

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Study aim

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

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.

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

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.

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**

Registration timing: **registered_while_recruiting**

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

Update count: **0**

Registration date

2023-09-05, 1402/06/14

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

Recruitment status

Recruitment complete

Funding source

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

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

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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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+92 331 7240977

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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 ·
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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 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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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