

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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Phone

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Web page address

<https://tuf.edu.pk/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Madina Teaching Hospital

Full name of responsible person

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West Canal Road, Faisal Town

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Email

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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

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Email

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

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Person responsible for updating data

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Name of organization / entity

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Lecturer

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Master

Other areas of specialty/work

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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