

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Investigating effect of vestibular stimulation on Cerebral-Palsied children balance performance 3-10 year old in Tehran

#### Protocol summary

##### Summary

Aim of this study is finding proper tool for assessment and treatment of balance in children with cerebral palsy. Study design is triple blinded for patients, researchers and analyzers. Allocation would be randomized. Inclusion criteria necessary for individuals to be involved in study: Children 3 to 10 years old with neurologist diagnose of cerebral palsy; They should be able to stand independently so they should be developmentally in levels before 4 according to Gross Motor Classification System for Cerebral Palsy; their Modified Ashworth's muscle tone grade should be till 3 in spastic type Study Exclusion Criteria: Dis-cooperation during assessment trial; Distortion in force plate signal recording; Dis-cooperation during vestibular stimulation practice; Being absent in 4 sessions per all or 2 successive sessions ;Being absent for final assessment; Orthopedic disorders (fractures in spinal cord or lower extremity); Epilepsy with confirmation of neurologist. 20 children would be selected from cerebral palsied children in Tehran .At first they will be assessed by force plate then intervention group would receive vestibular stimulation accompanied by current occupational therapy in 12 sessions and finally assessed again .Control group will receive only current occupational therapy. We hope that those receiving vestibular stimulation show better balance in these children. Outcome measures are X (Range side way) , Y(Range foreafter), area and Mean velocity.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015021521080N1**

Registration date: **2015-04-21, 1394/02/01**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-04-21, 1394/02/01

##### Registrant information

###### Name

Bahareh Zeynalzadeh Ghoochani

###### Name of organization / entity

University of Social Welfare and Rehabilitation

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3608 3280

###### Email address

ba.zeynalzadeh@uswr.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

University of Social Welfare and Rehabilitation Sciences  
Children Research Center

##### Expected recruitment start date

2015-02-19, 1393/11/30

##### Expected recruitment end date

2016-02-19, 1394/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating effect of vestibular stimulation on Cerebral-Palsied children balance performance 3-10 year old in Tehran

##### Public title

Investigating effect of vestibular stimulation on Cerebral-Palsied children 3-10 year old

##### Purpose

Treatment

**Inclusion/Exclusion criteria**  
Inclusion criteria necessary for individuals to be involved in study: Children 3 to 10 years old with neurologist diagnose of cerebral palsy; They should be able to stand independently so they should be developmentally in levels before 4 according to Gross Motor Classification System for Cerebral Palsy; their Modified Ashworth's muscle tone grade should be till 3 in spastic type Study Exclusion Criteria: Dis-cooperation during assessment trial;Distortion in force plate signal recording;Dis-cooperation during vestibular stimulation practice;Being absent in 4 sessions per all or 2 successive sessions ;Being absent for final assessment;Ortopedic disorders (fractures in spinal cord or lower extremity);Epilepsy with confirmation of neurologist

**Age**  
From **3 years** old to **10 years** old

**Gender**  
Both

**Phase**  
N/A

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

**Sample size**  
Target sample size: **20**

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

**Randomization description**

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
randomized selection of cerebral palsied children from Tehran Clinics that are under supervision of university of social welfare and rehabilitation sciences and randomized allocation of those into control and intervention groups

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical Committe of University of Social Welfare and Rehabilitation Sciences

##### Street address

kodakyar Ave., daneshjo Blvd.,Evin.

##### City

Tehran

##### Postal code

1985713834

#### Approval date

2014-09-28, 1393/07/06

#### Ethics committee reference number

400-190

## 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

X (Range side way) , Y(Range foreafter), (Area (Mean velocity

#### Timepoint

60s

#### Method of measurement

forceplate

## Secondary outcomes

### 1

#### Description

balance strategy

#### Timepoint

20s

#### Method of measurement

forceplate

## Intervention groups

### 1

#### Description

control group: current occupational therapy

#### Category

Rehabilitation

### 2

#### Description

intervention group: vestibular stimulation plus current occupational therapy

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

University of Social Welfare and Rehabilitation  
Sciences Centres

**Full name of responsible person**

Bahareh Zeynalzadeh Ghoochani

**Street address**

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**Email**

b\_zeynalzade@yahoo.com

**Web page address**

www.uswr.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice Chancellor of university of social welfare and  
rehabilitation sciences; Dr.Rushanak Vameghi, Ch

**Full name of responsible person**

Dr. Rushanak Vameghi

**Street address**

kodakyar Ave., daneshjo Blvd.,Evin

**City**

tehran

**Grant name**

تحقيقات اطفال

**Grant code / Reference number**

2846/88/4/801

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

Yes

**Title of funding source**

Vice Chancellor of university of social welfare and  
rehabilitation sciences; Dr.Rushanak Vameghi, Ch

**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**

Bahareh zeynalzadeh ghoochani

**Position**

student

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

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## Person responsible for updating data

**Contact**

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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*