

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effectiveness of Dual task training vs Nintendo Wii-fit to improve balance among older adults

#### Protocol summary

##### Study aim

- To assess the effectiveness of Dual task training vs Nintendo Wii-fit among older adults.
- To compare the quality of life and physical performance among the older adults in both groups

##### Design

All participants will be informed about the study and signed written informed consent before interventions. Participants for the study will be recruited from well-known older homes of Islamabad and Rawalpindi. All patients will come about into two groups the experimental group 1 and experiment group 2, keeping the process completely randomized (sealed envelope method will be used

##### Settings and conduct

Nijat Trust treatment center in Rawalpindi In this study simple random sampling technique is used by sealed envelop method

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: o Both male and female above 60 yrs.  
o Able to stand , no use of walking device o Mini mental status Examination those who scored more than 24 will be enrolled in study o Berg balance range 52 or less points out of 56 will be included 9 o Ability to walk 10m without the assistance of another person; Exclusion criteria: o Psychiatric disorder, inability to walk. o Who were unable to ambulate without assistive devices o Musculoskeletal impairment/injury o Medical conditions and medication affecting

##### Intervention groups

There are 2 groups DTT group (Dual task training ) and NWT group (Nintendo Wii-fit group) 0

##### Main outcome variables

Berg balance scale, Time up and go.Physical performance test , SF-36 survey, The Activities-Specific Balance Confidence (ABC) Scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211022052835N3**

Registration date: **2022-02-14, 1400/11/25**

Registration timing: **prospective**

Last update: **2022-02-14, 1400/11/25**

Update count: **0**

##### Registration date

2022-02-14, 1400/11/25

##### Registrant information

##### Name

Fouzia Batool

##### Name of organization / entity

Shifa Tameer-e-Millat University

##### Country

Pakistan

##### Phone

+92 51 8441752

##### Email address

fouzia\_dpt.ahs@stmu.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-25, 1400/12/06

##### Expected recruitment end date

2022-05-31, 1401/03/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Effectiveness of Dual task training vs Nintendo Wii-fit to improve balance among older adults

**Public title**

Effectiveness of Dual task training vs Nintendo Wii-fit to improve balance among older adults

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Both male and female above 60 yrs. Able to stand , no use of walking device Mini mental status Examination those who scored more than 24 will be enrolled in study Berg balance range 52 or less points out of 56 will be included Ability to walk 10m without the assistance of another person;

**Exclusion criteria:**

Psychiatric disorder, inability to walk. Who are unable to ambulate without assistive devices Musculoskeletal impairment/injury Medical conditions and medication affecting

**Age**

From **60 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **42**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study simple random sampling technique is used by sealed envelop method by using a computerized random number generator. The sequence of random allocation is done by an individual who has not directly involved in the study. Random numbers is written on index cards and placed in thick and opaque sealed envelopes before the study. After taking consent from the older adult for their participation in the study, the therapist opens the envelop and give the respective protocol to the individual. The study is single blinded as participants is not aware of the intervention group they are placed in. Elders will be placed either in to the experimental group 1 (Dual task training DTT) or experimental group 2 (NWF Nintendo Wii-fit) keeping the process completely randomized ,sealed envelope method will be used.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Prior to collecting data, participants would be informed about both the treatment techniques used in both groups; experimental group A (DDT) and experimental group B (NWF). Further they are informed that you will get one of these treatment depending upon the group written on the card inside the envelop you choose. The group A or B belongs to which way of treatment is known

to therapist but the patient doesn't know about it.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Institutional Review Board & Ethics Committee (IRB & EC) Shifa International Hospital Ltd. (SIH), Sh

**Street address**

Pitras Bukhari Road, Shifa international hospital Ltd. sector h-8/4 Islamabad

**City**

Islamabad

**Postal code**

44790

**Approval date**

2022-01-22, 1400/11/02

**Ethics committee reference number**

IRB#301-21

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

Unsteadiness on feet, Difficulty in balancing

**ICD-10 code**

R26.81

**ICD-10 code description**

Unsteadiness on feet

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

Balance

**Timepoint**

Before intervention, 4, 8 week after intervention

**Method of measurement**

Berg balance test, Time up and go test, Activities-Specific Balance Confidence (ABC) Scale

**Secondary outcomes****1****Description**

Physical performance

**Timepoint**

Before intervention, 4 and 8 weeks after intervention

### Method of measurement

Physical performance tests for measuring multiple domains of physical function

## 2

### Description

Quality of life

### Timepoint

Before intervention, 4 and 8 weeks after intervention

### Method of measurement

SF-36

## Intervention groups

### 1

### Description

Intervention group: Intervention for DDT group: • Week 1-6 (30 – 40minutes ) • Warm up 5mintues • Balance training • Dynamic weight shifting , shifting with eyes • Closed/open ,transfer , standing static/ • Dynamic , internal and external perturbations with timing and speed , • Reaching and walking forward and backward, tandem sideways walk , up and down stairs (plain and foam obstacles) • Week 6-12 (30-40minutes) • Dual task walking with subtraction n addition • Placing pencil in holes of covered cup , • Walking with fully filled glass of water , transferring objects at different heights , walking with Toss a ball from one hand to the other • Bounce a ball

### Category

Rehabilitation

### 2

### Description

Intervention group: Intervention for NWT group • Week 1-6 30 minutes • Warm up for 5 minutes • Soccer heading game • Yoga tree pose (once) • Week 6-12 10+10+10 minutes • Soccer heading • Ski slalom • Table tilt • Yoga tree pose (3 times)

### Category

Treatment - Devices

## Recruitment centers

### 1

### Recruitment center

#### Name of recruitment center

Nijat Trust treatment center in Rawalpindi

#### Full name of responsible person

Mehak Kiran

#### Street address

P-330, Janglat Road, Banni, Rawalpindi,

#### City

Rawalpindi

#### Postal code

46000

#### Phone

+92 51 5542000

### Email

mehakfaizan46@gmail.com

### Web page address

## Sponsors / Funding sources

### 1

### Sponsor

#### Name of organization / entity

Shifa Tameer-e-Millat University

#### Full name of responsible person

Fouzia Batool

#### Street address

Pitras Bukhari Road, Shifa Tameer-e-Millat University, H-8/4, Islamabad

#### City

Islamabad

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44000

#### Phone

+92 332 7120385

#### Email

fouzia\_dpt.ahs@stmu.edu.pk

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

No

### 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

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Shifa Tameer-e-Millat University

#### Full name of responsible person

Fouzia Batool

#### Position

Assistant Professor

#### Latest degree

Master

#### Other areas of specialty/work

Physiotherapy

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Pitras Bukhari Road, Shifa Tameer-e-Millat University, H-8/4, Islamabad

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shifa Tameer-e-Millat University  
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**Position**  
Assistant Professor  
**Latest degree**  
Master  
**Other areas of specialty/work**  
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## Person responsible for updating data

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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

There is no further information

### 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

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

Not applicable

### Title and more details about the data/document

There is no such plan

### When the data will become available and for how long

There is no such plan

### To whom data/document is available

There is no such plan

### Under which criteria data/document could be used

There is no such plan

### From where data/document is obtainable

There is no such plan

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

There is no such plan

### Comments