Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 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 extrimity will be restricted by the strap. Also, a less affected upper extrimity 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