# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Effectiveness of virtual reality rehabilitation-based approach compared to balance-specific training and conventional training on balance function of cerebral palsy children: A randomized controlled trial

## Protocol summary

**Study aim**

Find out the effectiveness of the virtual reality rehabilitation-based approach compared to the task-specific training and conventional training on the balance function of CP children.

**Design**

36 participants will be randomly allocated in one of 3 groups, this is a blinded, randomized controlled trial

**Settings and conduct**

Participants will be blinded. They will be assessed 3 times; T0: baseline assessment, T1: post-training assessment (after 6-week training) and T2: follow-up assessment (6 weeks after finishing the intervention).

**Participants/Inclusion and exclusion criteria**

Spastic CP with age between 4 to 12 years old; GMFCS-ER I and II no surgical intervention for spasticity, No injection of Botulinum for spasticity in the last 6 months.

**Intervention groups**

Group 1: Virtual Reality Rehabilitation-Based Therapy a 6-week program, 3 individual sessions per week of 60 minutes each. In the session, the child has the opportunity to play 10 games per session in order to practice 5 minutes for each game. A trained physical therapist will supervise and assist the child's practice by providing physical support if needed to maintain balance or by providing feedback to adjust the practice. He will consider the progression in the difficulty level of each game based on the balance performance improvement of each child over 6 weeks of training. Group 2: Balance-Specific Training The program includes 13 balance-specific exercises for 18 sessions over 6 weeks, 3 sessions per week. Group 3: control group Participants will continue their conventional rehabilitation protocol. 3 sessions per week for 6 weeks will be delivered.

**Main outcome variables**

Pediatric Balance Scale Gross Motor Function Measures - D & E 5 Times Sit-To-Stand Center of Pressure sway measures Center of Mass displacement measures

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20090301001722N25**
Registration date: **2020-07-30, 1399/05/09**
Registration timing: **prospective**

Last update: **2020-07-30, 1399/05/09**
Update count: **0**

**Registration date**

2020-07-30, 1399/05/09

**Registrant information**

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**Name of organization / entity**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-09-22, 1399/07/01

**Expected recruitment end date**

2021-06-22, 1400/04/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
Effectiveness of virtual reality rehabilitation-based approach compared to balance-specific training and conventional training on balance function of cerebral palsy children: A randomized controlled trial

**Public title**
Effectiveness of virtual reality rehabilitation-based approach compared to balance-specific training and conventional training on balance function of cerebral palsy children: A randomized controlled trial

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Cerebral palsy children diagnosed as spastic monoplegia, hemiplegic and diplegic patients; Children with age between 4 to 12 years old; Children able to walk (Grade I and II according to GMFCS-ER); The degree of spasticity in involved lower extremities according to the Modified Ashworth Scale should be ranged between grade 1 and grade 2. Children able to understand the instructions of the therapist and the games; Children did not receive any surgical intervention or any injection of Botulinum toxin in the last 6 months. No visual, cognitive or auditory impairments that would interfere with gameplay; Regular past use of an AVG system at home (more than 1 hour/week for more than 4 weeks in the past year).

**Exclusion criteria:**
Children who refused to continue the study.

**Age**
From **4 years** old to **12 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **36**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Block randomization The block randomization method is designed to randomize subjects into groups that result in equal sample sizes. This method is used to ensure a balance in sample size across groups over time. Blocks are small and balanced with predetermined group assignments, which keeps the numbers of subjects in each group similar at all times.[1,2] The block size is determined by the researcher and should be a multiple of the number of groups (i.e., with two treatment groups, block size of either 4, 6, or 8). Blocks are best used in smaller increments as researchers can more easily control balance.[10] After block size has been determined, all possible balanced combinations of assignment within the block (i.e., equal number for all groups within the block) must be calculated. Blocks are then randomly chosen to determine the patients' assignment into the groups. Although balance in sample size may be achieved with this method, groups may be generated that are rarely comparable in terms of certain covariates. For example, one group may have more participants with secondary diseases (e.g., diabetes, multiple sclerosis, cancer, hypertension, etc.) that could confound the data and may negatively influence the results of the clinical trial.[11] Pocock and Simon stressed the importance of controlling for these covariates because of serious consequences to the interpretation of the results. Such an imbalance could introduce bias in the statistical analysis and reduce the power of the study. Hence, sample size and covariates must be balanced in clinical research The size of each block in the present study (i.e. Sealed pocket) is 12 patients and in total 36 patients participate in 3 blocks. Thus, in intervention group 1 (block 1: virtual reality training, n = 12), in intervention group 2 (block 2: special balance training, n = 12) and in the control group (block 3: conventional rehabilitation, n = 12) will be allocated. Block Randomization will be used and stratified based on the time when the child joins the study with respect to GMFCS levels (I or II).

