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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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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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