Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Comparison between Action Observation Therapy and Virtual Reality Training on Upper Extremity Function And Speech Skill In Stroke Patients: Randomized Control Trial

Protocol summary

Study aim
A comparative study of the effect of functional observation therapy and virtual reality therapy based on Kinect along with conventional (traditional) physiotherapy on upper limb function and speech in stroke patients.

Design
Two intervention groups, which will be conducted in parallel and double-blind and randomized in phase 3 on 30 patients. Randomization through the site http://apps.who.int/classifications/icd10/browse /2010/en

Settings and conduct
The research is carried out in the special clinic of Qaim Mashhad Hospital on people with stroke in two randomized double-blind intervention groups (evaluator and allocator).

Participants/Inclusion and exclusion criteria
Inclusion criteria: First stroke, at least three weeks passed, unilateral infarct in the left hemisphere, right hand dominant, mild to moderate aphasia Exclusion criteria: Severe vision and hearing problems, medical instability, score greater than 2 on the Ashworth scale, complete half-body paralysis.

Intervention groups
Participants will initially receive 20 minutes of the main intervention, in one group of functional observation therapy and in the other group of Kinect-based virtual reality, after they will receive conventional physiotherapy treatment for 45 minutes. took Treatment sessions will be held three times a week for 10 sessions. 1) Functional observation therapy, videos of functional movements of the upper limb will be prepared by a healthy person.After 2 Min, the patients will be given three minutes to perform the corresponding movement. 2) Virtual reality based on Kinect: a virtual environment consisting of 4 games with 5 difficulty levels will be designed. The participant was asked to play the game based on the instructions of the therapist and the instructions and signs of the game.

Main outcome variables
Fugl-Meyer test

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221030056342N6**
Registration date: **2024-11-28, 1403/09/08**
Registration timing: **prospective**

Last update: **2024-11-28, 1403/09/08**
Update count: **0**

Registration date
2024-11-28, 1403/09/08

Registrant information

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Name of organization / entity

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2024-12-08, 1403/09/18

Expected recruitment end date
2026-12-09, 1405/09/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison between Action Observation Therapy and Virtual Reality Training on Upper Extremity Function And Speech Skill In Stroke Patients: Randomized Control Trial

Public title

Comparison of two therapeutic methods of functional observation and virtual reality in people with stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

First stroke At least three weeks have passed since the stroke Unilateral infarct in the left hemisphere The right hand should be the dominant hand based on the Edinburgh test Mild to moderate severity of aphasia

Exclusion criteria:

Severe vision and hearing problems Medical instability A score of more than 2 on the Ashworth scale Complete paralysis of half the body

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the quadruple random block method will be used. In this method, the volume of each block must be determined first (for example, a quadruple block). Then write the list of blocks and assign numbers to them (AABB(1)- ABAB(2)-ABBA(3)-BBAA(4)- BABA(5)- BAAB(6)) then choose random numbers between 1 and 6 (for example, 1, 4, 5, etc.) and finally specifying the treatment allocation list based on the previous random numbers (AABB-BBAA-BABA-).}

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients were randomly assigned to two groups of conventional (traditional) physiotherapy along with functional observation treatment (group A) and conventional (traditional) physiotherapy along with four groups by a person who is not involved in any of the intervention and evaluation stages. Virtual reality treatment based on Kinect (group B) will be assigned. At the same time, the person who measures the results before and after the treatment will also be blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

No 311,Central Organization of Mashhad University of Medical Sciences, Danesh and Salamat Township, between Shahid Al Shahidi Square and Shahid Javan Square, At the end of Shahid Fakuri Blvd

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Approval date

2024-09-28, 1403/07/07

Ethics committee reference number

IR.MUMS.FHMPM.REC.1403.143

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

164

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

Fugl-Meyer assessment scale for the upper limb

Timepoint

Before and immediately after treatment

Method of measurement

This scale has been validated in terms of psychometric properties and is a quantitative measure of motor disability in hemiplegia patients after stroke. It includes 6 areas of reflexes, voluntary movements, coordination, speed, sense and passive movements. In the movement part, the upper limbs, wrists and fingers and the speed and coordination of movements are evaluated. Items are scored using a three-point scale (0 = cannot do; 1 =

partially does; 2 = completely does) and a total score of 66 is calculated.

Secondary outcomes

1

Description
Functional reach test
Timepoint
Before and immediately after treatment
Method of measurement
In this test, the participant stands next to the wall and raises the upper body up to the shoulder with a straight elbow. This point is considered as zero, then the person bends forward or sideways by keeping the support level fixed. This distance is measured to the zero point.

2

Description
The score of the Persian version of the naming skill questionnaire
Timepoint
Before and immediately after treatment
Method of measurement
This test is performed in order to assess the vulnerability of verbal naming memory using semantic guidance and phonetic guidance of dyslexic patients. This test has 50 images in different categories, which are selected according to the type and diversity of the category in three groups of animals (12 items), natural categories (11 items) and man-made categories (27 items). To perform the test, each picture is shown to the patient one by one and in order, and he is asked to name them. The type of patient's answer is also noted in the answer letter. If the participant cannot answer after ten seconds, he will first receive semantic guidance, and if he is still unable to answer, phonetic guidance will be provided to the patient by repeating the beginning consonants of the target word. The participant's answers will also be recorded against the target word. In examining the validity of the test on 32 dyslexic patients aged 40 to 68, the internal consistency coefficient was 0.96 and the test-retest coefficient was 0.87.

