Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the Recovery of Hand Grasp Control in Children with Hemiparetic Cerebral Palsy Using a Passive Training Robot and Mechanoreceptor Stimulation

Protocol summary

Study aim

To investigate the effect of passive robotic hand training combined with hand mechanoreceptor stimulation on hand grasp control and upper limb function in children with hemiparetic cerebral palsy.

Design

A single-group, non-randomized, before-and-after clinical trial. All participants receive the same intervention. A pilot study will be conducted on five patients, followed by sample size calculation.

Settings and conduct

The study will be conducted at Ghaem Hospital, Mashhad. Participants will receive the intervention using a passive pneumatic robotic glove and mechanical stimulation of hand mechanoreceptors. Assessments will be performed before and after the intervention. Outcome assessments will be conducted by an evaluator other than the principal researcher. The study is not blinded.

Participants/Inclusion and exclusion criteria

Children aged 5–12 years with neurologist-diagnosed hemiparetic cerebral palsy, Manual Ability Classification System (MACS) levels I–III, and the ability to understand and follow simple instructions. Exclusion criteria: orthopedic surgery within the previous year; botulinum toxin injection within the previous six months; severe sensory problems.

Intervention groups

One intervention group receives passive pneumatic robotic hand training combined with mechanical stimulation of hand mechanoreceptors. The intervention consists of 20 sessions, approximately 20 minutes each, three times per week on alternate days.

Main outcome variables

Hand grasp control and upper limb sensorimotor function, assessed using the Fugl-Meyer Assessment (FMA) before and after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250624066242N9**
Registration date: **2026-11-09, 1405/08/18**
Registration timing: **prospective**

Last update: **2026-11-09, 1405/08/18**
Update count: **0**

Registration date

2026-11-09, 1405/08/18

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

Not yet recruiting

Funding source

Expected recruitment start date

2026-12-10, 1405/09/19

Expected recruitment end date

2027-02-08, 1405/11/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the Recovery of Hand Grasp Control in Children with Hemiparetic Cerebral Palsy Using a Passive Training Robot and Mechanoreceptor Stimulation

Public title
Investigating the Recovery of Hand Grasp Control in Children with Hemiparetic Cerebral Palsy Using a Passive Training Robot and Mechanoreceptor Stimulation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children aged 5 to 12 years. Clinical diagnosis of hemiparetic cerebral palsy confirmed by a pediatric neurologist. Manual Ability Classification System (MACS) level I–III. Ability to understand and follow simple instructions.

Exclusion criteria:
History of orthopedic surgery within the previous year. Botulinum toxin injection within the previous six months. Severe sensory problems.

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
Research Ethics Committee, Faculty of Medicine, Mashhad University of Medical Sciences

Street address
Shahid Dr. Khwarizmi Educational Complex – Vice Presidency for Research and Technology, East Gate of Ferdowsi University of Mashhad, Azadi Square, Mashhad, Khorasan Razavi

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2026-10-12, 1405/07/20

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1405.274

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
Hand grasp control in children with hemiparetic cerebral palsy.

Timepoint
At baseline before the intervention and immediately after completion of the intervention.

Method of measurement
Fugl-Meyer Assessment.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants receive passive hand training using a pneumatic robotic glove that moves the fingers in the sagittal plane, combined with mechanical stimulation of hand mechanoreceptors using coin vibrators incorporated into a wearable forearm section. Vibration is delivered in 3-second cycles at approximately 250 Hz and 70 Hz. The intervention consists of 20 sessions, approximately 20 minutes per session, three times per week on alternate days.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Quaem Hospital
Full name of responsible person
Javad Akhondian
Street address
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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Ghoreishi Department, Daneshgah street
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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
Fatemeh Poshtchaman
Position
Resident
Latest degree
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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
Not applicable
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
Start of access 6 months after publication of the results
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
Javad Akhondian
What processes are involved for a request to access data/document
Dr, Akhondian will be contacted by email or phone, and if approved, the necessary information will be provided.
Comments