

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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)

Phone

+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		Secondary Ids	
Public title		empty	
virtual reality in upper extremity of stroke patients		Ethics committees	
Purpose		<u>1</u>	
Supportive		Ethics committee	
Inclusion/Exclusion criteria		Name of ethics committee	
Inclusion criteria:		The Ethics Committee of the University of social welfare and Rehabilitation Sciences	
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.		Street address	
Exclusion criteria:		No.56,Nastaran 13 building,Shahid Beheshti Town,Babaei Hwy	
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).		City	
Age		Tehran	
From 40 years old to 80 years old		Province	
Gender		Tehran	
Both		Postal code	
Phase		1651139547	
N/A		Approval date	
Groups that have been masked		2024-09-23, 1403/07/02	
No information		Ethics committee reference number	
Sample size		IR.USWR.REC.1403.133	
Target sample size: 60		Health conditions studied	
Randomization (investigator's opinion)		<u>1</u>	
Randomized		Description of health condition studied	
Randomization description		cerebrovascular disease	
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.		ICD-10 code	
Blinding (investigator's opinion)		G46.4	
Not blinded		ICD-10 code description	
Blinding description		Cerebellar stroke syndrome	
Placebo		Primary outcomes	
Not used		<u>1</u>	
Assignment		Description	
Parallel		ROM of upper extremity	
Other design features		Timepoint	
		before and after	
		Method of measurement	
		goniametry	
		<u>2</u>	
		Description	
		Activity Of Daily Living	
		Timepoint	
		before and after	
		Method of measurement	
		modified bartel scale	
		<u>3</u>	
		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

Street address

Tehran Province, Tajrish, Nemati, QFX2+FCM

City

Tehran

Province

Tehran

Postal code

1935973476

Phone

+98 21 2267 8519

Email
rofeideh.hospital@uswr.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Nahid Rahmani

Street address

Kodakyar Ave, Daneshjo Blvd, Evin

City

Tehran

Province

Tehran

Postal code

198571387

Phone

+98 21 7173 2000

Email

pr@uswr.ac.ir

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

Street address

NO.56,Nastaran 13 building, Shahid Beheshti Town, Babaei Hwy

City

Tehran

Province

Tehran
Postal code
۱۶۵۱۱۳۹۵۴۷
Phone
+98 21 7710 4133
Email
monakamali9840@gmail.com

Person responsible for scientific 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
Street address
No56,Nastaran 13 building, Shahid Beheshti Town,
Babaei Hwy
City
Tehran
Province
Tehran
Postal code
1651139547
Phone
+98 21 7710 4133
Email
monakamali9840@gmail.com

Person responsible for updating data

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
Street address
No56,Nastaran 13 building, Shahid Beheshti Town,
Babaei Hwy
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Tehran
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monakamali9840@gmail.com

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

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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