Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Effect of Wii-fit based balance training combined with planter cutaneous sensory stimulation in older adults with diabetic neuropathy

Protocol summary

Study aim
To determine the effect of Wii-fit-based balance training combined with planter cutaneous sensory stimulation for balance control in older adults with diabetic neuropathy. To determine the effect of Wii-Fit based balance training alone in older adults with diabetic neuropathy To compare the effect of Wii-fit-based balance training combined with planter cutaneous sensory stimulation with Wii-fit-based balance training alone for balance control in older adults with diabetic neuropathy

Design
Randomized controlled trial

Settings and conduct
The Diabetes Center. Single blinded

Participants/Inclusion and exclusion criteria
Inclusion criteria: Older adults age limit between 60-90 years. Diagnosed Diabetes Mellitus for more than 1 year having neuropathy. Both genders. (Male and Female). Exclusion Criteria: Dependence on others to complete activities of daily living.Loss of protective foot sensations.Comorbidities including visual impairment, cerebrovascular accident, Orthopaedic trauma, Labyrinthitis, peripheral vascular disease, Heart failure. Using the assistive device for ambulation.

Intervention groups
The interventional group underwent conventional balance training for (20mins), Wii-fit Balance training (20mins) along with cutaneous sensory stimulations (10mins) which were given by using flannel cloth and brittle brush twice a week for the first four consecutive weeks.

Main outcome variables
Balance

General information

Reason for update

Acronym
Balance management in diabetic neuropathy patients (BMDN)

IRCT registration information
IRCT registration number: **IRCT20210615051585N3**
Registration date: **2022-01-11, 1400/10/21**
Registration timing: **retrospective**

Last update: **2022-01-11, 1400/10/21**
Update count: **0**

Registration date
2022-01-11, 1400/10/21

Registrant information

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Saima Gul

Name of organization / entity
Shifa Tameer - e - Millat University

Country
Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-12, 1400/01/23

Expected recruitment end date
2021-07-15, 1400/04/24

Actual recruitment start date
2021-04-12, 1400/01/23

Actual recruitment end date
2021-07-15, 1400/04/24

Trial completion date
2021-07-15, 1400/04/24

Scientific title
Effect of Wii-fit based balance training combined with planter cutaneous sensory stimulation in older adults

with diabetic neuropathy

Public title
Effect of Wii-fit based balance training combined with planter cutaneous sensory stimulation in older adults with diabetic neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Older adults age limit between 60-90 years Diagnosed Diabetes Mellitus for more than 1 year having neuropathy Both genders. (Male and Female)
Exclusion criteria:
Dependence on others to complete activities of daily living Loss of protective foot sensations Comorbidities including visual impairment, cerebrovascular accident, Orthopaedic trauma, Labyrinthitis, peripheral vascular disease, Heart failure Using the assistive device for ambulation
Age
From **60 years** old to **90 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **22**
Actual sample size reached: **21**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment for treatment using sealed envelope 26 Sheets of properly cut Aluminum paper double the size of the paper. 26 Sheets of Carbon paper cut into appropriate size according to the paper used. A standard-sized square paper was taken in which group "(Wiifit)" was marked. In this way, 11 papers were prepared marked with "(Wii-fit)" and 11 square-shaped papers marked with "(Wii-fit+SS)". The sheet of paper on which either (Wii-fit) or (Wii-fit + SS) was marked was folded to fit the envelope. A sheet of Carbon paper was placed on the top of the folded paper (marked either (Wii-fit) or (Wii-fit + SS)) facing the envelope. Then the sheet of Aluminum foil was wrapped on the carbon paper (with folded paper inside). All the above prepared were placed in the envelope (which was completely opaque), the envelope was then sealed. In this way 11 envelops of "(Wii-fit)" and 11 envelops of "(Wii-fit)" were prepared. With a total number of 22 envelopes. These 22 envelopes were then thoroughly shuffled like a deck of cards. The envelopes were then marked with numbers 1-22. Each participant picked the envelope in order from 1-22 and was given an intervention (Wii-fit or Wii-fit) accordingly.
Blinding (investigator's opinion)
Single blinded
Blinding description
Only the researcher doing the study knows which treatment or intervention the participant is receiving. It makes results less likely to be biased.
Placebo
Not used
Assignment
Parallel
Other design features
N/A

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Institutional Review Board and Ethics Committee (IRB and EC) Shifa International Hospital.
Street address
Department of Rehabilitation Sciences, Dar ul Shifa Campus, Shifa Tameer e Millat University
City
Islamabad
Postal code
25000
Approval date
2021-06-18, 1400/03/28
Ethics committee reference number
IRB#187-21

Health conditions studied

1

Description of health condition studied
Diabetic Neuropathy
ICD-10 code
E11.40
ICD-10 code description
Type 2 diabetes mellites with diabetic neuropathy

Primary outcomes

1

Description
Balance
Timepoint
Baseline, after intervention.
Method of measurement
Berg Balance Scale

Secondary outcomes

1

Description
To determine balance

Timepoint
8th week
Method of measurement
secondary outcome was measured by time up and go.

Intervention groups

1

Description
Wii-fit Group: Treatment for 20 min 2 sessions per week for 8 weeks along with the conventional therapy. Conventional therapy includes: passive stretching, repetitive task-specific activities, passive, active-assisted and active ROM exercises. The Wii-fit protocol included using Wii-fit set and the games. The game uses a unique platform peripheral called the Wii Balance Board, on which the player stands during exercise. The Board is not a rocking balance board but a device that tracks the user's center of balance. The patient played each game for 10-mins per session.
Category
Rehabilitation

2

Description
Wii-fit+SS Group: The same treatment (as above) given to the participants along with Cutaneous sensory stimulations (10mins) which was given by using flannel cloth and brittle brush
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
The Diabetes Center
Full name of responsible person
Dr. Tayyiba Zulqarnain
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Murree Expressway, near Toll Plaza, Islamabad Punjab
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Web page address
https://www.tdc.com.pk/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shifa Tameer e Millat University
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
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Position
Assosiate Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to ethical consideration
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available