

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Wii sports compared with Rood's neutral warmth technique in reducing spasticity and fatigue of chronic stroke patients.

Protocol summary

Study aim

To determine what will be the potential benefits of Wii sports and neutral warmth technique on spasticity and fatigue in chronic stroke patients and to compare the effects of Wii sports and neutral warmth technique.

Design

A randomized clinical trial with two parallel groups, a single-blinded study of 3rd phase with 13 patients in each group, which is 26 in total.

Settings and conduct

Allied Hospital Faisalabad and District Headquarters Hospital Faisalabad. patient was kept unaware about which group he was allocated to

Participants/Inclusion and exclusion criteria

- Ischemic or hemorrhagic stroke
- Adult (30 to 50 years)
- Lack of cognitive disability, visual impairment, or neglect that would have made it difficult to adhere to instructions for treatment.
- Able to voluntarily move the elbow, wrist, and shoulder to carry out game directions.
- Not frequent Nintendo Wii users
- They hadn't had a botulinum toxin injection in the three months prior to the study
- Cerebellar stroke
- Any episode of epilepsy during the previous year
- Pace maker
- visual defects left untreated
- Cognitive issues (mini mental score less than 20)
- No voluntary movement of upper limb
- Fixed contracture or bony deformity of upper limb
- Taking any drug that could affect balance

Intervention groups

Group A: Wii sports group Group B: Neutral warmth group

Main outcome variables

1. spasticity 2. fatigue 3. Active range of motion 4. Arm Dexterity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240311061261N1**

Registration date: **2024-04-18, 1403/01/30**

Registration timing: **registered_while_recruiting**

Last update: **2024-04-18, 1403/01/30**

Update count: **0**

Registration date

2024-04-18, 1403/01/30

Registrant information

Name

Ishal Ayub

Name of organization / entity

The University of Faisalabad

Country

Pakistan

Phone

+92 41 8555997

Email address

2022-ms-pt-060@tuf.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-17, 1403/01/29

Expected recruitment end date

2024-08-17, 1403/05/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Wii sports compared with Rood's neutral warmth technique in reducing spasticity and fatigue of chronic stroke patients.

Public title

Effect of Wii sports compared with Rood's neutral warmth technique in reducing spasticity and fatigue of chronic stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ischemic or hemorrhagic stroke Adult (30-50 years) Lack of cognitive disability, visual impairment, or neglect that would have made it difficult to adhere to instructions for treatment. Able to voluntarily move the elbow, wrist, and shoulder to carry out game directions. Not frequent Nintendo Wii users They hadn't had a botulinum toxin injection in the three months prior to the study

Exclusion criteria:

Cerebellar stroke Any episode of epilepsy during the previous year Pace maker visual defects left untreated Cognitive issues (mini mental score less than 20) No voluntary movement of upper limb Fixed contracture or bony deformity of upper limb Taking any drug that could affect the balance

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random sampling was used to allocate patients. The list of individuals was generated through online randomization generator. According to the list patients were assigned into group 1 and group 2

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants will be blinded in this study as they will be allocated into groups through the use of online randomization generator.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research and Ethics / Technical Committee for the University of Faisalabad

Street address

University Avenue, Faisal Town Canal Road, Faisalabad, Punjab

City

Faisalabad

Postal code

38000

Approval date

2024-02-17, 1402/11/28

Ethics committee reference number

TUF/DR/SA/MSPP/2024/420

Health conditions studied

1

Description of health condition studied

Chronic stroke

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Spasticity

Timepoint

Before intervention and at the end of 4 weeks of intervention.

Method of measurement

Modified Ashworth scale will be used

2

Description

Fatigue

Timepoint

Before intervention and at the end of 4 weeks of intervention.

Method of measurement

Fatigue severity scale will be used.

Secondary outcomes

1

Description

Active range of motion

Timepoint

Before intervention and at the end of 4 weeks of intervention.

Method of measurement

A goniometer will be used to measure the ranges of the shoulder.

2

Description

Arm dexterity

Timepoint

Before intervention and at the end of 4 weeks of intervention.

Method of measurement

Box and block test will be used.

Intervention groups

1

Description

Intervention group: Wii sports group

Category

Treatment - Devices

2

Description

Intervention group: Neutral warmth group

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Allied Hospital Faisalabad

Full name of responsible person

Sidra Majeed

Street address

Dr. Tusi Rd, Faisalabad, Punjab

City

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38000

Phone

+92 334 7731241

Email

Sidra.majeed@tuf.edu.pk

Web page address

<https://ahfsd.pk/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University Of Faisalabad

Full name of responsible person

Sidra majeed

Street address

University Avenue, Faisal Town Canal Road,

Faisalabad, Punjab

City

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Postal code

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Phone

+92 334 7731241

Email

Sidra.majeed@tuf.edu.pk

Web page address

<https://tuf.edu.pk/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

The University Of Faisalabad

Proportion provided by this source

100

Public or private sector

Private

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

The University of Faisalabad

Full name of responsible person

Ishal Ayub

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

No. p 2/7, Sundar house, Saeed colony No.1., East canal road., Faisalabad., Pakistan

City

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38000

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+92 41 8555997

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Effect of Wii sports compared with Rood's neutral warmth technique in reducing spasticity and fatigue of chronic stroke patients

When the data will become available and for how long

Starting six months after publication and it will remain available for everyone

To whom data/document is available

This will be available for everyone.

Under which criteria data/document could be used

Sidra.majeed@tuf.edu.pk 0092 334 7731241

From where data/document is obtainable

Ishal.ayub@gmail.com Mobile No. 0092 321 6695413

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

Any applicant just need to contact for data/file contact through email at ishal.ayub@gmail.com 0092 321 6695413

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

The University of Faisalabad

Full name of responsible person

Ishal Ayub

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Latest degree

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