Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Development of Rehabilitation Protocols Based on Predictive Modeling of the Effects of Mechanical Vibrations and Robotics on Neuromuscular Control and Gait Improvement in Children with Cerebral Palsy

Protocol summary

Study aim

Main Objective To evaluate the therapeutic effects of mechanical vibrations on ankle joint neuromuscular abnormalities and gait disorders in children with Cerebral Palsy (CP) using a rehabilitation robot.

Design

A total of 36 patients will be randomly allocated into two groups. The randomization process will be performed using the RAND() function in Microsoft Excel.

Settings and conduct

A total of 36 patients will be randomly allocated into two groups. The randomization process will be performed using the RAND() function in Microsoft Excel.

Participants/Inclusion and exclusion criteria

Inclusion Criterion: Children diagnosed with spastic hemiplegic and diplegic Cerebral Palsy (CP). Exclusion Criteria: Severe intellectual disability. A history of uncontrolled epilepsy or untreated seizures.

Intervention groups

The intervention group will undergo treatment with a neuromuscular rehabilitation robot for a duration of 2 months, with sessions held 3 times a week for 30 minutes each. The appropriate range of motion (ROM) for the individual's ankle joint will be determined. During the treatment session, low-amplitude, high-frequency vibrations will be applied to the individual, both throughout the entire range of motion and statically at the end-range of dorsiflexion. The control group: During this period, children in the control group will receive the same amount of conventional occupational therapy, with a focus on reducing ankle spasticity.

Main outcome variables

Neuromuscular parameters of the ankle joint Kinetic and kinematic parameters of the ankle joint Spatiotemporal gait parameters Dynamic balance Static balance Clinical test parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250629066292N1**
Registration date: **2025-07-21, 1404/04/30**
Registration timing: **prospective**

Last update: **2025-07-21, 1404/04/30**
Update count: **0**

Registration date

2025-07-21, 1404/04/30

Registrant information

Name

Mohammad Mehdi Mirbagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6646 6383

Email address

mehdi.northwestern@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-08-11, 1404/05/20

Expected recruitment end date

2027-08-11, 1406/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Development of Rehabilitation Protocols Based on Predictive Modeling of the Effects of Mechanical Vibrations and Robotics on Neuromuscular Control and Gait Improvement in Children with Cerebral Palsy

Public title
Development of Rehabilitation Protocols Based on Predictive Modeling of the Effects of Mechanical Vibrations and Robotics on Neuromuscular Control and Gait Improvement in Children with Cerebral Palsy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosed with spastic hemiplegic and diplegia Cerebral Palsy (CP). Ability to participate in the scheduled treatment and assessment sessions. Ability to communicate and follow instructions.

Exclusion criteria:
Severe intellectual disability. A history of uncontrolled epilepsy or untreated seizures.

Age
From **3 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly allocated to either an intervention group or a control group. The randomization process will be performed using the RAND() function in Microsoft Excel.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences Research Ethics Committee

Street address
Poursina st, Tehran university of medical science

City
Tehran

Province
Tehran

Postal code
1417466891

Approval date
2025-05-11, 1404/02/21

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1404.129

Health conditions studied

1

Description of health condition studied
Children with spastic hemiplegic Cerebral Palsy

ICD-10 code
G80.2

ICD-10 code description
Spastic hemiplegic cerebral palsy

2

Description of health condition studied
Children with spastic diplegic Cerebral Palsy

ICD-10 code
G80.1

ICD-10 code description
Spastic diplegic cerebral palsy

Primary outcomes

1

Description
Stiffness

Timepoint
Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), After two months of receiving the treatment program (Post-treatment), One month after the end of treatment (Follow-up)

Method of measurement
Neuromuscular rehabilitation robot

Secondary outcomes

1

Description
Active range of motion

Timepoint
Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), After two months of receiving the treatment program (Post-treatment), One month after the end of treatment (Follow-up)

Method of measurement
Position sensor of the neuromuscular rehabilitation robot.

2

Description
Maximum voluntary contraction force
Timepoint
Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), After two months of receiving the treatment program (Post-treatment), One month after the end of treatment (Follow-up)
Method of measurement
Torque sensor of the neuromuscular rehabilitation robot.

3

Description
Speed of voluntary joint movement
Timepoint
Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), After two months of receiving the treatment program (Post-treatment), One month after the end of treatment (Follow-up)
Method of measurement
Position sensor of the neuromuscular rehabilitation robot.

4

Description
Ankle joint angles
Timepoint
Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), After two months of receiving the treatment program (Post-treatment), One month after the end of treatment (Follow-up)
Method of measurement
Using marker positions in the motion capture lab

5

Description
Maximum step height
Timepoint
Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), After two months of receiving the treatment program (Post-treatment), One month after the end of treatment (Follow-up)
Method of measurement
Using marker positions in the motion capture lab

6

Description
Center of pressure fluctuations
Timepoint
Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), After two months of receiving the treatment program (Post-treatment), One month after the end of treatment (Follow-up)
Method of measurement
Force plate

7

Description
Static stability
Timepoint
Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), After two months of receiving the treatment program (Post-treatment), One month after the end of treatment (Follow-up)
Method of measurement
Force plate

8

Description
Timed up and Go
Timepoint
Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), After two months of receiving the treatment program (Post-treatment), One month after the end of treatment (Follow-up)
Method of measurement
Stopwatch

9

Description
10-meter walk test
Timepoint
Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), After two months of receiving the treatment program (Post-treatment), One month after the end of treatment (Follow-up)
Method of measurement
Stopwatch

10

Description
6-minute walk test
Timepoint
Before the start of treatment (Baseline), After one month of receiving the treatment program (Mid-point), After two months of receiving the treatment program (Post-treatment), One month after the end of treatment (Follow-up)
Method of measurement
Meter

Intervention groups

1

Description
Intervention group: The intervention group will undergo treatment with the neuromuscular rehabilitation robot for 30 minutes per session, 3 times a week, over a two-month period. Participants will be seated on the

adjustable chair of the robot, and their ankle will be secured in a custom brace to ensure the ankle joint's axis of rotation is aligned with that of the robot's motor .The appropriate range of motion (ROM) for the individual's ankle joint is determined. During the treatment session, low-amplitude, high-frequency vibrations are applied to the individual, both throughout the entire range of motion and statically at the end-range of dorsiflexion.

Category

Rehabilitation

2

Description

Control group: Children in the control group will receive a conventional occupational therapy program for the same duration and frequency, with a focus on reducing ankle spasticity.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Fakhre Sadeq Rehabilitation Center

Full name of responsible person

Shahrbanoo ,Mojtahedi

Street address

No. 42, Alipour Karami St., Mohandes El-Mamalek St., Jomhuri St.

City

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Province

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1146733711

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mehdi.northwestern@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Research and Technology Management, Tehran University of Medical Sciences

Street address

Poursina st, Tehran university of medical science

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1417466891

Phone

+98 21 8891 2090

Email

mehdi.northwestern@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

59

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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Mehdi Mirbagheri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Engineering

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1416753955

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Mehdi Mirbagheri

Position

Associate professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Mehdi Mirbagheri

Position

Associate professor

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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

Undecided - It is not yet known if there will be 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

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

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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