Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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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
dextrity
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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Minoo Kalantari

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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
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 Rahmanian

Position
student
Latest degree
Bachelor
Other areas of specialty/work
Occupational Therapy
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Person responsible for updating data

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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
sararahmanian@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