

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

**Age**

From **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target 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**

Khuzestan

**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

**Street address**

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

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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

**Street address**

Rehabilitation Science Faculty, In Front of MRI Center,  
University City

**City**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Latest degree**

Master  
**Other areas of specialty/work**  
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**Province**  
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Rezaie.so@ajums.ac.ir  
**Web page address**

## 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