Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of active and passive vestibular intervention on balance and function in children with spastic Cerebral Palsy (7-12y) Tehran-Iran

Protocol summary

Summary

This blinded Randomized Control Trail aims to examine:1) The effect of vestibular stimulation on static balance; 2) The relationship between balance changes and Quality of Life and Activity of Daily Living in school aged cerebral palsy children (ages: 7-12 years(. 42 children with spastic cerebral palsy(7-12), with"Gross Motor Function Classification System" level I or II and vestibular dysfunction according to Bruniniks-Oserstsky Test of Motor Proficiency will be randomized to 3 groups. First group will use active vestibular stimulation for 15 minutes and traditional Occupational Therapy program for 30 minutes. Second group will receive passive vestibular stimulation for 15 minutes and traditional Occupational Therapy program for 30 minutes. Third group (control) will use traditional Occupational Therapy program for 45 minutes. They will receive these programs for 6 weeks, 3 sessions on week. They will assess at three stages:after, before and 8 weeks after intervention by: VEMP and BOTMP for vestibular system function, Berg and Force Plat for balance changes, "Activities Scale for Kids" for Activity of Daily Living, and "Cerebral Palsy Quality of Life questionnaire "for Quality of Life. Data will be analyzed by "Repeated Measure ANOVA " and "Regression

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013082614481N1**
Registration date: **2013-10-25, 1392/08/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-10-25, 1392/08/03

Registrant information

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Recruitment status

Recruitment complete

Funding source

University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2012-10-06, 1391/07/15

Expected recruitment end date

2013-11-06, 1392/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of active and passive vestibular intervention on balance and function in children with spastic Cerebral Palsy (7-12y) Tehran-Iran

Public title

The effect of vestibular interventions on balance and function in children with spastic Cerebral Palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of spastic Cerebral Palsy; age of 7-12 y; to understand experimental procedures; to stand independently for at least 30 seconds; GMFCS(Gross Motor Function Classification System) level l or ll; Modified Ashworth 0-3 score of ankle. Exclusion criteria: Orthopedic surgery of the lower limbs within 6 months; history of dislocation, Subluxation,the difference between the length or other obvious deformity in hip ,knee and ankle joint; botulinum toxin injections within 6 months; uncontrolled seizure; moderate to severe intellectual disability; visual or hearing impairment .

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **14**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Social Welfare and Rehabilitation Sciences

Street address

Kodakyar Ave., Daneshjo Blvd.,Evin

City

Tehran

Postal code

1985713834

Approval date

2012-09-24, 1391/07/03

Ethics committee reference number

15914

Health conditions studied

1

Description of health condition studied

cerebral palsy

ICD-10 code

G80.0, G80

ICD-10 code description

G80.0, Spastic quadriplegic cerebral palsy Spastic tetraplegic cerebral palsy G80.1 Spastic diplegic cerebral palsy Congenital spastic paralysis (cerebral) Spastic cerebral palsy NOS G80.2 Spastic hemiplegic cerebral palsy

Primary outcomes

1

Description

Function

Timepoint

Before, 6 weeks after intervention and 8 weeks later

Method of measurement

Activities Scale for Kids, Cerebral Palsy Quality of Life Questionnaire

2

Description

Balance

Timepoint

Before, 6 weeks after intervention and 8 weeks later

Method of measurement

Force plate, Berg

Secondary outcomes

empty

Intervention groups

1

Description

Control group will receive traditional Occupational Therapy program for 45 minutes. Traditional Occupational Therapy program Consists of: muscle tone moderate, reflexes moderate, muscle stretch, balance training. Intervention duration will be 6 weeks, 3 times in week.

Category

Treatment - Other

2

Description

First intervention group will receive active vestibular stimulation according to special program for 15 minutes. This program developed by Hossieny(2007).Also they will receive traditional Occupational Therapy program (muscle tone moderate, reflexes moderate, muscle stretch, balance training) for 30 minutes. Intervention duration will be 6 weeks, 3 times in week.

Category

Other

3

Description
Second intervention group will receive passive vestibular stimulation by vestibular bed for 15 minutes. Vestibular bed implements controlled vestibular stimulation according to angle, direction and speed of movement. Also they will use traditional Occupational Therapy program (muscle tone moderate, reflexes moderate, muscle stretch, balance training) for 30 minutes. Intervention duration will be 6 weeks, 3 times in week

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
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2

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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Kodakyar Ave, Daneshjo Blvd, Evin
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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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty