

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Effect of Pain Neuroscience Education on Chronic Pain in Diabetic Neuropathy and its Impact on Quality of Life

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

##### Study aim

To find out the effect of pain neuroscience education on chronic pain in diabetic neuropathy and its impact on quality of life

Last update: **2023-09-05, 1402/06/14**

Update count: **0**

##### Registration date

2023-09-05, 1402/06/14

##### Design

A concealed, randomized, single blinded, clinical trial with a parallel group design of 30 patients, will enrolled between September 2023 and November 2023. per and post treatment assessment will taken.

##### Registrant information

###### Name

Anbreena Rasool

###### Name of organization / entity

The University of Faisalabad

###### Country

Pakistan

###### Phone

+92 41 8868220

###### Email address

anbreena.rasool@tuf.edu.pk

##### Settings and conduct

Study population will be selected from Neurology and Physical Therapy Department (OPD) of Madinah Teaching Hospital (MTH), Allied Hospital, Faisalabad.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria • Between age of 50 -70years • Both Male and Female Genders • Diabetic Neuropathy on basis of Monofilament testing (27) • History of Diabetes more than 5years • History of pain more than 6 months • HBA1C(Hemoglobin A1c)  $\geq$  6.5% Exclusion Criteria • Individuals with diagnosed Neurological Disease/ All other neuropathies • Wounds and Amputation in lower Extremity • With Auditory disorder

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Intervention groups

Group A will receive Pain Neuroscience Education with Conventional Therapy (TENS, stretching and strengthening exercises) which is interventional, and Group B will receive Conventional Therapy (TENS, stretching and strengthening exercises) which is Control Group.

##### Expected recruitment start date

2023-09-04, 1402/06/13

##### Expected recruitment end date

2023-11-15, 1402/08/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Main outcome variables

Pain Intensity, quality of Life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230731058981N1**

Registration date: **2023-09-05, 1402/06/14**

##### Scientific title

Effect of Pain Neuroscience Education on Chronic Pain in Diabetic Neuropathy and its Impact on Quality of Life

##### Public title

Effect of Pain Neuroscience Education on Chronic Pain in Diabetic Neuropathy and its Impact on Quality of Life

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Between age of 50 -70years Diabetic Neuropathy on basis of Monofilament testing History of pain more than 6 months HBA1C (Hemoglobin A1c)  $\geq$  6.5% History of Diabetes more than 5 years Both Male and Female Genders

**Exclusion criteria:**

Individuals with diagnosed Neurological Disease/ All other neuropathies Wounds and Amputation in lower Extremity With Auditory disorder

**Age**

From **50 years** old to **70 years** old

**Gender**

Both

**Phase**

1

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

All patients will be allocated in two groups (group A will be treatment group and group B will be control group). Computer based random number generator will be used to assign each patient a number from 1 to 30, and then will assign those with odd numbers to group A and those with even numbers to group B.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

only participants will be blind

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee****Name of ethics committee**

Ethics committee of The University of Faisalabad

**Street address**

The university of Faisalabad, main Sargodha road, Faisalabad

**City**

Faisalabad

**Postal code**

38000

**Approval date**

2023-08-01, 1402/05/10

**Ethics committee reference number**

TUF/Addl Reg/SB/I20

**Health conditions studied**

1

**Description of health condition studied**

Diabetic neuropathy

**ICD-10 code**

E13.40

**ICD-10 code description**

Other specified diabetes mellitus with diabetic neuropathy, unspecified

**Primary outcomes**

1

**Description**

Pain

**Timepoint**

Before intervention and 6 weeks after intervention

**Method of measurement**

Visual Analog scale (VAS) for pain intensity and Norfolk QOL-DN for quality of life will be measured as Baseline before start of Intervention and after 6 weeks at end of Intervention.

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: Pain Neuroscience educational sessions will be given by help of Hand drawings and by leaflets, in Individual session. PNE session will be administered 2 times per week for 6 weeks by a single physiotherapist for 1 hour. Conventional Therapy (TENS, Stretching and strengthening exercises), High-Frequency TENS with 100Hz frequency, adjustable 200-400 micro seconds pulse width and 20 minutes duration. The intensity of stimulus will gradually increase until the patient can recognize the stimulation but was not make uncomfortable. Strengthening(stair climbing) and 2-4 repetition of stretching exercises (static stretch with 30 second hold), 1-3 sets on 2-3 alternative days of week for 6 week.

**Category**

Rehabilitation

2

**Description**

Control group: Group B will receive Conventional Therapy (TENS, stretching and strengthening exercises) which is

Control Group.  
**Category**  
Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Neurology and Physical Therapy Department (OPD) of  
Madinah Teaching Hospital (MTH)

**Full name of responsible person**

Dr. Maryam Mehmood; PT

**Street address**

Madinah Teaching Hospital. Sargodha Road,  
Faisalabad, Punjab, Pakistan

**City**

Faisalabad

**Postal code**

38000

**Phone**

+92 41 8869861

**Email**

mariam.mehmood@tuf.edu.pk

### 2

#### Recruitment center

**Name of recruitment center**

Neurology and Physical Therapy Department (OPD) of  
Allied Hospital, Faisalabad

**Full name of responsible person**

Dr. Sobia Nawaz; PT

**Street address**

Allied Hospital, Faisalabad, Jail Road adjacent to  
Faisalabad Medical University, Near Sargodha Road,  
Faisalabad

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**Phone**

+92 331 7240977

**Email**

sobiaaliawan@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

The University of Faisalabad

**Full name of responsible person**

Dr. Sidra Majeed; PT

**Street address**

The University of Faisalabad, Health Sciences Wing ·  
University Town, Sargodha Road, Faisalabad

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**Phone**

+92 334 7731241

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sidra.majeed@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**

Dr Sidra Majeed

**Position**

Assistant professor/ post graduate coordinator

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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Dr Anbreena Rasool

**Position**

lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for updating data**

**Contact**

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**Full name of responsible person**

Dr Anbreena RAsool

**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

In order to maintain the confidentiality of study.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to  
make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable