Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Iran (Islamic Republic of)

Phone
+98 21 2222 7124

Email address
noorizadeh.sh@iums.ac.ir

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, approximately10 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. Aditionally, 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
Street address
Iran University of Medical Sciences, Hemmat Expressway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
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
Shohreh Noorizadeh Dehkordi
Street address
School of Rehabilitation Sciences, Madadkaran Street, Shahnazari Street, Madar Square, Mirdamad, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
15459-13487
Phone
+98 21 2222 7124
Email
noorizadeh.sh@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Falak
Street address
Iran University of Medical Sciences, Hemmmat Expressway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 4704
Fax
+98 21 8862 2707
Email
Falak.r@iums.ac.ir
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
Iran University of Medical Sciences
Full name of responsible person
Shohreh Noorizadeh Dehkordi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
School of Rehabilitation Sciences, Madadkaran Street, Shahnazari Street, Madar Square, Mirdamad, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
15459-13487
Phone
+98 21 2222 7124
Email
noorizadeh.sh@iums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Shohreh Noorizadeh Dehkordi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
School of Rehabilitation Sciences, Madadkaran Street, Shahnazari Street, Madar Square, Mirdamad, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
15459-13487
Phone
+98 21 2222 7124
Email
noorizadeh.sh@iums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Shohreh Noorizadeh Dehkordi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
School of Rehabilitation Sciences, Madadkaran Street, Shahnazari Street, Madar Square, Mirdamad, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
15459-13487
Phone
+98 21 2222 7124
Email
noorizadeh.sh@iums.ac.ir

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