

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Combined analysis of dynamic changes of EEG signals and MRI images before and after performing bimanual exercises based on computer games in hemiparetic children.

#### Protocol summary

##### Study aim

Investigating the existence of a quantitative/qualitative relationship between the location and extent of damaged brain regions (determined by MRI) and changes in the energy of brain signals in the delta, theta, alpha, beta, and gamma bands in the frontal, central, parietal, and occipital regions of the brain before and after playing a computer game.

##### Design

In this non-randomized and unblinded interventional study, rehabilitation measures are performed for 5 children with hemiparetic cerebral palsy, and changes in the energy of brain signals (before and after an intervention) and the anatomical location of the brain lesion (from brain MRI) are investigated.

##### Settings and conduct

Children diagnosed with hemiparetic cerebral palsy are entering a study at Akbar Hospital in Mashhad. Brain MRI is performed to investigate the location of the lesion, and brain waves (EEG) are evaluated before and after interventions involving bimanual exercises based on computer games.

##### Participants/Inclusion and exclusion criteria

Age between 5 and 18 Hemiparetic cerebral palsy

##### Intervention groups

Implementation of training interventions for children aged 5 to 18 years with hemiparetic cerebral palsy. In this phase, each patient participates in a one-month program consisting of 10 training sessions, each lasting between 3 and 20 minutes. During each session, the child is required to play a game in which they try to maintain the position of an object on the display screen.

##### Main outcome variables

evaluation of energy changes in brain signals

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250624066242N2**

Registration date: **2025-11-07, 1404/08/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2025-11-07, 1404/08/16**

Update count: **0**

##### Registration date

2025-11-07, 1404/08/16

##### 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

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-10-22, 1404/07/30

##### Expected recruitment end date

2026-04-19, 1405/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Combined analysis of dynamic changes of EEG signals and MRI images before and after performing bimanual exercises based on computer games in hemiparetic children.

## Public title

Combined analysis of dynamic changes of EEG signals and MRI images

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Cerebral palsy hemiparetic children with appropriate cooperation

### Exclusion criteria:

Children with severe visual and hearing impairments and autism

## Age

From **5 years** old to **18 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

Ahmad Abad Street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9919991766

#### Approval date

2025-04-15, 1404/01/26

## Ethics committee reference number

IR.MUMS.MEDICAL.REC.1404.061

## 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 month

#### Method of measurement

Gross Motor Function Measure, Corsi block-tapping test, Fugl-Meyer

## Secondary outcomes

### 1

#### Description

Before and after the intervention exercises, we will again record the children's brain signals in order to assess the effectiveness of the motor-cognitive exercises performed using the device. These assessments are divided into two categories. The first category involves administering standardized working memory tests. The Corsi Block-Tapping Test will be used under the supervision of a psychologist. In the next stage, the relationship and correlation between changes in the power of brain signal frequency bands in the target regions and brain imaging data will be examined. Brain signal studies are typically analyzed in terms of oscillations within electrophysiological frequency bands, which are classified as delta (1-3 Hz), theta (4-8 Hz), alpha (8-13 Hz), beta (12-25 Hz), and gamma (35-100 Hz).

#### Timepoint

Each patient participates in 10 training sessions over a month, with each session lasting between 20 and 30 minutes.

#### Method of measurement

The correlation between changes in the power of frequency bands of the brain signal in the target areas and brain images is investigated.

## Intervention groups

### 1

#### Description

Before and after the intervention exercises, we will again

record the children's brain signals to assess the effectiveness of the motor-cognitive exercises performed with the device. These assessments are divided into two categories. The first category involves administering standardized working memory tests. The Corsi Block-Tapping Test will be used under the supervision of a psychologist. In the next stage, the relationship and correlation between changes in the power of brain signal frequency bands in the target regions and brain imaging data will be examined. Brain signal studies are typically analyzed in terms of oscillations within electrophysiological frequency bands, which are categorized as delta (1-3 Hz), theta (4-8 Hz), alpha (8-13 Hz), beta (12-25 Hz), and gamma (35-100 Hz). In this study, there is no control group, and evaluations will be conducted by comparing pre- and post-intervention measurements within the same participants.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Akbar Children's Hospital

##### Full name of responsible person

Hedieh Riazhi

##### Street address

Ahmadabad Street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9919991766

##### Phone

+98 51 3844 0350

##### Email

Hedieh.riazi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

Daneshgah Street, Ghoreishi Department

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

99199-91766

##### Phone

+98 51 3844 0350

##### Email

tafaghodim@mums.ac.ir

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Vice Research of 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

Hadiyeh Riyazi

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Pediatrics

##### Street address

Ahmad Abad Street

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##### Province

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##### Postal code

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##### Phone

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##### Email

hedieh.riazi@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Hadiyeh Riyazi

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Pediatrics

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**Postal code**

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**Email**

Hedieh.riazi@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hediyeh Riyazi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

Ahmadabad Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

99199-91766

**Phone**

+98 51 3844 0350

**Email**

Hedieh.riazi@gmail.com

**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**

Dr. Hamidreza Kobravi hamidrezakobravi@gmail.com  
09153173567

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

First, Dr. Kobravi will be contacted by email or phone, and if approved, the necessary information will be provided within one month.

**Comments**