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Tehran University of Medical Sciences

**Street address**
School of Rehabilitation of Tehran University of Medical Sciences, Piche Shemiran, Enghelab Ave, Tehran, Iran

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Tehran

**Province**
Tehran

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**Approval date**
2020-06-27, 1399/04/07

**Ethics committee reference number**
IR.TUMS.VCR.REC.1399.537

## 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**
Gross Motor Function Measure (GMFM) - Dimensions D and E scores' change
**Timepoint**
Baseline, after 6 weeks training and 6 weeks follow-up
**Method of measurement**
Any change in the scores of Gross Motor Function Measure (GMFM) - Dimensions D and E

### 2

**Description**
Pediatric balance scale scores
**Timepoint**
Baseline, after 6 weeks training and 6 weeks follow-up
**Method of measurement**
Any change in Pediatric balance scale

### 3

**Description**
5 times sit to stand test
**Timepoint**
Baseline, after 6 weeks training and 6 weeks follow-up
**Method of measurement**
StopwatchTime change's in 5 times sit to stand test by chronometer

## Secondary outcomes

### 1

**Description**
Center of Pressure sway (velocity of displacement, and Standard deviation in medio-lateral and anteroposterior displacement)
**Timepoint**
Baseline, after 6 weeks training and after 6 weeks follow-up
**Method of measurement**
Stabilometer

### 2

**Description**
Digital Photography (Displacement of the center of mass, Body alignment, Segments alignment)
**Timepoint**
Baseline, after 6 weeks training and after 6 weeks follow-up
**Method of measurement**
Nikon COOLPIX L340 camera

## Intervention groups

### 1

**Description**
First Intervention Group: Virtual Reality Training: During virtual reality rehabilitation-based therapy period children ,CP children, will play a video game of the X-box One-S using the Kinect device for motion capture. The selection of the Xbox One-S (Microsoft) was based on to combine it with the Kinect, a full-body 3D motion capture system, that enables the user to control the avatar and to interact with the virtual environment without the need for a game controller, through a natural user interface mainly using gestures and body movements. The intervention consists of a 6-week program, 3 individual sessions per week of 60 minutes each. In the session, the child has the opportunity to play 10 games per session in order to practice 5 minutes for each game. In addition, we will ask him/her to play games from the entire below-mentioned games category in order to simulate the real movement practices. A trained physical therapist will supervise and assist the child’s practice by providing physical support if needed (i.e. in case that the child needs some help) to maintain balance or by providing feedback to adjust the practice. Specific balance training games will be used as intervention protocol as mentioned in the table below. The physiotherapist will consider regarding the progression in the difficulty level of each game based on the balance performance improvement of each child over 6 weeks of training. A pre-training session will be delivered for each participant in this group in order to ensure that all children know how the Xbox Kinect works and the goal of the individual games. For children with high risk of fall, small parallel bars will be used. Based on previous studies about the effectiveness of different Xbox games, we had chosen games that recruiting body movement and balance adjustments of the activity of daily living taken into account the possibility of increasing the difficulty level according to the balance performance of children. For this reason, the following Kinect games will be used: 1) Kinect Sports, 2) Kinect Adventures, 3) Your Shape Fitness Evolved, and 4) Carnival. An 18-session sequence of gaming will be established to help the therapist assure a controlled progression.
**Category**
Rehabilitation

### 2

**Description**
Second Intervention group: Balance-Specific Training: In this group our patients are trained by using the balance-specific training program including the following exercises: Sitting to standing/ Standing to sitting/

Transfers/ Standing unsupported/ Sitting with back unsupported / Standing with feet together/ Standing unsupported with one foot / Standing on one leg/ Turning 360 degrees/ Turning to look behind / Retrieving object from floor/ Placing alternate foot on step stool / Reaching forward

**Category**

Rehabilitation

**3**

**Description**

Control group: In this group, our participants,CP children, will continue their conventional rehabilitation protocol. 3 sessions per week for 6 weeks will be delivered with respect to some instructions such as the necessity of using functional exercises to manage the balance deficits, the use of stretching to maintain muscle elasticity and to prevent the dominance of spasticity and the use of exercises similar to that of the activity of daily living.An expert physiotherapist will provide the training (more than 5 years experience in the CP rehabilitation).

**Category**

Rehabilitation

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Lebanese University - Medical Center

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## Sponsors / Funding sources

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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**
Tehran 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**
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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