

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Evaluation of the effectiveness of a biofeedback-based rehabilitation model based on muscle synergy model in upper limb mobility in patients with cerebral palsy due to stroke

Protocol summary

Study aim

The purpose of this study was to design and evaluate the effectiveness of a biofeedback-based motor rehabilitation model based on muscle synergy using artificial intelligence tools that can generally improve the quality of life of stroke survivors and be a suitable tool for telemedicine.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 30 patients. Excel software rand function was used for randomization.

Settings and conduct

in order to evaluate and evaluate the motor function of the upper limbs of the subjects, in addition to recording and analyzing the superficial electromyogram signal and analyzing the motion tracking, two Fugel-Meyer and MMSE tests will be used. Specialist in the neurology department of Bu Ali Hospital in Sari will be completed.

Participants/Inclusion and exclusion criteria

entering the study: No myopathic or anatomical problems/Subjects must be right-handed /24 hours have passed since their stroke and they are in stable condition/Patients should be in the acute phase/The patients must be middle cerebral artery ischemic cerebral palsy/Signing the patient's informed consent form not entering the study: Cognitive problem/Unstable clinical condition/Vision problem hearing problem/They will not be able to record signals and cooperate in research in the day/Previous stroke history/Problem of myopathy before stroke/Hemorrhagic stroke/Chronic phase/Mental retardation

Intervention groups

1: Regular physiotherapy exercises 2: Regular physiotherapy exercises plus biofeedback-based exercises Duration: 10 sessions for 30 minutes per day in the intervention group on the affected hand(12 people in each group).

Main outcome variables

The characteristics of surface electromyogram signal and motion analysis are in the form of temporal and frequency analysis or Euclidean distance Fugl Meyer test score (226 points),MMSE (30 points)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200914048720N1**
Registration date: **2020-10-13, 1399/07/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-13, 1399/07/22**

Update count: **0**

Registration date

2020-10-13, 1399/07/22

Registrant information

Name

Seyyed Ali Zendeabad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-01, 1399/07/10

Expected recruitment end date

2021-10-02, 1400/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of a biofeedback-based rehabilitation model based on muscle synergy model in upper limb mobility in patients with cerebral palsy due to stroke

Public title

Design and Effect of Biofeedback Model for Motor Rehabilitation

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

These Subjects should be Healthy and have no myopathic or anatomical problems Subjects must be right-handed subjects must not athletes 24 hours have passed since their stroke and they are in stable condition Patients should be in the acute phase The patients must be middle cerebral artery ischemic cerebral palsy Signing the patient's informed consent form

Exclusion criteria:

Cognitive problem Unstable clinical condition Vision problem hearing problem They will not be able to record signals and cooperate in research in the day Previous stroke history Problem of myopathy before stroke Hemorrhagic stroke Chronic phase Mental retardation

Age

From **24 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **10**

Non-invasive recording of electromyography (sEMG) and kinematic synergy (4 channels).

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we use simple randomization models such as a Heads or Tails, using a random number table or using computer randomization methods and the Python program, and each client, for example, by dropping coins, head and tail in We put the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study was divided into control and intervention groups. In this study, patients in both groups were evaluated before the intervention using inclusion criteria and main tests. Group 1: Regular physiotherapy exercises Group 2: Regular physiotherapy exercises plus 30 minutes of biofeedback-based training (intervention on the affected hand). The intervention is also performed as a double-blind randomized clinical trial. Blinding is for 3 groups of subjects, researchers and analysts. In this study, the evaluators (specialist physician, occupational therapist, and medical engineer) will be completely blind to the type of intervention and the group, because the tests will be evaluated by another team that is familiar with these tools.

Placebo

Not used

Assignment

Parallel

Other design features

For the first time, it covers the challenge between clinical research and the engineering aspects of making biofeedback programs and can lead to the development of an efficient, inexpensive, and telemedicine method of rehabilitation.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Bu Ali Hospital (Avicenna Hospital), Pasdaran Boulevard, Sari, Mazandaran Province

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Sari

Province

Mazandaran

Postal code

4815838477

Approval date

2019-09-25, 1398/07/03

Ethics committee reference number

IR.MAZUMS.REC.1398.902

Health conditions studied**1****Description of health condition studied**

Hemiplegia due to ischemic stroke in the middle cerebral artery

ICD-10 code

G46.0

ICD-10 code description

Middle cerebral artery syndrome

Primary outcomes

1

Description

Surface electromyogram signal analysis and motion analysis and the score of two Fugl-Meyer and NHISS tests will be used.

Timepoint

1 day after stroke, before intervention, 10 sessions after intervention

Method of measurement

4-channel surface electromyography; Webcam recording; Questionnaires and clinical tests by a neurologist and physiotherapist

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Normal physiotherapy exercises Non-invasive movement exercises for adduction and abduction the arm

Category

Rehabilitation

2

Description

Intervention group: In addition to the usual physiotherapy exercises, movement exercises such as adduction and abduction the arm based on visual feedback and biofeedback-based voice in 10 sessions for 30 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Hospital (Avicenna Hospital)

Full name of responsible person

Athena Sharifi Razavi

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Bu Ali Hospital (Avicenna Hospital),Pasdaran Boulevard, Sari, Mazandaran Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

N/A

Proportion provided by this source

1

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Athena Sharifi Razavi

Position

Assistant professor of neurology of Mazandaran university of medical science

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

Contact

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Islamic Azad University

Full name of responsible person

Seyyed Ali Zendeabad

Position

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Latest degree

Master

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

Undecided - It is not yet known if there will be 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

All information except recorded raw data will be shared from subjects after the defense and publication of articles.

When the data will become available and for how long

Access period starts 6 months after the publication of results and articles

To whom data/document is available

Students and researchers in the field of rehabilitation

Under which criteria data/document could be used

Raw data is not available, but other results and documentation with reference to the source are not prohibited.

From where data/document is obtainable

Seyyed Ali Zendeabad ali.zendeabad@gmail.com

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

Only valid university email and send ID card photo

Comments

Be steadfast and victorious