

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8803 2381

##### Email address

j.alipour76@sbmu.ac.ir

##### 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

**City**

Tehran

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Info@tavanyab.ir

**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

**City**

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**Province**

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1985717443

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Mpajouhesh@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**

Reihaneh Askary Kachooosangy

**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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**Province**

Tehran

**Postal code**

1617763141

**Phone**

00982173430

**Email**

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

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Javad Alipour

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Occupational Therapy

**Street address**

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j.alipour76@sbmu.ac.ir

## 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**