Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
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Email address
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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

Kohgilouyeh-va-Boyrahmad

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
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
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Person responsible for updating data

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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