

# 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)

##### Phone

+98 11 3334 7289

##### Email address

ali.zendeabad@gmail.com

##### 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

**City**

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

##### Street address

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

##### City

Sari

##### Province

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##### Postal code

4815838477

##### Phone

+98 11 3334 3011

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##### Email

publicrel@mazums.ac.ir

##### Web page address

<https://www.mazums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Hamid Reza Kobravi

##### Street address

Biomedical Engineering Faculty, Ostad Yousefi Boulevard, Kuy-e-Honar, Mashhad,Razavi Khorasan Province

##### City

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##### Province

Razavi Khorasan

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##### Phone

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##### Fax

+98 51 3662 1056

##### Email

HamidRezaKobravi@gmail.com

##### Web page address

<http://mshdiau.ac.ir>

#### 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

**Street address**

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

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athena.sharifi@yahoo.com

**Web page address**

<https://scholar.google.com/citations?user=T8yrbtgAAAJ&hl=en>

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Seyyed Ali Zendeabad

**Position**

PhD candidate

**Latest degree**

Master

**Other areas of specialty/work**

Medical Engineering

**Street address**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Seyyed Ali Zendeabad

**Position**

PhD candidate

**Latest degree**

Master

**Other areas of specialty/work**

Medical Engineering

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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](mailto: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