

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Nintendo Wii on ankle spasticity in stroke patients: a randomized clinical trial

Protocol summary

Study aim

The effect of Nintendo Wii on ankle spasticity in patients with stroke

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 30 patients. Blocking method was used for randomization.

Settings and conduct

Patients who meet the inclusion criteria are invited to be present at the Neuron Neurology Clinic located in Isfahan. Then the patient enters one of the test groups according to the block table randomly entered by one uninformed person.

Participants/Inclusion and exclusion criteria

From patients with stroke who have ankle spasticity and able to stand without an aid for at least 30 seconds is invited to participate in the study.

Intervention groups

Individuals in the control and intervention groups receive treatment with valid scientific evidence to reduce spasticity. In addition to receiving routine treatment, the intervention group is treated with 30 minutes of Nintendo Wii games, 3 times a week for 12 sessions.

Main outcome variables

1. H- reflex Latency 2. H maximum /M maximum Ratio

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200101045970N3**

Registration date: **2020-10-03, 1399/07/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-03, 1399/07/12**

Update count: **0**

Registration date

2020-10-03, 1399/07/12

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

2020-09-09, 1399/06/19

Expected recruitment end date

2021-03-09, 1399/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Nintendo Wii on ankle spasticity in stroke patients: a randomized clinical trial

Public title

The Impact of the Nintendo Wii on Stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 85 years History of the first unilateral stroke by a neurologist through CT scan or MRI findings. Spasticity in the ankle joint according to the Modified Modified Ashworth Scale with MMAS \geq 1 Existence of appropriate

cognitive status based on Persian version of Mini mental Status Exam (MMSE> 24 Ability to maintain a standing position without the use of assistive devices for at least 30 seconds.

Exclusion criteria:

History of myocardial infarction or high-risk heart disease
Existence of other neurological disorders such as neuropathy, epilepsy, seizures, etc. Existence of diabetes as a metabolic disorder
Use of botulinum or other oral antispasmodics
Participate in other physiotherapy treatment interventions
Contracture and rigidity in plantar flexor muscles

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Due to the small sample size and consultation with a statistician, it was decided to use the random blocking method. Using a statistical software of 15 blocks that consisted of two members used for allocation. An uninformed person enters the persons into this study based on these blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients were unaware of the groups. Also, the person conducting the assessments was unaware of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan Medical University

Street address

Hezar Jrib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-09-06, 1399/06/16

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.309

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

G90-G99

ICD-10 code description

سایر بیماریهای سیستم اعصاب

Primary outcomes

1

Description

H Reflex Latency

Timepoint

Before the intervention and after the intervention

Method of measurement

Using a neural activity recorder.

2

Description

H max/M max Ratio

Timepoint

Before and after the intervention

Method of measurement

Use of nerve electrical activity recorder

Secondary outcomes

1

Description

Muscle Tone

Timepoint

Before and after the intervention

Method of measurement

Modified Modified Ashworth Scale

2

Description

Functional Mobility

Timepoint

Before and After Intervention

Method of measurement

Timed Up and Go test

3

Description

Quality of Life
Timepoint
Before and After Intervention
Method of measurement
SF36 Questionnaire

Intervention groups

1

Description

Intervention group: In addition to receiving routine treatment, the intervention group is treated with 30 minutes of N-Wii game three times a week for 12 sessions in the same session and after a 5-minute break. All games are played standing on the balance screen of the device without the use of assistive devices.

Category

Rehabilitation

2

Description

Control group: Individuals in the control and intervention groups receive treatment with valid scientific evidence to reduce spasticity. Positioning the limbs in the form of antispasmodic patterns, range of motion exercises and functional stretching for 30 minutes, there will be three sessions per week for 12 sessions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Neuron Neurology Center

Full name of responsible person

Narges Yousefi

Street address

Mohtasham Kashani St., corner of the dead end 34

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.....

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+98 31 3625 8575

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yousefi.pt@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoi Javanmard

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Hezar Jrib

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Isfahan

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8174673461

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Email

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

Ehsan Ghasemi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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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

We are excused from publishing information due to ethical and misuse of information.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The study protocol has been published as an article in the Journal of Research in Rehabilitation Sciences of Isfahan. The consent form is also available in the proposal. Clinical results will be published after the end of the study.

When the data will become available and for how long

Study protocol and consent already available. Clinical results will be published in the summer of 1400.

To whom data/document is available

Researchers working in scientific institutes and patients.

Under which criteria data/document could be used

In order to raise information and familiarity with the methods used in the study.

From where data/document is obtainable

To receive the protocol, they can refer to the Journal of Research in Rehabilitation Sciences. They can also contact Dr. Ehsan Ghasemi to receive a proposal.

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

It can be done by communication via email.

Comments