Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
Age
From **8 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target 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
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Province
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Hamid Reza Khnkeh
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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
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

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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
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

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

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.

When the data will become available and for how long

Access period starts 6 months after the publication of the article

To whom data/document is available

All experts who work in this field

Under which criteria data/document could be used

For clinical studies and in treatment

From where data/document is obtainable

Refer to the Department of Occupational Therapy at the University of Rehabilitation Sciences and Social Health

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

Obtaining permission from the Department of Occupational Therapy of the University of Rehabilitation Sciences and Social Health is required

Comments