

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

EFFECT OF VIRTUAL REALITY TRAINING AND ROUTINE PHYSICAL THERAPY ON BALANCE AND FUNCTIONAL INDEPENDENCE IN STROKE PATIENTS

Protocol summary

Study aim

This is an era of machine learning. There is need of immediate application of such machine learning in Health Care. Although the work has been done in virtual reality in performance labs, this study is one of few that is being conducted directly with patient involvement. The unique feature is incorporating functional and recreational activities in stroke patient's rehabilitation. The positive outcomes of this study can be integrated with machine learning algorithms that will be a revolution in field of stroke and other neurological rehabilitation.

Design

Randomized Clinical Trial

Settings and conduct

Kanaan Physiotherapy & Spine clinic, Shadman, Lahore, Pakistan

Participants/Inclusion and exclusion criteria

INCLUSION CRITERIA • male and female between Age 41-60 years with Unilateral involvement of extremity and First exposure of stroke episode either hemorrhagic or ischemic in origin and stroke evident by reports of CT Scan or MRI **EXCLUSION CRITERIA** • Ischemic heart disease with unstable angina, History of seizures, Motor impairment such as neuropathy or Parkinson's disease, Severe aphasia that can limit participation or feedback and Cognitive mental condition that can interfere with comprehension of commands

Intervention groups

Patients will be randomly allocated in two groups of 34 patients each i.e. Virtual Reality Group and Routine Physical Therapy Group by Coin Tossing method.

Main outcome variables

Any systematic disease, body mass index, status of speech inactivity, affected side of body and score of movements at shoulder, elbow, wrist, hip, knee and ankle joints against medical research council scale. Functional assessment of hand, Upper limb and lower limb, Balance assessment

General information

Reason for update

Acronym

VRTSP

IRCT registration information

IRCT registration number: **IRCT20190715044216N1**

Registration date: **2019-08-09, 1398/05/18**

Registration timing: **prospective**

Last update: **2019-08-09, 1398/05/18**

Update count: **0**

Registration date

2019-08-09, 1398/05/18

Registrant information

Name

Naveed Anwar

Name of organization / entity

Riphah International University

Country

Pakistan

Phone

+92 42 35126110

Email address

naveedanwar982@yahoo.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2639-12-11, 2018/09/20

Expected recruitment end date

2640-12-22, 2019/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

EFFECT OF VIRTUAL REALITY TRAINING AND ROUTINE PHYSICAL THERAPY ON BALANCE AND FUNCTIONAL INDEPENDENCE IN STROKE PATIENTS

Public title

EFFECT OF VIRTUAL REALITY TRAINING AND ROUTINE PHYSICAL THERAPY ON BALANCE AND FUNCTIONAL INDEPENDENCE IN STROKE PATIENTS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients of both genders i.e. male and female Age between 41-60 years Unilateral involvement of extremity First exposure of stroke episode either hemorrhagic or ischemic in origin and stroke evident by reports of CT Scan or MRI At least a score of 2 on medical research council scale Stable alert patient and able to follow the instructions of physical therapist

Exclusion criteria:

Ischemic heart disease with unstable angina History of seizures Motor impairment such as neuropathy or Parkinson's disease Severe aphasia that can limit participation or feedback Cognitive mental condition that can interfere with comprehension of commands

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly allocated in two groups of 34 patients each i.e. Virtual Reality Group and Routine Physical Therapy Group by Coin Tossing method. "Heads" is for Virtual Reality Group and "Tails" for Routine Physical Therapy Group

Blinding (investigator's opinion)

Single blinded

Blinding description

It will be a single blinded study blinding one of personnel of trial architecture i.e. assessors. Clinicians and patients are difficult to blind due to very nature of treatment protocol and study design.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

institutional Review Board

Street address

1km, defence road, bhobattian chowk, Lahore

City

Lahore

Postal code

60000

Approval date

2639-12-11, 2018/09/20

Ethics committee reference number

IRB-UOL-FAHS/373-III/2018

Health conditions studied

1

Description of health condition studied

Cerebrovascular Accident (CVA) (Stroke)

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes

1

Description

Functional independence

Timepoint

before intervention, 12 week after intervention, 24 week post intervention

Method of measurement

Strength testing on 0-5 scale and through Stroke impact scale questionnaire

2

Description

Balance

Timepoint

before intervention, 12 week after intervention, 24 week post intervention

Method of measurement

Balance measurement through balance board and through Berg balance scale

3

Description

Hand function

Timepoint

before intervention, 12 week after intervention, 24 week post intervention

Method of measurement

wolf motor hand function test

Secondary outcomes

empty

Intervention groups

1

Description

Virtual Reality group: The Wii is a home video game console released by Nintendo on November 19, 2006. As a seventh-generation console, the Wii competed with Microsoft's Xbox 360 and Sony's PlayStation 3. Nintendo states that its console targets a broader demographic than that of the two others. This device is the most suitable one to be utilized in this trial due to its control on three dimensional measurement. Patients in this group will get daily 60 minutes session, 3 days a week for 12 weeks.

Category

Other

2

Description

Routine physical therapy group: These include proven methods such as sustained stretching program for hypo flexibility, strengthening program for extensibility and balance training and coordination exercise to improve motor control and deficit. Also include motivational sessions over the time. Patient in this group will get 60 minutes session, 3 days a week for 12 weeks

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Kanaan Physiotherapy & Spine clinic, Shadman, Lahore, Pakistan.

Full name of responsible person

Naveed Anwar

Street address

Kanaan Healthcare center, near governor house, lahore, Pakistan.

City

Lahore

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Phone

+92 42 36282885

Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kanaan Physiotherapy & Spine clinic

Full name of responsible person

Khalid Yaseen

Street address

36, Street 4, Baagbanpura, Mughalpura, Lahore

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

university of Lahore

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Riphah International University, Lahore, Pakistan

Full name of responsible person

Naveed Anwar

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Analysed data will be shared for publication purpose

When the data will become available and for how long

Data will be available in January 2020

To whom data/document is available

It will be shared with nominated person of registry

Under which criteria data/document could be used

It can be used in health related research

From where data/document is obtainable

Data can be obtained by researcher

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

Email requests

Comments