

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of virtual reality on balance in acute and sub acute stroke patients

Protocol summary

Study aim

This study investigates the effect of virtual reality (VR) intervention in improving balance, in acute and sub acute stroke patients

Design

Parallel, Single blinded, Randomised control trial with 50 sample size

Settings and conduct

Allied hospital Faisalabad, Punjab, Pakistan. It was a single-blinded study, the participants were unaware whether they are receiving the experimental treatment or a placebo. This design helps to reduce bias that may occur if participants know whether they are receiving the treatment or not, which could influence their responses or behavior.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willing to give consent! Patients having age between 45 to 60 years !Both male and female !Mini mental scale more than 18 score !Berg Balance Scale score less than 20 Exclusion criteria: Recurrent stroke episodes !Any other neurological conditions that causes balance disturbs that is Alzheimer! Parkinson's! dementia! Malignancy, infectious disease! Any surgery within last 6 months! Chronic stroke patients

Intervention groups

Group A received baseline treatment that is Functional electrical stimulation and Range of motion exercises for balance. Range of motion exercises are Ankle movements, stand tall, feet together, side steps, Hip abduction, Heel rises, weight shift, and leg stance, balance walking. Each exercises performed with the repetitions of 10 reps, 5 sets. Functional electrical stimulation used for the stimulation and improving balance. FES delivered with 0.3-ms pulses at 30 HZ with the maximum tolerance of intensity 20-30 mA in acute stage Goup B received protocol which includes virtual reality along with baseline treatment. A total of 18 sessions (3 alternate sessions per week or 45 min each) performed on the participants in 40 minute session.

Main outcome variables

Berg Balance Scale Postural assessment scale for stroke

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240307061204N2**

Registration date: **2024-05-08, 1403/02/19**

Registration timing: **retrospective**

Last update: **2024-05-08, 1403/02/19**

Update count: **0**

Registration date

2024-05-08, 1403/02/19

Registrant information

Name

Zainab Boota

Name of organization / entity

The University of Faisalabad

Country

Pakistan

Phone

+92 41 87509715

Email address

2022-ms-pt-042@tuf.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-17, 1402/11/28

Expected recruitment end date

2024-03-30, 1403/01/11

Actual recruitment start date

2024-02-17, 1402/11/28

Actual recruitment end date

2024-04-30, 1403/02/11

Trial completion date

2024-05-02, 1403/02/13

Scientific title

Effect of virtual reality on balance in acute and sub acute stroke patients

Public title

Effect of virtual reality in stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willing to give consent Patients having age between 45 to 60 years Both male and female Mini mental scale more than 18 score Berg Balance Scale score less than 20 Stroke patient clinically diagnosed or with CT and MRI

Exclusion criteria:

Recurrent stroke episodes Any other neurological conditions that causes balance disturbs that is Alzheimer, parkinsons, dementia Malignancy, infectious disease Any surgery within last 6 months Chronic stroke patients Any intracranial implant Patients with severe cardiopulmonary complications

Age

From **45 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Non probability consecutive sampling , is a sampling method where researchers select participants who are readily available and accessible to them. In this method, individuals who are conveniently located, easily approachable, or readily willing to participate are included in the study without any random selection process from one setting.

Blinding (investigator's opinion)

Single blinded

Blinding description

Single blinded study was conducted to minimize the chance of biasness, this study design was used to allocate the members in comparable groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research and Ethics/technical committe for the university of faisalabad

Street address

Faisal Town, West Canal Road, Faisalabad, Punjab

City

Faisalabad

Postal code

38000

Approval date

2024-01-05, 1402/10/15

Ethics committee reference number

TUF/Addl Reg/SB/755

Health conditions studied

1

Description of health condition studied

Acute, Sub-acute Stroke

ICD-10 code

164

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

Balance

Timepoint

before intervention and 6 weeks after intervention

Method of measurement

Berg Balance Scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Functional electrical stimulation and Range of motion exercises for balance.

Category

Rehabilitation

2

Description

Intervention group: Virtual Reality

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Allied Hospital Faisalabad

Full name of responsible person

Dr. Zainab Boota

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Dr. Tusi Rd, Faisalabad, Punjab

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Faisalabad

Full name of responsible person

Dr. Syed Saqlain Babar; PT

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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

Dr. Syed Saqlain Babar; PT

Position

Clinical Consultant Physiotherapist

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

Contact

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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 virtual reality on balance in acute and sub-acute stroke patients

When the data will become available and for how long

Fifteen days after publication

To whom data/document is available

Google Scholar

Under which criteria data/document could be used

Access to the data will be facilitated through a specified

mechanism, such as a secure online portal or data sharing platform. Requests for access will be reviewed by a designated committee or entity responsible for ensuring that they meet the establishment criteria and comply with relevant regulation and guidelines. Additional supporting information and documents may be provided to assist requesters in understanding the available data and its potential application.

From where data/document is obtainable

The University of Faisalabad 3800 <https://tuf.edu.pk/>
00924187509715

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

To receive the documents or data files, the process typically involves the following steps: 1. Request Initiation: The applicant submits a formal request specifying the documents or data files they need. 2. Verification and Authorization: The organization verifies the request and ensures that the applicant is authorized to access the requested documents or data files. This may involve confirming the identity of the requester and checking their permissions. 3. Processing Time: The processing time varies depending on the complexity of the request, the volume of documents or data files, and any legal or regulatory requirements. It could range from a few hours to several weeks. 4. Document Retrieval or Data Extraction: Once the request is approved, the organization retrieves the documents from their archives or extracts the requested data from their databases. 5. Quality Assurance: Before releasing the documents or data files to the applicant, the organization may conduct quality checks to ensure accuracy and completeness. 6. Delivery: The documents or data files are delivered to the applicant through a secure channel, such as encrypted email, secure file transfer protocols, or a secure online portal. 7. Confirmation of Receipt: The applicant acknowledges receipt of the documents or data files, confirming that they have received the information they requested.

Comments