

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Use of Challenge Point Framework to Guide Motor Learning of Stepping Reactions for Improved Balance Control in Children with Unilateral Cerebral Palsy

Protocol summary

Study aim

To study the role of challenge point framework intervention in learning stepping reaction and dynamic balance in 4-12 years old children with unilateral cerebral palsy

Design

One intervention group, pre-test/post-test. 12 participants Not blinded

Settings and conduct

Study was performed in occupational therapy clinics in Tehran

Participants/Inclusion and exclusion criteria

The criteria for entering the study were the ability to walk without the help of a person or assistive device for at least six minutes, the ability to understand and follow the therapist's guidelines, and levels one to three of the GMFCS Convulsion during the study or any disease that interfered with the study process, failure to attend three consecutive sessions, refusing to complete the training sessions, heart disease, and severe vision or hearing problems were exclusion criteria.

Intervention groups

One intervention group, pre-test/post-test . In this procedure, the person was asked to bend from the ankle joint in four directions, forward, backward, right and left, while standing. People should not try to prevent falling, but should allow themselves to fall like a fallen tree, to the point where they feel they have to take a step to prevent it from falling. To reduce the fear of falling, participants were encouraged to concentrate on increasing the speed and length of the stepping reaction so as not to pay attention to the limits of their stability (by the therapist). People had similar exercises with both legs as the initial stepping leg in maintaining balance. Although they could take as many steps as they need to regain balance, they were encouraged to keep their balance in just two to three steps.

Main outcome variables

Step length in stepping reaction Step velocity in stepping reaction Dynamic balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200905048619N1**

Registration date: **2020-09-09, 1399/06/19**

Registration timing: **retrospective**

Last update: **2020-09-09, 1399/06/19**

Update count: **0**

Registration date

2020-09-09, 1399/06/19

Registrant information

Name

Somayeh Ashouri

Name of organization / entity

Kharazmi university

Country

Iran (Islamic Republic of)

Phone

+98 21 3373 3247

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-07, 1398/06/16

Expected recruitment end date

2019-09-17, 1398/06/26

Actual recruitment start date

2019-09-07, 1398/06/16
Actual recruitment end date
2019-09-17, 1398/06/26
Trial completion date
2019-12-10, 1398/09/19

Scientific title
Use of Challenge Point Framework to Guide Motor Learning of Stepping Reactions for Improved Balance Control in Children with Unilateral Cerebral Palsy

Public title
To study the role of CPF motor learning on balance control in hemiplegic CP children

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Ability to walk without the help of a person or assistive device for at least six minutes Ability to understand and follow the therapist's guidelines Levels one to three of the GMFCS Hemiplegic cerebral palsied children aged 4 to 12
Exclusion criteria:
Convulsion during the study or any disease that interfered with the study process. , Failure to attend three consecutive sessions Heart disease, and severe vision or hearing problems Refusing to complete the training sessions

Age
From **4 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **12**
Actual sample size reached: **12**

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 research of Kharazmi university
Street address
No.2,Shaqayeq Alley,Golha town,Southern Nabard St.,Pirouzi Ave
City
Tehran
Province
Tehran
Postal code
1777934155
Approval date
2019-07-28, 1398/05/06
Ethics committee reference number
IR.KHU.REC.1398.019

Health conditions studied

1

Description of health condition studied

Balance disorder in unilateral cerebral palsied children

ICD-10 code

G80

ICD-10 code description

Cerebral palsy

Primary outcomes

1

Description

Step length in stepping reaction

Timepoint

Pre-test1, pre-test2, post-test

Method of measurement

Tracker software to estimate step length

2

Description

Step velocity in stepping reaction

Timepoint

Pre-test1, pre-test2, post-test

Method of measurement

Tracker software to estimate step velocity

3

Description

Statics and Dynamic balance

Timepoint

Pre-test1, pre-test2, post-test

Method of measurement

Pediatric Balance Scale (PBS) to test static and dynamic balance

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: received 12 sessions (twice a week) exercises based on challenge point framework. Each session lasted for 45 minutes. In this procedure, the person was asked to bend from the ankle joint in four directions, forward, backward, right and left, while standing. People should not try to prevent falling, but should allow themselves to fall like a fallen tree, to the point where they feel they have to take a step to prevent it from falling.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehravarvan Rehabilitation and Occupational Therapy Clinic

Full name of responsible person

Hossein Ashouri

Street address

N.47, Abouzar 6th bridge, Pirouzi Ave.

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1779843636

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kharazmi university

Full name of responsible person

Amir Letafatkar

Street address

Kharazmi university, Kousha St., Mirdamad

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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

Kharazmi university

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

Kharazmi university

Full name of responsible person

Somayeh Ashouri

Position

Student

Latest degree

Master

Other areas of specialty/work

Therapeutic Exercises

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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

Not applicable

Data Dictionary

Not applicable