

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 21 2613 0694

Email address

msoheilifar1@yahoo.com

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 in conventional therapy alone group, 21, 22, 23, 24, 25 in 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

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No. 1, northern door, Poursina St., Quodds St., Enghelab St.

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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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1st floor, No. 26, West Bagherkhan Avenue

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<https://tabassomclinic.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Maryam Soheilifar

Full name of responsible person

Maryam Soheilifar

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No. 1, Behzad alley, Sabari Avenue (Ajoudanieh),
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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**

Maryam Soheilifar

Full name of responsible person

Maryam Soheilifar

Position

Specialist Physician

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Position

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Other areas of specialty/work

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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 data 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.