Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Studying the effect of using biofeedback based on processing of electrical muscle activity and mechanical stimulation of hand skin mechanoreceptors on hand function in children with cerebral palsy of the torso

Protocol summary

Study aim

The primary objective of this study is to develop and evaluate an innovative bimanual rehabilitation approach involving mechanical stimulation of cutaneous mechanoreceptors in the hand and the provision of tactile feedback during gameplay, aiming to enhance motor and cognitive functions in children with hemiparetic cerebral palsy.

Design

Phase II (pilot) clinical trial on 5 patients.

Settings and conduct

In this single-group trial at Ghaem Hospital in Mashhad, 15 sessions of two-handed play were conducted with EMG recording and tactile feedback, and changes in spasticity (Ashworth) and hand function (Fogel-Meyer) before and after were evaluated with statistical tests.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Age 5–12 years with a diagnosis of hemiparetic cerebral palsy and GMFCS level ≤ II • Ability to sit independently, follow instructions, and participate in bimanual games • Sufficient wrist and finger range of motion to perform the training tasks Exclusion Criteria: • Diagnosis of bilateral or quadriplegic cerebral palsy • Severe cognitive, behavioral, visual, or hearing impairment • Musculoskeletal limitations of the wrist or fingers that preclude hand exercises • Lack of informed consent from the child’s legal guardian

Intervention groups

Five children with hemiparetic cerebral palsy participated in 15 45-minute sessions of two-handed play, during which wrist EMG was recorded and when the signal crossed the threshold, vibrocutaneous feedback was given; spasticity and hand motor function were compared with the Ashworth and Fogel-Meier scales before and after.

Main outcome variables

Wrist spasticity score; hand motor function score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251109067922N1**
Registration date: **2025-11-11, 1404/08/20**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-11, 1404/08/20**
Update count: **0**

Registration date

2025-11-11, 1404/08/20

Registrant information

Name
Hamideh Azizi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 991 371 0614
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drazizi1375@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-11, 1404/08/20

Expected recruitment end date

2025-11-16, 1404/08/25

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Studying the effect of using biofeedback based on processing of electrical muscle activity and mechanical stimulation of hand skin mechanoreceptors on hand function in children with cerebral palsy of the torso

Public title
Effects of Muscle Biofeedback and Mechanical Skin Stimulation of the Hand on Improving Hand Function in Children with Hemiplegic Cerebral Palsy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
clinically confirmed diagnosis of hemiparetic cerebral palsy by a pediatric neurologist or pediatric specialist. Gross Motor Function Classification System (GMFCS) level I–II (mild to moderate impairment); children with levels III or higher are excluded. Age between 5 and 12 years. Ability to understand and follow experimental instructions (no severe cognitive or behavioral impairments). Absence of significant visual or hearing impairments that would interfere with performing motor-cognitive tasks. No orthopedic abnormalities (e.g., structural or range-of-motion limitations in the wrist or fingers) that would prevent participation in the exercises.
Exclusion criteria:
Diagnosis of bilateral or quadriplegic cerebral palsy by a specialist physician. Gross Motor Function Classification System (GMFCS) level III or higher. Age below 5 years or above 12 years. Severe cognitive or behavioral impairment preventing instruction following. Severe visual impairment is hindering motor-cognitive task performance. Severe hearing impairment affects interaction with the game and feedback. Structural orthopedic abnormalities or limited wrist/finger range of motion. Lack of written informed consent from the child’s legal guardian.
Age
From **5 years** old to **12 years** old
Gender
Both

Phase
2
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
Ethics Committee of Mashhad University of Medical Sciences
Street address
Central Organization of Mashhad University of Medical Sciences, Danesh and Salamat Town, between Shahid Al-Shehidi Square and Shahid Javan Square, at the end of Shahid Fakouri Boulevard.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Approval date
2024-11-26, 1403/09/06
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1403.355

Health conditions studied

1

Description of health condition studied
Hemiplegic Cerebral Palsy
ICD-10 code
G80.2
ICD-10 code description
Spastic hemiplegic cerebral palsy

Primary outcomes

1

Description
Wrist Spasticity
Timepoint
It will be conducted once before the interventions and once after the completion of the intervention sessions.
Method of measurement
Wrist Spasticity Score

2

Description
Hand Motor Function
Timepoint
It will be conducted once before the interventions and once after the completion of the intervention sessions.
Method of measurement

Fugl-Meyer Assessment

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This study is conducted at Ghaem Hospital, Mashhad, in a quiet room of the Children's Rehabilitation Clinic, utilizing a single-group design. During 15 sessions of bimanual motor-cognitive games, wrist EMG recording and tactile feedback are provided via a vibrator on the palmar skin. Spasticity is assessed with the Ashworth scale and hand motor function with the Fogel-Meier test before and after the intervention, and changes are examined with appropriate statistical tests.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem Hospital

Full name of responsible person
Hamideh Azizi

Street address
Ghaem Hospital, Ahmadabad Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

Street address
Central Organization of Mashhad University of Medical Sciences, Danesh and Salamat Town, between Shahid Al-Shehidi Square and Shahid Javan Square, at the end of Shahid Fakouri Boulevard.

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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
Hamideh Azizi

Position
Children's specialist assistant

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

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Opposite Shahid Kaveh 14, Shahid Kaveh Blvd., Mashhad, Khorasan Razavi, IRAN

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Person responsible for scientific inquiries

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Name of organization / entity

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Position
Children's specialist assistant

Latest degree
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Person responsible for updating data

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Individual data will be completely de-identified, and only the variables necessary to reproduce the main results (baseline and post-intervention) will be shared.

When the data will become available and for how long
The exact time for the publication of documents and data files will be determined after the design is completed and the analyses are finalized.

To whom data/document is available
The data and documentation of this study will only be made available to academic researchers (professors and graduate students), researchers at research centers, physicians and clinical therapists, medical technology companies, and related non-governmental organizations.

Under which criteria data/document could be used
Access to the data and documentation of this study is limited to academic researchers and research centers, clinicians and therapists, medical technology companies, and non-governmental organizations. Applicants must submit an application, a formal letter of introduction, ethics committee approval, and a resume to the lead investigator. The data are provided in a completely de-identified form and may only be used for research and educational purposes in accordance with the approved application; any changes to the research questions or commercial use require separate written permission. Statistical analysis must be performed according to the analysis plan, and the results must be published with reference to the original article.

From where data/document is obtainable
Individuals can send their request to Dr. Hamideh Azizi (project manager) via the following email to receive data and documentation of this study: drazizi1375@gmail.com

What processes are involved for a request to access data/document
To receive the data and documentation package for this research, the applicant must first send an email containing their official request to drazizi1375@gmail.com. After the request is approved, the responsible researcher will prepare the data in an anonymized form within a week based on confidentiality criteria and prepare the files related to the analysis codes, data descriptions, and statistical analysis plan.

Comments