

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### The effects of two night splints on the pain and quality of life of people with plantar faciitis

#### Protocol summary

##### Study aim

To investigate the effects of two night splints on the pain and quality of life of people with plantar faciitis

##### Design

A clinical trial with a parallel-group design that included two intervention groups and a control group. 30 participants were allocated to three groups using the strata randomization method.

##### Settings and conduct

This study was a parallel-groups clinical trial. Participants were allocated into study groups using a stratified randomization method (gender was the stratification factor). Participants were recruited through a convenience sampling method and from outpatient clinic of the Alzahra Hospital, Isfahan, Iran. There was no blinding for participants and assessor.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria were pain complain at the heel and stiffness and pain at the heel in morning. The exclusions were the history of surgery and fracture in the foot and leg and sensory loss in the foot.

##### Intervention groups

Intervention group used a neoprene splint for night stretching and a pair of silicon heel pad for daily use. Control group used a plastic ankle-foot splint for night stretching and a pair of silicon heel pad for daily use (the conventional orthotic management).

##### Main outcome variables

The main outcome measures included range of motion at the ankle and foot, pain intensity, and quality of life.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150210021034N5**

Registration date: **2020-02-06, 1398/11/17**

Registration timing: **retrospective**

Last update: **2020-02-06, 1398/11/17**

Update count: **0**

##### Registration date

2020-02-06, 1398/11/17

##### Registrant information

###### Name

Ebrahim Sadeghi-Demneh

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3792 5235

###### Email address

sadeghi@rehab.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-02-19, 1395/12/01

##### Expected recruitment end date

2017-09-23, 1396/07/01

##### Actual recruitment start date

2017-10-23, 1396/08/01

##### Actual recruitment end date

2018-05-22, 1397/03/01

##### Trial completion date

2018-05-31, 1397/03/10

##### Scientific title

The effects of two night splints on the pain and quality of life of people with plantar faciitis

##### Public title

Orthotic effects on the symptoms of plantar faciitis

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Pain complain at the heel ( score 3 and more based on visual analogue scale) Stiffness and pain at the heel in morning

**Exclusion criteria:**

History of surgery and fracture in the foot and leg  
Sensory loss in the foot

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

Actual sample size reached: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization was stratified by gender to pursue equal distribution of the gender for all intervention and control groups. Randomization in each stratum was carried out by having a piece of paper that has the phrase "intervention 1 (heel stretching splint+heel pad)", "intervention 2 (toe stretching splint+heel pad)"and "control (heel pad only)" placed inside an envelope. The outside of the envelops were sequentially numbered. After participants have been enrolled in the study and consented, a sequence number envelope on the stack will be randomly drawn and opened to determine the study group that the participant will enter.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

ethical committee of Isfahan University of Medical Sciences, Isfahan, Iran

**Street address**

Hezar Jerib St.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2017-01-22, 1395/11/03

**Ethics committee reference number**

IR.MUI.REC.1395.3.726

**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**

Pain intensity

**Timepoint**

The measurement was carried out before intervention and 4 weeks after intervention.

**Method of measurement**

Pain intensity was measured using visual analogue scale.

**2**

**Description**

Range of motion at the heel and metatarsophalangeal joints

**Timepoint**

The measurement was carried out before intervention and 4 weeks after intervention.

**Method of measurement**

The passive range of motion was measured using a digital goniometer.

**3**

**Description**

Quality of life

**Timepoint**

The measurement was carried out before intervention and 4 weeks after intervention.

**Method of measurement**

The quality of life was measured using the Persian version of SF-36 questionnaire.

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

First intervention group: an ankle-foot splint was used for night-time stretching of the plantar fascia and a pair of silicone heel pad for day-time use. The ankle-foot splint

is a plastic-made device that extends from the dorsal aspect of the leg to the toes. This device is used during resting or sleeping time and fitted on the limb with three straps. This device maintains the ankle in the dorsiflexion position and thereby exerts a stretching force on the plantar fascia. The silicone heel pad is used to reduce the local pressure on the lesion area.

**Category**

Treatment - Devices

**2****Description**

Second intervention group: a neoprene ankle-foot support was used for night-time stretching the plantar fascia and a pair of silicone heel pad for day-time use. The ankle-foot support is made of a neoprene rubber that is put on like a sock. This device is used during resting or sleeping time and pulls the toes toward the shank using an adjustable strap. This device extends the toes and thereby exerts a stretching force on the plantar fascia. The silicone heel pad is used to reduce the local pressure on the lesion area.

**Category**

Treatment - Devices

**3****Description**

Control group: the use of silicone heel pad during day. A pair of silicone heel pad was used to reduce the pressure on the lesion area.

**Category**

Treatment - Devices

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Alzahra Hospital, Isfahan, Iran

**Full name of responsible person**

Shahriar Mirshams

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Sofeh Blvd

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8174675731

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alzahra@mui.ac.ir

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<http://alzahra.mui.ac.ir>

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mahdi Nematbakhsh

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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**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ebrahim Sadeghi-Demneh

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Orthopedics

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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Associate professor  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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Esfahan University of Medical Sciences  
**Full name of responsible person**  
Ebrahim Sadeghi-Demneh  
**Position**  
Associate professor  
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**Other areas of specialty/work**

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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

Undecided - It is not yet known if there will be 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

The study data (excluding the personal details) can be shared with other researchers or systematic reviewers.

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

No specific limitation is considered.

### To whom data/document is available

No limit was set.

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

No terms and conditions is considered for sharing the data.

### From where data/document is obtainable

People can send their request to the correspondence and obtain the data.

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

Request can be sent through an email.

### Comments