Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 Burg 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 Azheimer, 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 Faislabad
Full name of responsible person
Dr. Zainab Boota
Street address
Dr. Tusi Rd, Faisalabad, Punjab
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2022-ms-pt-042@tuf.edu.pk

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
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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 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 acess 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