

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Design and Clinical Evaluation of a Novel Therapeutic Exercise Device for Reducing Plantar Flexor Spasticity in Children with Hemiparetic Cerebral Palsy

Protocol summary

Study aim

This study aims to develop and clinically evaluate a therapeutic exercise device designed to reduce plantar flexor spasticity in children with spastic hemiparetic cerebral palsy.

Design

This study is a single-arm, non-randomized, pre-post interventional clinical trial conducted on 15 children aged 6–10 years with spastic hemiparetic cerebral palsy.

Settings and conduct

Study Location and Procedures: The study will be conducted at Akbar Hospital Clinic using a therapeutic exercise device designed by the Medical Engineering Research Center of Islamic Azad University, Mashhad. Eligible children will be evaluated by pediatric neurology specialists. Baseline assessments will include the Ashworth Scale and Fugl-Meyer score. Participants will undergo 20 sessions of 30-minute exercise using the device. Spasticity and functional outcomes will be measured before and after the intervention. After completing the intervention, outcomes will be re-evaluated and compared with baseline data to assess the effectiveness of the device and exercises.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Spastic hemiplegic CP Age 6–10
Minimal cognition Knee and hip motor ability No interfering treatments No other neurological/psychological disorders
Exclusion Criteria: No consent

Intervention groups

Children with spastic hemiparetic cerebral palsy will receive 20 sessions of therapeutic exercise using the designed mechanical ankle training device.

Main outcome variables

Change in plantar flexor spasticity measured by the Ashworth Scale at baseline and after completion of 20 intervention sessions. Change in motor function

measured by the Fugl-Meyer Assessment score at baseline and post-intervention.

General information

Reason for update

Considering the limited number of eligible patients and that most participants are referred by Pediatric Neurology specialists, we propose expanding the age range of the study participants to facilitate patient recruitment and achieve the required sample size. Therefore, the age criterion for this clinical trial will be changed from 6–10 years to 6–17 years (from the beginning of 6 years of age up to the end of 17 years of age).

Acronym

IRCT registration information

IRCT registration number: **IRCT20250825066984N1**
Registration date: **2026-02-18, 1404/11/29**
Registration timing: **prospective**

Last update: **2026-06-08, 1405/03/18**

Update count: **1**

Registration date

2026-02-18, 1404/11/29

Registrant information

Name

Kosar Shabani Varaki

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date

2026-03-01, 1404/12/10

Expected recruitment end date

2026-08-23, 1405/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design and Clinical Evaluation of a Novel Therapeutic Exercise Device for Reducing Plantar Flexor Spasticity in Children with Hemiparetic Cerebral Palsy

Public title

Therapeutic Exercise Device in Children with Hemiparetic Cerebral Palsy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of spastic hemiparetic cerebral palsy confirmed by a pediatric neurologist Having at least minimal cognitive ability to follow instructions Having motor capability in the knee and hip joints No other diagnosed neurological or severe psychological disorders. Age between 6 and 10 years; Not receiving other interventions that may interfere with the study;

Exclusion criteria:

Withdrawal of consent at any stage of the study

Age

From **6 years** old to **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

This study is a single-arm, non-randomized, pre-post interventional clinical trial. Participants will be evaluated at baseline and after completion of the intervention sessions.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhhad University of Medical Sciences

Street address

Ethics Committee of Mashhad University of Medical Sciences, Mashhad University of Medical Sciences Campus, Mashhad, Khorasan Razavi, 9178195853, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9178195853

Approval date

2025-12-02, 1404/09/11

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1404.435

Health conditions studied

1

Description of health condition studied

Muscle Spasticity

ICD-10 code

G80.2

ICD-10 code description

Spastic hemiplegic cerebral palsy

Primary outcomes

1

Description

Change in plantar flexor spasticity

Timepoint

Baseline and after completion of 20 intervention sessions

Method of measurement

Ashworth Scale

Secondary outcomes

1

Description

Change in motor function

Timepoint

Fugl-Meyer Assessment Score

Method of measurement

Baseline and post-intervention

Intervention groups

1

Description

Participants will receive 20 sessions of therapeutic exercise using the designed mechanical ankle training device. The child will be seated, and the affected ankle will be positioned on a movable platform providing controlled mechanical stimulation to the soleus muscle.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Hospital

Full name of responsible person

Narges Hashemi

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Akbar Hospital, Shahid Kaveh Boulevard, Opposite Kaveh 14, Mashhad, Khorasan Razavi, 9177897157, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Narges Hashemi

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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

Narges Hashemi

Position

University professor

Latest degree

Subspecialist

Other areas of specialty/work

Neuroscience

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Latest degree

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Other areas of specialty/work

Neuroscience

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Person responsible for updating data

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Full name of responsible person

Kosar Shabani Varaki

Position

Resident

Latest degree

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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

No - There is not 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

The data are displayed after individuals have been
anonymized

When the data will become available and for how long

six months after the publication of the results

To whom data/document is available

Will be available to researchers affiliated with academic
and scientific institutions.

Under which criteria data/document could be used

The use of the data is permitted provided that the source
is properly acknowledged.

From where data/document is obtainable

dr. Hamidreza Kobravi hamidrezakobravi@gmail.com dr
Shabani kosarshabaniv@gmail.com

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

They must email the designated contacts, introduce
themselves, and state their request. After the email is
reviewed, the materials will be sent to them if possible.
(within one month)

Comments