

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

designing and adaptation of task oriented intervention using virtual reality and comparing the effectiveness with usual occupational therapy on participation and performance in people with cerebral palsy

Protocol summary

Study aim

designing and adaptation of task oriented intervention using virtual reality and comparing the effectiveness with usual occupational therapy on participation and performance in people with cerebral palsy

Design

The samples are selected from among people with cerebral palsy referring to rehabilitation centers. The sampling method is simple non-probability; they are randomly divided into two intervention and control groups and it is done by sealed envelope method. The sample size is based on the primary outcome at least 22 people, who will enter 30 people. In the clinical trial phase, The samples are randomly divided into intervention and control groups. The control group of conventional occupational therapy exercises and the intervention group will receive the virtual reality program (SANA software technology) in addition to conventional intervention.

Settings and conduct

blinding: after selecting the samples, they were randomly divided into two intervention and control groups and it will be done by a researcher who has no role in the evaluation and treatment using the sealed envelope method. The place where the study is carried out is in the occupational therapy Rehabilitation clinic and Mofaqian's Knowledge-Based Rehabilitation Center.

Participants/Inclusion and exclusion criteria

inclusion criteria: Diagnosis of cerebral palsy: mild and moderate Age: 8 to 12 GMFCS I to III MACS I to III SPARCLE: up to 70 exclusion criteria: Inability to understand instructions and implement therapeutic interventions.

Intervention groups

The control group will receive conventional occupational therapy exercises including clinical task-based intervention based on conventional occupational therapy

guidelines, and the intervention group will receive task-based virtual reality program along with conventional occupational therapy exercises.

Main outcome variables

Occupational performance Participation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230907059375N1**

Registration date: **2024-02-01, 1402/11/12**

Registration timing: **registered_while_recruiting**

Last update: **2025-01-28, 1403/11/09**

Update count: **1**

Registration date

2024-02-01, 1402/11/12

Registrant information

Name

Madineh Hassani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 4612 7282

Email address

madinehh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

designing and adaptation of task oriented intervention using virtual reality and comparing the effectiveness with usual occupational therapy on participation and performance in people with cerebral palsy

Public title

Comparison of virtual reality task oriented intervention with usual occupational therapy on participation and performance in people with cerebral palsy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age: 8_12 years old levels I I to III of the Gross Motor Function Classification System (GMFCS) 2) levels I I to III of the Manual Ability Classification System levels of SPARCLE: up to 70

Exclusion criteria:

Existence of vision and hearing problems Existence of disorders and associated diseases Having a seizure Botulinum toxin injection in the last 6 months Inability to understand instructions and perform therapeutic interventions

Age

From **8 years** old to **12 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method will be done in the form of blocks of four in a ratio of one to one (1:1) in two intervention and control groups by a researcher who is not involved in the evaluation and treatment and is outside the research team and will be done by sealed envelopes. After allocating group people, each person will be placed inside secret envelopes that are not known.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the evaluators are among the blind group

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Shahnazari street. Mirdamad blv.rehabilitation faculty.

City

Tehran

Province

Tehran

Postal code

6791954874

Approval date

2023-07-03, 1402/04/12

Ethics committee reference number

IR.IUMS.REC.1402.310

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

Cerebral Palsy

ICD-10 code

G80

ICD-10 code description

Cerebral palsy

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

Participation: involvement in life situations

Timepoint

2 month

Method of measurement

Participation was measuring using COPM

Secondary outcomes**1****Description**

visual perception

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

Test of Visual Perceptual Skills

2

Description

Upper limb function

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

Box and Block Test (BBT)

3

Description

Manual ability to perform daily activities

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

ABILHAND-kids

4

Description

Participation in daily life activities

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

children participation assessment scale (CPAS)

Intervention groups

1

Description

Intervention group: The intervention group will receive the task-based virtual reality program along with conventional occupational therapy exercises. The virtual reality technology of the Sana software, which is used by the engineers of Knowledge base Institute with the Kinect device, where the patients are placed on a chair without handles and firmly at a distance of 2 meters from the Kinect camera, in a standing or sitting position. They will perform the virtual reality exercises in five different activities including, random reach, tracking, library and rotate wheel in the clinic and under the supervision of the therapist..

Category

Rehabilitation

2

Description

Control group: The control group will receive conventional occupational therapy intervention based on a neurodevelopmental approach. which was compiled based on the results of the latest guidelines and expert panel meetings and common occupational therapy in Iran.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation faculty

Full name of responsible person

Madineh Hassani

Street address

Shah Nazari Street, Mirdamad Blvd

City

Tehran

Province

Tehran

Postal code

6791954874

Phone

+98 83 4613 6132

Email

Madinehh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Mehdi Alizadeh Zarei

Street address

Shah Nazari Street, Mirdamad Blvd, Rehabilitation Faculty

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 8051

Email

madinehh@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical 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

Sponsor**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr Kazem Musazadeh

Street address

Shahid Hammat Subway, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۳۴۸۷ ۱۵۴۵۹

Phone

+98 21 2222 8051

Email

mousavizadeh.k@iums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran University of Medical 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**

Iran University of Medical Sciences

Full name of responsible person

Dr Mehdi Alizadeh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

Street address

ShahNazari Street, Mirdamad Blvd

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 8052

Email**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Madineh Hassani

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

Street address

Mehmansara street, Shohada Square

City

Paveh

Province

Kermanshah

Postal code

6791954874

Phone

+98 83 4612 7282

Email

madinehh@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Madineh Hassani

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

Street address

Mehmansara street, Shohada Square

City

Paveh

Province

Kermanshah

Postal code

6791954874

Phone

+98 83 4612 7282

Email

madineh@gmail.com

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
No - There is not a plan to make this available

Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable