Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of virtual reality plus conventional rehabilitation therapy versus conventional rehabilitation alone on the wrist and elbow spasticity and motor function beside active range of motion in shoulder abduction, wrist extension, and elbow extension in patients with stroke

Protocol summary

Study aim

Determination of the effects of virtual reality plus conventional rehabilitation therapy versus conventional rehabilitation alone on the wrist and elbow spasticity and motor function beside active range of motion in shoulder abduction, wrist extension, and elbow extension in patients with stroke

Design

The 30 subjects will be randomly assigned by block randomization (5 cases in each block) into two groups of 15 cases including conventional 45-minute conventional therapy session and conventional plus VR therapy, with a single blinding.

Settings and conduct

The data is calculated by single blinded assessor, and the trial is performed in Tabassom Physiotherapy Clinic. The 30 patients who meet the inclusion criteria are divided into two groups. In conventional group, traditional physiotherapy methods are used. In VR group, non-immersive type of VR is used, in which patients sit in front a monitor to move their upper extremity in various directions according to instructions of their specific video games.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with ischemic stroke in past three to 12 months with age range from 30 to 80 years, admitted in a referral training tertiary healthcare center in 2020. Exclusion criteria: severe neuropsychological impairments interfering with recovery, and impossibility to follow-up the patients.

Intervention groups

The intervention group consists of those patients who undergo VR gaming along with the conventional rehabilitation. The control group consists of those patients who only undergo the conventional rehabilitation.

Main outcome variables

At baseline and after six weeks: the wrist and elbow spasticity by Modified Ashworth upper extremity score; motor function by Fugle-Meyer upper extremity score; active range of motion of shoulder abduction, wrist extension, and elbow extension with goniometry.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200811048372N1**
Registration date: **2020-10-16, 1399/07/25**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-16, 1399/07/25**
Update count: **0**

Registration date

2020-10-16, 1399/07/25

Registrant information

Name

Maryam Soheilifar

Name of organization / entity

Private office

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-08-25, 1399/06/04
Expected recruitment end date
2021-02-22, 1399/12/04
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of virtual reality plus conventional rehabilitation therapy versus conventional rehabilitation alone on the wrist and elbow spasticity and motor function beside active range of motion in shoulder abduction, wrist extension, and elbow extension in patients with stroke

Public title
Comparison of virtual reality plus conventional rehabilitation and conventional rehabilitation alone in patients with stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with age range from 30 to 80 years with ischemic stroke in past three to 12 months Patients admitted in a referral training tertiary healthcare center in 2020
Exclusion criteria:
Severe neuro-psychological impairments interfering with recovery Impossibility to follow up the patients
Age
From **30 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
(number in each block 5 cases with 1:1 ratio for randomization. Patients are numbered according to the time of their registration (the first registered patient: number 1, the second registered patient: number 2, ...). The first five patients will be allocated in one group and the second five patients will be allocated in the other group and this order will be carried out alternatively till the sample size is completed and 15 patients are present each group it is shown in this order; patients 1, 2, 3, 4, 5 in conventional plus VR therapy group, 6, 7, 8, 9, 10 in conventional therapy alone group, 11, 12, 13, 14, 15 in conventional plus VR therapy group, 16, 17, 18, 19, 20 conventional therapy alone group, 21, 22, 23, 24, 25 conventional plus VR therapy group, and 26, 27, 28, 29, 30 in conventional therapy alone group). Overall, there will be six blocks, each with 5 members, with three groups categorized into each method of treatment.
Blinding (investigator's opinion)
Single blinded
Blinding description
In the single blinding, the assessor is not aware of in which group each patient is.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Tehran University of Medical Sciences
Street address
No. 1, northern door, Poursina St., Quodds St., Enghelab St.
City
Tehran
Province
Tehran
Postal code
1956765163
Approval date
2020-08-21, 1399/05/31
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.333

