Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Study aim
Investigating the effect of specific therapeutic exercise using virtual reality system on the lower limb's function of stroke patients

Design
Clinical trial with control group, with parallel groups, simple randomization with coin toss method, 60 patients

Settings and conduct
The study takes place at Rofeydeh Rehabilitation Hospital. People suffering from stroke admitted or referred to Rofeydeh Hospital are included in the study, which are divided into two control and intervention groups using a simple sampling method according to the entry and exit criteria and by random grouping .They will receive 10 treatment sessions according to their group. The control group will perform therapeutic exercises without the virtual reality system and the intervention group will perform the same exercises using the virtual reality system. Tests related to variables will be taken from people once before the beginning of the sessions and once after 10 sessions.

Participants/Inclusion and exclusion criteria
Inclusion criteria: • At least 6 months and at most 36 months have passed since the stroke. • Spasticity should not be excessive (score of 3 and 4 in the MAS questionnaire). • The patient should be able to stand independently or with assistive devices Exclusion criteria: • Use of botulinum toxin or surgery last 6 months • Vision or Vestibular disorders • presence of orthopedic disorders that prevent the desired movements • Apraxia disorder

Intervention groups
control group : 10 conventional physiotherapy sessions including electrotherapy, general therapeutic exercise and specific therapeutic exercise. intervention group: In addition to receiving conventional physiotherapy will perform specific therapeutic exercise using virtual reality for 10 sessions.

Main outcome variables
1. Berg Balance Scale 2. Lower limb function (Timed up and go Test) 3. Ability to perform daily activities (Modified Barthel Scale)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241016063383N1**
Registration date: **2024-10-19, 1403/07/28**
Registration timing: **prospective**

Last update: **2024-10-19, 1403/07/28**
Update count: **0**

Registration date
2024-10-19, 1403/07/28

Registrant information

Name
Nika Zarrabi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2276 4272

Email address
nikazarrabi97@gmail.com

Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2025-06-20, 1404/03/30

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 lower extremity function of stroke patients

Public title

Effect of therapeutic exercise using virtual reality on the performance of stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient has suffered a stroke for the first time and has been confirmed by a neurologist. At least 6 months and at most 36 months have passed since the stroke Spasticity should not be excessive (with a score of 3 and 4 in the MAS questionnaire) The patient should be in a favorable condition in terms of understanding and cognition and should be able to communicate. The patient should be able to stand independently or with assistive devices (cane, walker)

Exclusion criteria:

The patient is not in a stable medical condition (heart problems, blood pressure, breathing). The patient has a history of other neurological problems or psychological problems Use of botulinum toxin in the past 6 months Surgery in the last 6 months Apraxia disorder The presence of orthopedic and skeletal disorders in a person that prevents the desired movements. Vestibular disorders Visual disorders

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

The grouping will be done by a simple random method of coin toss and the patients will be randomly divided into two control and intervention groups by tap or line method and will be treated in each group according to the specific method of that group.

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

Ethics Committee of the University of Social Welfare and rehabilitation sciences

Street address

No.17, East Biglarpor, Jahantab Ave, East Akhlaghi Ave, Kaveh Blvd, Dolat Ave.

City

Tehran

Province

Tehran

Postal code

1939945511

Approval date

2024-09-23, 1403/07/02

Ethics committee reference number

IR.USWR.REC.1403.132

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

I69.4

ICD-10 code description

Sequelae of stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

Changes in the individual's static and dynamic balance score based on the Berg Balance Scale short test.

Timepoint

Once before the intervention and once after 10 treatment sessions

Method of measurement

Short Berg Balance Scale

2

Description

Functional changes of the lower limb using the Timed up and go test

Timepoint

Once before the intervention and once after 10 treatment sessions

Method of measurement

Timed up and Go test

3

Description
Determining the ability to perform daily activities using the modified Barthel scale

Timepoint
Once before the intervention and once after 10 treatment sessions

Method of measurement
modified Barthel Index of ADL

Secondary outcomes

empty

Intervention groups

1

Description
The tool used in this study is the Sana virtual reality system, which provides the ability to perform exercises in different fields of rehabilitation. The system used, has a Kinect camera (it is a motion detection system based on photography) that records motion data from the patient's limb movements and then analyzes the motion data by a pre-processing unit. It also uses a 32-inch monitor that has been trained to show the virtual space to the patient and provide appropriate audio and visual feedback in each exercise. Intervention group: The participants will be treated 3 days a week and every other day for 10 sessions. In the specific therapeutic exercise, each exercise will be done in three sets of ten. In addition to receiving electrotherapy and general therapeutic exercise, the intervention group will perform specific therapeutic exercise using virtual reality, 10 sessions of each exercise in three sets of ten. Functional tests related to the study once before the treatment and once after 10 treatment sessions will be taken from people and the results will be compared. Specific therapeutic exercises include: trunk control exercises, weight shifting, bearing weight on the non-affected limb and bringing the knee of the affected limb to the desired goal, bearing weight on the affected limb and bringing the leg of the other limb to the desired goal and bringing the hand and foot of the affected side alternately to the intended target.

Category
Rehabilitation

2

Description
Control group: The participants will be treated 3 days a week and for 10 sessions every other day. The control group will receive 10 conventional physiotherapy sessions including electrotherapy, general therapeutic exercise and specific therapeutic exercise. In the specific therapeutic exercise, each exercise will be done three sets of ten .Specific therapeutic exercises include: trunk control exercises, weight shifting, bearing weight on the non-affected limb and bringing the knee of the affected limb to the desired goal, bearing weight on the affected limb and bringing the leg of the other limb to the desired goal and bringing the hand and foot of the affected side alternately to the intended target.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Rofeyde rehabilitation hospital

Full name of responsible person
Nika zarrabi

Street address
No. 17,Biglarpur East, Jahantab, East akhlaghi, Kaveh Blvd, Dolat Street

City
Tehran

Province
Tehran

Postal code
1939945511

Phone
+98 21 2276 4272

Fax
+98 919 426 7536

Email
nikazarrabi97@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Nika zarrabi

Street address
kodakyar Ave., daneshjo Blvd.,Evin

City
Tehran

Province
Tehran

Postal code
1985713871

Phone
+98 21 7173 2000

Email
nikazarrabi97@gmail.com

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
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

University of social welfare and rehabilitation sciences

Full name of responsible person

Nika Zarrabi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

No.17 ,East Biglarpour, Jahantab, East Akhlaghi, Kaveh blvd, Dolat street, Tehran

City

Tehran

Province

Tehran

Postal code

1939945511

Phone

+98 21 2276 4272

Fax

Email

nikazarrabi97@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Nika Zarrabi

Position

master's student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

No.17 ,East Biglarpour, Jahantab, East Akhlaghi, Kaveh blvd, Dolat street, Tehran

City

Tehran

Province

Tehran

Postal code

1939945511

Phone

+98 21 2276 4272

Fax

Email

nikazarrabi97@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Nika Zarrabi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

No.17 ,East Biglarpour, Jahantab, East Akhlaghi, Kaveh blvd, Dolat street, Tehran

City

Tehran

Province

Tehran

Postal code

1939945511

Phone

+98 21 2276 4272

Fax

Email

nikazarrabi97@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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data on key variables and their statistical results can be shared after de-identifying individuals.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers in all levels and disciplines

Under which criteria data/document could be used

The requester of the documents will be able to use the data only by mentioning the source and the name of the researcher.

From where data/document is obtainable

To access the information, send a message to this email: nikazarrabi97@gmail.com

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

The applicant should express his/her request by sending an email and she will be answered within a week.

Comments