Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Phone
+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

Street address
Faisal Town, West Canal Road, Faisalabad, Punjab

City
Faisalabad

Postal code
38000

Phone
+92 41 8868326

Email
studentaffairshsw@tuf.edu.pk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University of Faisalabad

Full name of responsible person
Rubeena Zulfiqar

Street address
Faisal Town, West Canal Road, Faisalabad, Punjab

City
Faisalabad

Postal code
38000

Phone
+92 41 8868326

Email
studentaffairshsw@tuf.edu.pk

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

Street address
Faisal Town, West Canal Road, Faisalabad, Punjab

City
Faisalabad

Province
Punjab

Postal code
38000

Phone
+92 41 8868326

Email
asst.prof.rehab.446@tuf.edu.pk

Person responsible for scientific 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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Faisal Town, West Canal Road, Faisalabad, Punjab

City
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Province
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+92 41 8868326

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asst.prof.rehab.446@tuf.edu.pk

Person responsible for updating data

Contact

Name of organization / entity
The University of Faisalabad

Full name of responsible person
Rubeena Zulfiqar

Position
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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