Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Niloofar 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
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Parastar Street, Ghaem Hospital
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drazizi1375@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
mohsen tafaghodi
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Daneshgah street, Ghoreishi Department
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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 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
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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
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