

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### The effect of meaningful action observation training on upper limb function and participation in 6 to 12-year-old children with spastic cerebral palsy

#### Protocol summary

##### Study aim

The effect of meaningful action observation training on upper limb function and participation of children with spastic cerebral palsy

##### Design

This study is a double-blind randomized controlled trial with a parallel design and 1:1 allocation ratio, in which 40 participants are randomly divided into control and experimental groups using computer software

##### Settings and conduct

This study is a randomized controlled trial with a parallel design that will be conducted in the rehabilitation clinic of the Iran University of Medical Sciences. In this research, the evaluator and the participants are kept blind to the study grouping. For this reason, the evaluator is selected out of the research team and the placebo is used for the control group

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: spastic cerebral palsy, 6 to 12 years old, having therapeutic priority the same as therapeutic videos, and getting less than 4 according to MACS  
Exclusion criteria: Botox injection in the upper limb, the existence of other neurological diseases, uncontrolled seizures, cognitive problems, visual and auditory deficits, and contracture in the upper limb joints

##### Intervention groups

"Intervention group": they receive traditional occupational therapy treatments along with meaningful action observation training for one month, 3 times a week. In the meaningful action observation training method, a predetermined movie of activities is played for children and they should repeat and practice the predetermined activities like those in the movie. Treatment sessions continue for 45 minutes "Control group": the intervention of the control group is identical to that of the treatment group, but participants watch cartoon pictures instead of predetermined activity

movies. The intervention lasts for one month, three times a week, and 45 minutes in each session

##### Main outcome variables

upper limb function score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160808029260N4**

Registration date: **2022-07-15, 1401/04/24**

Registration timing: **prospective**

Last update: **2022-07-15, 1401/04/24**

Update count: **0**

##### Registration date

2022-07-15, 1401/04/24

##### Registrant information

##### Name

Afsson Hassani Mehraban

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 22227124

##### Email address

mehraban.a@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-22, 1401/09/01

##### Expected recruitment end date

2023-11-22, 1402/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of meaningful action observation training on upper limb function and participation in 6 to 12-year-old children with spastic cerebral palsy

**Public title**

The effect of action observation training on upper limb function and participation in children with spastic cerebral palsy

**Purpose**

Treatment

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

Diagnosis of spastic cerebral palsy based on a review of the child's medical record 6 to 12 years old Having therapeutic priority, the same as therapeutic videos which are prepared based on the results obtained using the Canadian Occupational Performance Measure (COPM) Getting less than 4 according to Manual Ability Classification System (MACS)

**Exclusion criteria:**

Existence of uncontrolled seizures Existence of other neurological diseases based on the child's medical records Botox injection in the upper limb up to 6 months before attending the research project Existence of cognitive problems according to the SPARCLE classification system Existence of visual and auditory deficits that cannot be compensated by assistive devices Existence of contracture in the upper extremity joints based on the clinical examination of the therapist

**Age**From **6 years** old to **12 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**Target sample size: **40****Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this research, randomization will be done with the Block method using block sizes of 4 to 6 by Stata software. A statistics expert arranges the assigned order of randomized groups; He, based on this ordering, selects the study groups and puts them in separate envelopes. The envelopes are arranged according to the assigned randomized order achieved by the Block method. A person who is blind to the aims of the study, during examining the inclusion criterion and registering the client information, gives the envelopes to the

participants according to the arranged order. When the client enters the occupational therapist's room, the envelope will be opened and the study group will be assigned based on this method.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Evaluator: In this study, in order to keep the evaluator blind, an attempt is made to choose the evaluator among experts who are not in the research team and are unaware of the grouping of participants. Participants: In this study, in order to keep the participants blind, the same treatment program is considered for the control and intervention groups, but in the control group, instead of showing therapeutic videos, cartoon pictures and natural scenes are shown.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

In this study, therapeutic videos are designed according to the principles of a task-oriented approach and the participation of cerebral palsy children similar to the participants.

**Secondary Ids**

empty

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

Research Ethics Committees of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Next to Milad tower, Hemmat Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۳۹۶۱۴۵۳۵

