

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating and comparing the effect of therapeutic exercise using Nintendo Wii and conventional physiotherapy on the risk of falling in patients with stroke

#### Protocol summary

##### Study aim

Determining and comparing the effect of therapeutic exercise using Nintendo Wii and conventional physiotherapy treatment on the risk of falling in stroke patients

##### Design

A clinical trial with a control group, with parallel groups, double-blind and randomized, which is performed on 42 patients.

##### Settings and conduct

The intervention of the control group will be done in Kashani Hospital and the intervention of the test group will be done in Isfahan Faculty of Rehabilitation Sciences. The control group will receive conventional physiotherapy and the experimental group will receive conventional physiotherapy and Nintendo exercise for 12 sessions. The results are evaluated by an evaluator who is blind to the groups. The data analyst is also blind to each group.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: - Age 40 to 80 years - Having a suitable cognitive state - The ability to maintain a standing position without the use of aids for 30 seconds  
Exclusion Criteria: - Vision, hearing and vestibular disorders - Presence of other neurological disorders such as Parkinson's, neuropathy, epilepsy and seizures... - The presence of orthopedic disorders such as contracture, severe deformities, etc.

##### Intervention groups

Control and experimental groups: According to previous studies, conventional physical therapy includes range of motion and stretching exercises for the lower limbs, weight lifting on the affected side, and walking parallel to the front and back, which are performed for 30 minutes in each session. In addition to conventional treatment, the intervention group is treated with 30 minutes of Wii Fit game in the same session and after a 5-minute break.

All games are played while standing on the balance board of the device without the use of aids.

##### Main outcome variables

Assessments include fall risk and range of stability using a posturography device.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200101045970N9**

Registration date: **2024-05-25, 1403/03/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-05-25, 1403/03/05**

Update count: **0**

##### Registration date

2024-05-25, 1403/03/05

##### Registrant information

##### Name

Ehsan Ghasemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3669 3089

##### Email address

eghasemi@rehab.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-04-20, 1403/02/01

##### Expected recruitment end date

2024-09-20, 1403/06/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating and comparing the effect of therapeutic exercise using Nintendo Wii and conventional physiotherapy on the risk of falling in patients with stroke

**Public title**

Investigating the effect of Nintendo Wii game on the risk of falling in stroke patients

**Purpose**

Treatment

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

Having a suitable cognitive status (MMSE<24) based on the Persian version of the Mini Mental Status Exam  
Ability to maintain a standing position without the use of assistive devices for 30 seconds

**Exclusion criteria:**

Visual or hearing impairments  
History of heart attack or high-risk disease  
Presence of other neurological disorders such as Parkinson's, neuropathy, epilepsy and seizures  
Presence of orthopedic disorders  
The presence of severe pain in the lower limb based on the pain VAS scale between 75 and 100 mm  
Taking drugs that affect balance function.  
Participation in other physical therapy interventions

**Age**

From **18 years** old to **85 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **42**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, after checking the entry and exit criteria, patients are randomly divided into one of two test and control groups. In this study, after consultation with a statistician, it was decided to use the random block method. Using the website <https://www.sealedenvelope.com/simple-randomiser/v1/lits>, the statistician designed 21 blocks of 2 people, considering that we had 2 groups, using the resulting table and considering We have identified the test group with the letter A and the control group with the letter B. The patients are equally placed in each group according to the order in the table. A person who divides patients into two groups based on this table is unaware of the study.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Evaluation is done by a person who is unaware of the groups. The data analyst is also unaware of the groups.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

University of Isfahan medical Sciences

**Street address**

Hezar Jrib

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2024-04-16, 1403/01/28

**Ethics committee reference number**

IR.MUI.NUREMA.REC.1403.010

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

stroke

**ICD-10 code**

G46

**ICD-10 code description**

Vascular syndromes of brain in cerebrovascular diseases

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

Range of stability

**Timepoint**

The evaluation of the participants in the study plan will be done before the start of the intervention, after the end of the physiotherapy program and after one month of the treatment program in the rehabilitation faculty of Isfahan University of Medical Sciences.

**Method of measurement**

Synapsys Posturography System is used.

## 2

### **Description**

Fear of Falling

### **Timepoint**

The evaluation of the participants in the study plan will be done before the start of the intervention, after the end of the physiotherapy program and after one month of the treatment program in the rehabilitation faculty of Isfahan University of Medical Sciences.

### **Method of measurement**

Synapsys Posturography System is used.

## **Secondary outcomes**

### 1

#### **Description**

Dynamic balance

#### **Timepoint**

The evaluation of the participants in the study plan will be done before the start of the intervention, after the end of the physiotherapy program and after one month of the treatment program in the rehabilitation faculty of Isfahan University of Medical Sciences.

#### **Method of measurement**

The Timed Up and Go (TUG) test is used to evaluate the dynamic balance.

### 2

#### **Description**

Quality of Life

#### **Timepoint**

The evaluation of the participants in the study plan will be done before the start of the intervention, after the end of the physiotherapy program and after one month of the treatment program in the rehabilitation faculty of Isfahan University of Medical Sciences.

#### **Method of measurement**

To evaluate the quality of life, the Stroke Specific Quality of Life Scale questionnaire will be used, the validity and reliability of the Persian version of which has already been proven.

## **Intervention groups**

### 1

#### **Description**

Intervention group: Conventional physiotherapy, according to previous studies, includes range of motion and stretching exercises related to the lower limb, weight bearing on the involved side, and walking in parallel to the front and back, which are performed for 30 minutes in each session. In addition to conventional treatment, the intervention group is treated with 30 minutes of Wii Fit game in the same session and after a 5-minute break. All games are played while standing on the balance board of the device without the use of aids. The patient plays games under the supervision of a physiotherapist to increase safety. 5 types of games are

considered, three games are played in each session. In the first 6 sessions, 3 games of slalom skiing, rope walking and sliding penguin are performed, and in the next 6 sessions, table tilt and balance bubble games replace slalom skiing and walking on the rope. The patient rests for 5 minutes between each game.

#### **Category**

Rehabilitation

### 2

#### **Description**

Control group: Conventional physiotherapy, according to previous studies, includes range of motion and stretching exercises related to the lower limb, weight bearing on the involved side, and walking in parallel to the front and back, which are performed for 30 minutes in each session.

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Kashani Hospital

##### **Full name of responsible person**

Dr. Iman Adibi

##### **Street address**

Ayatollah Kashani

##### **City**

Isfahan

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##### **Postal code**

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##### **Phone**

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##### **Email**

kashani@kashani.mui.ac.ir

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Al-Zahra Hospital (S)

##### **Full name of responsible person**

Dr. Mohammad Saadat Nia

##### **Street address**

Sofeh Boulevard

##### **City**

Isfahan

##### **Province**

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##### **Postal code**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Gholamreza Askari

**Street address**

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research@mui.ac.ir

**Web page address**<https://research.mui.ac.ir>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Ehsan Ghasemi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Ehsan Ghasemi

**Position**

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**Latest degree**

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Ehsan Ghasemi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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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**

Because of confidentiality

### **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