

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Effects of Combined Myofascial Release and Fascia Stretching Therapy Versus Myofascial Release Alone on Pain and Function in Chronic Plantar Fasciopathy: A Randomized Controlled Trial

#### Protocol summary

##### Study aim

Comparative effects of Myofascial Release and Fascia Stretching Therapy Versus Myofascial Release Alone on pain intensity and functional disability in individuals with chronic plantar fasciitis

##### Design

A controlled clinical trial practical groups, single blind, randomized, phase 3, conducted on 90 patient. Computer software was used for randomization

##### Settings and conduct

Participants diagnosed by a physician and referred to Arvand Physiotherapy Clinic were invited to participate, provided that the duration of their condition was at least 3 months.

##### Participants/Inclusion and exclusion criteria

Individuals with a history of chronic plantar fasciopathy lasting more than 3 months

##### Intervention groups

The intervention group received myofascial release and fascia stretching therapy. The control group received no therapeutic intervention during the study period and continued their usual daily activities.

##### Main outcome variables

Scores of the visual analog scale for pain and the Foot Functional Index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250519065806N3**

Registration date: **2026-05-01, 1405/02/11**

Registration timing: **prospective**

Last update: **2026-05-01, 1405/02/11**

Update count: **0**

##### Registration date

2026-05-01, 1405/02/11

##### Registrant information

###### Name

Mostafa Jalili Bafrouei

###### Name of organization / entity

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2026-05-05, 1405/02/15

##### Expected recruitment end date

2026-06-05, 1405/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Combined Myofascial Release and Fascia Stretching Therapy Versus Myofascial Release Alone on Pain and Function in Chronic Plantar Fasciopathy: A Randomized Controlled Trial

##### Public title

Combined myofascial release and fascia stretching therapy for chronic heel pain

##### Purpose

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Adults aged 25–40 years Clinical diagnosis of chronic plantar fasciopathy (symptom duration >3 months) by doctor of medicine Presence of localized tenderness at the medial calcaneal tuberosity Pain during the first steps after a period of rest Willingness to participate and provide written informed consent absence of specific spinal pathology or musculoskeletal disorders lower limbs No prior structured physiotherapy for the condition in the last 3 months Ability to participate in the full intervention period

**Exclusion criteria:**  
History of corticosteroid injection in the affected foot within the previous 6 months Previous foot or ankle surgery Systemic inflammatory or rheumatologic diseases (e.g., rheumatoid arthritis, lupus) Neurological disorders affecting lower limb function (e.g., neuropathy, radiculopathy) Structural foot deformities (e.g., severe pes planus, pes cavus, or congenital deformities) Acute musculoskeletal injuries of the lower extremity during the study period Participation in other physical therapy or rehabilitation programs during the study Use of analgesic or anti-inflammatory medication that could affect pain outcomes without a stable dosage Failure to attend more than 20% of treatment sessions or poor adherence to protocol Pregnancy (for females)

**Age**  
From **25 years** old to **40 days** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **90**  
More than 1 sample in each individual  
Number of samples in each individual: **1**  
Chronic Plantar Fasciopathy data on plantar fascia function

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
After completion of baseline assessments, participants were randomly allocated to one of three groups: Myofascial Release, Myofascial Release and Fascia Stretching Therapy, or control. Randomization was performed using a simple random allocation procedure with a 1:1:1 ratio to ensure equal group sizes. The randomization sequence was generated using a computer-based random number generator by a researcher who was not involved in participant recruitment, intervention delivery, or outcome assessment. Allocation assignments were placed in sequentially numbered opaque sealed envelopes, which were opened only after completion of baseline

measurements. To reduce assessment bias, the outcome assessor remained blinded to group allocation throughout the study. Participants were instructed not to disclose their assigned intervention during post-intervention testing.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Outcome assessor and data and statistical analyzer will be blinded from knowing intervention groups. This individual, a physiotherapist, is blinded to group allocation and is unaware of which participants belong to the intervention group and which belong to the control group.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**  
Sports Sciences Research Institute

**Street address**  
No 32 , Miremad Avenue, Motahary street, Tehran

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Tehran

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**Postal code**  
1423654185

