

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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 extension 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 extension, 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

Name

Akbar Narimani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3288 0817

Email address

minookalantari@sbmu.ac.ir

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 extension and Supination

Timepoint

Measurement of ROM before intervention and after intervention

Method of measurement

ROM is measured using Guniometer

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

Akbar Narimani

Street address

2nd Floor, Atteba building, Next to Nikookari Hospital, Abbasi Street

City

Tabriz

Province

East Azarbaijan

Postal code

5186836453

Phone

+98 41 3659 0565

Email

minookalantari@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Minoo Kalantari

Street address

Ayatollah Taleghani Hospital, Shahid Araghi Ave, Yemeni Ave, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 7756 1721

Email

mn_kalantari@email.com

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

Street address
6th Floor, Next to Sahel Pool, Azarbaijan Ave

City
Tabriz

Province
East Azarbaijan

Postal code
5186836453

Phone
+98 41 3288 0817

Email
narimani.ofogh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Minoos Kalantari

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

Street address
at the Bu'ali Hospital, Damavand Avenue (Tehran-Nou), Imam Hossein Square

City
Tehran

Province
Tehran

Postal code
1616913111

Phone
+98 21 7756 1721

Email
mn_kalantari@yahoo.com

Person responsible for updating data

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

Street address
6th floor, Milad Building, Next to sahel, Azarbaijan Ave

City
Tabriz

Province
East Azarbaijan

Postal code
5186836453

Phone
+98 41 3288 0817

Email
narimani.ofogh@gmail.com

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