

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative effectiveness of plantar massage and reflexology foot massage on pain, balance and functional reach among patients with peripheral neuropathy

#### Protocol summary

##### Study aim

To find out what is better in reducing neuropathic pain and increasing balance and functional reach between plantar massage and reflexology foot massage among patients with peripheral neuropathy

##### Design

A randomized clinical trial with two parallel intervention groups, a study of phase 3 with 18 people in each group, 36 in total.

##### Settings and conduct

Allied hospital Faisalabad General hospital Samanabad

##### Participants/Inclusion and exclusion criteria

Both genders are between 35 and 60 years old.  
Diagnosed patients with grade II peripheral neuropathy.  
Ability to stand on both feet. Can perform the given instructions. There was no cardiac problem. No fracture, injury, or amputation of the lower or upper limb. Any neurological problem. No foot or toe ulcer. There is no peripheral thrombosis. Ambulation difficulties or using any walking devices were excluded. No vision impairment.

##### Intervention groups

Group A: Plantar massage group Group B: Reflexology foot massage group

##### Main outcome variables

Pain Balance Functional reach

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240311061253N1**

Registration date: **2024-05-10, 1403/02/21**

Registration timing: **prospective**

Last update: **2024-05-10, 1403/02/21**

Update count: **0**

##### Registration date

2024-05-10, 1403/02/21

##### Registrant information

###### Name

Rabea Saeed

###### Name of organization / entity

The university of Faisalabad

###### Country

Pakistan

###### Phone

+92 303 0449224

###### Email address

2022-ms-pt-032@tuf.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-05-15, 1403/02/26

##### Expected recruitment end date

2024-09-26, 1403/07/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative effectiveness of plantar massage and reflexology foot massage on pain, balance and functional reach among patients with peripheral neuropathy

##### Public title

Effect of plantar massage vs reflexology foot massage on peripheral neuropathy

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Age between 35 and 60 years Diagnosed patient of grade II peripheral neuropathy Ability to stand on both feet Cooperative patients Can perform given instructions Volunteered to participate

**Exclusion criteria:**  
Cardiac problem upper limb or lower limb amputation at any level foot or toe ulcer severe visual impairment any vestibular disorder edema, peripheral thrombosis, burn, injury or fracture of lower extremity ambulation difficulties or using any walking device neurological disorders, including stroke, parkinson's disease, and dementia

**Age**  
From **35 years** old to **60 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **36**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Simple random sampling was used for sample collection. The list of individuals was generated through online randomization generator. According to the list the participants were divided into both groups.

**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**

Research and Ethics / Technical committee of The University of Faisalabad

**Street address**

House no. 68, street no. 1 defence paradise in front of sheikhon wala railway crossing

**City**

Faisalabad

**Postal code**

38000

**Approval date**

2024-02-15, 1402/11/26

## Ethics committee reference number

TUF/DR/SA/MSPP/2024/397

## Health conditions studied

### 1

#### Description of health condition studied

Peripheral neuropathy

**ICD-10 code**

G90.0

**ICD-10 code description**

Idiopathic peripheral autonomic neuropathy

## Primary outcomes

### 1

#### Description

Pain

**Timepoint**

Pain was measured at 0 weeks before intervention and after the application of the intervention at 3 weeks.

**Method of measurement**

Self-report version of the Leeds assessment of signs and symptoms of neuropathic pain scale (S-LANSS)

### 2

#### Description

Balance

**Timepoint**

Balance was measured at 0 weeks before intervention and after the application of the intervention at 3 weeks.

**Method of measurement**

Balance was measured through Berg Balance Scale (BBS)

### 3

#### Description

Functional reach

**Timepoint**

Functional reach was measured at 0 weeks before intervention and after the application of the intervention at 3 weeks.

**Method of measurement**

Functional reach was measured through functional reach test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: plantar massage. Plantar massage will be given through sensory brush for 3 days per week dor 3 weeks. The brush will be held horizontal to the plantar aspect of the foot. Brushing will be done slowly,

never back and forth on the same spot, and with enough pressure to cause the brush's bristles to bend. The goal is to trigger the feet's pressure touch receptors rapidly. Participants will be informed that the therapy might "tickle." Massage will be given for 5 minutes on each foot

### Category

Treatment - Other

## 2

### Description

Intervention group: Reflexology foot massage group. Three weeks of foot reflexology will be conducted, with two sessions each week lasting thirty minutes, 15 minutes for each foot. Applying the reflexology method will involve raising the participant's leg level to the practitioner's chest level. Effleurage massage will be given to the dorsal area, plantar region, tibialis anterior, peroneus longus-brevis, and gastro soleus muscles for five minutes. Effleurage will be utilized to stimulate the autonomic nervous system, and also the reflex mechanism of action, capillaries, and lymphatic function. Reflexology massage will be done according to the following application protocol: solar plexus and diaphragm reflexes, adrenal gland reflexes, the arm and shoulder reflexes, the spine reflexes, the hip, thigh and leg reflexes, the sciatic nerve reflexes, solar plexus and diaphragm reflexes. All of these are done for 7\*2 on each foot.

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Allied hospital Faisalabad

##### Full name of responsible person

Anbreena Rasool

##### Street address

West canal road, Faisalabad

##### City

Faisalabad

##### Postal code

38000

##### Phone

+92 345 7936825

##### Email

anbreena.rasool@tuf.edu.pk

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

The University of Faisalabad

##### Full name of responsible person

Anbreena Rasool

##### Street address

West canal road

##### City

Faisalabad

##### Postal code

38000

##### Phone

+92 345 7936825

##### Email

anbreena.rasool@tuf.edu.pk

##### Web page address

https://tuf.edu.pk/

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### 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

Rabeea Saeed

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Physiotherapy

##### Street address

House no. 68, street no. 1 defence paradise in front of sheikhon wala railway crossing

##### City

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##### Province

Punjab

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## Person responsible for scientific inquiries

### Contact

##### Name of organization / entity

The University of Faisalabad  
**Full name of responsible person**  
Rabeea Saeed  
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Student  
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**Web page address**

## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
The University of Faisalabad  
**Full name of responsible person**  
Rabeea Saeed  
**Position**  
Student  
**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

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Comparative effectiveness of plantar massage and the reflexology foot massage on pain, balance and functional reach among patients with peripheral neuropathy

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

Starting 6 months after publication and it will remain available for everyone

### To whom data/document is available

This will be available for everyone

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

anbreena.rasool@tuf.edu.pk

### From where data/document is obtainable

rabeasaeed@gmail.com +923030449224

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

Any applicant will just need to contact for the data file at rabeasaeed@gmail.com or at +923030449224

### Comments