Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
kodakyar Ave., daneshjo Blvd.,Evin

City
Tehran

Phone
+98 51 3608 3280

Fax
+98 21 2218 0109

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
تحقیقات 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

Street address
kodakyar Ave., daneshjo Blvd.,Evin

City
tehran

Postal code
9188637185

Phone
+98 51 3608 3280

Fax
+98 21 2218 0109

Email
b_zeynalzade@yahoo.com

Web page address
www.uswr.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Social Welfare and Rehabilitation

Full name of responsible person
Bahareh zeynalzadeh ghoochani

Position
student

Other areas of specialty/work

Street address
kodakyar Ave., daneshjo Blvd.,Evin

City
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9188637185

Phone
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+98 21 2218 0109

Email
b_zeynalzade@yahoo.com

Web page address
www.uswr.ac.ir

Person responsible for updating data

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

Street address
kodakyar Ave., daneshjo Blvd.,Evin

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Fax
+98 21 2218 0109

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b_zeynalzade@yahoo.com

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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