3

Description
Severity of aphasia
Timepoint
Before and immediately after treatment
Method of measurement
To check the severity of aphasia, the speech and language pathologist will use Dr. Nilipour's aphasia test, the validity and reliability of which has been obtained in Farsi. In this test to check the severity of aphasia, the version of the aphasia questionnaire includes five items that include conversation and impromptu speech (answering targeted questions, free speech and describing illustrated stories), listening comprehension (yes and no questions, listening comprehension of words, commands continuous and short story comprehension), oral expression (psychomotor speech, automatic speech, memorizing song fragments, single word answers, repeating words and phrases, reading words and sentences and naming), Reading (reading and questioning texts) and understanding written language (recognition of letters and words, phonetic association, word-to-picture matching, transcription, dictation and free writing) will be used. In this questionnaire, the cutoff score is 93.8. Scores lower than this amount will be classified in four categories. Mild severity (AQ = 76-93), moderate severity (AQ = 51-75), severe (AQ = 25-50) and very severe (less than 25) (AQ). In this study, patients were divided into two groups. severe (AQ = less than 50) and non-severe (above AQ = 50) will be classified.

4

Description
Persian version of the Stroke and Aphasia Quality of Life Scale
Timepoint
Before and immediately after treatment
Method of measurement
This questionnaire, which is completed by the patient, has 39 items that include 12 areas: movement, self-care, upper limb function, occupational activities, language, thinking, personality, mood, energy level, role in society. and family This questionnaire was translated and localized in Farsi by Khatunabadi et al.

5

Description
Montreal Cognitive Assessment Test score
Timepoint
Before and immediately after treatment
Method of measurement
The Montreal Cognitive Assessment Test is a valid and repeatable test and is used to evaluate the cognitive performance of neurological patients. The test items include 8 cognitive domains, which are visual-spatial and executive, naming, memory, attention, language, abstract concepts, delayed recall, and awareness. Each domain contains several questions and is scored out of 30.

Intervention groups

1

Description
Intervention group: Videos of the functional movements of the upper limbs in different directions and angles will be prepared by a healthy person under the supervision of the research team at the virtual training center of Mashhad University of Medical Sciences. In the therapy session, each training movement will be shown to the participants for two minutes and for better understanding, first at half speed and then at normal speed. After observing the desired therapeutic

movement, patients will be given three minutes to perform targeted functional exercise to perform the corresponding movement. After a minute of rest, the next video will be shown, and in the same way, people with stroke will watch and practice the next movement therapy video. In each session, 4 movements will be given for therapeutic exercise and the range of movement will gradually increase in the next sessions according to the conditions of each patient. On the other hand, the degree of difficulty and complexity of the movements will also increase. For example, in the first week, the movement in question will include only one joint, and in the last week, the movement will take place in several joints at the same time. After that, the people participating in the research will be treated with conventional (traditional) physiotherapy for 45 minutes. Treatment sessions will be held three times a week for 10 sessions. which includes 17 minutes of electrotherapy in the form of placing FES current on the extensor muscles of the elbow, wrist and fingers in the upper limb and dorsiflexor in the lower limb. After that, there will be a therapeutic exercise for 20 minutes.

Category

Rehabilitation

2

Description

Intervention group: In this study, Kinect xbox 360 imaging system and Kinect for windows SDK 1.8 will be used to track and record and receive upper limb movement information of stroke patients, a 52-inch monitor and a laptop system with Windows 10.Also, a virtual environment consisting of 4 games with 5 levels of difficulty will be designed by engineers using Unity 2020 game software. Python 3 programming language and opencv library were also used to process images. sqlserver database will also be used to store information. Participants will be familiar with the process of playing practice games. The choice of sports game will be made by the therapist based on the abilities, interests and motivation of the patient. The participant was asked to stand or sit and be at a distance of 4 meters from the Kinect device and play the game based on the instructions of the therapist and the instructions and signs of the game. If necessary, patients could use a chair without a handle and back to prevent falling. The patient will be placed in front of the monitor and the camera will receive the person's movements and enter the virtual reality environment. The treatment consists of several games that involve upper limb movements in different directions and joints. By doing the movements correctly, for example, passing the obstacles, the participant earns points. For every 5 minutes of the game, one minute rest is given to the person to avoid fatigue. In order to improve the practice in the coming weeks, the degree of difficulty of the games will increase according to the conditions of each person. After that, the people participating in the research will be treated with conventional (traditional) physiotherapy for 45 minutes. Treatment sessions will be held three times a week for 10 sessions,which includes 17 minutes of electrotherapy in the form of placing FES current on the extensor muscles of the elbow, wrist and fingers in the upper limb and dorsiflexor in the lower limb. After that, there will be a therapeutic exercise for 20 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Parsa Physiotherapy Clinic

Full name of responsible person

Mohammad Parsa

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector
Public

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
Mashhad University of Medical Sciences

Full name of responsible person
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Associate Professor, Department of Physiotherapy, Mashhad University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available