Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of adding a mechanical plantar massager to routine physiotherapy on pain intensity and function in patients with plantar fasciitis: a single-blind randomized controlled trial

Protocol summary

Study aim

To investigate the effect of adding a home-based mechanical plantar massage device to exercise therapy and therapist-administered myofascial release on pain intensity and function in individuals with plantar fasciopathy

Design

Randomized, parallel-group, single-blind (outcome assessor blinded) active-controlled (no placebo) clinical trial, with a 1:1 allocation ratio and block randomization with variable block sizes

Settings and conduct

This study will be conducted at the Rehabilitation Clinic, School of Rehabilitation Sciences, Shiraz University of Medical Sciences, located at Chamran Hospital

Participants/Inclusion and exclusion criteria

Inclusion Criteria Age 18–65 years Clinical diagnosis of plantar fasciopathy Tenderness at plantar fascia-calcaneal insertion Symptoms ≥3 months (chronic) Able to walk independently and perform study interventions Willing to participate and sign informed consent Exclusion Criteria Findings suggesting other causes of heel pain Signs of nerve involvement Inflammatory/systemic disease affecting heel pain or outcomes History of foot/ankle surgery or severe lower limb injury affecting gait Known plantar fascia rupture or structural injury precluding intervention Uncontrolled concurrent treatment for plantar fasciopathy Overt structural foot abnormality (e.g., pes planus/cavus)

Intervention groups

Control Group: Exercise therapy with plantar fascia myofascial release Intervention Group: Exercise therapy and myofascial release with use of a mechanical plantar massage device

Main outcome variables

To assess the effect of adding a home-based mechanical plantar massage device to exercise therapy and myofascial release on pain and function in plantar fasciopathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250629066291N7**
Registration date: **2026-09-28, 1405/07/06**
Registration timing: **prospective**

Last update: **2026-09-28, 1405/07/06**
Update count: **0**

Registration date

2026-09-28, 1405/07/06

Registrant information

Name

Farzaneh Haghighat

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-27, 1405/08/05

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding a mechanical plantar massager to routine physiotherapy on pain intensity and function in patients with plantar fasciitis: a single-blind randomized controlled trial

Public title

The effect of adding a mechanical plantar massager to routine physiotherapy on pain intensity and function in patients with plantar fasciitis: a single-blind randomized controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 65 years Clinical diagnosis of plantar fasciopathy based on pain in the plantar and medial heel region, particularly at the site of insertion of the plantar fascia into the medial calcaneal tuberosity, accompanied by exacerbation of pain during the first steps after waking up or after a period of rest Presence of localized tenderness to palpation at the site of insertion of the plantar fascia into the medial calcaneal tuberosity on clinical examination Duration of symptoms of at least three months prior to enrollment, in order to select individuals with chronic plantar fasciopathy Ability to walk independently and to perform the exercise therapy program and interventions specified in the study Willingness to participate in the study and to complete the informed consent form

Exclusion criteria:

Presence of symptoms or findings inconsistent with a clinical diagnosis of plantar fasciopathy, or suggestive of other causes of heel pain, including calcaneal fracture or stress fracture, heel fat pad disorders, peripheral nerve irritation or entrapment, and other known causes of heel pain Presence of symptoms or clinical findings suggestive of nerve involvement, including numbness, tingling, radiating pain, or other sensory symptoms indicating possible neural involvement or a non-local origin of pain Presence of known inflammatory or systemic diseases that could contribute to heel pain or foot dysfunction and that could affect the diagnosis or assessment of study outcomes, including spondyloarthropathies History of surgery on the affected foot or ankle, or history of severe lower limb injury with a significant effect on foot function or gait pattern Presence of a known plantar fascia rupture or other defined structural injuries of the foot and ankle that would render the study interventions inappropriate Receipt of any specific therapeutic intervention outside the study protocol for plantar fasciopathy that continues concurrently with the start of the study and cannot be discontinued or controlled during the intervention period Presence of overt structural foot abnormalities, including pes planus or pes cavus, observed and confirmed on clinical assessment

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated to the intervention and control groups using block randomization with variable block sizes and a 1:1 allocation ratio. The randomization sequence will be generated by an individual independent of participant recruitment and intervention delivery. To ensure allocation concealment, the sequence will be placed in sequentially numbered, opaque, sealed envelopes (SNOSE). After completion of each participant's baseline assessments and confirmation of eligibility, the corresponding envelope will be opened in numerical order to reveal group allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be conducted as a single-blind randomized controlled trial. In this design, the outcome assessor will be blinded to participants' group allocation and the type of intervention received. Pre- and post-intervention assessments will be performed by a trained assessor independent of the treatment delivery process. To maintain assessor blinding, participants will be instructed not to disclose the type of intervention received to the assessor during outcome assessments. Given the nature of the interventions (exercise therapy, myofascial release, and use of the home-based mechanical device), blinding of participants and the treating therapist to the intervention type will not be feasible.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Ethics committee, Research and Technology Vice-Chancellor, 7th floor, Central building of Shiraz

University of Medical Sciences, Zand Street

City
Shiraz

Province
Fars

Postal code
7198754361

Approval date
2021-10-11, 1400/07/19

Ethics committee reference number
IR_SUMS.REC.1400.544

Health conditions studied

1

Description of health condition studied
plantar fasciitis

ICD-10 code
M72.2

ICD-10 code description
Plantar fascial fibromatosis

Primary outcomes

1

Description
Heel pain intensity

Timepoint
Pain during the day and pain during the first steps in the morning

Method of measurement
The Visual Analogue Scale (0–10)

Secondary outcomes

1

Description
Foot and ankle function (FAAM)

Timepoint
Before the intervention, immediately after the 4-week treatment period, and 4 weeks after completion of treatment

Method of measurement
FAAM questionnaire (21-item ADL subscale); each item scored 0 (unable to perform) to 4 (no difficulty); lower scores indicate greater functional limitation.

2

Description
Pressure pain threshold of the plantar surface

Timepoint
Before the intervention, immediately after the 4-week treatment period, and 4 weeks after completion of treatment

Method of measurement
Pressure algometer; patient prone, the most tender plantar point marked, algometer applied perpendicular to the point at approximately 1 kg/s; the moment pain is first felt is recorded; two measurements 3 minutes apart, averaged.

3

Description
Ankle dorsiflexion range of motion

Timepoint
Before the intervention, immediately after the 4-week treatment period, and 4 weeks after completion of treatment

Method of measurement
Standard goniometer; patient sitting on the treatment table, the tested knee in full extension, the opposite limb hanging off the edge of the table.

Intervention groups

1

Description
Intervention group:

Category
Treatment - Devices

2

Description
Control group:

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinic of Rehabilitaion School, Shiraz University of Medical Sciences

Full name of responsible person
فرزانه حقیقت

Street address
Mehr Building, Shahid Chamran Hospital, Shahid Chamran Boulevard

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Hamid Mohammadi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shiraz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Farzaneh Haghighat

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Information collection form including primary and secondary outcomes, informed consent form and SSPS file.
When the data will become available and for how long
After publication of the results of the study
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Only for recording information in scientific databases
From where data/document is obtainable
correspondence with the project manager by email. Haghighat_fa@yahoo.com
What processes are involved for a request to access data/document
Maximum one month after sending the request by email.
Comments