Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Virtual Reality combined with modified Constraint-Induced Movement Therapy based upper limb training on chronic stroke survivors

Protocol summary

Study aim
To compare effect of virtual reality alone with the combined effect of Virtual reality and modified constraint induced movement therapy on upper limb motor function in stroke

Design
Randomized Control Trial

Settings and conduct
Dar ul Rehmat medical complex, Charsadda. Single blinded

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Ischemic stroke of MCA subjects suffering from stroke for at least 6 months Both genders of age between 40 to 60 years Having at least 10° of active extension of each MCP joint, IP joints of all the digits, and 10° wrist extension of the affected limb Spasticity Grade 1 to 3 according to Modified Ashworth Scale Exclusion criteria: Patients with visual deficits Patients not willing to use virtual reality or CIMT Patients with cognitive disorders Patients with upper limb contracture

Intervention groups
1. Group (I) Virtual reality 2. Group (II) Virtual reality combined with modified constraint induced movement therapy

Main outcome variables
Stroke

General information

Reason for update

Acronym
Upper limb motor function recovery in stroke

IRCT registration information
IRCT registration number: **IRCT20210615051585N2**
Registration date: **2021-11-24, 1400/09/03**
Registration timing: **retrospective**
Last update: **2021-11-24, 1400/09/03**
Update count: **0**

Registration date
2021-11-24, 1400/09/03

Registrant information

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Name of organization / entity
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Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-01, 1400/01/12

Expected recruitment end date
2021-05-01, 1400/02/11

Actual recruitment start date
2021-05-01, 1400/02/11

Actual recruitment end date
2021-07-01, 1400/04/10

Trial completion date
2021-08-01, 1400/05/10

Scientific title
Effect of Virtual Reality combined with modified Constraint-Induced Movement Therapy based upper limb training on chronic stroke survivors

Public title
Effect of Virtual Reality combined with modified Constraint-Induced Movement Therapy based upper limb training on chronic stroke survivors

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ischemic stroke of MCA subjects suffering from stroke for at least 6 months Both genders of age between 40 to 60 years Having at least 10° of active extension of each MCP joint, IP joints of all the digits, and 10° wrist extension of the affected limb Spasticity Grade 1 to 3 according to Modified Ashworth Scale

Exclusion criteria:

Patients with visual deficits Patients not willing to use virtual reality or CIMT Patients with cognitive disorders Patients with upper limb contracture

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **32**

Actual sample size reached: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment for treatment using sealed envelope 26 Sheets of properly cut Aluminum paper double the size of the paper. 26 Sheets of Carbon paper cut into appropriate size according to the paper used. A standard-sized square paper was taken in which group "(VR)" was marked. In this way, 13 papers were prepared marked with "(VR)" and 13 square-shaped papers marked with "(VR+mCIMT)". The sheet of paper on which either (VR) or (VR+mCIMT) was marked was folded to fit the envelope. A sheet of Carbon paper was placed on the top of the folded paper (marked either (VR) or (VR+mCIMT)) facing the envelope. Then the sheet of Aluminum foil was wrapped on the carbon paper (with folded paper inside). All the above prepared were placed in the envelope (which was completely opaque), the envelope was then sealed. In this way 13 envelops of "(VR)" and 13 envelops of "(VR+mCIMT)"were prepared. With a total number of 26 envelopes. These 26 envelopes were then thoroughly shuffled like a deck of cards. The envelopes were then marked with numbers 1-26. Each participant picked the envelope in order from 1-26 and was given an intervention (VR or VR+mCIMT) accordingly.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participant don’t know about in what group they are. Only the researcher doing the study knows which treatment or intervention the participant is receiving.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board and Ethics Committee (IRB and EC) Shifa International Hospital and Shifa

Street address

Department of Rehabilitation Sciences, Dar ul Shifa Campus, Shifa Tameer e Millat University

City

Islamabad

Postal code

25000

Approval date

2021-04-01, 1400/01/12

Ethics committee reference number

IRB # 080-21

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

Upper limb motor function

Timepoint

Baseline, 2nd week and 4th week after intervention

Method of measurement

Wolf motor function test

Secondary outcomes

1

Description

Spasticity

Timepoint

4th week

Method of measurement

Modified Ash worth scale

Intervention groups

1

Description
Virtual reality Group: Treatment for 20 min 3 sessions per week for 4 weeks along with the conventional therapy. The VR protocol included using VR headset and the games used were Rally ball and Reflex ridge. In the Rally ball game, balls approaching the player from multiple angles are hit from a chair. The Reflex Ridge game involves hitting, grasping obstacles while sitting in a chair. The patient played each game for 10-mins per session. Conventional therapy includes: passive stretching, repetitive task-specific activities, passive, active-assisted and active ROM exercises

Category
Rehabilitation

2

Description
Virtual reality combined with m-CIMT Group: Treatment for 20 min 3 sessions per week for 4 weeks along with the conventional therapy. The unaffected hand of participant was restrained and then the same VR treatment (as above) given to the participants.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Dar ul Rehmat medical complex

Full name of responsible person
Dr Akmal khan

Street address
Main GT road, Charsadda

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Sponsors / Funding sources

1

Sponsor

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Grant name
NONE

Grant code / Reference number
NONE

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shifa Tameer e Millat University

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
Shifa Tameer e Millat University

Full name of responsible person
Dr Saima Gul

Position
Associate Professor

Latest degree
Ph.D.

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Neuroscience

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to Ethical Considerations
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available