Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Name of organization / entity
Iran University of Medical Sciences

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Iran (Islamic Republic of)

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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
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Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
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
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Sponsors / Funding sources

1

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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
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Person responsible for updating data

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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
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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