

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Name

Nazila Akbarfahimi

###### Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2218 0037

###### Email address

n-fahimi@uswr.ac.ir

##### 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 I or II; 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**

Teran Special Education Organization

###### **Full name of responsible person**

Vagihoallah Parvizi

###### **Street address**

Salimi Jahromi ST, Ayatoallah Kashani Blve, Second Sadeghieh Sq

###### **City**

Teharan

#### 2

##### **Recruitment center**

###### **Name of recruitment center**

Rofideh Rehabilitation Hospital

###### **Full name of responsible person**

Ahmad Ali Akbari Kamrani

###### **Street address**

Neemati Alley, Baradaran Soleimani St, Gheytaarieh

###### **City**

Tehran

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

University of Social Welfare and Rehabilitation Sciences

###### **Full name of responsible person**

Hassan Shakeri

###### **Street address**

Kodakyar Ave, Daneshjo Blvd, Evin

###### **City**

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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**

#### **Contact**

##### **Name of organization / entity**

University of Social Welfare and Rehabilitation Sciences

##### **Full name of responsible person**

Mohammad Reza Khodaei

##### **Position**

Vice-chancellor for Education, Student and Cultural Affairs

##### **Other areas of specialty/work**

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#### **Contact**

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## **Person responsible for updating data**

### **Contact**

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University of Social Welfare and Rehabilitation  
Sciences

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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*