

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effect of "Dynamic Neuromuscular Stabilization" training and "Core Stability" training on mobility, trunk control, hypertonicity and grip strength in children with spastic hypertonia cerebral palsy

Protocol summary

Study aim

To compare the effect of "DNS" training and "CS" training on mobility, trunk control, hypertonicity, and hand grip power in cerebral palsy

Design

This study is 2-armed, double-blind RCT compared "DNS" exercise, to "CS" exercises. with one to one allocation in two groups (group 1: DNS exercise, group 2: CS exercise). Where the person evaluating the outcome measures, is completely blind to the type of exercise that each group received. It is also expected that there will be no difference between the two groups in terms of exercise positions, and duration treatment sessions.

Settings and conduct

The intervention is performed in the physiotherapy. In this study, both the participants and the assessor are blind.

Participants/Inclusion and exclusion criteria

Children will be included in the study if the diagnosis of participants as spastic hypertonia CP (hemiplegic), diplegic CP, hemiparesis, will be confirmed by the neurologist, having GMFCS levels between 1 and 3, age range between 7 and 11 years old, able to follow verbal commands, ability to walk as much as 3 meter with/without walking aid, not received Botox within 6 months in upper and lower limb. Children will be excluded if they have other serious neuromuscular disorders such as neuropathies, myopathies, apraxia (Inability to learn and practice exercises), a history of a major surgery (on the elbows, wrists, and fingers), having any cardiovascular disease, involuntary movements, severe contractures and deformities in the limbs, serious hearing and speech problems, uncontrolled diabetes, Explicit postural abnormalities in the spine and lower limbs such as scoliosis and kyphosis.

Intervention groups

They, will receive "Dynamic neuromuscular stabilization exercise" and in control group, they will receive "core stability exercise" 5 weeks, three sessions per week.

Main outcome variables

The mobility score is the main outcome.

General information

Reason for update

Acronym

DNS (Dynamic Neuromuscular Stabilization) and CS (Core Stability)

IRCT registration information

IRCT registration number: **IRCT20140222016680N10**

Registration date: **2024-09-05, 1403/06/15**

Registration timing: **prospective**

Last update: **2024-09-05, 1403/06/15**

Update count: **0**

Registration date

2024-09-05, 1403/06/15

Registrant information

Name

Shohreh Noorizadeh Dehkordi

Name of organization / entity

Iran University of Medical Sciences, School of Rehabilitation Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-22, 1403/07/01

Expected recruitment end date

2025-09-23, 1404/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of "Dynamic Neuromuscular Stabilization" training and "Core Stability" training on mobility, trunk control, hypertonicity and grip strength in children with spastic hypertonia cerebral palsy

Public title

Comparison of two trunk stabilization training on mobility, trunk control, muscle stiffness and grip strength in cerebral palsy children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

- Confirming the diagnosis of participants as spastic hypertonia CP (hemiplegic), diplegic CP, hemiparesis, by the neurologist
- Having Motor Function levels between 1 and 3 based on the GMFCS
- Having age range between 7 and 11 years old
- Able to follow verbal commands
- Ability to walk as much as 3 meter with/without walking aid
- Have not received Botox within 6 months in upper and lower limb

Exclusion criteria:

Children with other serious neuromuscular disorders such as neuropathies, myopathies Having apraxia (Inability to learn and practice exercises) Having a history of a major surgery on the elbows, wrists, and fingers Having any cardiovascular disease Having involuntary movements Having severe contractures and deformities in the limbs Having serious hearing and speech problems Having uncontrolled diabetes Explicit postural abnormalities in the spine and lower limbs such as scoliosis and kyphosis

Age

From **7 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Random blocks (permuted block randomization) with four

blocks will be used for randomization. According to the sample size of 38, approximately 10 blocks will be generated using the online site (www.sealedenvelope.com). For concealment in the randomization process, unique code will be used on each envelope with the type of training specified inside.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the assessor who evaluates the outcome measures of the study, will be blind to the allocation of the two treatment groups. Additionally, the data also will be evaluated by a person who is blind to the allocation and treatment of groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Iran University of Medical Sciences

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Iran University of Medical Sciences, Hemmat Expressway, Tehran, Iran

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۱۴۳۹۶۱۴۵۳۵

Approval date

2024-08-13, 1403/05/23

Ethics committee reference number

IR.IUMS.REC.1403.405

Health conditions studied**1****Description of health condition studied**

Spastic Cerebral Palsy

ICD-10 code

G80

ICD-10 code description

Cerebral Palsy

Primary outcomes**1****Description**

"Mobility Score"

Timepoint

Before intervention, after intervention

Method of measurement

"Timed Up and Go Test"

Secondary outcomes**1****Description**

Trunk control score

Timepoint

Measurement of trunk control before intervention, after intervention

Method of measurement

"Trunk Control Measurement Scale"

2**Description**

Hypertonia Score

Timepoint

before intervention, after intervention

Method of measurement

"Modified Ashworth Scale"

3**Description**

Grip Strength Score

Timepoint

before intervention, after intervention

Method of measurement

"Grip Dynamometer"

Intervention groups**1****Description**

Intervention group: In this group, Dynamic Neuromuscular Stabilization exercises, will be given in a period of 5 weeks, three sessions per week. During fifteen sessions, progressively 21 exercises are given with focus on improving trunk control in supine, prone, sitting, quadruped and standing positions. Each treatment session, depending on the patient needs to rest, lasts between 40 and 60 minutes. Required equipment are mats, gymnastics ball, chair, and wall bar.

Category

Rehabilitation

2**Description**

Control group: Core Stability exercises a period of 5 weeks, will be given in a period of 5 weeks, three sessions per week. During fifteen sessions, progressively 16 exercises are given with focus on improving trunk control in supine, prone, sitting, and standing positions. Each treatment session, depending on the patient needs

to rest, lasts between 40 and 60 minutes. Required equipment are mats, gymnastics balls, chair and wall bar.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Neurological physiotherapy Clinic, School of Rehabilitation Sciences,

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name

Vice Cancellor for Research of Iran University of Medical Sciences

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source
Iran 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
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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

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