

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of virtual reality rehabilitation by EEG signal

Protocol summary

Study aim

1- Comparison of EEG signal specificity in rehabilitation of stroke patients with two traditional therapies and rehabilitation using virtual reality games 2- Proposing clinical evaluation and rehabilitation methods using patients' brain signal recording 3- Determining the effect of virtual reality on how motor learning in the brain using EEG signal

Design

Clinical trials with control groups, with parallel groups two blind strains are accidental phase 3 on 30 patients. statistical analysis of the study was conducted using spss software and by an uninformed statistical expert on the study.

Settings and conduct

Rehabilitation clinic is performed in Hamadan province. A number of 30 patients with range of motion who are diagnosed with shoulder and elbow mobility problems by a physician are divided into groups A and B after double-blind correction and are rehabilitated by intervention and control. Nine participants are not aware of the expertise of the participants to the study groups.

Participants/Inclusion and exclusion criteria

1 - Lack of cooperation of stroke patients in the study 2- Noise in EEG signal (solution: repeat signal reception) "

Intervention groups

Patients with stroke patients after visiting if they were in the study criteria and tended to participate in the study he said. This sequence is characterized by a non sample individual using jl Software Software. A representative of the control group that they receive in traditional rehabilitation. B The intervention group that receive rehabilitation with virtual reality.

Main outcome variables

Clinical parameters of remission Coping quality parameters related to EEG signal

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210614051570N1**

Registration date: **2021-09-25, 1400/07/03**

Registration timing: **retrospective**

Last update: **2021-09-25, 1400/07/03**

Update count: **0**

Registration date

2021-09-25, 1400/07/03

Registrant information

Name

Farshid Sheykhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

sheykhi1372@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-21, 1400/03/31

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of virtual reality rehabilitation by EEG signal

Public title

Investigating the Effect of rehabilitation along with virtual games on Motor learning functional development

to improve motor impairments using EEG

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Rad has limited mobility due to stroke A maximum of three months have passed since their stroke.
Exclusion criteria:
 Abuse of psychotropic drugs - drugs - alcohol and ... Has limited movement in various parts other than the head and neck. Be sure not to have birth defects (shoulder and elbow) and be due to stroke. Have the ability to take an electroencephalogram.

Age
From **2 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Inside the sealed packets was one of the numbers associated with the control group or the intervention group. This number is determined by the person who is not a sampler and is characterized by the use of Random Software Software. The stroke patients randomly selects a number following the visit to the clinic according to the priority of their arrival to the centre, which decides the choice of the code and the patient group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Inside the sealed packets was one of the numbers associated with the control group or the intervention group. This number is determined by the person who is not a sampler and is characterized by the use of Random Software Software. The stroke patients randomly selects a number following the visit to the clinic according to the priority of their arrival to the centre, which decides the choice of the code and the patient group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of kermanshah University of Medical Sciences
Street address
 Rostay chenar sofia(sheykh)- hajiabad
City
 Asadaad
Province
 Hamadan
Postal code
 65461-43331

Approval date
2021-06-14, 1400/03/24

Ethics committee reference number
IR.KUMS.REC.1400.199

Health conditions studied

1

Description of health condition studied
Patients with limited mobility on the right side of the body due to stroke

ICD-10 code
G46.4

ICD-10 code description
Cerebellar stroke syndrome

Primary outcomes

1

Description
Eeg signal changes due to rehabilitation

Timepoint
45 days

Method of measurement
By recording brain signals

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group: this group received conventional upper extremity rehabilitation for stroke patients who need a shoulder and elbow rehabilitation. Conventional rehabilitation means hybrid upper limb functional patterns, scapular, elbow, forearm, wrist, and finger mobility, and slow muscle stretching. The purpose of these exercises is to strengthen weak muscles of the shoulder and elbow in balanced or unbalanced weights to increase joint mobility, relieving muscle power imbalance, gaining control of a transverse limb, reducing muscle stiffness, and gaining a complete range of

motion. Shoulder exercises with SWS without VR were performed for maximally 60 minutes by these patients in that way.

Category

Rehabilitation

2

Description

Control group: the stroke patients that receives traditional rehabilitation. this group received conventional upper extremity rehabilitation for stroke patients who need a shoulder and elbow rehabilitation. Conventional rehabilitation means hybrid upper limb functional patterns, scapular, elbow, forearm, wrist, and finger mobility, and slow muscle stretching. The purpose of these exercises is to strengthen weak muscles of the shoulder and elbow in balanced or unbalanced weights to increase joint mobility, relieving muscle power imbalance, gaining control of a transverse limb, reducing muscle stiffness, and gaining a complete range of motion. The patients practiced SWS therapy without using an HMD for maximally 60 minutes, three times a week, and 12 appointments and functional physiotherapy was performed.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tavanbakhshi & Physiotherapy alamat

Full name of responsible person

Morteza Heydari Nasir

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Rostay Chenar Sofla-Hajiabad

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Moavenat Tahghighat & Fanavari

Street address

Kermanshah, Bolvar shahid beheshti, Sakhteman

Shomare 2 Olompezeshti, Moavenat tahghighat & fanavari

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Fax

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research_it@kums.ac.ir

Web page address

<https://vc-research.kums.ac.ir/fa/tamas>

Grant name

8000000 - Hasht milion toman

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah University of Medical 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

Kermanshah University of Medical Sciences

Full name of responsible person

Farshid sheykhi

Position

Student

Latest degree

Master

Other areas of specialty/work

Medical Engineering

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Person responsible for scientific inquiries

Contact

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Position

Associate professor

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Other areas of specialty/work

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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

The whole data is potentially indivisible after
unrecognizable identification.

When the data will become available and for how long

Access period starts 6 months after the results are
published

To whom data/document is available

Allowed for the public

Under which criteria data/document could be used

After requesting the email address and obtaining consent
and not using it negatively, it is free.

From where data/document is obtainable

sheykhi1372@gmail.com

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

After verification, a test will be provided to them for
optimal use.

Comments