

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

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

Protocol summary

2020-10-03, 1399/07/12

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

Registrant information

Name

Ehsan Ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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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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Sponsors / Funding sources

- 1**
Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person

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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
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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