Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of specific exercise training using virtual reality on upper extremity function of stroke patients

Protocol summary

Study aim
Investigating the effect of specific exercise therapy using virtual reality on upper limb function in stroke patients

Design
A controlled clinical trial with parallel groups, non-blinded, randomized, conducted on 60 patients. The randomization will be done using the dice-rolling method.

Settings and conduct
Eligible stroke patients with unilateral upper limb involvement will be enrolled after approval by a specialist, provided with study details, and randomly assigned to either a control group (conventional therapy) or an intervention group (virtual reality therapy). Treatment will be 90 minutes, 3 times a week, for 10 sessions, with resistance bands added from session 5 for both groups. The study takes place at Rofeideh Hospital in Tehran.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with ischemic or hemorrhagic stroke confirmed by a neurologist, aged 18 or older, with relative active movement in the affected upper limb and stable medical conditions.Exclusion criteria: Severe cognitive impairment, orthopedic conditions limiting movement, complete paralysis or sensory impairment, and fractures or dislocations in the affected upper limb.

Intervention groups
the only difference being that one group receives the exercises through a virtual reality system, while the other group receives them with the help of a therapist.Treatment is conducted for 90 minutes, 3 days a week, over 10 sessions

Main outcome variables
The range of motion of the upper limb, which includes the range of motion of flexion and extension of the elbow and wrist, and the movement of supination and pronation of the forearm; functional activity of the upper limb; daily activity of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241016063384N1**
Registration date: **2024-11-04, 1403/08/14**
Registration timing: **prospective**

Last update: **2024-11-04, 1403/08/14**
Update count: **0**

Registration date
2024-11-04, 1403/08/14

Registrant information

Name
Mona Kamali

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 7710 4133

Email address
monakamali9840@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-30, 1403/09/10

Expected recruitment end date
2025-03-19, 1403/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of specific exercise training using virtual reality on upper extremity function of stroke patients

Public title
virtual reality in upper extremity of stroke patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients diagnosed with ischemic or hemorrhagic stroke confirmed by a neurologist. Stroke patients aged 40 years or older who are willing and able to give informed consent to participate in the study. Only patients experiencing their first stroke or recurrent stroke without any lasting motor impairment from a previous stroke. Individuals who have had a stroke within the past 36 months. Individuals with relative and minimal active movement in the proximal and distal parts of the affected upper limb Individuals should be free of apraxia. No complete paralysis of the upper limb. No fractures or dislocations of the affected upper limb.
Exclusion criteria:
The participant's unwillingness to continue the study for any reason Lack of medical stability Musculoskeletal pain that prevents the treatment Patients with cognitive impairment (score of 20 or lower on the mental status assessment test) should be excluded. excessive spasticity, MAS score no higher than 2).
Age
From **40 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization of the dice roll type For each participant, we use a dice or similar random device. For example, if the dice is six-sided: Number 1 to 3: The participant is assigned to group A (eg, the experimental group). Number 4 to 6: The participant is assigned to group B (ie, the control group). Conclusion: With this method, each participant has an equal chance to be placed in each group, which helps to reduce the influence of biases and increase the accuracy of the study.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee of the University of social welfare and Rehabilitation Sciences
Street address
No.56,Nastaran 13 building,Shahid Beheshti Town,Babaei Hwy
City
Tehran
Province
Tehran
Postal code
1651139547
Approval date
2024-09-23, 1403/07/02
Ethics committee reference number
IR.USWR.REC.1403.133

Health conditions studied

1

Description of health condition studied
cerebrovascular disease
ICD-10 code
G46.4
ICD-10 code description
Cerebellar stroke syndrome

Primary outcomes

1

Description
ROM of upper extremity
Timepoint
before and after
Method of measurement
goniametry

2

Description
Activity Of Daily Living
Timepoint
before and after
Method of measurement
modified bartel scale

3

Description
upper extremity function
Timepoint

before and after

Method of measurement

wolf motor function test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Initially, the treatment involves electrotherapy and routine exercises such as hand bicycle, push-ups, and pulley system exercises. Afterward, the patient performs specialized exercises, including tasks such as reaching for a target with the hand, moving the upper torso and head towards a target, grabbing, moving, and tracking an object, and finally hand supination and pronation exercises. All of these exercises are shown to the patient through a virtual reality system via a monitor, which then provides feedback to the patient.

Category

Rehabilitation

2

Description

Control group:Initially, electrotherapy and routine exercises such as hand cycling, push-ups, and pulley system exercises are performed. Then, the patient performs specific exercises, which include: reaching the hand towards a target, reaching the head and upper trunk towards a target, reaching the hand to a target, grasping, moving, and tracking it, and finally, supination and pronation exercises of the hand. All these exercises are demonstrated by the therapist, who then provides feedback to the patient."

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofeideh Rehabilitation Hospital

Full name of responsible person

Mona Kamali

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Nahid Rahmani

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Kodakyar Ave, Daneshjo Blvd, Evin

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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

University of social welfare and rehabilitation sciences

Proportion provided by this source

10

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

University of social welfare and rehabilitation sciences

Full name of responsible person

Mona Kamali

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

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When the data will become available and for how long

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To whom data/document is available

--

Under which criteria data/document could be used

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From where data/document is obtainable

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

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Comments