Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of virtual reality on balance, postural control and stability in acute and sub-acute stroke patients

Protocol summary

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

Design
Non-probability consecutive sampling

Settings and conduct
Allied hospital Faisalabad

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 • Burg Balance Scale score less than 20 Exclusion Criteria • Recurrent stroke episodes • Any other neurological conditions that causes balance disturbs that is Azheimer, parkinsons, dementia • Malignancy, infectious disease • Any surgery within last 6 months • Chronic stroke patients

Intervention groups
Group A recieved an active control group will receive 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 repitions of 10 reps, 5 sets. Functional electrical stimulation used for the stimulation and improving balance. FES deilievered 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
Balance Berg Scale Postural assessment scale for stroke

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240307061204N1**
Registration date: **2024-03-23, 1403/01/04**
Registration timing: **registered_while_recruiting**

Last update: **2024-03-23, 1403/01/04**
Update count: **0**

Registration date
2024-03-23, 1403/01/04

Registrant information

Name
Zainab Boota
Name of organization / entity
The University of Faisalabad
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Pakistan
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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, postural control and stability 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 40 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, Parkinson, dementia Malignancy, infectious disease Any surgery within last 6 months Chronic stroke patients Any intracranial implant patients with severe cardiopulmonary complications
Age
From **40 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
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
Balance, postural control and stability. improvements checked by the berg balance scale. Virtual reality used as a intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research and Ethics / technical committee 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
ICD-10 code description

Primary outcomes

1

Description
Postural Control
Timepoint
Before intervention and 6 weeks after intervention
Method of measurement
Postural Assessment Scale for Stroke

2

Description
Postural Stability
Timepoint
Before intervention and 6 weeks after intervention
Method of measurement
Postural Assessment Scale for Stroke

Secondary outcomes

1

Description
Balance
Timepoint
Before intervention and 6 weeks after intervention
Method of measurement
Berg Balance Scale

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; PT
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Dr. Tusi Road, Faisalabad, Punjab
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Faisalabad
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Dr. Syed Saqlain Babar; PT
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Syedsaqlain264@gmail.com
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. Gulraiz Ayub; PT
Position
Clinical Consultant Physiotherapy
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Person responsible for updating data

Contact
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The University of Faisalabad

Full name of responsible person

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Position

Consultant Physiotherapist

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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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, postural control and stability 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 established criteria and comply with relevant regulations and guidelines. Additional supporting information and documents may be provided to assist requester.

From where data/document is obtainable

The University of Faisalabad 38000 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