

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of task oriented virtual reality on hand function and activity performance of children with spastic hemiplegia

Protocol summary

Study aim

Investigating the effect of task-based virtual reality on grip, active range of motion of hands and fingers during daily activities (eating and self-feeding). the effect of task-based virtual reality on improving manual skills of hemiplegic children.

Design

A clinical randomized trial with a control group, with an equal sample size of 30, randomization with quadruple blocks, double-blind.

Settings and conduct

The University of Rehabilitation and Social Health and specialized centers of this university and occupational therapy clinics located in Tehran. Necessary tests such as the modified Ashworth scale, manual ability classification system, and gross motor function classification system will be used for children's screening.

Participants/Inclusion and exclusion criteria

Age range from 6 to 10 years; Not using virtual reality approaches before intervention; Located in level 1 or 2 manual ability classification system; Located in level 1 to 3 of the gross motor function classification system (for proper trunk control).

Intervention groups

The interventional groups, children with cerebral palsy, receive virtual reality in addition to common occupational therapy treatments for 6 weeks. In the control group, common occupational therapy is performed. After 6 weeks, the measurements will be repeated in both groups for 45 minutes per session, twice a week for 6 consecutive weeks.

Main outcome variables

Upper extremity motion control, Wrist active range of motion, Active range of motion of fingers, Hand function Power grip

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220627055296N1**

Registration date: **2022-09-18, 1401/06/27**

Registration timing: **prospective**

Last update: **2022-09-18, 1401/06/27**

Update count: **0**

Registration date

2022-09-18, 1401/06/27

Registrant information

Name

Fateme Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-21, 1401/06/30

Expected recruitment end date

2022-12-20, 1401/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of task oriented virtual reality on hand function and activity performance of children with spastic hemiplegia	
Public title	Effect of virtual reality on hand function and activity performance of children with spastic hemiplegia
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Parents consent for children's participation in the study (completing the consent form) Age range from 6 to 10 years No use of Virtual reality approaches before intervention Located in level 1 or 2 manual ability classification system Located in level 1 to 3 of the gross motor function classification system (for proper trunk control) No history of Botox injections, surgery or fractures during at least 6 months before the intervention Grade 2 or less spastic tone based on Ashworth modified scale in all upper extremity joints involved Studying in primary schools, normal or physically motor schools. No obvious and tangible deformity in the upper extremity Absence of obvious and noticeable deformity in the involved upper limb No severe vision problems or blindness of the child Exclusion criteria: The presence of other neurological, orthopedic and psychological diseases in the child based on the medical record
Age	From 6 years old to 10 years old
Gender	Both
Phase	N/A
Groups that have been masked	- Care provider - Investigator - Outcome assessor
Sample size	Target sample size: 30
Randomization (investigator's opinion)	Randomized
Randomization description	The method of assigning random to the two groups is the four blocks. Random numbers are generated so that even numbers are related to the control group, and odd numbers are related to the intervention group. Each number is placed in an envelope and a number is given to it. Then, each newly arrived child is assigned an envelope whose number is matched with the child's number (numbered in order of arrival), and his/her group is determined. Therefore, the opinion of the researcher and assessor will not be considered in the allocation of children
Blinding (investigator's opinion)	Double blinded
Blinding description	Researcher, Assessor According to blocks of four, random numbers are generated in such a way that even numbers correspond to the control group and odd numbers correspond to the intervention group, and each number is placed in an envelope and given a number. Then, each child who has just entered the study is assigned an envelope whose number matches the child's number (they are numbered in the order of entry) and his group is determined. Therefore, the opinion of the researcher and evaluator will not be considered in the allocation of children
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	1 Ethics committee Name of ethics committee Ethics committee of university of social welfare and rehabilitation sciences Street address Velenjak, Koodakyar City Tehran Province Tehran Postal code 1461712345 Approval date 2022-08-20, 1401/05/29 Ethics committee reference number IR.USWR.REC.1401.080
Health conditions studied	1 Description of health condition studied Hemiplegia cerebral palsy ICD-10 code G80.2 ICD-10 code description Spastic hemiplegic cerebral palsy
Primary outcomes	1 Description Hand performance based on the duration obtained from the Jebsen-Taylor test Timepoint start of study ,after 6 weeks Method of measurement Jebsen Taylor hand function test

Secondary outcomes

1

Description

motor control of upper extremity

Timepoint

start of the study, after 6 weeks

Method of measurement

Performance based upper extremity motor control test

2

Description

Active range of motion of carpo meta carpal

Timepoint

start of the study, after 6 weeks

Method of measurement

Leap motion

3

Description

Active range of motion of the fingers

Timepoint

start of the study, after 6 weeks

Method of measurement

Leap motion

4

Description

Grip strength

Timepoint

start of the study, after 6 weeks

Method of measurement

Jamar dynamometer

Intervention groups

1

Description

Intervention group: cerebral palsy hemiplegia age 6 -10 so these children receive common occupational therapy treatments, the intervention of virtual reality for 6 weeks. After six weeks, measurements are made again in both groups. The treatment in both groups is Each session lasts 45 minutes, twice a week, for 6 consecutive weeks. People in the intervention group receive the upper limb virtual reality program for 15 minutes in addition to neurodevelopmental therapy in each session. The virtual reality program includes picking up a glass and reaching it to the mouth, picking up a knife and cutting, picking up a spoon and filling it, and Finally, take it to the mouth. Based on Leap Motion, hand movements are read and the child sees the means of doing the activity (spoon, glass, etc.) on the opposite screen and the movements are displayed virtually

Category

Treatment - Other

2

Description

Control group: In the control group, common occupational therapy treatments such as neurodevelopmental therapy are implemented. The treatment in this group takes place for 45 minutes in each session, twice a week, for 6 consecutive weeks. After the completion of six weeks, the measurements are performed again. The neurodevelopmental program is used for both groups according to the individual needs of the children and includes the regulation of muscle tone during activities, facilitation of normal movements for upper limb activities, training Upper extremity functional skills, activities of daily living such as eating, drinking, holding various objects are done with emphasis on practicing functional tasks as much as possible and fine motor activities.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Special hospital of university of social welfare care and rehabilitation sciences

Full name of responsible person

Hamidreza Khankeh

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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Province

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Phone

+98 21 7173 2000

Email

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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

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

University of social welfare and rehabilitation sciences

Full name of responsible person

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Position

student

Latest degree

Bachelor

Other areas of specialty/work

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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

only part of the data such as information related to the main outcome can be shared

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

cerebral palsy children and their parents, researchers, people who work in medical field

Under which criteria data/document could be used

for scientific and medical purposes

From where data/document is obtainable

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

after the official release of the data

Comments