

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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

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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