

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the Effect of Adding Dual Task Motor-Cognitive Training to Sensory-Motor Exercise, on Postural Stability and Gait in Older Adults with diabetic Peripheral Neuropathy

Protocol summary

Study aim

Investigating the Effects of Adding Cognitive Dual-Task Training to Sensory-Motor Exercises on Postural Stability and Gait in Older Adults with Diabetic Peripheral Neuropathy

Design

In this research, 50 older adults with Diabetic Peripheral Neuropathy referring to Diabetes Association were chosen purposefully and a code was allocated to each one of them. Then patients were randomly divided into two sensory-motor exercise and sensory-motor with cognitive dual-task exercise.

Settings and conduct

This research was done in Rehabilitation Science Faculty of Ahvaz Medical Science University. Participants, Data Collector and Outcome Assessor were blinded to research.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diabetes Mellitus Type 1 & 2; Diabetic Peripheral Neuropathy; Age above 50 Years; BMI < 30; Disease Duration>3 Years; MMSE> 24 Exclusion Criteria: Foot Sore in Assessment Moment; Non Corrective Visual & Vestibular Impairments; Use of Assisstive Device; Neurologic & Muscular or Rheumatoid Disease without Relation to Diabetes that Affect Gait and Balance Ability; Partial or Complete Amputation; Use of Drugs that Affect Negatively on Cognition and Consciousness

Intervention groups

Duration of intervention is 8 weeks and every other day. In both groups, same sensory-motor exercises were done but in second group, cognitive dual-task were added.

Main outcome variables

Measurement devices are Force Plate for static balance; Biodex Balance System for dynamic balance;Bberg Balance Scale for functional balance and 10 Meter Walking Test for gait assessment. Patients assess before and after intervention and just single and dual task.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160710028865N1**

Registration date: **2017-12-17, 1396/09/26**

Registration timing: **prospective**

Last update: **2019-07-06, 1398/04/15**

Update count: **1**

Registration date

2017-12-17, 1396/09/26

Registrant information

Name

solmaz rezaie

Name of organization / entity

rehabilitation research center

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3101

Email address

rezaie.so@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz medical science university

Expected recruitment start date

2017-12-25, 1396/10/04

Expected recruitment end date

2018-07-13, 1397/04/22

Actual recruitment start date

2017-12-30, 1396/10/09

Actual recruitment end date

2018-07-21, 1397/04/30

Trial completion date

2018-07-21, 1397/04/30

Scientific title

Investigating the Effect of Adding Dual Task Motor-Cognitive Training to Sensory-Motor Exercise, on Postural Stability and Gait in Older Adults with diabetic Peripheral Neuropathy

Public title

Investigating the Effect of Adding Dual Task Motor-Cognitive Training to Sensory-Motor Exercise, on Postural Stability and Gait in Older Adults with Diabetic Peripheral Neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diabetes Mellitus Type 1 & 2 Diabetic Peripheral Neuropathy Age above 50 Years BMI < 30 Disease Duration>3 Years MMSE> 24

Exclusion criteria:

Foot Sore in Assessment Moment Non Corrective Visual & Vestibular Impairments Use of Assisstive Device Neurologic & Muscular or Rheumatoid Diseases without Relation to Diabetes that Affect Gait and Balance Ability Partial or Complete Amputation Use of Drugs that Affect Negatively on Cognition and Consciousness

AgeFrom **50 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample sizeTarget sample size: **50**Actual sample size reached: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

Blocked Randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants Data Collector Outcome Assessor

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of ahvaz University of Medical Sciences

Street address

Musculoskeletal Rehabilitation Research Center,
Ahvaz Jundishapur University of Medical Sciences,
Golestan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

61354 54387

Approval date

2017-02-25, 1395/12/07

Ethics committee reference number

IR. ajums .REC.1395.761

Health conditions studied**1****Description of health condition studied**

Diabetes Mellitus

ICD-10 code

E10-E14

ICD-10 code description

Diabetes Mellitus

Primary outcomes**1****Description**

Static Balance Status

Timepoint

Before Intervention, After Intervention

Method of measurement

Force Plate

2**Description**

Dynamic Balance Status

Timepoint

Before Intervention, After Intervention

Method of measurement

Biodex Balance System

3**Description**

Functional Balance Status

Timepoint

Before Intervention, After Intervention

Method of measurement

Berg Balance Scale

4

Description

Walking Status

Timepoint

Before Intervention, After Intervention

Method of measurement

10 Meters Walking Test

Secondary outcomes

1

Description

Cognitive Status

Timepoint

Before Intervention, After Intervention

Method of measurement

Trail Making A,B Tests, Forward & Backward Digit Span,
Rey Osterrieth Test, Letter & Category Fluency

Intervention groups

1

Description

First Interventional Group: Sensory-Motor Exercises
include Balance Training, Stretching and Strengthening
exercises and Electrical Stimulation

Category

Rehabilitation

2

Description

Second Interventional Group: Sensory-Motor Exercises
Adding Dual Task Training include Balance Training,
Stretching, Strengthening Exercises and Electrical
Stimulation Adding Cognitive-Motor Dual Task

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Musculoskeletal Rehabilitation Research Center,
Ahvaz University of Medical Sciences

Full name of responsible person

Solmaz Rezaie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Behzad Sharif Zadeh

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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

Solmaz Rezaie

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

All Data in A SPSS File

When the data will become available and for how long

6 Months After Acceptance of Extracted Article

To whom data/document is available

Scientific Researchers

Under which criteria data/document could be used

Only for Studying Purpose

From where data/document is obtainable

Responsive's Email

What processes are involved for a request to access data/document

During One Week After Request

Comments