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

Name

Samira Karimpour

Name of organization / entity

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Iran (Islamic Republic of)

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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

City
Tehran

Province
Tehran

Postal code
1148965111

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

Full name of responsible person
Medical Center of the Lebanese University

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Tehran University of Medical Sciences

Full name of responsible person
Hussein Ziab

Position
Ph.D. Candidate

Latest degree
Master

Other areas of specialty/work
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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