Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of occupation-based Integrated intensive Bilateral Upper–Lower Limb Training on participation in Activities of Daily Livings (ADLs) in 6-12 years old children with unilateral spastic cerebral palsy

Protocol summary

Study aim

The aim of this study was to investigate the effect of Integrated intensive Bilateral Upper–Lower Limb Training on participation in daily life activities in children with unilateral spastic cerebral palsy aged 6 to 12 years.

Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 30 patients. A random number table will be used for randomization.

Settings and conduct

This study is conducted at the Tavanyaab Center located in Enghelab Square, Tehran. Each individual is individually intervened. The intervention lasts for 14 days and 2-4 hours a day (Depending on the child's circumstances), and the protocol is determined in advance for each child. The study is single-blind and the assessor is blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria include age between 6 to 12. The child must also have received a diagnosis of cerebral palsy of the spastic unilateral hemiplegia type. According to the MACS scale, it must be at levels 2 and 3 and according to the GMFCS scale, it must be at levels 2 to 4. Exclusion criteria include uncontrollable seizures, visual and cognitive problems.

Intervention groups

The therapist will conduct therapy sessions in and pre-determined locations based on the goals set. Then, based on the child's deficiencies and the interests of each child, a therapy program in the form of play and daily life activities is designed by the therapist and made available to the parents to practice with the child. Parents will also be given the necessary training to perform interventions in the form of play at home. In the control group, children with spastic unilateral hemiplegic cerebral palsy will receive routine occupational therapy.

Main outcome variables

The main outcomes include the Pediatric balance scale, Canadian occupational performance measure, and the Children's Hand Use Experience Questionnaire.

General information

Reason for update

Providing a more complete and precise title that covers all aspects of the intervention

Acronym

IRCT registration information

IRCT registration number: **IRCT20241119063772N1**
Registration date: **2025-05-08, 1404/02/18**
Registration timing: **prospective**

Last update: **2026-10-22, 1405/07/30**
Update count: **1**

Registration date

2025-05-08, 1404/02/18

Registrant information

Name

Seyyed Ali Mir Asadi Nia

Name of organization / entity

Country

Iran (Islamic Republic of)

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ali.mirasadi.2000@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-24, 1404/03/03

Expected recruitment end date

2026-03-18, 1404/12/27

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of occupation-based Integrated intensive Bilateral Upper–Lower Limb Training on participation in Activities of Daily Livings (ADLs) in 6-12 years old children with unilateral spastic cerebral palsy

Public title
The effect of occupation-based Integrated intensive Bilateral Upper–Lower Limb Training in children with unilateral spastic cerebral palsy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The child has received a diagnosis of spastic unilateral hemiplegia cerebral palsy. The child is between 6 and 12 years old. The child is at levels II, III, and IV of the GMFCS scale. The child is at levels II and III of the MACS scale. The child has the ability to grasp light objects and raise the more affected hand more than 15 cm above the table surface. The child has not received upper and lower limb surgery and Botox injections in the past 6 to 12 months and does not intend to do so during the implementation of the interventions. The child's intelligence score is above 70
Exclusion criteria:
The family or the child is unwilling to continue the interventions. The child has uncontrolled seizures. The child has visual or cognitive problems. The child is unable to actively participate in the assessment process.
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
The participants will be recruited from the clients referred to occupational therapy clinics in Tehran based on the inclusion criteria and will be allocated to the control and intervention groups using a random number table. Accordingly, one of the researchers who is not involved in the intervention process will determine the placement of the participants in one of the two control and intervention groups based on the random number table. Participants and the outcome assessor will be blind about group allocation.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this single-blind study, the outcome assessor will be blind to the allocation of participants to groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Shahid Beheshti University of Medical Sciences Vice President of Resear
Street address
Shahid Beheshti University of Medical Sciences, School of Rehabilitation, opposite Bu Ali Hospital, Damavand Street (New Tehran), Imam Hossein (AS) Square, Tehran
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tehran
Province
Tehran
Postal code
1616913111
Approval date
2024-11-10, 1403/08/20
Ethics committee reference number
IR.SBMU.RETECH.REC.1403.445

