Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The efficacy of mirror therapy on lower limb motor function in children with Hemiplegic cerebral palsy 5 to 12 years

Protocol summary

Study aim
Evaluation of the effectiveness of mirror therapy on lower limb motor function in children with hemiplegic cerebral palsy aged 5 to 12 years.

Design
The clinical trial consists of a control group and a treatment group, double blind study, randomized by lottery method.

Settings and conduct
To evaluate people, they refer to the movement laboratory of Shahid Beheshti Rehabilitation School and to perform the intervention to Tavanyab Rehabilitation Clinic. At the beginning and end of the intervention, two stages of evaluation are performed and one month after the end of the intervention, the last stage of evaluation is performed.

Participants/Inclusion and exclusion criteria
Having a diagnosis of spastic hemiplegia cerebral palsy Ability to walk independently at least 10 meters Absence of uncontrolled seizures No orthopedic surgery on the lower extremities Absence of fixed limitations in the lower limb joints Do not inject Botox for at least 6 months before the intervention No visual or auditory problems that have not been corrected or treated Ability to follow verbal instructions GMFCS levels one and two Absence of hemianopsia and unilateral neglect Absence of other neurological diseases The modified Ashworth Scale is less than 3

Intervention groups
The intervention is held for both groups 5 sessions per week for one month. Each session consists of 30 minutes of conventional occupational therapy intervention and 15 minutes of mirror therapy. Then, while people should look at the image of a healthy body in the mirror (in the control group, people look at the image of the affected side in the mirror), people are asked to do the following three movements: 1. Ankle dorsiflexion with knee extension 2.flexion knee, ankle and hip joints 3. flexion the knee more than 90 degrees.

Main outcome variables
Static/dynamic balance, step/stride length, stance/swing phase time, spasticity score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211106052977N1**
Registration date: **2022-08-12, 1401/05/21**
Registration timing: **retrospective**

Last update: **2022-08-12, 1401/05/21**
Update count: **0**

Registration date
2022-08-12, 1401/05/21

Registrant information

Name
Javad Alipour

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
2021-05-10, 1400/02/20

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
2021-06-22, 1400/04/01

Actual recruitment end date

2022-07-21, 1401/04/30

Trial completion date

2022-08-06, 1401/05/15

Scientific title

The efficacy of mirror therapy on lower limb motor function in children with Hemiplegic cerebral palsy 5 to 12 years

Public title

The effect of mirror therapy on the lower extremities of children with Hemiplegic cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The child should be between 5 and 12 years old. The child should be diagnosed with spastic hemiplegia according to a pediatric neurologist. The child must be able to walk independently at least 10 meters. The child's muscle tone should be less than 3 on the MODIFIED ASHWORTH scale. The child must be able to follow verbal instructions. The child should be at levels one and two according to the GMFCS scale in terms of gross motor function.

Exclusion criteria:

The child has uncontrolled seizures. The child has a cognitive disability according to medical history. The child has a problem with hemianopia and unilateral neglect. The child has other neurological diseases. The child has had orthopedic surgery on the lower limb according to medical history. The child has a fixed limit on range of motion in the lower limb joints. According to medical history, the child has Auditory acuity problems that have not been corrected or treated. According to medical history, the child has Visual acuity problems that have not been corrected or treated. The child had a Botox injection in the lower limb for up to 6 months before the intervention.

Age

From **5 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **24**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

By simple random sampling using lottery (random allocation law) and without placement (according to the number of people in both groups, the two letters A and B, where the letter A represents the control group and the letter B represents the treatment group, on paper In the next step, the papers are poured into the bag, then the papers are randomly removed from the bag without replacement and the sequence created is recorded.) The children are divided into a control group and a treatment group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this research, participants are unaware that they are in the control or treatment group because the treatment group receives mirror therapy and the control group receives sham therapy. The evaluator is also unaware of the assignment of individuals to the control and treatment group. In addition, the data analyzer is unaware of assigning individuals to the control and treatment groups because they are defined as groups A and B.

