | | | | |
| Foot Posture - FPI-6 | | X | | | |
| Pain intensity - NRPS | | X | X | X | X |
| Foot Function - FFI | | X | X | X | X |
| Functional walking capacity - 6MT | | X | | X | |
| Pain catastrophizing - PCS | | X | | | |
| Expectation with treatment | | X | | | |
| Self-assessment of treatment | | | X | X | |
| Blinding test | | | | X | |
| Daily hours of use - Diary | | | | X | |
| Use of other analgesic modality | | | | X | X | X | X |

Figure 5  Ratings and times according to SPIRIT. Source: created by the authors. SPIRIT, Standard Protocol Items Recommendations for Interventional Trials.
**Patient and public involvement**

Individuals will not be involved in the study design (ie, establishing research questions or enrollment procedures). At the end of the study, results may be reported to individuals in a lecture. If the treatment of insoles adapted in flip-flop sandals is more effective than that of flip-flop sandals with sham insoles, the insoles will be offered and guaranteed to the individuals of the sham-controlled group.

**Training of researchers**

Researchers will be trained before the study regarding the following steps: assessments, production of insoles adapted in flip-flop sandals, recommendations for using flip-flop sandals, standardisation and consensus among researchers.

**Sample size calculation**

The sample size was calculated based on the NRPS from a previous study. The statistical power of 80% was used to detect a mean difference of 1.8 points in pain, based on a difference found between groups in a study by Costa et al. Each group will need 36 individuals considering an estimated SD of 3.2 points and a 5% significance level. However, a sample loss of 10% was added, leading to a sample of 40 individuals per group.

**Statistical analysis**

A blinded researcher will perform the statistical analyses using Software IBM SPSS 22. Independent variables of group (insole adapted in flip-flop sandals and flip-flop sandals with sham insole) and time (T0, T6, T12 and T16) will be considered for each dependent variable: pain intensity, foot function, functional walking capacity, pain catastrophising, expectation for treatment and self-assessment of treatment. Kolmogorov-Smirnov test will verify data distribution, and the Levene test will assess the homogeneity of variance.

If data are normally distributed, analysis of variance with mixed design will be performed for primary and secondary outcomes, with time as a within-subject factor and group as a between-subject factor. If needed, an analysis of covariance will be performed using other therapeutic resources as a covariate. Friedman’s test will be used for data not normally distributed. Interaction between time and group and intergroup and intragroup differences will be analysed for all variables. Bonferroni correction for multiple comparisons will be performed for secondary outcomes to eliminate multiple positives. The number of comparisons required a decrease in the alpha value.

An intention-to-treat analysis will be applied to ensure the effects of randomisation and uniform distribution of prognostic factors between groups. A significance level of 5% and a 95% CI will be considered for statistical analysis. If adverse events occur, they will be described in the manuscript using relative frequency.

**DISCUSSION**

This study will compare the effects of insoles adapted in flip-flop sandals with flip-flop sandals with sham insoles for persistent heel pain. Individuals will be assessed during a 12-week treatment and after 4 weeks of follow-up.

The types of orthoses used to treat heel pain are not a consensus in the literature. Studies in the most recent guideline on plantar pain management did not include this type of orthosis, and studies differed in prescription, casting technique, coating material, upper coverings and modifications. Although this limits experimental comparison, evidence supports recommending insole-type orthotics to manage heel pain.

The guideline on plantar pain management considered as primary evidence of efficacy a study that included prefabricated and customised foot orthoses for short-term pain compared with placebo. However, a single orthosis prescription is not recommended for all patients since prefabricated orthoses are ineffective. Similarly, previous studies recommend orthoses to improve pain intensity and function in individuals with persistent heel pain.

Few studies used insoles adapted to flip-flop sandals as therapeutic resources. A previous study observed that insoles adapted in flip-flop sandals were superior to flat flip-flop sandals after a 12-week use in individuals with heel pain caused by plantar fasciitis. Another study observed that flip-flop sandals with moulded foot-bed improved foot pain and function of individuals with foot pain in the short term (12 weeks) compared with normal sandals.

Vicenzino et al. compared the effects of a contoured sandal for plantar heel pain with flat flip-flops and contoured in-shoes insole orthosis. Authors found that contoured sandals were 61% more likely to report improvement than flat sandals; however, contoured sandals were not significantly different from sham insoles. In our study, the insoles will be customised according to the hind foot of the individual, possibly being a more efficient pragmatic strategy.

The study design must be precise to strengthen research about orthoses, and resources used to prescribe and personalise insoles for individuals with heel pain must be properly described. This protocol presents all steps favouring a high-quality methodological study. Procedures and outcome measures were clearly defined, the sample will be properly randomised with adequate size and the researchers responsible for the assessments and statistical analysis will be blinded. A self-reported tool will be used for pain management during the intervention, and an intention-to-treat approach will be performed. Also, a postintervention assessment and a 4-week follow-up will be conducted to verify short-term and medium-term effects.

A limitation of the study is the non-restricted use of other therapeutic resources to reduce the pain of individuals during the study. Individuals will be asked before each assessment about any analgesic therapeutic resource (pharmacological or not) used during assessments to
minimise this limitation; this information will be recorded and analysed.

Since no consensus is available on the most effective type of insoles and standardisation about their use, this blinded randomised sham-controlled clinical trial protocol may provide scientific direction and prescription for the clinical use of insoles adapted in flip-flops sandals for individuals with persistent heel pain.

**Ethical approval, consent to participate and dissemination**

This study was approved by the research ethics committee (registry no.: 4,018,821) of the Faculty of Health Sciences of Trairi (Federal University of Rio Grande do Norte) and complied with guidelines and standards for research involving human beings (resolution 466/12 of the National Health Council). An informed consent form will be explained and signed by each individual.

Procedures will be conducted according to the Declaration of Helsinki. Respect for individuals will be ensured, and autonomy will be maintained. Individuals will be informed about the aims of the study, risks and benefits, and the right to withdraw from the study at any time without explanations. This protocol was registered on ClinicalTrials.gov (NCT 04784598), and the results will be disseminated in peer-reviewed journals, lectures and scientific meetings.

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Study conception and design: all authors. Data analysis: GMB. Drafting of the manuscript: all authors. Critical revisions: all authors. Final approval of the article: all authors. Funding: MCOUS. Responsible for the integrity of the study: marcellogv@hotmail.com.

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**Competing interests**

None declared.

**Patient and public involvement**

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication**

Not applicable.

**Provenance and peer review**

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**Supplemental material**

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