Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

study of the effect of mirror therapy on upper limb function in the children with hemiplegic cerebral palsy aged 9_14 years old

Protocol summary

Study aim
Comparison of the mean score of Dexterity,supination and wrist extention and grasp of the affected limb before and after the intervention in two groups of control and intervention in children and adolescents of spastic hemiplegia aged 9 to 14 years

Design
The subjects of the study group were selected in a sample size of 30 people and randomly selected (draw) in the control and intervention groups. This study is based on a single blind clinical evaluation.

Settings and conduct
The study site is a rehabilitation center. For both individuals, the routine occupational therapy program is performed. the subjects in the intervention group are treated with a mirror for 5-6 weeks and one day (three days a week) and each session for 30 minutes by the researcher. The initial and final evaluation is done by another therapist who is not aware of the division of the groups

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of spastic hemiplegic cerebral palsy by a pediatric neurologist Children and adolescents aged 14 to 9 years. No Botox injection in the upper 6 months Exclusion criteria: If the child or his family are reluctant to continue treatment at each stage of the treatment If he or she participates in another program at the same time

Intervention groups
People are divided into two groups: intervention and control. Individuals of both groups are under the routine rehabilitation program. In addition to the current program, the intervention group undergoes mirror therapy for 6 weeks and 3 days a week

Main outcome variables
In this study, variables such as Dexterity, forearm Supination and Wrist extention, and Grasp are examined

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180627040262N1**
Registration date: **2018-07-11, 1397/04/20**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-11, 1397/04/20**
Update count: **0**

Registration date
2018-07-11, 1397/04/20

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-07-06, 1397/04/15
Expected recruitment end date
2018-08-11, 1397/05/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

study of the effect of mirror therapy on upper limb function in the children with hemiplegic cerebral palsy aged 9_14 years old

Public title
Effect of mirror therapy in cerebral palsy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of spastic hemiplegic cerebral palsy by pediatric neurologist Children aged 9 to 14 years old Lack of cognitive impairment and half-body forgetfulness and lack of orthopedic defects based on expert examination and diagnosis Non-verbal and visual impairment based on a doctor's examination no surgical procedures including tendon transfer Having attention and concentration to the mirror and the ability to perform the relevant exercises within a specified time (at least 10 minutes) based on the interventionist view Acquire level1 - 3 of the Manual Ability classification System (MACS) Tone of the affected upper limb less than or equal to 2, was corrected based on the modified Ashworth scale. Not having Botox injections over the last 6 months
Exclusion criteria:
Patients who for any reason have more than four alternate sessions or two consecutive sessions unable to participate in the program are excluded If the child or his family are reluctant to continue treatment at each stage of the treatment If the child fails to focus on the duration of the treatment If he or she participates in another program at the same time
Age
From **9 years** old to **14 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this clinical trial study, a list of spastic hemiplegia children and adolescents in public, private and extraordinary schools in Tabriz, which were in the age range of 14 to 9 years old, were selected and entered randomly. (Lottery) were divided into two groups of control and intervention.
Blinding (investigator's opinion)
Single blinded
Blinding description
The initial evaluation and final evaluation will be done by another therapist who is not aware of the grouping of the groups. . Individuals' referrals for implementing the therapeutic interventions of the two control and intervention groups are adjusted so that the two groups do not have contact during the study.
Placebo
Not used
Assignment
Other
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
Ayatollah Taleghani Hospital, Shahid Araghi Shaheed Ave, Yemeni Ave, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2017-10-07, 1396/07/15
Ethics committee reference number
IR.SBMU.RETECH.REC.1396.409

Health conditions studied

1

Description of health condition studied
Hemiplegic Cerebral Palsy
ICD-10 code
G80.2
ICD-10 code description
Spastic hemiplegic cerebral palsy

Primary outcomes

1

Description
Dexterity
Timepoint
Measurement of dexterity before intervention and after intervention
Method of measurement
Dexterity is measured using box and block.

2

Description
Active ROM of wrist extention and Supination
Timepoint
Measurement of ROM before intervention and after intervention

Method of measurement
ROM is measured using Guniameter

3

Description
Grasp
Timepoint
Measurement of Grasp before intervention and after intervention
Method of measurement
Grasp is measured using Dynamometer

4

Description
Upper limb function
Timepoint
Measurement of Upper limb function before intervention and after intervention
Method of measurement
Upper limb function is measured using Fugle meyer test

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: In addition to the routine rehabilitation program, the subjects in the intervention group receive mirror therapy for 6 weeks (three days a week) and each session for 30 minutes. In the routine rehabilitation program, Bobath exercises, such as RIP, active and passive exercises(flexion, and extension of the shoulder, elbow, and wrists) are used. In addition to these exercises, several functional exercises, such as bring a cup up into the mouth, drawing a circle and, squeeze a towel will done.
Category
Rehabilitation

2

Description
Control group:subjects in this group receive a routine rehabilitation for six weeks. In the routine rehabilitation program, Bobath exercises, such as RIP, active and passive exercises(flexion, and extension of the shoulder, elbow, and wrists) are used. In addition to these exercises, several functional exercises, such as bring a cup up into the mouth, drawing a circle and, squeeze a towel will done.program
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ofogh
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
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
20
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
Akbar Narimani

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Occupational Therapy

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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
According to the request of the participants, the information remains confidential

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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Data is published as an article

When the data will become available and for how long
After thesis and collecting data

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
For use in similar research

From where data/document is obtainable
The author of the article extracted from the research project

What processes are involved for a request to access data/document
Contact authors by mentioning the reason for using the data

Comments