Placebo

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

No 26, shiraz Street, west zayandeh rood Avenue, vanak square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1991613651

Approval date

2021-03-09, 1399/12/19

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.1382

Health conditions studied

1

Description of health condition studied

cerebral palsy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Dynamic balance score in the timed up and go test

Timepoint

Determining the dynamic balance score before the intervention, at the end of the intervention period and one month after the intervention

Method of measurement

Timed Up and Go Test

2

Description

Static balance score in the pediatric balance scale

Timepoint

Determining the static balance score before the intervention, at the end of the intervention period and one month after the intervention

Method of measurement

pediatric balance scale

3

Description

Step length obtained by analyzing data of gait analysis system

Timepoint

Determining the length of the step before the intervention, at the end of the intervention period and one month after the intervention

Method of measurement

gait analysis system

4

Description

stride length obtained by analyzing data of gait analysis system

Timepoint

Determining the length of the stride before the intervention, at the end of the intervention period and one month after the intervention

Method of measurement

gait analysis system

5

Description

stance phase time obtained by analyzing data of gait analysis system

Timepoint

Determining the stance phase time before the intervention, at the end of the intervention period and one month after the intervention

Method of measurement

gait analysis system

6

Description

swing phase time obtained by analyzing data of gait analysis system

Timepoint

Determining the swing phase time before the intervention, at the end of the intervention period and one month after the intervention

Method of measurement

gait analysis system

7

Description

Spasticity score calculated using the modified Ashworth scale.

Timepoint

Determination of spasticity before the intervention, at the end of the intervention period and one month after the intervention

Method of measurement

modified Ashworth scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group undergoes rehabilitation treatment 5 days a week for 4 weeks. In each session, 30 minutes of conventional occupational therapy intervention and 15 minutes of mirror therapy intervention are performed (10 minutes of rest is provided between occupational therapy and mirror therapy), in which a mirror is placed vertically between the two lower limbs so that People see the healthy side in the mirror, then while people should look at the image of a healthy body in the mirror, they are asked to do the following three movements: 1. Ankle dorsiflexion with knee extension 2. hip & knee & ankle flexion 3. knee flexion more than 90 degrees.

Category

Rehabilitation

2

Description

Control group: This group undergoes rehabilitation treatment 5 days a week for 4 weeks. In each session, 30 minutes of conventional occupational therapy intervention and 15 minutes of mirror therapy intervention are performed (10 minutes of rest is provided between occupational therapy and mirror therapy), in which a mirror is placed vertically between the two lower limbs so that People see the unhealthy side in the mirror, then while people should look at the image of a healthy body in the mirror, they are asked to do the following three movements: 1. Ankle dorsiflexion with knee extension 2. hip & knee & ankle flexion 3. knee flexion more than 90 degrees.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Tavanyab Rehabilitation Center

Full name of responsible person
mahmood oliaee

Street address
No. 2, Javaheri ave, N Kargar st, Enghelab Sq, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Vice Chancellor for Research and Technology of Shahid Beheshti University of Medical Sciences

Street address
Floor 5, Headquarters Building 2, Shahid Beheshti University of Medical Sciences and Health Services, Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway

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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
Reihaneh Askary Kachoosangy

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

Street address
Imam Hussein Hospital, Madani St, Tehran

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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
Javad Alipour

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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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

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

Data related to the main outcomes and demographic factors can be shared after the individuals are not identified.

When the data will become available and for how long

It is possible to start the data access period after 6 months from the printing of the results.

To whom data/document is available

Research-related data is only available upon request to researchers affiliated with academic institutions.

Under which criteria data/document could be used

Research-related data and documentation can only be used if used in conjunction with related research.

From where data/document is obtainable

To receive the documents, researchers can apply by sending a message with sufficient explanations to j.alipour76@gmail.com to receive the documents and data.

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

After sending the message to the mentioned email, the researchers will be notified of the result of the request after one to two weeks.

Comments