# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 stoke 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 seizers, 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 stoke 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 seizers 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 extensiblity 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

**Postal code**
60000

**Phone**
+92 42 36282885

**Email**
naveedanwar982@yahoo.com

## 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

**City**
Lahore

**Postal code**
60000

**Phone**
+92 42 36282885

**Email**
naveedanwar982@yahoo.com

**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

**Street address**
524/E Shah Rukn e alam, Multan

**City**
Lahore

**Province**
Punjab

**Postal code**
60000

**Phone**
+92 42 36282885

**Email**
naveedanwar982@yahoo.com

## Person responsible for scientific

## inquiries

**Contact**
**Name of organization / entity**
Riphah International University
**Full name of responsible person**
Naveed Anwar
**Position**
Assistant Professor
**Latest degree**
Master
**Other areas of specialty/work**
Physiotherapy
**Street address**
85, B Canal Gardens, Lahore
**City**
Lahore
**Province**
Punjab
**Postal code**
60000
**Phone**
+92 42 36282885
**Email**
naveedanwar982@yahoo.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Riphah International University
**Full name of responsible person**
Kehkshan Khalid
**Position**
Lecturer
**Latest degree**
Master
**Other areas of specialty/work**
Physiotherapy
**Street address**
524/E Shah Rukn e alam, Multan
**City**
Multan
**Province**
Punjab
**Postal code**
60000
**Phone**
+92 42 36282885
**Email**
naveedanwar982@yahoo.com

## 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**