**Approval date**  
2025-02-11, 1403/11/23

**Ethics committee reference number**  
IR.SSRC.REC.1403.081

## Health conditions studied

**1**

**Description of health condition studied**  
Chronic Plantar Fasciopathy

**ICD-10 code**  
M72.2

**ICD-10 code description**  
Plantar fascial fibromatosis

## Primary outcomes

**1**

**Description**  
Pain intensity and functional capacity

**Timepoint**

First week and 8 weeks

## Method of measurement

Visual Analog Scale (VAS) and Foot Functional Index

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: After obtaining ethics approval, individuals with chronic plantar fasciopathy who met the inclusion criteria were invited to participate in the study. Participants were identified through structured interviews and questionnaires that included demographic and medical history information, conducted by the researcher. The inclusion criteria were: age between 25 and 40 years, clinical diagnosis of chronic plantar fasciopathy (symptoms lasting more than 3 months), localized tenderness at the medial calcaneal tuberosity, pain during the first steps after rest (especially morning pain), no structured physiotherapy within the past 3 months, ability to complete the intervention period, and written informed consent. Exclusion criteria included: history of corticosteroid injection in the affected foot within the previous 6 months, previous foot or ankle surgery, systemic inflammatory or rheumatologic diseases (e.g., rheumatoid arthritis or lupus), neurological disorders affecting lower limb function (e.g., neuropathy or radiculopathy), structural foot deformities (e.g., severe pes planus, pes cavus, or congenital deformities), acute musculoskeletal injury of the lower limb during the study period, concurrent participation in other rehabilitation or physiotherapy programs, use of analgesic or anti-inflammatory medications that could affect outcomes (unless on a stable dose), and pregnancy (if applicable). All participants provided written informed consent after receiving a full explanation of the study objectives, procedures, and their responsibilities. Demographic and clinical data, including age, height, weight, physical activity history, and pain intensity, were collected through questionnaires and face-to-face interviews. A total of 90 eligible participants were randomly allocated with equal probability into three groups: myofascial release (MFR) (n = 30), combined myofascial release and fascia stretching therapy (MFR+FST) (n = 30), and control (n = 30). The two intervention groups participated in an 8-week supervised training program, consisting of three 45-minute sessions per week. Each session included 10 minutes of warm-up, 30 minutes of the main intervention, and 5 minutes of cool-down. Exercise intensity and difficulty were progressively increased based on participant tolerance and adaptation. In both intervention groups, standardized myofascial release (MFR) was applied. Participants were positioned supine with the lower limb supported in an extended position and the ankle maintained in a neutral position by the therapist. The therapist applied sustained ischemic pressure using the

thumb at three anatomical sites: the medial calcaneal tuberosity, the distal first metatarsal, and the distal fifth metatarsal. Each point received 90 seconds of pressure, repeated three times, with a total treatment duration of approximately 15 minutes per session. In the combined intervention group, fascia stretching therapy (FST) was additionally performed. Participants stood in a forward lunge position facing a wall, with the contralateral limb placed anteriorly and in contact with the wall. The therapist stood behind the participant, holding the affected ankle and tibia while applying controlled posterior traction toward the therapist's trunk. Stretching was performed in two variations: with the knee extended to target the gastrocnemius muscle and with the knee flexed to target the soleus muscle. All participants were evaluated before and after the intervention period. Outcome measures included pain intensity assessed using the Visual Analogue Scale (VAS) and functional ability assessed using the Foot Function Index (FFI).

#### Category

Rehabilitation

### 2

#### Description

Control group: No intervention was performed before ethics approval and trial registration. After obtaining ethical approval, eligible individuals were invited to participate in the study. For participant recruitment, the researcher visited the physician's clinic and reviewed medical records of patients diagnosed with chronic plantar fasciopathy. Potential participants were screened according to the predefined inclusion and exclusion criteria. Eligibility was assessed for each individual through direct contact and clinical screening based on the study criteria. Based on the required sample size, eligible individuals who initially agreed to participate were selected. The objectives of the study, as well as potential benefits and possible risks of participation, were fully explained to all participants. Participants were informed that their participation was voluntary and that they could withdraw from the study at any stage without any consequences. Written informed consent was obtained from all participants who agreed to participate. Demographic information, including age, weight, and height, was collected through face-to-face interviews. All participants underwent baseline (pre-intervention) assessment before the start of the intervention. Outcome measures included pain intensity assessed using the Visual Analogue Scale (VAS) and functional ability assessed using the Foot Function Index (FFI). The order of assessment was identical for all participants. A pre-test was also conducted for the control group before the intervention period. The control group did not receive any intervention for 8 weeks and continued their usual daily activities throughout the study period. All participants were reassessed after the 8 weeks using the same outcome measures

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Arvand Physiotherapy

**Full name of responsible person**

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Sports Sciences Research Institute

**Full name of responsible person**

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Sports Sciences Research Institute

**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**

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**Full name of responsible person**

Mohammadreza Seyedi

**Position**

Assistant professor

**Latest degree**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

#### Contact

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

There is no further information

**When the data will become available and for how long**

3 Month after pulication

**To whom data/document is available**

Everyone

**Under which criteria data/document could be used**

For research and rehabilitation

**From where data/document is obtainable**

Email

**What processes are involved for a request to access data/document**

One week time to gather the needed data

**Comments**