

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of virtual reality camera-based mirror therapy on upper extremity motor function in patients with hemiplegic cerebral palsy 8 to 12 years: a pilot study

Protocol summary

Study aim

Assessing the effect of virtual reality camera-based mirror therapy on upper extremity motor function in children with hemiplegic cerebral palsy

Design

A clinical trial with a control group, with parallel groups, one-way blind, evaluator of uninformed allocation, randomized, on 20 patients. Randomized program was used.

Settings and conduct

All clients of rehabilitation centers affiliated with the University of Rehabilitation Sciences and Social welfare, who are eligible to enter the research and express their consent, will participate in the research (in writing). This study is double-blind; in which the participant and the evaluator were unaware of the allocation of individuals.

Participants/Inclusion and exclusion criteria

Do not use mirror therapy approaches before the intervention; Being at levels I, II, and III of the MACS manual ability classification system; Ability to study at school; Mild spasticity involved in wrist flexor (modified Ashworth scale less than 2); Do not inject Botox or surgery on the upper limb for up to 1 year before the intervention; Occurrence of orthopedic disease or seizures.

Intervention groups

Control group (Common rehabilitation treatment group): Patients receive occupational therapy sessions three times a week for 8 weeks and the duration of each session is 45 minutes. Intervention group: Mirror Therapy group receives a virtual reality-based camera-based mirror therapy program in addition to conventional treatments.

Main outcome variables

Selective control of the upper extremity scale; gross manual dexterity; the range of motion; the great hand muscles strength; the strength of the delicate muscles of

the hand; upper extremity skills quality

General information

Reason for update

The study was conducted in a pilot study, due to the situation of the coronavirus in the country and the lack of available samples, the statistics consultant selected the number of 10 people. By increasing the number of clients in the rehabilitation centers, we realized that we could increase the number of samples. With the number of 20 people, we started sampling after consulting and checking with the statistics consultant professor, and supervisors.

Acronym

IRCT registration information

IRCT registration number: **IRCT20211024052860N1**
Registration date: **2022-04-14, 1401/01/25**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-23, 1401/05/01**

Update count: **1**

Registration date

2022-04-14, 1401/01/25

Registrant information

Name

Amir Hossein Nasiri Naeini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8808 8666

Email address

ah.nasiri@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of virtual reality camera-based mirror therapy on upper extremity motor function in patients with hemiplegic cerebral palsy 8 to 12 years: a pilot study

Public title

The effect of virtual reality camera-based mirror therapy on upper extremity motor function in patients with hemiplegic cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range 8 to 12 years Hemiplegic cerebral palsy, diagnosed by a neurologist Being at levels I, II and III of the MACS (manual ability classification system) Ability to study at school Mild spasticity involved in wrist flexor (modified Ashworth scale less than 2)

Exclusion criteria:

Unwillingness to participate in the study (not completing the consent form) Use mirror therapy approaches before the intervention Injection of Botox or surgery on the upper limb for up to 1 year before the intervention

AgeFrom **8 years** old to **12 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample sizeTarget sample size: **20****Randomization (investigator's opinion)**

Randomized

Randomization description

Before starting the study, a list of letters A and B is generated using the randomization site, which indicates the assignment of individuals to study groups, and individuals are placed in groups according to the order of entering the research.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluator is unaware of the assignment of individuals to the groups and the participants are divided into two groups of control and intervention by randomized program.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of University of Social Welfare and Rehabilitation Sciences

Street address

Kodakyar Ave., Daneshjo Blvd.,Evin, Tehran

City

Tehran

Province

Tehran

Postal code

1985713871

Approval date

2021-10-20, 1400/07/28

Ethics committee reference number

IR.USWR.REC.1400.168

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**

Selective Control of the Upper Extremity Scale

Timepoint

The beginning of the intervention, after 8 weeks, the follow-up period after 4 weeks

Method of measurement

Selective Control of the Upper Extremity Scale Test

2**Description**

Gross manual dexterity

Timepoint

The beginning of the intervention, after 8 weeks, the follow-up period after 4 weeks

Method of measurement

Box and block test

3

Description

Range of motion

Timepoint

The beginning of the intervention, after 8 weeks, the follow-up period after 4 weeks

Method of measurement

Goniometer

4

Description

Large hand muscles strength

Timepoint

The beginning of the intervention, after 8 weeks, the follow-up period after 4 weeks

