

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Effectiveness of occupation-based bilateral 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 bilateral occupational-based exercises 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 5 hours a day, 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, which means the child must be between 6 and 12 years old. 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 pre-arranged 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

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20241119063772N1**

Registration date: **2025-05-08, 1404/02/18**

Registration timing: **prospective**

Last update: **2025-05-08, 1404/02/18**

Update count: **0**

##### 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)

##### Phone

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##### 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**

Effectiveness of occupation-based bilateral training on participation in Activities of Daily Livings (ADLs) in 6-12 years old children with unilateral spastic cerebral palsy

**Public title**

Effectiveness of occupation-based bilateral 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

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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

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**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**

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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

##### **Street address**

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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USRC@sbmu.ac.ir

**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

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**Full name of responsible person**  
Marzieh Pashmdar Fard

**Position**  
assistant professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Occupational Therapy

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Position**  
student

**Latest degree**  
Bachelor

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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**