

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of motor learning based mirror therapy on the hand function of 7 to 12-year-old children with hemiplegic cerebral palsy

Protocol summary

Study aim

To explore of the effectiveness of motor learning based mirror therapy on the hand function of 7 to 12-year-old children with hemiplegic cerebral palsy

Design

Single-blinded two arm parallel group randomized control trial

Settings and conduct

After obtaining the necessary licenses and submitting them to the relevant centers (Rehabilitation Centers affiliated to Isfahan University of Medical Sciences and Asude Mawa Charitable Association), according to the inclusion and exclusion criteria of the participants, a sampling frame will be prepared. In the next step, among all eligible children, thirty 7 to 12 years old children with unilateral cerebral palsy will selected randomly. After the pre-test, they will be randomly assigned to two groups of mirror therapy based on the principles of motor learning and common mirror therapy (participants, testers, and statistical analysts will be blinded), then the post-test is performed and finally the results are analyzed statistically. In order to follow-up one month after the post-test, participants will be assessed for a third time.

Participants/Inclusion and exclusion criteria

Diagnosis of partial cerebral palsy based on the MACS grading scale, participants have the hand function ability to rank 1 to 3. Having at least intelligence 70 based on the Raven's Colored Progressive Matrices. Health problems unrelated to cerebral palsy. Treatment-resistant epilepsy. Visual problems that interfere with the performance of the intervention or test Muscle tone above 3.5 (mean for elbow and wrist joint movements) based on modified Ashworth Scale.

Intervention groups

Motor learning based mirror therapy; Common mirror therapy

Main outcome variables

Uni-manual function; bi-manual skills; grasp strength; tactile discrimination; passive range of motion (P-ROM);

active range of motion (A-ROM); parent perception; dexterity; bilateral coordination; visual-motor control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200224046604N1**

Registration date: **2020-03-15, 1398/12/25**

Registration timing: **prospective**

Last update: **2020-03-15, 1398/12/25**

Update count: **0**

Registration date

2020-03-15, 1398/12/25

Registrant information

Name

Hossein Sourtiji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5094

Email address

sourtiji@rehab.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2020-04-24, 1399/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of motor learning based mirror therapy on the hand function of 7 to 12-year-old children with hemiplegic cerebral palsy

Public title

Effect of mirror therapy on hand of children with cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of partial cerebral palsy Based on the MACS grading scale, participants have the hand function ability to rank 1 to 3. Having at least intelligence 70 based on the Raven's Colored Progressive Matrices

Exclusion criteria:

Health problems unrelated to cerebral palsy Treatment-resistant seizures Visual problems that interfere with the intervention or test. Muscle tone above 3.5 (mean for elbow and wrist joint movements) based on modified Ashworth Scale

Age

From **7 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: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Sealed envelopes. Participants will choose one envelope between two separate envelopes. It is noteworthy that in each envelope there is a sheet in which the name of one of the groups is written.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants, data analyzer, and outcome evaluator will not know which of the participants belonged to the intervention group and which one was in the comparison group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The institutional research ethics committee of vice-chancellor of Isfahan University of medical science

Street address

Hezar Jarib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-02-05, 1398/11/16

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.618

Health conditions studied

1

Description of health condition studied

cerebral palsy

ICD-10 code

G81

ICD-10 code description

Hemiplegia and hemiparesis

Primary outcomes

1

Description

Hand function

Timepoint

Before the intervention, after the intervention, one month after the post-test

Method of measurement

Bruininks-Oseretsky test of motor proficiency, Jebsen-Taylor Hand Function Test

Secondary outcomes

1

Description

Grasp strength

Timepoint

Before the intervention, after the intervention, one month after the post-test

Method of measurement

Vigorimeter

2

Description

Two-point discrimination

Timepoint

Before the intervention, after the intervention, one month after the post-test

Method of measurement

Two-point discrimination scale

3

Description

Active and passive range of motion

Timepoint

Before the intervention, after the intervention, one month after the post-test

Method of measurement

Goniometry

4

Description

Parent perception

Timepoint

Before the intervention, after the intervention, one month after the post-test

Method of measurement

Caregiver Functional Use Survey (CFUS)

5

Description

Visual motor coordination

Timepoint

Caregiver Functional Use Survey (CFUS)

Method of measurement

Bruininks-Oseretsky test of motor proficiency

Intervention groups

1

Description

Intervention group: Motor learning based mirror therapy that is designed based on the principles of motor learning including behavior shaping, types and grading of the tasks and types of practice. Intervention protocol will consist of twenty 30-45 minute sessions for 7 weeks and 3 sessions per week.

Category

Rehabilitation

2

Description

Control group: Common mirror therapy intervention consists of 3 repetitions of 10 sets of 7 symmetrical motor tasks and simultaneously upper limb and hand. Exercises include fine motor exercises, full range of motion exercises, and finger and forearm strength exercises. Intervention protocol will consist of twenty 30-45 minute sessions for 7 weeks and 3 sessions per week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation faculty, Isfahan University of medical sciences

Full name of responsible person

Hossein Sourtiji

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjooy Javanmard

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Isfahan University of Medical sciences Hezar Jarib Ave

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۷۳۴۶۱-۸۱۷۴۶

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+98 31 3668 8138

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research@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hossein Sourtiji

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

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Person responsible for scientific inquiries

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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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

Statistical indicators related to the total data

When the data will become available and for how long

Start of access period from 2022

To whom data/document is available

Researchers working in academic and scientific
institutions

Under which criteria data/document could be used

If data is needed for systematic review (meta-analysis)
studies.

From where data/document is obtainable

Hossein Sourtiji Occupational therapy department,
Rehabilitation sciences faculty, Isfahan University of
medical sciences 00983137925049

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

Request from the applicant's person or organization
Approved by the President of the University, Approved by
the head of the faculty

Comments