

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Saima Gul

Name of organization / entity

Shifa Tameer - e - Millat University

Country

Pakistan

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Email address

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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 "(Wii-fit)" 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 envelopes of "(Wii-fit)" and 11 envelopes 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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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**

Shifa Tameer e Millat University

Full name of responsible person

Dr. Saima Gul

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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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