Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of adding cognitive training to balance exercises on gait, motor performance, balance, brain activation pattern, quality of life, and fall risk in children with cerebral palsy.

Protocol summary

Study aim
The aim of this study is to evaluate the effects of cognitive–balance and specific balance training on motor performance, balance, gait, brain activation patterns, quality of life, and fall risk in children with cerebral palsy.

Design
Sample size and study groups: The sample includes 42 children with cerebral palsy, who will be divided into three groups of 14 participants each: Control group Balance training group Cognitive–balance training group Allocation will be performed randomly using the Randomizer software.

Settings and conduct
Assessments will be conducted at Kharazmi University Laboratory, and interventions in the school. Motor function, balance, and walking will be measured using standardized tools, under researcher supervision. The study is single-blind, with participants unaware of their group allocation.

Participants/Inclusion and exclusion criteria
inclusion criteria: Diagnosis of spastic cerebral palsy by a physician Age 7 to 18 years Gross Motor Function Classification System (GMFCS) level I or II General good health Written informed consent from parents No participation in similar training programs during the past 6 months exclusion criteria: Surgery or medical conditions that prevent participation in exercises Lack of cooperation or inability to follow instructions

Intervention groups
Participants were divided into three groups. The cognitive–balance group performed balance exercises with cognitive tasks (counting, problem-solving, color/shape recognition) three times a week for eight weeks (45–60 min/session). The specific balance group performed similar balance exercises without cognitive tasks. The control group received no intervention and only took part in assessments.

Main outcome variables
motor function, balance, gait, brain activation patterns, quality of life, and fall risk.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250726066634N1**
Registration date: **2025-10-14, 1404/07/22**
Registration timing: **prospective**

Last update: **2025-10-14, 1404/07/22**
Update count: **0**

Registration date
2025-10-14, 1404/07/22

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-17, 1404/07/25

Expected recruitment end date
2025-11-21, 1404/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of adding cognitive training to balance exercises on gait, motor performance, balance, brain activation pattern, quality of life, and fall risk in children with cerebral palsy.

Public title

The effect of balance and cognitive balance exercises on improving balance and movements in children with cerebral palsy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Major inclusion criteria before randomization: - Diagnosis of spastic cerebral palsy (CP) by a specialist physician - Age range between 7 and 18 years - Ability to understand and perform the proposed exercises and research tests - No participation in a similar training program during the past three months - Written informed consent from parents or legal guardian - General good health (no severe chronic diseases or psychological disorders that prevent exercise participation) - Gross Motor Function Classification System (GMFCS) levels I and II

Exclusion criteria:

Major exclusion criteria before randomization : - Any surgery or medical conditions that prevent participation in exercises - Lack of cooperation or unwillingness of the child or parents to participate in the study - Participation in similar training programs or other interventions that may interfere with study outcomes - Occurrence of severe cognitive or motor problems that prevent continuing the exercises

Age

From **7 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated to three study groups using block randomization with fixed block size of 6 and an allocation ratio of 1:1:1. Considering the total sample size of 42 participants, randomization will be performed in 7 consecutive blocks (7×6=42). In each block: Two participants will be assigned to the cognitive–balance training group Two participants will be assigned to the specific balance training group Two participants will be assigned to the control group The random sequence will be generated using the website Randomizer (https://www.randomizer.org/). To ensure allocation concealment, each group assignment will be placed in opaque, sealed, and sequentially numbered envelopes. After confirming eligibility and obtaining written informed consent from the parents or legal guardians, each participant will be given an envelope by an independent person who is not involved in data collection or intervention implementation. The participant will then be assigned to the group indicated inside the envelope. This procedure ensures that participants enter the random sequence in a sequential and concealed manner, preventing any investigator or staff involved in the intervention or data collection from knowing the group assignment in advance.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor will be blinded, so that they will not be aware of the participants' group allocation. Participants, their parents, and the intervention administrators (therapists) will not be blinded, as it is necessary for them to perform and supervise the exercises.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kharrazmi University

Street address

Kharazmi University, University Square, Shahid Beheshti Street, Karaj, Iran

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Tehran

Province

Tehran

Postal code

15719-14911

Approval date

2025-06-26, 1404/04/05

Ethics committee reference number

IR.KHU.REC.1404.065

Health conditions studied

1

Description of health condition studied

cerebral palsy

ICD-10 code
G80.9
ICD-10 code description
Cerebral palsy, unspecified

Primary outcomes

1

Description
Balance
Timepoint
Immediately before the intervention begins and immediately after the intervention ends
Method of measurement
Dynamic balance (TUG), static balance (modified Romberg), functional balance (PBS)

Secondary outcomes

1

Description
Gait
Timepoint
Immediately before the intervention begins and immediately after the intervention ends
Method of measurement
Using 2D video analysis in Kinovea software (while walking)

2

Description
Gross Motor Function
Timepoint
Immediately before the intervention begins and immediately after the intervention ends
Method of measurement
Using the Gross Motor Function Measure-88 (GMFM-88) test, two of the five motor domains of this test (D to E) are measured.

3

Description
Brain activation pattern
Timepoint
Measurement of outcome variables is carried out in two time phases: 1- Before the start of the intervention (pre-test) 2- After the end of the intervention (post-test)
Method of measurement
Using electroencephalography (EEG)

4

Description
quality of life
Timepoint
Immediately before the intervention begins and immediately after the intervention ends
Method of measurement
Persian-translated CP QOL-Child Quality of Life Questionnaire (based on age, either the patient or the patient's parents fill it out) Two questionnaire models based on age range

5

Description
Fall Risk
Timepoint
Immediately before the intervention begins and immediately after the intervention ends
Method of measurement
Fall risk using the Dynamic Gait Index (DGI) test

Intervention groups

1

Description
Intervention Group 1 (Balance-Specific Training – BST):Participants in this group receive specialized balance training, including transfer exercises, static balance, and dynamic balance activities. The purpose of these exercises is to strengthen motor skills and improve balance control to reduce the risk of falls. Each session lasts 60 minutes and is conducted three times per week for 8 weeks. The intensity and difficulty of the exercises are gradually adjusted based on the child’s abilities.
Category
Rehabilitation

2

Description
Intervention group: Intervention Group 2 (Cognitive-Balance Training):Participants in this group perform combined motor and cognitive exercises. The exercises include cognitive tasks performed simultaneously with balance activities to improve motor control, balance, and cognitive function. Each session lasts 60 minutes and is conducted three times per week for 8 weeks. The exercises gradually become more challenging to maximize the child’s progress.
Category
Rehabilitation

3

Description
Control group: This group does not receive any intervention and only undergoes assessments before and after the research period.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center

Exceptional Education Schools in Tehran

Full name of responsible person
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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

Grant code / Reference number

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

Title of funding source
Kharazmi University

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
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Other areas of specialty/work

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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