

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of using biofeedback based on processing the electrical activity of muscles and mechanical stimulation of mechanoreceptors of the hand skin on hand function in hemiparetic children

Protocol summary

Study aim

The main goal is to present a new approach to bimanual rehabilitation based on mechanical stimulation of hand cutaneous mechanoreceptors and providing appropriate visual feedback during play based on electromyographic biofeedback, to improve upper body motor functions in children with hemiparetic cerebral palsy.

Design

Interventional study in the form of a pre-and-post assessment on 5 children without a control group

Settings and conduct

The degree of spasticity of the wrist muscles is first measured using the Ashworth test. In addition, the patients' upper body motor capabilities are also evaluated using criteria such as the Fogel-Meier. The next phase of the work is the implementation of training interventions, combined with electromyographic biofeedback and stimulation of hand cutaneous mechanoreceptors. In this phase, each patient participates in 15 training sessions. After performing the intervention exercises and in the final stage of implementing the plan, the effectiveness of the mental-motor exercises performed on the device will be examined.

Participants/Inclusion and exclusion criteria

Five to 12 years old children with hemiparetic cerebral palsy (CP) with no sever loss of visual acuity or sever hearing loss and not sever Gross Motor Scale problems

Intervention groups

Five to 12 years old children with hemiparetic CP
Exercise interventions are performed along with electromyographic biofeedback and stimulation of cutaneous mechanoreceptors of the hand.

Main outcome variables

Wrist muscle spasticity level based on Ashworth and Fogel-Meier tests

General information

Reason for update

Acronym

CP

IRCT registration information

IRCT registration number: **IRCT20250624066242N1**

Registration date: **2025-10-30, 1404/08/08**

Registration timing: **prospective**

Last update: **2025-10-30, 1404/08/08**

Update count: **0**

Registration date

2025-10-30, 1404/08/08

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

2025-11-06, 1404/08/15

Expected recruitment end date

2026-01-05, 1404/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of using biofeedback based on processing the electrical activity of muscles and mechanical stimulation of mechanoreceptors of the hand skin on hand function in hemiparetic children

Public title

Investigating the effect of using biofeedback based on processing the electrical activity of muscles and mechanical stimulation of mechanoreceptors of the hand skin on hand function in hemiparetic children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

children with hemiparetic Cerebral Palsy (CP)

Exclusion criteria:

sever low visual acuity sever deafness sever problem in gross motor skills (GMS)

Age

From **5 years** old to **12 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

Niloofer 3

City

mashhad

Province

Razavi Khorasan

Postal code

9187834663

Approval date

2024-12-03, 1403/09/13

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1403.355

Health conditions studied**1****Description of health condition studied**

cerebral palsy

ICD-10 code

G80

ICD-10 code description

Cerebral palsy

Primary outcomes**1****Description**

all hand movements

Timepoint

3 months

Method of measurement

Ashworth, fagel mir test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: After selecting patients and before implementing the interventions, the spasticity of the wrist muscles is first measured using the Ashworth scale. In addition, upper-body motor capabilities of the patients are evaluated using criteria such as the Fugl-Meyer assessment [2]. Conducting the training interventions, along with electromyographic biofeedback and stimulation of the skin mechanoreceptors of the hand, constitutes the next phase of the work. In this phase, each patient participates in 15 training sessions. In each session, the child should strive, within the framework of a game, to maintain the position of an object on the display screen. As described in the explanations of the first stage, the most important feature of this motor-cognitive task is the requirement to use both hands. Furthermore, the task is designed so that its execution resembles solving a multivariable problem and requires the performance of various cognitive processes such as attention, focus, anticipation, and ... etc.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Hamideh Azizi Fadafan

Street address

Parastar Street, Ghaem Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

91234

Phone

+98 51 3841 2081

Email

drazizi1375@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

91234

Phone

+98 51 3841 2081

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 the university

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

Hamideh azizi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

parstar street, ghaem hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

91234

Phone

+98 51 3841 2081

Email

drazizi1375@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

hamideh azizi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

parastar street , qhaem hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

91234

Phone

+98 51 3841 2081

Email

drazizi1375@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

hamideh azizi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

parastar street, qhaem hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

91234

Phone

009838412081

Email

drazizi1375@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

No - There is not a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identification of individuals.

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

Only available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Access will be granted on the condition of a written request via email and having access permission.

From where data/document is obtainable

The email request should be sent to Dr. Hamidreza Kobravi. HAMIDREZAKOBRAVI@GMAIL.COM

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

After a request to Dr. Kabravi's email, the information will be provided after a one-month review process, if the conditions are met.

Comments