

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

the Effect of Virtual Reality Practice on balance and Walking speed In children with spastic cerebral palsy

Protocol summary

Study aim

Determining the effect of virtual reality technique on the balance and walking speed of children 5-12 years old spastic cerebral pals

Design

Clinical trials with control groups, with parallel, two-way blind, randomized groups, were used to randomize the software.

Settings and conduct

The present study was a randomized clinical trial of two suckers that was performed in Yekta and Raha occupational therapy clinics in Khorramabad city. Walking was measured by walking speed. The control group received occupational therapy exercises as 30-minute sessions twice a week for 6 weeks. In addition to occupational therapy exercises, the intervention group also used the virtual reality technique. The intervention phase in this study was 18 20-minute sessions that were held for 6 weeks and 3 times a week. In each session, participants performed selective games

Participants/Inclusion and exclusion criteria

Age between 5 and 12 years, GMFCS II, I level, no use of sedatives during the intervention time, no hearing and vision impairment that cannot be compensated by assistive devices, no treatment-resistant seizures. Criteria for non-entry: non-cooperation of the child and absence of more than three sessions in treatment sessions

Intervention groups

The control group received occupational therapy exercises as 30-minute sessions twice a week for 6 weeks. In addition to occupational therapy exercises, the intervention group also used virtual reality techniques

Main outcome variables

Walking speed, balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200415047094N1**
Registration date: **2020-06-07, 1399/03/18**
Registration timing: **retrospective**

Last update: **2020-06-07, 1399/03/18**

Update count: **0**

Registration date

2020-06-07, 1399/03/18

Registrant information

Name

Maryam naderi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3340 9713

Email address

naderi.maryam0071@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-23, 1399/02/04

Expected recruitment end date

2020-05-25, 1399/03/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the Effect of Virtual Reality Practice on balance and Walking speed In children with spastic cerebral palsy

Public title

the Effect of Virtual Reality on cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children with spastic cerebral palsy range in age from 5 to 12 years Be based on GMFCS classification systems at levels I and II Do not use sedatives during the intervention Lack of any hearing or vision defects that cannot be compensated by assistive devices and impair the child's performance Lack of treatment-resistant seizures

Exclusion criteria:

Lack of cooperation of the child in medical sessions
Absence of more than three sessions in treatment sessions

Age

From **5 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The present study was a randomized double-blind clinical trial. The number of 30 children with spastic cerebral palsy was selected from the available community and after filling out the consent form, they were randomly divided into control and intervention groups using the software. And the intervention took place on different days so that the children and families could remain unaware of the child's presence in the control and intervention group. Also, the occupational therapist who performed the assessments was unaware of the division of patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, control and intervention group meetings were held on different days so that children and families were unaware of the child's presence in the control and intervention group. Also, the occupational therapist who performed the assessments was unaware of the division of patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Chamran Highway, Yemen St., Shahid Arabi St., next to Taleghani Hospital

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Province

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Postal code

1985717443

Approval date

2019-09-14, 1398/06/23

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.206

Health conditions studied**1****Description of health condition studied**

cerabla palsy

ICD-10 code

G80.1

ICD-10 code description

Spastic diplegic cerebral palsy

Primary outcomes**1****Description**

Equilibrium score on functional tests,

Timepoint

After the intervention and 3 months after the end of the intervention

Method of measurement

Functional tests

2**Description**

walking speed score on functional tests

Timepoint

After the intervention and 3 months after the end of the intervention

Method of measurement

Functional tests

Secondary outcomes

empty

Intervention groups

1

Description

control group: receive occupational therapy exercises alone.

Category

Rehabilitation

2

Description

Intervention group : receive occupational therapy exercises along with receiving therapeutic interventions using virtual reality

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Raha and Yekta Occupational Therapy Center

Full name of responsible person

Maryam Naderi

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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?

No

Title of funding source

Kardarmani Raha

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

Maryam Naderi

Position

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Latest degree

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available