Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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 incluce 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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Rezaie.so@ajums.ac.ir

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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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