Health conditions studied

1

Description of health condition studied
stroke
ICD-10 code
I64
ICD-10 code description
Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description
1) The wrist spasticity at baseline and after six weeks by Modified Ashworth upper extremity score.
Timepoint
one turn before intervention, and another 6 weeks after intervention
Method of measurement
Modified Ashworth upper extremity score

2

Description
2) The elbow spasticity at baseline and after six weeks by Modified Ashworth upper extremity score.
Timepoint
one turn before intervention, and another 6 weeks after intervention
Method of measurement
Modified Ashworth upper extremity score

3

Description
3) Motor function at baseline and after six weeks by Fugle-Meyer upper extremity score.
Timepoint
one turn before intervention, and another 6 weeks after intervention
Method of measurement
Fugle-Meyer upper extremity score

4

Description
4) Active range of motion in shoulder abduction calculated by single blinded assessor with goniometry at baseline and after six weeks.
Timepoint
one turn before intervention, and another 6 weeks after intervention
Method of measurement
calculated by single blinded assessor with goniometry

5

Description
5) Active range of motion in wrist extension calculated by single blinded assessor with goniometry at baseline and after six weeks.
Timepoint
one turn before intervention, and another 6 weeks after intervention
Method of measurement
calculated by single blinded assessor with goniometry

6

Description
6) Active range of motion in elbow extension calculated by single blinded assessor with goniometry at baseline and after six weeks.
Timepoint
one turn before intervention, and another 6 weeks after intervention
Method of measurement
calculated by single blinded assessor with goniometry

Secondary outcomes

empty

Intervention groups

1

Description
Interventional group: patients in this group are subjected to a 6 week long period of rehabilitation, three sessions a week, each session consisted of 45 minutes of conventional rehabilitation and 20 minutes of non-immersive Virtual Reality computer gaming. In this VR gaming, patients sit in front of a monitor in order to move their upper extremity according to the instruction of their in-advanced-prepared, specific computer game. In conventional rehabilitation, methods of stretch, positioning, and splint are used in order to improving spasticity; passive movements and assistive movements are used in order to improve range of motion; and targeted movements and active movements are used in order to improve motor function.
Category
Rehabilitation

2

Description
Control group: patients in this group are subjected to a 6 week long period of rehabilitation, three sessions a week, each session consisted of 45 minutes of conventional rehabilitation. In conventional rehabilitation, methods of stretch, positioning, and splint are used in order to improving spasticity; passive movements and assistive movements are used in order to improve range of motion; and targeted movements and active movements are used in order to improve motor function.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabassom Physiotherapy Clinic
Full name of responsible person
Maryam Soheilifar
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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No. 1, Behzad alley, Sabari Avenue (Ajoudanieh), Kashanak Avenue
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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
Maryam Soheilifar
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
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Position
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Latest degree
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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
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
different physical assessments of patients as; spasticity, motor function, range of motion. demographic data as; age, sex, involved hemisphere, time after stroke.

When the data will become available and for how long
the data will be available since December, 2020, and it will be so for 6 months after the publication

To whom data/document is available
people working in academic institutions or physical therapy clinics, neurologists, physicians, and software and IT engineers.

Under which criteria data/document could be used
Any analysis on the date is permitted. Those people who work/study in relevant subjects are eligible for request.

From where data/document is obtainable
through email, telephone calls, and posting letters.

What processes are involved for a request to access data/document
After making a connection through one of the eligible ways, and after providing personal information and the purpose of pursuing this data, after almost 1 week, all answers could be checked and data could be available to the requester.

Comments
According to the significant raise in the number of strokes happening across the globe (one stroke per 2-seconds worldwide, and 100 thousand cases of stroke in Iran annually) , and that stroke is the leading cause of disability , this trial could be quite helpful for an unbelievably great number of people across the globe who suffer from disabilities caused by strokes, and it could help them to come back into their normal lives sooner and better than before.