

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating of the changes in the functional and structural brain connectivities due to electromyographic biofeedback training related for hand grasping in hemiparetic children using processing of the EEG signals and the DTI images

#### Protocol summary

##### Study aim

The main objective is to evaluate a novel bimanual rehabilitation approach, focusing on functional and structural brain changes to improve motor and cognitive performance in children with hemiparetic cerebral palsy.

##### Design

Children older than five years with unilateral cerebral palsy or spastic hemiplegia, diagnosed by a specialist physician, will be selected and enrolled in the study.

##### Settings and conduct

The patient sits in front of a computer, and after the exercise is explained and demonstrated, the intervention is performed, consisting of electromyographic biofeedback combined with tactile feedback delivered through a vibrator. The muscle tension threshold is set by the therapist so that the patient can visualize their muscle contractions in graphical form and improve performance through visual feedback.

##### Participants/Inclusion and exclusion criteria

Children older than five years with unilateral cerebral palsy or spastic hemiplegia, diagnosed by a specialist physician, will be selected and enrolled in the study. The exclusion criteria include patients with severe spasticity, severe visual or hearing impairments, and children who are unable to perform the tasks due to cognitive or behavioral difficulties.

##### Intervention groups

The interventions, including electromyographic biofeedback and stimulation of cutaneous mechanoreceptors of the hand, will be performed for each patient over 10 training sessions. During these sessions, the child will be required to attempt, in the form of a game, to maintain the position of an object on a display screen.

##### Main outcome variables

The extent of improvement in wrist spasticity and

enhancement of patients' motor function will be evaluated.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250624066242N3**

Registration date: **2026-05-14, 1405/02/24**

Registration timing: **prospective**

Last update: **2026-05-14, 1405/02/24**

Update count: **0**

##### Registration date

2026-05-14, 1405/02/24

##### Registrant information

##### Name

Mehran Beiraghi Toosi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3801 2469

##### Email address

beiraghitm@mums.ac.ir

##### Recruitment status

**recruiting**

##### Funding source

##### Expected recruitment start date

2026-05-19, 1405/02/29

##### Expected recruitment end date

2026-07-20, 1405/04/29

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Investigating of the changes in the functional and structural brain connectivities due to electromyographic biofeedback training related for hand grasping in hemiparetic children using processing of the EEG signals and the DTI images

**Public title**  
Investigating of the changes in the functional and structural brain connectivities due to electromyographic biofeedback training related for hand grasping in hemiparetic children using processing of the EEG signals and the DTI images

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Children with unilateral cerebral palsy or spastic hemiplegia will be selected based on a specialist diagnosis. Children over 5 years of age will be included in the study.  
**Exclusion criteria:**  
If the patient's grade is determined to be severe based on criteria such as gross motor function, they will not be included in the study. Children with severe visual and hearing impairments will be excluded from the study. If children are unable to perform the task due to cognitive or behavioral impairments, they will be excluded from the study. If there are orthopedic defects in the hands that prevent the desired movement, the child will not be included in the study.

**Age**  
From **5 years** old to **16 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **5**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Faculty of Medicine, Mashhad University of Medical Sciences (Research Ethics Committee)

##### Street address

Niloofar 3

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9187834663

#### Approval date

2026-01-19, 1404/10/29

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1404.511

## Health conditions studied

### 1

#### Description of health condition studied

cerebral palsy

#### ICD-10 code

G80.2

#### ICD-10 code description

Spastic hemiplegic cerebral palsy

## Primary outcomes

### 1

#### Description

All hand movements

#### Timepoint

3 months

#### Method of measurement

Fugl-Meyer Assessment and Ashworth test

## Secondary outcomes

### 1

#### Description

The analysis of brain dynamic changes conducted using EEG signals and the evaluation of structural brain connectivity changes using DTI. For this purpose, five pediatric patients will be selected. After completing the intervention exercises, the effectiveness of the motor-cognitive training delivered through the device will be evaluated. The first assessment will be the Ashworth test, which measures the level of wrist muscle spasticity.

#### Timepoint

Five patients, each undergoing 15 training sessions

#### Method of measurement

The level of wrist muscle spasticity will be assessed

using the Ashworth test. The results will be obtained before the start of the intervention and after completion of the 15 sessions and will then be compared to determine the extent of improvement in cognitive and hand motor functions.

## 2

### Description

The analysis of brain dynamic changes conducted using EEG signals and the evaluation of structural brain connectivity changes using DTI. For this purpose, five pediatric patients will be selected. In the next stage, the Fugl-Meyer Assessment will be used to evaluate hand motor function.

### Timepoint

Five patients, each undergoing 15 training sessions

### Method of measurement

Fugl-Meyer Assessment of the upper extremity will be administered to evaluate motor abilities. The results will be obtained before the start of the intervention and after completion of the 15 sessions and will then be compared to determine the extent of improvement in cognitive and hand motor functions.

## Intervention groups

### 1

#### Description

Intervention group: Children with unilateral cerebral palsy (spastic hemiplegia) will participate in therapeutic intervention sessions combined with electromyographic biofeedback and stimulation of hand cutaneous mechanoreceptors. Each patient will attend 10 training sessions. In each training session, the child will attempt, in the form of a game, to maintain the position of an object on the display screen. The most important feature of this motor-cognitive task is the requirement to use both hands. Moreover, the task will be designed in such a way that its execution resembles solving a multivariable problem, requiring the engagement of various cognitive processes such as attention, concentration, prediction, and related functions.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Akbar Children's Hospital

##### Full name of responsible person

Javad Akhondian Yazdi

##### Street address

Ahmadabad Street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9919991766

##### Phone

+98 51 3844 0350

##### Email

Akhondianj@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

Mashhad University of Medical Sciences

##### City

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##### Province

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tafaghodim@mums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Javad Akhondian Yazdi

##### Position

Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Pediatric Neurology

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Ahmadabad Street

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Javad Akhondian Yazdi  
**Position**  
Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Javad Akhondian Yazdi  
**Position**  
professor  
**Latest degree**  
Subspecialist  
**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

Not applicable

### Title and more details about the data/document

All data is potentially shareable after individuals are made unidentifiable.

### When the data will become available and for how long

The course starts 6 months after the results are published.

### To whom data/document is available

Will be available to researchers working in academic and scientific institutions

### Under which criteria data/document could be used

It is permissible to use the data provided that the source is acknowledged.

### From where data/document is obtainable

Javad Akhondian Yazdi, Akhondianj@mums.ac.ir

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

First, Dr. Akhondian will be contacted by email or phone, and if approved, the necessary information will be provided.

### Comments