

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of occupation-based modified constraint-induced movement therapy on participation children with cerebral palsy: A double-blind randomized controlled trial

#### Protocol summary

##### Study aim

The aim of this study was to investigate the effect of constraint induced movement therapy using with activity analysis strategy on participation of children with hemiplegia and emphasis on generalizing skills that learned in activities of daily living; the treatment of each child is based on the client centered paradigm in occupational therapy and is special for each child and the goals of the treatment will be based on what child and their parent wants.

##### Design

Clinical trial with intervention and control group, single blind, and randomized by stratified randomization .

##### Settings and conduct

interventions are performed by parents at home based on the treatment plan and training that provided by the therapist. This study is a double blind, and the assessor and participants will be blind at all stages of the study.

##### Participants/Inclusion and exclusion criteria

Children between the ages of 5 and 12 who have been diagnosed with hemiplegia and have good balance and no history of seizure or have controlled seizures, and do not intend to inject Botox or surgery during the intervention. They also have the ability to tolerate the restriction of less affected upper extremity.

##### Intervention groups

In the intervention group, the m-CIMT technique will be performed by using the activity analysis strategy and will be done based on the goals that child and their parent wants, and in the control group, the m-CIMT technique will be performed routinely and will be done based on the goals that child and their parent wants.

##### Main outcome variables

participation; manual ability

#### General information

##### Reason for update

Based on the reviews done during the study, it was decided to shorten the title. Also, during the sampling, the parents agreed not to be aware of the allocation in the groups in order to make the study result more valuable. For this reason, the double-blind was added in title and its type was changed in the blinding field. Also, the start and end dates of sampling were updated. goal attainment scaling was added to primary measures.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191109045376N1**

Registration date: **2020-07-16, 1399/04/26**

Registration timing: **prospective**

Last update: **2021-05-09, 1400/02/19**

Update count: **1**

##### Registration date

2020-07-16, 1399/04/26

##### Registrant information

###### Name

Ali Ostadzadeh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4407 2090

###### Email address

ostadzadeh.a@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-22, 1399/05/01

**Expected recruitment end date**

2020-10-22, 1399/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of occupation-based modified constraint-induced movement therapy on participation children with cerebral palsy: A double-blind randomized controlled trial

**Public title**

Investigating the effect of using activity analysis strategy when using m-CIMT

**Purpose**

Other

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

The child has been diagnosed by a neurologist with cerebral palsy The child has levels I, II and III of the MACS scale The child can actively extend the wrist of the affected limb by 20 degrees The child can actively extend the fingers of the affected limb by 10 degrees The child achieve score above 44 in PBS test The child does not have vision problems The child does not have a behavioral problem that can withstand the restriction The child's IQ is above 70 The child has not received upper limb surgery and Botox injections in the past 6 months and does not intend to do so during the interventions

**Exclusion criteria:**

Lack of desire of family or child to continue interventions

**Age**

From **5 years** old to **12 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A stratified randomization is performed to assign children to groups. Two categories, MACS level I and II and MACS level III, are included in the table of random numbers. Plaques are enclosed in matte numbered sealed envelopes that are stored by the therapist.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the assessor will be blind at all stages, the assessment before the intervention, the assessment after the intervention, and the assessment at the time of

follow-up, and the assessor will not know which group each child is in. Also, parents and clients will not be informed about the assignment in the groups.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of IranUniversity of Medical Sciences

**Street address**

No. 39, Unit 5, Asadi Alley, between Jeyhun and Zanjan, Toos St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1343977753

**Approval date**

2020-04-15, 1399/01/27

**Ethics committee reference number**

IR.IUMS.REC.1399.299

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

cerebral palsy

**ICD-10 code**

G80.2

**ICD-10 code description**

Spastic hemiplegic cerebral palsy

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

The score obtained is related to the two categories of satisfaction and performance in the canadian occupational performance measure questionnaire

**Timepoint**

Measure participation at the beginning of the study (before the intervention), 1 and 3 months after the start of the intervention.

