

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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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

City

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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

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

Occupational Therapy

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Latest degree

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Person responsible for updating data

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Full name of responsible person

Samira Boroumand

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Other areas of specialty/work

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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

1) Samira Boroumand Phone number:0098 9365799466
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School of Rehabilitation, Madadkaran Alley, Shahnazari
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2) Afsoon Hassani Mehraban Phone number: 0098 21
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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