

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effect of proprioception practice and auriculotherapy on the balance and proprioception of lower extremity in patients with diabetic neuropathy

Protocol summary

Study aim

Determining and Comparison of the effect of proprioception practice and auriculotherapy on the balance and proprioception of lower extremity in patients with diabetic neuropathy

Design

Clinical trial with control group, with parallel, non-blind, randomized groups, 69 people

Settings and conduct

Patients with diabetic neuropathy referred to Shahid Mofteh Yasuj Educational and Medical Clinic No. 4. At the beginning of the study, demographic characteristics questionnaires, Michigan neuropathy to diagnose diabetic neuropathy and the use of Toronto Clinical Scoring System to classify the severity of neuropathy to mild, moderate and severe. Then perform the intervention using the Star and Base test to check the dynamic and static balance and use the goniometer tool to assess the proprioception as well as perform auriculotherapy using Vacaria seeds.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Diabetes based on the diagnosis of a specialist 2. Diabetic neuropathy based on Michigan questionnaire Output criteria: 1. Existence of deformity or neurological and rheumatic diseases in the lower extremities 2. Existence of foot ulcers and no report of history of dizziness and ankle sprains

Intervention groups

The three intervention groups include proprioception practice, auriculotherapy, and control. In the proprioception practice group, the exercises are performed for 6 weeks and 3 sessions per week, 30 minutes per session and a total of 18 sessions as a group to match the place and time for patients. In the auriculotherapy group, 10 sessions are performed twice a week for a total of 5 weeks. There is no training in the control group.

Main outcome variables

Balance and proprioception

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200502047260N1**

Registration date: **2020-05-26, 1399/03/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-26, 1399/03/06**

Update count: **0**

Registration date

2020-05-26, 1399/03/06

Registrant information

Name

Nayereh Ghazavi Khorasgani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3521 0921

Email address

nayer.uni@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-12, 1398/12/22

Expected recruitment end date

2020-06-30, 1399/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of proprioception practice and auriculotherapy on the balance and proprioception of lower extremity in patients with diabetic neuropathy

Public title
Comparison of the effect of proprioception practice and auriculotherapy on the balance and proprioception of lower extremity in patients with diabetic neuropathy

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Diabetes based on the diagnosis of a specialist Diabetic neuropathy based on Michigan questionnaire Ability to communicate and answer questions Be at least 18 years old and at most 65 years old Satisfaction to participate in the study and signing of the Conscious Consent Form
Exclusion criteria:
 Existence of deformity or neurological and rheumatic diseases in the lower extremities Existence of foot ulcers and no report of history of dizziness and ankle sprains

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **69**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible participants in the study are selected from among the available individuals. Once selected, participants will be assigned a random blockchain allocation between the three groups. Eligible individuals will be assigned admission criteria after obtaining informed consent, using the List Randomization site and creating a number of different blocks.

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
 Ethics committee of Yasuj University of Medical Sciences
Street address
 Yasuj, Shahid Motahari Blvd., Yasuj University of Medical Sciences
City
 Yasuj
Province
 Kohgiluyeh-va-Boyer-Ahmad
Postal code
 7591741417
Approval date
 2020-03-11, 1398/12/21
Ethics committee reference number
 IR.YUMS.REC.1399.025

Health conditions studied

1

Description of health condition studied
 Diabetic Neuropathy
ICD-10 code
 E11.40
ICD-10 code description
 Type 2 diabetes mellitus with diabetic neuropathy, unspecified

Primary outcomes

1

Description
 Balance
Timepoint
 Equilibrium at the beginning of the study (before the start of the intervention) and after the start of the study
Method of measurement
 Star Excursion Balance Test(SEBT) & Balance Error Scoring System test(BESS) & Vaccaria seed

2

Description
 Proprioception
Timepoint
 Proprioception at the beginning of the study (before the intervention begins) and after the study begins
Method of measurement
 Goniometer & Vaccaria seed

Secondary outcomes
empty

Intervention groups

1

Description

First intervention group: proprioception practice : Exercises for 6 weeks and 3 sessions per week, each session for 30 minutes and a total of 18 sessions as a group to match the place and time, for patients. The sessions will begin with warm-up exercises for 5 minutes. Warming-up activities include: walking back and forth, running softly and slowly, and performing stretching exercises for different parts of the body, as well as cooling down at the end of the workout. The main proprioception practice include: 1- Maintaining the position: standing on one leg, jumping to the sides and forward - backward. 2- Strength: Strengthening the front of the thigh, back of the thigh, squat and the sides of the thigh. 3- Plyometric: jumps (single-legged - two-legged, rotations 90 and 180 degrees). 4- Speed and agility exercises: running figure 8, running forward - Back and sides (straight and spiral paths). The intensity of the exercises will be adjusted based on the patients' abilities. The number and duration of exercises will be the same in the first two sessions and will then change according to the patients' abilities. Rest time between exercises will be as much as changing position and being in a new position. All tests, like the pre-test, will be performed 48 hours after completing the 6-week training protocol and the results will be recorded.

Category

Rehabilitation

2

Description

Second Intervention Group: auriculotherapy: In this group, patients are taught the required information such as the purpose of the work, the time required to pressurize the desired points, the number of times a day and the length of the auriculotherapy course are also taught to patients. The adhesive of the auriculotherapy seeds, please contact the researcher's phone number given to them so that the seeds can be repositioned on the previous point. The researcher begins auriculotherapy using the Vaccaria seed adhesive at the points designated for the intervention group. The samples were taken 2 times a week for 10 sessions and a total of 5 weeks treated with Vaccaria seed adhesive on the equilibrium points. Both ears are located in the right ear, including the equilibrium point, Thalamic point, Lumbago point, and in the left ear, including Shenmen's point, pancreatic point, and Hippocampus point, and these adhesives are removed by the researcher every 3 days. And at least 1 to 2 hours later (for the rest of the ear, the adhesives are removed for 1 to 2 hours) again, a glue with Vaccaria seed No longer connected. After the intervention sessions, the level of balance and depth is measured again by the researcher. The results are reviewed and statistical analysis is performed according to the research objectives. During this time, 3 phone calls will be made to each patient to answer questions and resolve any potential issues. The results are reviewed in two stages before and after the intervention and statistical study is performed according to the

research objectives.

Category

Rehabilitation

3

Description

Control group: No intervention: This training group will not be given.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mofteh Yasuj Educational and Medical Clinic
No. 4

Full name of responsible person

Ghazavi Khorasgani

Street address

No. 67, 13th Alley, Masjed Ali St., Jay St., Esfahan

City

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Province

Isfahan

Postal code

8156173811

Phone

+98 31 3521 0921

Email

nayer.uni@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Hossein Mari Oryad

Street address

Yasuj., Shahid Motahari Blvd., Yasuj University of
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Oryad.hossein@yums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasouj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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**

Yasouj University of Medical Sciences

Full name of responsible person

Nayereh Ghazavi Khorasgani

Position

M.S student of internal surgery nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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No. 67, 13th Alley, Masjed Ali St., Jay St., Esfahan

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Nayereh Ghazavi Khorasgani

Position

M.S student of internal surgery nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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