Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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/lists, 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
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Province
Isfehan
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 Posturoghraphy 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 Posturoghraphy 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
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2

Recruitment center
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Sponsors / Funding sources

1

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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
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

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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