

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of Action Observation on upper extremity function of hemiplegic children from 3 to 5 years old

#### Protocol summary

##### Study aim

Determining the effect of using movement observation on upper limb function of children with cerebral palsy, hemiplegia, aged 3 to 5 years.

##### Design

The clinical trial will have a control group with parallel groups and simple randomization by the method of even and odd numbers in two groups.

##### Settings and conduct

Samples will be collected as available from occupational therapy clinics. The study is blinded.

##### Participants/Inclusion and exclusion criteria

1) Children diagnosed with hemiplegic cerebral palsy by a pediatric neurologist 2) Age range from 3 to 5 years 3) Mother being a housewife 4) Absence of vision and hearing problems 5) IQ above 70 based on Sparkle questionnaire 6) Modified Ashworth score less than 3 in passive upper limb movements 7) mini-MACS score maximum 3 for children 3-4 years old and MACS score maximum 3 for children 4-5 years old

##### Intervention groups

In the intervention group, in addition to the routine occupational therapy interventions, the movement observation approach will be used in such a way that the samples will receive 4 weeks of intervention (5 days a week and 30 minutes each time) at home with the guidance of the therapist and by the mother. In the control group, only routine occupational therapy treatments including botox injection along with upper limb training, forced therapeutic restriction, intensive bimanual training and neurodevelopmental therapy are performed.

##### Main outcome variables

The quality of upper limb function, bimanual function and dexterity are the main variables.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20241016063385N1**  
Registration date: **2024-10-22, 1403/08/01**  
Registration timing: **prospective**

Last update: **2024-10-22, 1403/08/01**

Update count: **0**

##### Registration date

2024-10-22, 1403/08/01

##### Registrant information

##### Name

Sara Rahmanian Kooshkaki

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5444 2348

##### Email address

sarahmanian@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-11-05, 1403/08/15

##### Expected recruitment end date

2024-12-05, 1403/09/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Action Observation on upper extremity function of hemiplegic children from 3 to 5 years old

**Public title**

Effects of Action Observation on upper extremity function

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Children diagnosed with hemiplegic cerebral palsy by a pediatric neurologist Age range from 3 to 5 years Mother being a housewife Absence of vision and hearing problems IQ above 70 based on Sparkle questionnaire Modified Ashworth score less than 3 in passive upper limb movements mini-MACS score maximum 3 for children 3-4 years old and MACS score maximum 3 for children 4-5 years old Ability to follow instructions Lack of uncontrolled seizures Children should not receive any intervention other than routine treatments during the 4 weeks of AO intervention.

**Exclusion criteria:**

Botox injection during intervention Seizures while studying Non-cooperation of parents or child

**Age**

From **3 years** old to **5 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Considering that in this study the samples are entered gradually, each of the samples is assigned a number from one to the last, and to remove the bias of the researcher, it was initially decided that the samples with odd numbers entered the intervention group and Samples with even numbers enter the control group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Shahid Beheshti University of Medical Sciences

**Street address**

Shahid Beheshti University Faculty of Rehabilitation

Sciences, Imam Hossein Square, Damavand St., in front of Bo Ali Hospital, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1616913111

**Approval date**

2023-07-31, 1402/05/09

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1402.241

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

Cerebral palsy, hemiplegia

**ICD-10 code**

Cerebral p

**ICD-10 code description**

G80

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

Quality of upper extremity

**Timepoint**

At the beginning of the study and 4 weeks after the start of the intervention and 2 weeks after the end of the intervention

**Method of measurement**

Quest

**2****Description**

Bimanual function

**Timepoint**

At the beginning of the study and 4 weeks after the start of the intervention and 2 weeks after the end of the intervention

**Method of measurement**

ABILHAND-Kids

**3****Description**

dexterity

**Timepoint**

At the beginning of the study and 4 weeks after the start of the intervention and 2 weeks after the end of the intervention

**Method of measurement**

Nine hole peg test

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: In this study, the intervention group will undergo movement observation therapy in five sessions of 30 minutes per week for 4 weeks. Before starting, the parents of the intervention group will spend a training session in groups of three to four people to learn how to implement the treatment in the home environment, then they will enter a virtual group that will explain the framework of the activities and how to implement each one in this group. Activities (stacking colored cubes and building a tower, removing the stamp and pressing it on the paper in the horizontal and vertical plane to print the shape, turning over the colored cards and matching with the card of the same color, removing the magnet and putting it on the fridge, pouring water inside glass and drinking water, taking the pencil and drawing on the paper, pressing the water spray on the flowers, Folding a shirt, taking a coin and putting it in a wallet, opening a container and taking a chocolate out of it, putting cards in a clothespin, opening toothpaste and pouring it on a toothbrush) are divided into 4 sets of three according to the level of each child and her cooperation. The intervention program takes place in the home environment. The therapist defines the framework for each activity and the equipment needed for the parent. At the appropriate time, the parent should perform the activities that include targeted daily one-handed or two-handed activities from simple to complex within the said framework for 3 minutes for the child. Then, for 3 minutes, the child practices the activity with the help and guidance of the caregiver, and then we give the child 3 minutes to imitate the activity. The execution method for the other two activities is the same.

#### Category

Rehabilitation

### 2

#### Description

Control group: The control group does not receive any other intervention apart from the usual occupational therapy interventions (including botox injection along with upper limb training, forced therapeutic restriction, intensive bimanual training and neurodevelopmental therapy).

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tavanyab NGO

##### Full name of responsible person

Sahar Firoozbakht

##### Street address

No. 2, Shahid Jafarzadegan Alley, North Kargar St.,  
Revolution Square

##### City

Tehran

##### Province

Tehran

##### Postal code

0000000000

##### Phone

+98 21 6693 5533

##### Email

anjoman.ehya1@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Minoo Kalantari

##### Street address

Imam Hossein Square, in front of Bu Ali Hospital,  
Faculty of Rehabilitation of Shahid Beheshti University  
of Medical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

1616913111

##### Phone

+98 21 7756 1721

##### Email

info@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

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Sara Rahmani

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Occupational Therapy

**Street address**

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**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Sara Rahmania

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Occupational Therapy

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**Email**

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Sara Rahmania

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

To comply with the trust

**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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The data will be published in accordance with the principle of confidentiality and without mentioning names.

**When the data will become available and for how long**

2 months after printing the results

**To whom data/document is available**

Participants, researchers and people working in this field

**Under which criteria data/document could be used**

There is no further information.

**From where data/document is obtainable**

sarahmanian@sbmu.ac.ir

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

This confidential information will be published only with a letter from the relevant center and other health centers.

**Comments**