

# 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**

Faisalabad

#### **Postal code**

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,

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#### **City**

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#### **Postal code**

38000

#### **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**

Faisalabad

#### **Province**

Punjab

#### **Postal code**

38000

#### **Phone**

+92 41 8555997

#### **Fax**

#### **Email**

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

## **Person responsible for scientific inquiries**

### **Contact**

**Name of organization / entity**

The University of Faisalabad

**Full name of responsible person**

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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

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