Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of effects of single session auditory versus visual feedback on balance in the children with Hemiplegic Spastic Cerebral Palsy

Protocol summary

Study aim
To compare the effects of single-session auditory versus visual feedback on balance in hemiplegic Cerebral Palsy.

Design
Two parallel groups randomized control trial with assessor-blinded

Settings and conduct
The assessor will have no knowledge of the type of intervention and will employ a pre-test/post-test design immediately following a single session for the same patients: first receiving conventional therapy plus visual or auditory feedback and after 48 hours as washing time they will receive conventional therapy plus auditory or visual feedback depend to the sampling result.

Participants/Inclusion and exclusion criteria
Inclusion 1. Aged between 6 years to 12 years; 2. Diagnosis of hemiplegic spastic CP, 3. Grade of 1 & 2 on the Modified Ashworth Scale (MAS) 4. Level I & II (able to walk without limitations) of the Gross Motor Function Classification System according to child's age, 5. No uncorrected vision or hearing impairments; 6. Able to follow and accept the verbal instructions. 7. Able to stand without lower limbs brace. Exclusion The participants will exclude if they having: 8. Other neurological condition like hydrocephalus. 9. Having leg length and Muscles shortening. 10. Having pes cavus. 11. Having any recent fracture or any other condition that poses a threat to stability. 12. Having vestibular or Optical pathology.

Intervention groups
Conventional Balance Therapy by balance board + Visual Feedback or Auditory Feedback Then after 48 hours will receive Conventional Balance Therapy by balance board + Auditory Feedback or visual feedback based on the result of sampling. Total treatment time will be Conventional Physical Therapy 30 mins + 10 mins of visual or auditory feedback training.

Main outcome variables
Modified Ashworth Scale Pediatric Balance Scale (Berg Balance) Timed One-Leg Stance test Time Up and Go test (TUG) Centre of Pressure (COP) displacement

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230903059340N1**
Registration date: **2023-11-19, 1402/08/28**
Registration timing: **prospective**

Last update: **2023-11-19, 1402/08/28**
Update count: **0**

Registration date
2023-11-19, 1402/08/28

Registrant information

Name
Ghaith Alhashimi

Name of organization / entity

Country
Iraq

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+964 773 004 6618

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-01, 1402/09/10

Expected recruitment end date
2024-04-01, 1403/01/13

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of effects of single session auditory versus visual feedback on balance in the children with Hemiplegic Spastic Cerebral Palsy

Public title
Effects of auditory and visual feedback on balance in the children with cerebral palsy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Aged between 6 years to 12 years; Diagnosis of hemiplegic spastic CP, Grade of 1 & 2 on the Modified Ashworth Scale (MAS) scoring from 0 = (No increase in tone) to 4 = (limb rigid in flexion or extension) in the ankle plantar flexors muscles and quadriceps muscles. Level I & II (able to walk without limitations) of the Gross Motor Function Classification System according to child's age, the levels range is (Level I: able to walk without limitations) to (Level V: transported in manual wheelchair). No uncorrected vision or hearing impairments; Able to follow and accept the verbal instructions. Able to stand without lower limbs brace.

Exclusion criteria:
Other neurological conditions like hydrocephalus. Having leg length and Muscles shortening. Having pes cavus. Having any recent fracture or any other condition that poses a threat to stability. Having vestibular or Optical pathology.

Age
From **6 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The researcher will use a convenience sampling method with sample random for the participants who meet the inclusion criteria to determine which intervention the patient will receive in the beginning with consideration of the matching between the groups in terms of side effects of the body and age. The lottery method will be used for randomization to minimize bias.

Blinding (investigator's opinion)
Single blinded

Blinding description
The assessor will have no knowledge of the type of intervention

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics committee of Tehran University of Medical Sciences

Street address
No. 21, Dameshgh St., Vali-e Asr Ave., Tehran , Iran

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Tehran

Province
Tehran

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1416753955

Approval date
2023-11-18, 1402/08/27

Ethics committee reference number
IR.TUMS.FNM REC.1402.158

Health conditions studied

1

Description of health condition studied
Spastic Hemiplegic Cerebral palsy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Spasicity

Timepoint
Before intervention and after finish the intervention immediately.

Method of measurement
The modified Ashworth scale.

2

Description
Balance ability

Timepoint
Before intervention and after finish the intervention immediately.

Method of measurement
Berg Balance scale

3

Description

Walking speed

Timepoint

Before intervention and after finish the intervention immediately.

Method of measurement

Time up and go test

4

Description

Balance Time

Timepoint

Before intervention and after finish the intervention immediately.

Method of measurement

One leg stands test

5

Description

Center of Pressure displacement

Timepoint

Before intervention and after finish the intervention immediately.

Method of measurement

Nintendo Wii Balance Board

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Conventional Balance Therapy by balance board Plus Visual Feedback.

Category

Rehabilitation

2

Description

Intervention group: Conventional Balance Therapy by balance board plus Auditory Feedback.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sadr Alqanat Medical Rehabilitation Center

Full name of responsible person

Iemad Khudair AlQaisy

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Ghaith Fadhil Lafta Alhashimi

Grant code / Reference number

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

No

Title of funding source

Personal Funding

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

IQ

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ghaith Fadhil Lafta Alhashimi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available