**Approval date**

2022-03-14, 1400/12/23

**Ethics committee reference number**

IR.IUMS.REC.1400.1231

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

Cerebral palsy

**ICD-10 code**

G80

**ICD-10 code description**

Cerebral palsy

## Primary outcomes

### 1

#### **Description**

Upper limb function score

#### **Timepoint**

Before and after the intervention

#### **Method of measurement**

ABILHAND-kids questionnaire

## Secondary outcomes

### 1

#### **Description**

the score of participation in outside school activities

#### **Timepoint**

before and after the intervention

#### **Method of measurement**

The Iranian Children's Participation Assessment Scale

### 2

#### **Description**

upper limb coordination score

#### **Timepoint**

before and after the intervention

#### **Method of measurement**

The Bruininks-Oseretsky Test of Motor Proficiency

### 3

#### **Description**

upper limb speed and dexterity score

#### **Timepoint**

before and after the intervention

#### **Method of measurement**

The Bruininks-Oseretsky Test of Motor Proficiency

### 4

#### **Description**

gripping power

#### **Timepoint**

before and after the intervention

#### **Method of measurement**

The Dynamometer

### 5

#### **Description**

Range of motion

#### **Timepoint**

before and after the intervention

#### **Method of measurement**

The Goniometer

### 6

#### **Description**

occupational performance score

#### **Timepoint**

before and after the intervention

#### **Method of measurement**

The Canadian Occupational Performance Measure

## Intervention groups

### 1

#### **Description**

Intervention group: rehabilitation treatment in this group includes traditional occupational therapy service as well as "meaningful action observation training". Each session lasts for 45 minutes and it will be repeated three times a week for one month. The first 15 minutes of each session is devoted to initial preparation techniques for example muscle warming up, stretching, etc. Then, the "meaningful action observation training" method is performed. In this method, a film including a performance of a number of predetermined activities is played, and the child is required to watch the model performance in the film carefully. Next, the child should repeat the steps of the performance of the activity as in the model video. Each session, the performance of meaningful action observation training lasts for 15 minutes. Then, the traditional occupational therapy service continues for 15 minutes. These services are selected according to the needs of the participants and include strengthening exercises, balancing, coordination, etc.

#### **Category**

Rehabilitation

### 2

#### **Description**

Control group: In this group, rehabilitation treatment includes traditional occupational therapy services along with a placebo. Each session lasts for 45 minutes and it will be repeated three times a week for one month. The first 15 minutes of each session, similar to the experimental group, is devoted to initial preparation techniques for example muscle warming up, stretching, etc. Then, the child watches nature scenes and cartoon pictures (as a placebo) and practices predetermined treatment activities continue for 15 minutes. These activities are similar to those of the intervention group and their Placebo videos are similar to treatment videos in the intervention group in terms of length and repetition. The last 15 minutes of each session, are devoted to traditional occupational therapy services. These services are selected according to the needs of the participants from strengthening exercises, balancing, coordination, etc.

#### **Category**

Rehabilitation

## Recruitment centers

### 1

#### **Recruitment center**

**Name of recruitment center**

School of Rehabilitation Sciences of Iran University of Medical Sciences

**Full name of responsible person**

Samira Boroumand

**Street address**

School of Rehabilitation, Madadkaran Alley,  
Shahnazari Street, Madar Square, Mirdamad  
Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

15459-13487

**Phone**

+98 21 2222 2059

**Email**

sa.boroumand@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Hossein keyvani

**Street address**

Iran University of Medical Sciences, next to Milad  
Tower, Hemmat Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 8670 2503

**Fax**

+98 21 8862 2703

**Email**

mehraban.a@iums.ac.ir

**Grant name**

**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**

Afsoon Hassani Mehraban

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Therapy

**Street address**

School of Rehabilitation, Madadkaran Alley,  
Shahnazari Street, Madar Square, Mirdamad  
Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

15459-13487

**Phone**

+98 21 2222 2059

**Email**

mehraban.a@iums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Afsoon Hassani Mehraban

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Therapy

**Street address**

School of Rehabilitation, Madadkaran Alley,  
Shahnazari Street, Madar Square, Mirdamad  
Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

15459-13487

**Phone**

+98 21 2222 2059

**Email**

mehraban.a@iums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Samira Boroumand

**Position**

Ph.D. Candidate

**Latest degree**

Master

**Other areas of specialty/work**

Occupational Therapy

**Street address**

School of Rehabilitation, Madadkaran Alley,  
Shahnazari Street, Madar Square, Mirdamad  
Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

15459-13487

**Phone**

+98 21 2222 2059

**Email**

sa.boroumand@yahoo.com

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

Yes - There is 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

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

demographic data of the study participants after making them unidentifiable; Primary and secondary outcome information

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

After publishing the results of the study

**To whom data/document is available**

Researchers who are working in academic and scientific institutions

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

For doing meta-analysis review studies

**From where data/document is obtainable**

1) Samira Boroumand Phone number:0098 9365799466  
Email address: Sa.boroumand@yahoo.com Address:  
School of Rehabilitation, Madadkaran Alley, Shahnazari  
Street, Madar Square, Mirdamad Boulevard, Tehran, Iran  
2) Afsoon Hassani Mehraban Phone number: 0098 21  
22228051 Email address: mehraban.a@iums.ac.ir  
Address: School of Rehabilitation, Madadkaran Alley,  
Shahnazari Street, Madar Square, Mirdamad Boulevard,  
Tehran, Iran

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

The researcher can access the data of this research up to one month after sending the request and attaching the registered protocol of the review article to the introduced emails.

**Comments**