Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the effects of one session of perturbation-based balance training with block and random sequences on reactive balance control in individuals with diabetic neuropathy

Protocol summary

Study aim

The aim of this single-blind clinical trial study is to compare the effect of perturbation-based balance training with blocked and random sequences on the acquisition, retention and generalizability of acquired reactive balance skills in people with diabetic neuropathy. This study is conducted on 50 people with diabetic neuropathy.

Design

Randomized, parallel-group, single-blind, sham controlled clinical trial of 50 patients. Random Allocation computer software was used for randomization.

Settings and conduct

In one session (1 trainer to 1 participant), perturbation-based balance training with two blocked or random sequences will be given to people with type 2 diabetes at the rehabilitation research center of Jundishapur University, Ahvaz, and the effect of these training on reactive and functional balance will be investigated.

Participants/Inclusion and exclusion criteria

Inclusion criteria include having type 2 diabetes and diabetic peripheral neuropathy, age range between 45-60 years, ability to stand independently for 30 minutes, neuropathy Deficit Score between 3 and 6, obtaining Minimum score of 24 on mini-mental State Examination. Also, foot ulcer and amputation, orthopedic problems, symptoms of central nervous system involvement, uncorrected vision problems, hearing problems, history of vertigo, patient report of problems Peripheral vessels and heart problems, taking anti psychotic drugs, suffering from major depression based on the score of the modified version of the short Beck Depression Inventory above are exclusion criteria.

Intervention groups

The control group will not receive any training. Blocked group receiving perturbation-based balance training with blocked sequence. A random group that receives a perturbation-based balance with a random sequence.

Main outcome variables

Functional balance Balance Confidence Dynamic Balance Static Balance Reactive balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240111060675N1**
Registration date: **2024-01-29, 1402/11/09**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-29, 1402/11/09**
Update count: **0**

Registration date

2024-01-29, 1402/11/09

Registrant information

Name

Razieh Mofateh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of one session of perturbation-based balance training with block and random sequences on reactive balance control in individuals with diabetic neuropathy

Public title

Comparing the effect of two types of exercises on balance control in individuals with diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having type 2 diabetes and diabetic peripheral neuropathy based on clinical and laboratory diagnostic criteria as diagnosed by an endocrinologist Age range between 45-60 years Ability to stand independently for 30 minutes Obtaining a neuropathy deficit score higher than 3 and less than or equal to 6 between 3 and 6 Ability to read and write in Persian Obtaining Minimum score of 24 on mini-mental State Examination (MMSE)

Exclusion criteria:

Foot ulcer and amputation (Complete and incomplete) Any orthopedic problems or a history of surgery in the lower limbs that interferes with walking and standing, and a history of sprained ankles in the last year and skeletal-muscular deformities in the lower limbs Severe pain in the soles of the feet caused by diabetic neuropathy Symptoms of central nervous system involvement such as dementia, Parkinson's and multiple sclerosis and a history of stroke Uncorrected vision problems Hearing problem History of vertigo Report of peripheral vascular problems and heart problems, including a history of unstable angina, uncontrolled blood pressure, and a history of resting tachycardia or arrhythmia Professional or regular exercise for at least 6 months before the study Taking anti psychotic and anti-anxiety drugs Suffering from major depression based on the score of the modified version of the short Beck Depression Inventory above 18

Age

From **45 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After checking the inclusion criteria, people are divided into three groups using Stratified Permuted Block randomization method.Using this randomization method, people will be classified according to gender. The advantage of this method is that while keeping the number of people in the three groups equal, the balance of the groups will also be maintained in terms of the dispersion of the influencing variables (gender in this study). For this purpose, a random order of three letters A (intervention with random approach), B (intervention with blocked approach) and C (control) is made in groups of 6 by random assignment computer software. Then the batches are hidden by opaque envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessor will not be aware of the type of grouping of receiving treatment methods of the participants.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Science

Street address

Ground floor, Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Science

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2024-01-06, 1402/10/16

Ethics committee reference number

IR.AJUMS.REC.1402.537

Health conditions studied

1

Description of health condition studied

Type 2 diabetes and diabetic peripheral neuropathy

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description
Reactive balance
Timepoint
Baseline, immediately after intervention and 24 hours after the end of the intervention
Method of measurement
Computerized dynamic posturography device

Secondary outcomes

1

Description
Static balance
Timepoint
Baseline
Method of measurement
Functional Reach clinical test

2

Description
Balance Confidence
Timepoint
Baseline
Method of measurement
Activities Specific Balance Confidence questionnaire

3

Description
Dynamic balance
Timepoint
Baseline
Method of measurement
Mini-BES Test questionnaire

Intervention groups

1

Description
The blocked group receives perturbation-based balance training in one session in the form of 6 sets and each set with 4 repetitions, a total of 24 repetitions of perturbation with blocked sequence.
Category
Rehabilitation

2

Description
The random group receives perturbation-based balance training in one session in the form of 6 sets and each set with 4 repetitions, a total of 24 repetitions of perturbation with a random sequence.
Category
Rehabilitation

3

Description
The control group will not receive any training. But they will receive all evaluations exactly the same as other groups.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Rehabilitation Research Center
Full name of responsible person
Zahra Najarzade
Street address
Rehabilitation Research Center, School of Rehabilitation Sciences, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
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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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Ground floor, Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Science
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Email
itc@ajums.ac.ir
Web page address
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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
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Razieh Javadian Kootenaie

Position
PhD Student of Physical Therapy

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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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