Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Effect of Instrument Assisted Soft Tissue Mobilization Ergon Technique on Pain, Strength and Range of Motion in Plantar Fasciitis Patients: A Randomized Controlled Trial.

Protocol summary

Study aim

To compare the effects of Ergon Therapy with Routine physical therapy treatment (cryotherapy, ultrasound therapy and stretching exercises) in treating plantar fasciitis.

Design

A single blinded randomized controlled trial study will be carried out on patients having Planter fasciitis. Patients will be recruited from Department of Physiotherapy, University of Lahore Teaching Hospital, Lahore and Citi hospital Lahore. They will be assessed on selection criteria and eligible participants will be randomly allocated into two groups, using sealed enveloped method. Patients will be treated three times a week for total 5 weeks. After allocation in groups, participants will be assessed at baseline. Afterwards data will be collected at 1st-week intervals then 3rd week until the conclusion of 5th-week of interventions. All assessments will be performed by the same assessor at all stages of data collection for all patients.

Settings and conduct

Physical Therapy Department of University of Lahore teaching hospital, Citi hospital Lahore

Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Diagnosed patients of plantar fasciitis. • Age more than 18 years and less than 40 and Both genders. • Connective tissue disorders (Osteoarthritis, Rheumatoid arthritis, Osteoporosis, Fibromyalgia). Exclusion Criteria: • History of previous surgical treatment or cancer of the heel • Foot and/or ankle fracture Congenital deformity

Intervention groups

Group A will be treated with routine physiotherapy program Group B will be treated with routine physiotherapy program combined with Ergon technique

Main outcome variables

Visual Analogue Scale, Manual muscle testing and Goniometer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210816052201N2**
Registration date: **2021-10-11, 1400/07/19**
Registration timing: **retrospective**

Last update: **2021-10-11, 1400/07/19**
Update count: **0**

Registration date

2021-10-11, 1400/07/19

Registrant information

Name

Sana Akram

Name of organization / entity

The University of Lahore, Lahore Pakistan

Country

Pakistan

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+92 42 35183083

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-01, 1399/12/11

Expected recruitment end date

2021-05-10, 1400/02/20

Actual recruitment start date

2021-03-13, 1399/12/23

Actual recruitment end date

2021-07-15, 1400/04/24

Trial completion date

2021-11-25, 1400/09/04

Scientific title

Effect of Instrument Assisted Soft Tissue Mobilization Ergon Technique on Pain, Strength and Range of Motion in Plantar Fasciitis Patients: A Randomized Controlled Trial.

Public title

Effect of Instrument Assisted Soft Tissue Mobilization Ergon Technique on Pain, Strength and Range of Motion in Plantar Fasciitis Patients: A Randomized Controlled Trial.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed patients of plantar fasciitis Connective tissue disorders (Osteoarthritis, Rheumatoid arthritis, Osteoporosis, Fibromyalgia

Exclusion criteria:

History of previous surgical treatment or cancer of the heel Foot and/or ankle fracture Congenital deformity

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **32**

Actual sample size reached: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly allocated in two treatment groups by computer generated table number. After randomization, opaque sealed envelope will be offered to the patients. Once a patient has consented to enter a trial, an envelope is opened by clinician and treatment will be provided according to the group mention on the envelope. Group A will be treated with routine physiotherapy program Group B will be treated with routine physiotherapy program combined with Ergon technique .

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessor will be blinded by hiding the identity of patients. The patients will be trained not to give any hint about their allocation and their treatment groups. Blinding will be assessed by asking the assessor(force choice) to tell about patient group and a significant test will be used to see if there is a substantial chance that the assessor know about patient group identity for this p-value less than .05 will be used as significant value.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Lahore(Institutional Review Board)

Street address

The University of Lahore

City

Lahore

Postal code

54000

Approval date

2021-02-25, 1399/12/07

Ethics committee reference number

822

Health conditions studied

1

Description of health condition studied

Planter Fasciitis

ICD-10 code

M72.2

ICD-10 code description

Plantar fascial fibromatosis

Primary outcomes

1

Description

Primary outcome variables are pain, range of motion and strength

Timepoint

Patients will be recruited from Department of Physiotherapy, University of Lahore Teaching Hospital, Lahore and Citi hospital Lahore. They will be assessed on selection criteria and eligible participants will be randomly allocated into two groups, using sealed enveloped method. Patients will be treated three times a week for total 5 weeks. After allocation in groups, participants will be assessed at baseline. Afterwards data will be collected at 1st-week intervals then 3rd week until the conclusion of 5th-week of interventions. All assessments will be performed by the same assessor at all stages of data collection for all patients

Method of measurement

Visual Analogue Scale (VAS):It is used in clinical research to measure the intensity or frequency of Pain. Universal

Goniometer: An instrument which measures the available range of motion (ROM) at a joint. Strength: Manual Muscle Testing is the most commonly used method for documenting impairments in muscle strength.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: will receive instrument assisted soft tissue mobilization technique for fifteen minutes using ergon tools and conventional treatment including cryotherapy (10 minutes), ultrasound therapy (10 minutes) and Planter fascia stretching exercises (10 minutes), total time (45minutes/session). The Ergon with Conventional Therapy group will treated with 3 sessions per week.
Category
Treatment - Other

2

Description
Control group: will receive conventional treatment including cryotherapy (10 minutes), ultrasound therapy (10 minutes) and Planter fascia stretching exercises (10 minutes), total time (30minutes/session).The conventional group will also treated with 3 session per week.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
The University of Lahore teaching hospital
Full name of responsible person
Sana Akram
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Lahore
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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
The University of Lahore
Proportion provided by this source
100
Public or private sector
Private
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
The University of Lahore, Lahore Pakistan
Full name of responsible person
Asim Arif
Position
Assistant Professor
Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Effect of Instrument Assisted Soft Tissue Mobilization Ergon Technique on Pain, Strength and Range of Motion in Plantar Fasciitis Patients: A Randomized Controlled Trial.

When the data will become available and for how long
After publication of article the data will be available

To whom data/document is available
The data will be available to all kinds of Academic researchers

Under which criteria data/document could be used
A request can be processed by the study sponsor or by a delegate of the sponsor (e.g., an academic institution).

From where data/document is obtainable
Applicant must contact cores ponder of a research through email address

What processes are involved for a request to access data/document
Applicant must contact cores ponder of a research through email address

Comments
I am very thankful to Iranian trial registry team for making steps brief and to the point for registration