Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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) ≥ 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

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Anbreena Rasool

Name of organization / entity
The University of Faisalabad

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Pakistan

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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) ≥ 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 be will 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/l20

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University of Faisalabad

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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