Health conditions studied

1

Description of health condition studied
Children with unilateral cerebral palsy
ICD-10 code
G80.2
ICD-10 code description
Spastic hemiplegic cerebral palsy

Primary outcomes

1

Description
The level of children's participation in daily life activities
Timepoint
All study variables will be assessed before the start, after the intervention (day 14), and one month after the intervention (follow-up assessment).
Method of measurement
Canadian occupational performance measure

2

Description
Assessing the ability level of children's balance and lower extremities
Timepoint
All study variables will be assessed before the start, after the intervention (day 14), and one month after the intervention (follow-up assessment).
Method of measurement
Pediatric balance scale

3

Description
Assessing children's manual skills
Timepoint
All study variables will be assessed before the start, after the intervention (day 14), and one month after the intervention (follow-up assessment).
Method of measurement
Children's Hand-use Experience Questionnaire

Secondary outcomes

1

Description
Assessment of gross motor skills
Timepoint
All study variables will be assessed before the start, after the intervention (day 14), and one month after the intervention (follow-up assessment).
Method of measurement
The Gross Motor Function Measure

2

Description
Assessing the level of upper extremities ability and manual dexterity
Timepoint
All study variables will be assessed before the start, after the intervention (day 14), and one month after the intervention (follow-up assessment).
Method of measurement
Box and Block Test

3

Description
Investigating the level of children's participation in daily life activities
Timepoint
All study variables will be assessed before the start, after the intervention (day 14), and one month after the intervention (follow-up assessment).
Method of measurement
Pediatric Evaluation of Disability Inventory

Intervention groups

1

Description
Intervention group: In the intervention group, which consists of 15 children, children with unilateral cerebral palsy receive bilateral upper and lower limb exercises, the precise protocol of which was designed by a panel of experts. The intervention is provided over 14 days both in the clinic setting and remotely (online). The number of hours of intervention in face-to-face sessions ranges from 3 to 5 hours, depending on the conditions (the child's attention level, etc.).
Category
Rehabilitation

2

Description
Control group: In this group, children with unilateral spastic hemiplegic cerebral palsy will receive routine occupational therapy to treat this condition.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Tavanyaab Rehabilitation Center
Full name of responsible person
Marzieh Pashmdar Fard
Street address
No. 2,Shahid Masoud Jafarzadegan Alley, Kargarshmal Street ,Enghelab Square, Tehran,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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Tehran, Shahid Beheshti University of Medical Sciences and Health Services, Next to Ayatollah Taleghani Hospital, Shahid Arabi Street, Yemen Street, Shahid Chamran Highway
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Marzieh Pashmdar Fard
Position
assistant professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
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

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

Data Dictionary

Not applicable

Title and more details about the data/document

Group data of participants from both the control and intervention groups will be shared with professors and researchers who request the data from the corresponding author of the article via email after the intervention ends and its results are published.

When the data will become available and for how long

Group data of participants from both the control and intervention groups will be shared with professors and researchers who request the data from the corresponding author via email after the intervention ends and the resulting article is published.

To whom data/document is available

Group data of participants from both the control and intervention groups will be shared with professors and researchers who request the data via email from the corresponding author of the article after the intervention ends.

Under which criteria data/document could be used

For each author who requests information, details, and the reason for requesting the data via email from the corresponding author, after reviewing with the other authors, group data of the participants in 2 groups will be provided.

From where data/document is obtainable

For each author who requests information, details, and the reason for requesting the data via email from the corresponding author, after reviewing with the other authors, group data of the participants in 2 groups will be provided.

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

For each author who requests information, details, and the reason for requesting the data via email from the corresponding author, after reviewing with the other authors, group data of the participants in 2 groups will be provided.

Comments