**Method of measurement**

Canadian occupational performance measure questionnaire

## 2

### **Description**

Score obtained from the amount of goal achievement by the goal attainment scaling tool

### **Timepoint**

Measure participation at the beginning of the study (before the intervention), 1 and 3 months after the start of the intervention.

### **Method of measurement**

goal attainment scaling

## **Secondary outcomes**

## 1

### **Description**

Score obtained in the ABILHAND-Kids questionnaire

### **Timepoint**

Measure manual ability at the beginning of the study (before the intervention), 1 and 3 months after the intervention.

### **Method of measurement**

ABILHAND-Kids questionnaire

## 2

### **Description**

Score obtained in the pediatric motor activity log questionnaire

### **Timepoint**

Measure manual ability at the beginning of the study (before the intervention), 1 and 3 months after the intervention.

### **Method of measurement**

pediatric motor activity log questionnaire

## **Intervention groups**

## 1

### **Description**

Intervention group: Based on the set goals, the child will be analyzed on the basis of OTPF motor skills items. Then, based on the child's defects based on OTPF activity analysis items, according to the interests of each child, a treatment plan in the form of play and activities of daily living is designed and graded based on the principles of motor learning by the therapist and given to parents to practice with the child. Parents will also be given the necessary training (the nature and manner of doing exercises such as shaping, hardening, and repetition) to perform interventions at home. Participants in this group will be treated at home for 4 weeks, 3 days a week and 1 hour a day by the parents according to the program prepared by the therapist, during this time the less affected upper extremity will be restricted by the strap. Also, a less affected upper extremity will be restricted to 5 to 6 hours apart from interventions during activities of daily living. At the end of each session, the therapist will call with each parents and asked about the time limit and activities during intervention restriction time and other

restriction time and activities are done by child in non-restricted time, and based on the purpose of the study (performing M-CIMT interventions based on activity analysis), parents will be given the necessary feedback.

### **Category**

Rehabilitation

## 2

### **Description**

Control group: According to the child's interests, the treatment plan in the form of play and activities of daily living is designed and graded (being more difficult) based on principles of motor learning by the therapist and given to the parents to practice with the child at home. Parents will also be given the necessary training (the nature and manner of doing exercises such as shaping, hardening, and repetition) to perform interventions at home. Participants in this group will receive routine m-CIMT interventions (without activity analysis and no emphasis on defects in OTPF activity analysis items when performing this technique); The duration of the interventions will be the same as the intervention group for 4 weeks, 3 days a week and 1 hour per day. Also, less affected upper extremity will be restricted 5 to 6 hours apart from interventions during daily life activities. At the end of each session, the therapist will call with each parents and asked about the time limit and activities during intervention restriction time and other restriction time and activities are done by child in non-restricted time, and based on the purpose of the study (performing routine m-CIMT interventions without activity analysis), parents will be given the necessary feedback.

### **Category**

Rehabilitation

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

occupational therapy clinic of school rehabilitation of Iran University of Medical Sciences and othe

#### **Full name of responsible person**

Malek amini

#### **Street address**

Madadkaran St., Shah Nazari St., Madar Square, Mirdamad Blvd, Tehran

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1545913487

#### **Phone**

+98 21 2222 7124

#### **Email**

rehab@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Abbas Motevalian

**Street address**

Next to Milad Tower, Hemmat Highway, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 8670 2503

**Email**

research-m@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**

Malek Amini

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Therapy

**Street address**

Madadkaran St., Shah Nazari St., Madar Square, Mirdamad Blvd, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1545913487

**Phone**

0098 21 222228051

**Email**

malekamini8@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Malek Amini

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Therapy

**Street address**

Madadkaran St., Shah Nazari St., Madar Square, Mirdamad Blvd, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1545913487

**Phone**

0098 21 222228051

**Email**

malekamini8@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Ali Ostadzadeh

**Position**

MSc student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Occupational Therapy

**Street address**

No. 39, Unit 5, Asadi Alley, Between Jeyhun and Zanjan, Toos St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1343977753

**Phone**

+98 21 6604 8100

**Email**

aliostadzadeh4@gmail.com

## **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