Method of measurement

Dynamometer

5

Description

The strength of the delicate muscles of the hand

Timepoint

The beginning of the intervention, after 8 weeks, the follow-up period after 4 weeks

Method of measurement

Pinched gauge

6

Description

Quality of Upper Extremity Skills

Timepoint

The beginning of the intervention, after 8 weeks, the follow-up period after 4 weeks

Method of measurement

Quality of Upper Extremity Skills Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mirror Therapy group will receive a virtual reality-based camera-based mirror therapy program in addition to conventional treatments three sessions per week for 8 weeks. The duration of each session will be 45 minutes, of which 20 minutes belong to the camera-based mirror therapy program based on virtual reality.

Category

Rehabilitation

2

Description

Control group: Common rehabilitation treatment group -

Patients in this group will receive occupational therapy sessions three times a week for 8 weeks and the duration of each session will be 45 minutes. Patients in the standard rehabilitation group will perform standard therapy, routine rehabilitation therapy based on neuromuscular facilitation techniques (diagonal patterns), and Bobet neurodevelopmental technique with emphasis on practicing functional tasks as much as possible and fine motor activities. Weightlifting, reflex inhibition patterns, torso rotation, and scapula protrusion will also be used to reduce spasticity, if necessary, during exercise. Nearly 25 percent of the usual rehabilitation treatment time will be spent on compensatory techniques using a healthy limb to perform functional tasks and help the affected limb with a healthy hand during homework.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofeideh Rehabilitation Hospital

Full name of responsible person

Amir Hossein Nasiri Naeini

Street address

Tehran, Qeytariyeh, Shahid Baradaran Soleiman St., Nemat Allee, Rofeideh Rehabilitation Hospital

City

Tehran

Province

Tehran

Postal code

1985713871

Phone

+98 21 2220 5326

Fax

+98 21 2223 2741

Email

rofeideh.hospital@uswr.ac.ir

Web page address

<https://rofeideh.uswr.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Hamid Reza Khnkeh

Street address

Kodakyar Ave., Daneshjo Blvd.,Evin

City

Tehran

Province

Tehran

Postal code

1985713871

Phone

+98 21 7173 2000

Email

Webmaster@uswr.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of social welfare and rehabilitation sciences

Proportion provided by this source

1

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

University of social welfare and rehabilitation sciences

Full name of responsible person

Amir Hossein Nasiri Naeini

Position

Masters student of Occupational Therapy

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

Street address

No. 22, First Floor, Shahid Navarani Blvd., Intersection of DaryaBlvd., Farahzadi Blvd., Sanat Sq., Gharb Town, Tehran,

City

Tehran

Province

Tehran

Postal code

1468973841

Phone

+98 21 8808 8666

Fax

Email

ah.nasiri@uswr.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Amir Hossein Nasiri Naeini

Position

Masters student of Occupational Therapy

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

Street address

No. 22, First Floor, Shahid Navarani Blvd., Intersection of DaryaBlvd., Farahzadi Blvd., Sanat Sq., Gharb Town, Tehran.

City

Tehran

Province

Tehran

Postal code

1468973841

Phone

+98 21 8808 8666

Fax

Email

ah.nasiri@uswr.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Amir Hossein Nasiri Naeini

Position

Masters student of Occupational Therapy

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

Street address

No. 22, First Floor, Shahid Navarani Blvd., Intersection of DaryaBlvd., Farahzadi Blvd., Sanat Sq., Gharb Town, Tehran.

City

Tehran

Province

Tehran

Postal code

1468973841

Phone

+98 21 8808 8666

Fax

Email

ah.nasiri@uswr.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

Undecided - It is not yet known if there will be 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	article
Analytic Code	To whom data/document is available
Yes - There is a plan to make this available	All experts who work in this field
Data Dictionary	Under which criteria data/document could be used
Not applicable	For clinical studies and in treatment
Title and more details about the data/document	From where data/document is obtainable
The dissertation is kept in the occupational therapy department of the University of Rehabilitation Sciences and Social Health and the relevant articles are published in the relevant journals.	Refer to the Department of Occupational Therapy at the University of Rehabilitation Sciences and Social Health
When the data will become available and for how long	What processes are involved for a request to access data/document
Access period starts 6 months after the publication of the	Obtaining permission from the Department of Occupational Therapy of the University of Rehabilitation Sciences and Social Health is required
	Comments