Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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≥ 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

Isfehan

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

City

Isfahan

Province

Isfehan

Postal code

.....

Phone

+98 31 3625 8575

Email

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

Street address

Hezar Jrib

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 8138

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

Street address

Hezar Jrib

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3792 5043

Fax

+98 31 3668 7270

Email

ehsan_kowsar@yahoo.com

Person responsible for scientific 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

Street address
HezarJrib

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 5043

Fax
+98 31 3668 7270

Email
ehsan_kowsar@yahoo.com

Person responsible for updating data

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

Street address
Hezar Jrib

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 5043

Fax
+98 31 3668 7270

Email
ehsan_kowsar@yahoo.com

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