Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 Riazi

Street address

Ahmadabad Street

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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

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Mashhad

Province

Razavi Khorasan

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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

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

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Ahmad Abad Street

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Person responsible for updating data

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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
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