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

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Ebrahim Sadeghi-Demneh

Name of organization / entity
Isfahan University of Medical Sciences

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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 fasciitis

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.

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Province

Isfehan

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 metatarsophalengeal 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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

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

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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 shred 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 sent 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