Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 pateints 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, Faisalabad, Punjab
City
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+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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Person responsible for updating data

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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 remail 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