Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

EFFECTS OF VIRTUAL REHABILITATION ON UPPER EXTREMITY MOTOR RECOVERY IN PATIENTS WITH SUBACUTE STROKE

Protocol summary

Study aim
1. To investigate the effects of Microsoft Xbox Kinect-based Virtual Reality game training on the upper extremity motor rehabilitation of sub-acute post stroke survivors

Design
Single Blind, Randomized Controlled Clinical Trial

Settings and conduct
Trial will be conducted at Re Active Rehabilitation Center of The University of Faisalabad. The Trial is Single Blinded, Participants are blinded through Lottery Method.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Ischemic or hemorrhagic stroke, Stroke onset > 2 weeks and < 6 months • First-ever ischemic or hemorrhagic stroke confirmed by MRI or CT • Patients > age 25 • Unilateral upper extremity weakness, • Patients who could perform the reaching activity with their hemiparetic arm. • Both genders will be included • Voluntary shoulder, elbow and wrist movement which is able to perform In-game commands. Exclusion Criteria: • Patients with co-morbidities or neurodegenerative diseases, • Patients who are unable to follow verbal commands due to cognitive impairment or aphasia • Patients who are unable to participate Kinect-based VR due to any reason (e.g., visual impairment, hemi spatial neglect, apraxia) • History of seizures/fits, • Psychological illness,

Intervention groups
Group A: In this group patients will be treated with routine physiotherapy combined with virtual rehabilitation. Xbox Kinect will used for training. The exercise program consists of stretching, strengthening and isometric exercises. Virtual rehabilitation consists of 30 minutes session 5 days per week for 4 weeks Group B: In this group patients will be treated with routine physiotherapy program. Routine physiotherapy will be performed 30 minutes 10 repetitions, twice a day 5 days per week for 4 weeks.

Main outcome variables
Fugl-Meyer Assessment Brunnstrom Recovery Stages Modified Ashworth Scale The Motricity Index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210507051203N1**
Registration date: **2021-07-05, 1400/04/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-05, 1400/04/14**
Update count: **0**

Registration date
2021-07-05, 1400/04/14

Registrant information

Name
Osama Saeed

Name of organization / entity
The University of Faisalabad

Country
Pakistan

Phone
+92 41 8750971

Email address
osama.saeed@tuf.edu.pk

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-05, 1399/12/15

Expected recruitment end date
2021-09-10, 1400/06/19

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

EFFECTS OF VIRTUAL REHABILITATION ON UPPER EXTREMITY MOTOR RECOVERY IN PATIENTS WITH SUBACUTE STROKE

Public title

EFFECTS OF VIRTUAL REHABILITATION ON UPPER EXTREMITY MOTOR RECOVERY IN PATIENTS WITH SUBACUTE STROKE

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

• Ischemic or hemorrhagic stroke • Stroke onset with less than 2 weeks and more than 6 months • First-ever ischemic or hemorrhagic stroke confirmed by MRI or CT • Patients with more than 25 years and less than 65 years Old • Unilateral upper extremity weakness, • Patients who could perform the reaching activity with their hemiparetic arm. • Both genders will be included • Voluntary shoulder, elbow and wrist movement which is able to perform In-game commands. • Subjects willing to participate in the study.

Exclusion criteria:

• Patients with co-morbidities or neurodegenerative diseases, • Uncontrolled medical condition (e.g., active infection, pulmonary embolism, unstable angina), • Patients who are unable to follow verbal commands due to cognitive impairment or aphasia • Patients who are unable to participate Kinect-based VR due to any reason (e.g., visual impairment, hemi spatial neglect, apraxia) • History of seizures/fits, • Psychological illness, • Bony deformities • Prior history of drugs that could alter balance will be excluded from the study

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization will be generated by Online Randomizer

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessor will not have any information about the treatment given in both groups

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

UIPT Ethical Review Committee

Street address

Defence Road, Near Bhuptian Chowk

City

Lahore

Postal code

36000

Approval date

2021-02-10, 1399/11/22

Ethics committee reference number

UIPT/201/ERC/2018

Health conditions studied

1

Description of health condition studied

Subacute Stroke

ICD-10 code

I63.9

ICD-10 code description

Cerebral infarction, unspecified

Primary outcomes

1

Description

Fugl Meyer Assessment

Timepoint

Before Intervention, 2 Weeks and 4 Weeks

Method of measurement

226 points multi-item questionnaire used for the evaluation of recovery from stroke

Secondary outcomes

1

Description

• Brunnstrom Recovery Stages

Timepoint

Baseline, 2 Weeks and after 4 Weeks

Method of measurement

Brunnstrom recovery stages or BRS is 6-stage evaluation tool indicating the recovery after stroke

2

Description
Modified Ashworth Scale
Timepoint
Baseline, 2 Weeks and after 4 Weeks
Method of measurement
It is 6 points scale ranging from 0-4 and lower reading indicates the normal tone of muscle and higher score means more resistance to passive movement or spasticity

Intervention groups

1

Description
Intervention Group 1: In this group patients will be treated with routine physiotherapy combined with virtual rehabilitation. The exercise program consists of stretching, strengthening and isometric exercises. Virtual rehabilitation consists of 30 minutes session 5 days per week for 4 weeks
Category
Rehabilitation

2

Description
Intervention Group 2 In this group patients will be treated with routine physiotherapy program. Routine physiotherapy will be performed 30 minutes 10 repetitions, twice a day 5 days per week for 4 weeks.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Re Active Rehabilitation Center
Full name of responsible person
Muhammad Mohsin Hussain
Street address
West Canal Road, Faisal Town Faisalabad
City
Faisalabad
Postal code
36000
Phone
+92 41 8750971
Email
m.mohsinhussain@tuf.edu.pk
Web page address
https://tuf.edu.pk/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Madina Teaching Hospital
Full name of responsible person
Muhammad Mohsin Hussain
Street address
West Canal Road, Faisal Town
City
Faisalabad
Postal code
38000
Phone
+92 41 8750971
Email
m.mohsinhussain@tufedu.pk
Web page address
Grant name
N/A
Grant code / Reference number
N/A
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
NA
Proportion provided by this source
1
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
Osama Saeed
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
West Canal Road, Faisal Town
City
Faisalabad
Province
Punjab
Postal code
36000
Phone
+92 41 8750971
Email

osama.saeed@tuf.edu.pk

Person responsible for scientific inquiries

Contact

Name of organization / entity
Madina Teaching Hospital

Full name of responsible person
Muhammad Mohsin Hussain

Position
Assistant Professor

Latest degree
Master

Other areas of specialty/work
Physiotherapy

Street address
West Canal Road, Faisal Town

City
Faisalabad

Province
Punjab

Postal code
38000

Phone
+92 41 8750971

Email
m.mohsinhussain@tuf.edu.pk

Person responsible for updating data

Contact

Name of organization / entity
Madina Teaching Hospital

Full name of responsible person
Osama Saeed

Position
Lecturer

Latest degree
Master

Other areas of specialty/work
Physiotherapy

Street address
West Canal Road, Faisal Town

City
Faisalabad

Province
Punjab

Postal code
38000

Phone
+92 41 8750971

Email
osama.saeed@tuf.edu.pk

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
It will depend upon the journal where it will be published

When the data will become available and for how long
It will depend upon the journal where it will be published

To whom data/document is available
Researchers , Scholars, Physiotherapist

Under which criteria data/document could be used
None

From where data/document is obtainable
Direct Contact with Responsible

What processes are involved for a request to access data/document
Access as per policy

Comments