Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
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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 hemyplegia 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 os socal wealth care and rehabilitation sciensces
Full name of responsible person
Hamidreza Khankeh
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Sponsors / Funding sources

1

Sponsor
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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

fateme salehi nasab

Position

student

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

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, re searchers,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

fateme salehi fateme.salehi.817@gmail.com Dr saeid fatorehchy saeidfatorehchy@yahoo.com

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

after the official release of the data

Comments