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
Upper limb motor function recovery in stroke

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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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 envelopes of “(VR)” and 13 envelopes 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
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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