Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of virtual reality training compared with convectional physiotherapy on kinematics and spasticity of lower limb during gate of post stroke patients

Protocol summary

Study aim

Evaluation of the effect of virtual reality(VR) training on gait kinematics and spasticity of stroke patients in comparison with conventional physiotherapy exercises

Design

Parallel clinical trial with control group. The treatment group receives VR and the control group receives routine physiotherapy treatment. Double-blind trial The grouping method is random and through envelopes 24 patients in each group; Performing treatment for 3 weeks and 3 days a week.

Settings and conduct

Blinding: unawareness of the evaluator and analyst of grouping and treatment; Referring patients to laboratory from Imam Hossein Hospital and collage clinic for evaluation and treatment; Performing treatment in collage Clinic

Participants/Inclusion and exclusion criteria

Inclusion: Age between 18 and 75 with ischemic stroke; At least 3 months have passed since stroke; Have a history of stroke only once; Can walk at least 10 meters independently; Don't have a history of VR therapy; Organ involvement would be hemiplegia; Exclusion: Have acute cardiorespiratory problems; Have severe orthopedic or biomechanical disorders on lower limb; Have cognitive or vision disorders.

Intervention groups

Both treatments performed for 40 minutes a day, 3 times a weed for 3 weeks Intervention: Use 2 games of VR Game One: Football. The patient in the form of a player must pass the ball to his teammate and shot the ball. Game two: Track and field. The patient raises his knees in front of the camera so that the avatar starts running. Control: Using exercises based on the theory of Bobath, stretching and mobilization and balance exercises.

Main outcome variables

Range of motion (ROM) flexion and extension, abduction and adduction of hip, flexion and extension of knee and plantar flexion and dorsiflexion of ankle Spasticity of adductors of hip, quadriceps and gastrocnemius Investigating the relationship between muscle spasticity and ROM

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211017052790N1**
Registration date: **2021-11-08, 1400/08/17**
Registration timing: **prospective**

Last update: **2021-11-08, 1400/08/17**
Update count: **0**

Registration date

2021-11-08, 1400/08/17

Registrant information

Name

danial sajjadi khoshkrodi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of virtual reality training compared with convectional physiotherapy on kinematics and spasticity of lower limb during gate of post stroke patients

Public title
Effect of virtual reality on gait of post stroke patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-75 years with ischemic stroke Stroke occurred at least 3 month ago Patient just had 1 stroke Patient can independently walk at least 10 meters Patient didn't experience therapy with VR Complications of the limbs should be hemiplegia
Exclusion criteria:
Patient have acute cardio respiratory disorders Patient have severe orthopedic or bio mechanical disorders in lower limb Patient have cognitive or vision disorders
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
In each envelopes, we write number 1 or 2. If patient pick envelope with number 1, patient will allocate in experience group and if patient pick envelope with number 2, patient will allocate in control group
Blinding (investigator's opinion)
Double blinded
Blinding description
The initial and final evaluation is performed by a therapist who does not know the allocation of patients. The outcome analyzer has no knowledge of patient grouping.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of shahid beheshti medical university
Street address
No. 26, West zayande rood alley, North shirazi St. Molla sadra Ave., Vanak Sq.
City
Tehran
Province
Tehran
Postal code
1991613651
Approval date
2021-10-11, 1400/07/19
Ethics committee reference number
IR.SBMU.RETECH.REC.1400.423

Health conditions studied

1

Description of health condition studied
Ischemic Cerebral Vascular accident
ICD-10 code
G81
ICD-10 code description
Hemiplegia and hemiparesis

Primary outcomes

1

Description
Hip flexion and extension, abduction and adduction Range of motion during gait
Timepoint
Before and after intervention
Method of measurement
Motion analysis system, cameras and markers

2

Description
Knee flexion and extension range of motion during gait
Timepoint
Before and after intervention
Method of measurement
motion analysis system, cameras and markers

3

Description
Ankle plantar flexion and dorsi flexion range of motion during gait
Timepoint
Before and after intervention
Method of measurement
Motion analysis system, cameras and markers

4

Description
Spasticity of Adductors of hip, Quadriceps and Gastrocnemius muscles
Timepoint
Before and after intervention
Method of measurement
modify modify Ashworth scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group receive virtual reality treatment with Xbox 360 console. Every sessions of treatment have 40 minute virtual reality, using 2 games, 3 days per week for 3 weeks. Patients play each game for 20 minutes. The first game used is soccer. The game is that the patient is in the form of a football player who uses the movement of the lower limb in front of the Kinect camera to pass the ball to his teammates and finally enter the goal with a shot.The second game is track and field, which is a collection of athletics games. In this game, the patient must stand in front of the camera and raise his lower limbs in a running position with the sound of a whistle and the start of the race, so that the knees rise. The purpose of this game is to win the race. The faster this limb movement, the faster the avatar runs.
Category
Rehabilitation

2

Description
In the control group, patients receive ND-Bobath (Neuro developmental Therapy -Bobath) for 40 minutes per day, 3 sessions per week (every other day) and 3 weeks. The emphasis of the exercises is on the rehabilitation of the lower limbs and walking of these patients.parallel walking, balance exercises, weightlifting on the affected lower limb, isolated dorsi flexion and knee flexion control, pelvic control, bridging exercises, ankle mobilization and Gastrocnemius muscle stretching are some of the exercises for these patients. It is performed in each session in the clinic environment and under the supervision of the therapist. During the treatment of patients in the control group, the therapist accelerates the treatment process by providing appropriate feedback to correct incorrect patterns.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein hospital
Full name of responsible person
Danial Sajjadi
Street address
Imam Hossein hospital, Madani St., Imam Hossein Sq.
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2

Recruitment center
Name of recruitment center
Physiotherapy clinc of schol rehablitation of shahid beheshti medical university
Full name of responsible person
Danial sajjadi
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School of rahblitation of shahid beheshti medical university, Damavand St, Imam Hossein Sq.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
School of rehablitation of shahid beheshti medical university, Dmavand St, Imam hossein Sq.
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minoo_kh@yahoo.com

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice-Chancellor's Office for Research of Shahid Beheshti medical university

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Minoo Khalkhali

Position

associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Minoo Khalkhali

Position

Associate professor

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Person responsible for updating data

Contact

Name of organization / entity

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Email

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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

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

Title and more details about the data/document

The file of the participants will be presented in general and in detail in the form of a dissertation. Also, the study protocol, statistical analysis map along with statistical methods used in the study and clinical study report will be presented in the form of a dissertation. The informed consent form of the patients will be made available to the public as an attachment along with the dissertation.

When the data will become available and for how long

Start of the access period 3 months after the publication of the results and the defense of the dissertation

To whom data/document is available

All researchers working in academic and scientific institutions Community Verified icon

Under which criteria data/document could be used

In order to use the study to treat patients as well as the scientific development of the study, they will be allowed to access the study.

From where data/document is obtainable

Ḍr. Minoo Khalkhali (responsible for the study) Danial Sajjadi (Executor of plan) E-mail: danial199728@gmail.com School of rehabilitation of Shahid Beheshti medical university

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

By providing the necessary documents for the reason for using or how to use the study, they can have full access to the study through the study manager and the project manager.

Comments