

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative effects of primal reflex release technique versus positional release technique on tightened calf muscles

Protocol summary

Study aim

To evaluate the effectiveness of the primal reflex release technique on calf tightness

Design

Design of the study was randomized clinical trial, sample size was 32, parallel groups, single blind

Settings and conduct

Madina teaching Hospital, Faisalabad and The University of Faisalabad

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Adult Age 20 to 30 years Both gender (male, female) Prolong standing for more than six hours from more than two months. Reduced ROM (ankle dorsiflexion<15). Tender nodules or tender points in calf muscles on deep palpation. NPRS showing more than 3(3-10). Exclusion Criteria: Lower limb surgery (six months). Medical or surgical complication e.g infection, necrosis, ulcer. Fibromyalgia. Congenital foot and ankle deformity e.g club foot, cleft foot, pes cavus. Lower limb fracture. Deep vein thrombosis both acute and chronic. Diabetic neuropathy.

Intervention groups

Two interventional groups numbered as group A and group B in which group A received primal reflex release technique and group B received positional release technique while the baseline treatment was hot pack.

Main outcome variables

Pain, ROM, Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240721062499N1**

Registration date: **2024-08-03, 1403/05/13**

Registration timing: **retrospective**

Last update: **2024-08-03, 1403/05/13**

Update count: **0**

Registration date

2024-08-03, 1403/05/13

Registrant information

Name

Sana Talib

Name of organization / entity

The University of Faisalabad

Country

Pakistan

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+92 41 8868326

Email address

2022-ms-pt-023@tuf.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-29, 1402/12/10

Expected recruitment end date

2024-05-10, 1403/02/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effects of primal reflex release technique versus positional release technique on tightened calf muscles

Public title

Primal reflex release technique for calf tightness

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult Age 20 to 30 years Both gender (Male, Female)
Prolong standing for more than six hours from more than two months. Reduced ROM (ankle dorsiflexion<15).
Tender nodules or tender points in calf muscles on deep palpation. NPRS showing more than 3(3-10).

Exclusion criteria:

Lower limb surgery (six months). Medical or surgical complication e.g infection, necrosis, ulcer. Fibromyalgia. Congenital foot and ankle deformity e.g club foot, cleft foot, pes cavus. Lower limb fracture. Deep vein thrombosis both acute and chronic. Diabetic neuropathy.

Age

From **20 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization clinical trial was conducted by using stratified randomization. Unit of randomization were individuals. The tools used in randomization were random numbers. Random sequence was done by selecting the individuals one by one as they met the criteria of inclusion. Allocation concealment was carried out.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants were blinded in the study. The researcher did not inform the participant that in which intervention group they have been added.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research and Ethics / technical committee for The University of Faisalabad

Street address

Faisal Town, West Canal Road, Faisalabad, Punjab

City

Faisalabad

Postal code

38000

Approval date

2024-01-05, 1402/10/15

Ethics committee reference number

TUF/Addl Reg/SB/769

Health conditions studied**1****Description of health condition studied**

Calf tightness

ICD-10 code

M79.606

ICD-10 code description

Pain in leg, unspecified

Primary outcomes**1****Description**

pain

Timepoint

Before intervention and after 4 weeks after intervention

Method of measurement

NPRS

Secondary outcomes**1****Description**

Range of motion

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

Goniometer

Intervention groups**1****Description**

Intervention group 1 or group A was provided with primal reflex release technique and hot pack as baseline treatment. Two sessions were done during a week and duration of each session was of 15 minutes. In a single session 3 sets of the technique was given with each set of 10-15 seconds and hot pack for 10 minutes. The procedure of the technique is as follows; With knee flexed at 90 degrees ask patient to dorsiflex ankle while keeping toes flexed. Now apply strokes on anterior tibialis tendon while patient holds ankle in dorsiflexion against resistance.

Category

Treatment - Other

2

Description

In intervention group 2 or group B, participants received positional release technique (3 sets in which each set was of 90 seconds) for calf tightness and hot pack (10 minutes) as baseline treatment. Total time for each session was 15 minutes. For gastrocnemius the subject in prone position and ankle in plantar flexion and knee in 90-degree flexion. For 90 seconds, the therapist applies intense pressure to palpable taut band for 3 times.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

The University of Faisalabad, Madina teaching Hospital

Full name of responsible person

Rubeena Zulfiqar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Faisalabad

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?

No

Title of funding source

The University of Faisalabad

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 Faisalabad

Full name of responsible person

Rubeena Zulfiqar

Position

Assistant professor

Latest degree

Master

Other areas of specialty/work

Anatomy

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not 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

Comparative effects of primal reflex release technique versus positional release technique on tightened calf muscles / results for primary outcome measures

When the data will become available and for how long

starting of October 2024

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

medical students, teachers

From where data/document is obtainable

2022-ms-pt-023@tuf.edu.pk

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

2022-ms-pt-023@tuf.edu.pk

Comments