

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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)

##### Phone

+98 66 3340 7776

##### Email address

fateme.salehi.817@gmail.com

##### 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

##### **Street address**

Velenjak

##### **City**

Tehran

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##### **Postal code**

1985713834

##### **Phone**

+98 21 7173 2000

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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**

Hamidreza Khankeh

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##### **Province**

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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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## 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**

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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fatorehchy saeidfatorehchy@yahoo.com

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

after the official release of the data

**Comments**