

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 \leq 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-Meyer 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)

Phone

+98 991 371 0614

Email address

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

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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

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Hamideh Azizi

Position

Children's specialist assistant

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Person responsible for updating data

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Full name of responsible person

Hamideh Azizi

Position

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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