

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Action Observation on upper extremity function of hemiplegic children from 3 to 5 years old

Protocol summary

Study aim

Determining the effect of using movement observation on upper limb function of children with cerebral palsy, hemiplegia, aged 3 to 5 years.

Design

The clinical trial will have a control group with parallel groups and simple randomization by the method of even and odd numbers in two groups.

Settings and conduct

Samples will be collected as available from occupational therapy clinics. The study is blinded.

Participants/Inclusion and exclusion criteria

1) Children diagnosed with hemiplegic cerebral palsy by a pediatric neurologist 2) Age range from 3 to 5 years 3) Mother being a housewife 4) Absence of vision and hearing problems 5) IQ above 70 based on Sparkle questionnaire 6) Modified Ashworth score less than 3 in passive upper limb movements 7) mini-MACS score maximum 3 for children 3-4 years old and MACS score maximum 3 for children 4-5 years old

Intervention groups

In the intervention group, in addition to the routine occupational therapy interventions, the movement observation approach will be used in such a way that the samples will receive 4 weeks of intervention (5 days a week and 30 minutes each time) at home with the guidance of the therapist and by the mother. In the control group, only routine occupational therapy treatments including botox injection along with upper limb training, forced therapeutic restriction, intensive bimanual training and neurodevelopmental therapy are performed.

Main outcome variables

The quality of upper limb function, bimanual function and dexterity are the main variables.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241016063385N1**
Registration date: **2024-10-22, 1403/08/01**
Registration timing: **prospective**

Last update: **2024-10-22, 1403/08/01**

Update count: **0**

Registration date

2024-10-22, 1403/08/01

Registrant information

Name

Sara Rahmanian Kooshkaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5444 2348

Email address

sarahmanian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-05, 1403/08/15

Expected recruitment end date

2024-12-05, 1403/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Action Observation on upper extremity function of hemiplegic children from 3 to 5 years old

Public title
Effects of Action Observation on upper extremity function

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children diagnosed with hemiplegic cerebral palsy by a pediatric neurologist Age range from 3 to 5 years Mother being a housewife Absence of vision and hearing problems IQ above 70 based on Sparkle questionnaire Modified Ashworth score less than 3 in passive upper limb movements mini-MACS score maximum 3 for children 3-4 years old and MACS score maximum 3 for children 4-5 years old Ability to follow instructions Lack of uncontrolled seizures Children should not receive any intervention other than routine treatments during the 4 weeks of AO intervention.

Exclusion criteria:

Botox injection during intervention Seizures while studying Non-cooperation of parents or child

Age

From **3 years** old to **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Considering that in this study the samples are entered gradually, each of the samples is assigned a number from one to the last, and to remove the bias of the researcher, it was initially decided that the samples with odd numbers entered the intervention group and Samples with even numbers enter the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University Faculty of Rehabilitation

Sciences, Imam Hossein Square, Damavand St., in front of Bo Ali Hospital, Tehran

City

Tehran

Province

Tehran

Postal code

1616913111

Approval date

2023-07-31, 1402/05/09

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.241

Health conditions studied

1

Description of health condition studied

Cerebral palsy, hemiplegia

ICD-10 code

Cerebral p

ICD-10 code description

G80

Primary outcomes

1

Description

Quality of upper extremity

Timepoint

At the beginning of the study and 4 weeks after the start of the intervention and 2 weeks after the end of the intervention

Method of measurement

Quest

2

Description

Bimanual function

Timepoint

At the beginning of the study and 4 weeks after the start of the intervention and 2 weeks after the end of the intervention

Method of measurement

ABILHAND-Kids

3

Description

dexterity

Timepoint

At the beginning of the study and 4 weeks after the start of the intervention and 2 weeks after the end of the intervention

Method of measurement

Nine hole peg test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, the intervention group will undergo movement observation therapy in five sessions of 30 minutes per week for 4 weeks. Before starting, the parents of the intervention group will spend a training session in groups of three to four people to learn how to implement the treatment in the home environment, then they will enter a virtual group that will explain the framework of the activities and how to implement each one in this group. Activities (stacking colored cubes and building a tower, removing the stamp and pressing it on the paper in the horizontal and vertical plane to print the shape, turning over the colored cards and matching with the card of the same color, removing the magnet and putting it on the fridge, pouring water inside glass and drinking water, taking the pencil and drawing on the paper, pressing the water spray on the flowers, Folding a shirt, taking a coin and putting it in a wallet, opening a container and taking a chocolate out of it, putting cards in a clothespin, opening toothpaste and pouring it on a toothbrush) are divided into 4 sets of three according to the level of each child and her cooperation. The intervention program takes place in the home environment. The therapist defines the framework for each activity and the equipment needed for the parent. At the appropriate time, the parent should perform the activities that include targeted daily one-handed or two-handed activities from simple to complex within the said framework for 3 minutes for the child. Then, for 3 minutes, the child practices the activity with the help and guidance of the caregiver, and then we give the child 3 minutes to imitate the activity. The execution method for the other two activities is the same.

Category

Rehabilitation

2

Description

Control group: The control group does not receive any other intervention apart from the usual occupational therapy interventions (including botox injection along with upper limb training, forced therapeutic restriction, intensive bimanual training and neurodevelopmental therapy).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tavanyab NGO

Full name of responsible person

Sahar Firoozbakht

Street address

No. 2, Shahid Jafarzadegan Alley, North Kargar St.,
Revolution Square

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Email

anjoman.ehya1@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Minoo Kalantari

Street address

Imam Hossein Square, in front of Bu Ali Hospital,
Faculty of Rehabilitation of Shahid Beheshti University
of Medical Sciences

City

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1616913111

Phone

+98 21 7756 1721

Email

info@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sara Rahmadian

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sara Rahmania

Position

student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sara Rahmania

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

To comply with the trust

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data will be published in accordance with the principle of confidentiality and without mentioning names.

When the data will become available and for how long

2 months after printing the results

To whom data/document is available

Participants, researchers and people working in this field

Under which criteria data/document could be used

There is no further information.

From where data/document is obtainable

sarahmanian@sbmu.ac.ir

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

This confidential information will be published only with a letter from the relevant center and other health centers.

Comments