Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Evaluating the Effect of Motor Imaginary Training on Motor Learning of Adults with Cerebral Palsy: the role of anxiety and age

Protocol summary

Study aim
Evaluating the effect of motor imagery training on the gait of adults with CP

Design
A controlled, parallel-group, double-blind, randomized clinical trial on 90 patients. Randomization will be generated using the website http://www.randomizer.org

Settings and conduct
Study location: Rehabilitation clinics in Tehran; Study population: Adults over 18 years of age with cerebral palsy who are able to stand and walk with or without assistance; Type of blinding: Double-blind; Blinding method: Participants, outcome assessors, and therapists are blinded.

Participants/Inclusion and exclusion criteria
Inclusion: Spastic CP diagnosis and no other neurological disorders, Age > 18, Able to stand/walk (with/without assistance), No severe depression, Ability to communicate, Understanding simple task instructions
Exclusion: Contraindications to training, BoTox injection in the past 6 months, Intrathecal baclofen pump or surgery in the past 12 months

Intervention groups
Intervention group 1: participants with CP receive conventional occupational therapy, Intervention group 2: participants with CP receive the conventional occupational therapy combining with MIT. Intervention group 3: healthy control group receiving no intervention

Main outcome variables
Functional balance, Functional mobility, Quality of life, Gait parameters (gait speed, step length and width), Motor Imagery ability, Brain activity level, Muscle activity level, Anxiety level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140304016830N15**
Registration date: **2025-07-28, 1404/05/06**
Registration timing: **prospective**

Last update: **2025-07-28, 1404/05/06**
Update count: **0**

Registration date
2025-07-28, 1404/05/06

Registrant information

Name
Ghorban Taghizadeh

Name of organization / entity
School of Rehabilitation Sciences, Iran University of Medical

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-08-23, 1404/06/01

Expected recruitment end date
2026-08-23, 1405/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the Effect of Motor Imaginary Training on Motor Learning of Adults with Cerebral Palsy: the role of anxiety and age

Public title
Evaluating the Effect of Mental Practices on the Movement of Adults with Cerebral Palsy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
a diagnosis of spastic CP and no other neurological disorders upon self-declaration of participant having the age of more than 18 years the ability to stand and walk either with or without assistance Not having severe depression the ability to communicate discomfort or pain the comprehension of simple instructions of the tasks during intervention and data collection sessions
Exclusion criteria:
Any contraindications to participating in the training sessions botulinum toxin (BoTox) injections within six months before the assessment the presence of an intrathecal baclofen pump or any surgical intervention in the past 12 months
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The type of randomization used in this study is block randomization, which will be performed using the website http://www.randomizer.org by a person independent of the therapist and evaluator. Participants in different groups will have no contact with each other and will receive the interventions on different days. All participants in the three groups will be assessed before the intervention, after the intervention, and at follow-up (two months after the end of the intervention).
Blinding (investigator's opinion)
Single blinded
Blinding description
The participants in this study will be blinded to their group allocation. Although they are aware that they are participating in a research project involving cognitive-practical interventions, they will not be informed about the number of groups, the specific differences between the groups, or the hypotheses of the study. The outcome assessors, data collectors, and the statistician responsible for data analysis will also be blinded to group allocation. The participants and therapists delivering the interventions will also be blinded to the assignments.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences (IUMS), next to Milad Tower, Hemmat Expressway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2025-07-15, 1404/04/24
Ethics committee reference number
IR.IUMS.REC.1404.428

Health conditions studied

1

Description of health condition studied
Spastic cerebral palsy
ICD-10 code
G80.1
ICD-10 code description
Spastic diplegic cerebral palsy

Primary outcomes

1

Description
Functional mobility
Timepoint
Baseline, post-intervention (month 2), and follow-up (month 2)
Method of measurement
Functional mobility will be assessed through Timed Up and Go (TUG) test to evaluate a person's mobility, balance, walking ability, and fall risk. lower score in this test indicates better performance in movement.

Secondary outcomes

1

Description
Functional balance
Timepoint

Baseline, post-intervention (month 2), and follow-up (month 2)

Method of measurement

Berg Balance Scale (BBS)

2

Description

Quality of life

Timepoint

Baseline, post-intervention (month 2), and follow-up (month 2)

Method of measurement

World Health Organization Quality of Life questionnaire-Brief version

3

Description

Gait parameters

Timepoint

Baseline, post-intervention (month 2), and follow-up (month 2)

Method of measurement

measuring speed, step length, and step width during walking

4

Description

Motor imagery ability

Timepoint

Baseline, post-intervention (month 2), and follow-up (month 2)

Method of measurement

Chronometer test, and Laterality test

5

Description

Anxiety level

Timepoint

Baseline, post-intervention (month 2), and follow-up (month 2)

Method of measurement

Anxiety subscale of Hospital and Depression Scale (HADS)

Intervention groups

1

Description

Intervention Group 1 (Occupational-Based Group with MIT): Participants in this group will attend a total of 23 sessions. The first session will consist of a data collection session, including clinical and laboratory assessments. The intervention sessions will be held after the initial analysis of variables. The intervention phase will begin in the second session, focusing on physical rehabilitation. This rehabilitation program will include targeted exercises designed to strengthen and stretch the muscles involved in walking. Participants will receive an additional 15 minutes of MIT training at the end of each rehabilitation session. In this section, participants will first select a meaningful scenario of daily activities that they prefer the most. These scenarios will vary in walking speed, stride length, amount of load they carry, and characteristics of the walking path (path width, slope, slippery surface). It is worth noting that all of these scenarios must be imagined and will not be presented in reality. The intervention will last for 20 sessions (2-3 sessions per week) and will end in session 21. Two more data collection sessions will be held after the intervention and after the 2-month follow-up (sessions 22 and 23) at the end of this group's participatory program.

Category

Rehabilitation

2

Description

Intervention Group 2 (occupation-based group without MIT): Participants will attend a total of 23 sessions. The first session will consist of a data collection session, including clinical and laboratory assessments. The intervention sessions will be held after the initial analysis of variables. The intervention phase will begin in the second session with a focus on physical rehabilitation. This rehabilitation program will include targeted exercises designed to strengthen and stretch the muscles involved in walking. The intervention will last for 20 sessions (2-3 sessions per week) and will end in session 21. Two more data collection sessions will be held after the intervention and after a 2-month follow-up (sessions 22 and 23) at the end of the group's participatory program.

Category

Rehabilitation

3

Description

Control Group: In the healthy control group, they will undergo a data collection session including clinical and laboratory assessments. These data will be used as a baseline for further comparison and analysis. There is no other session regarding data recording and intervention for this group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Movement Disorder centers and rehabilitation clinics

Full name of responsible person

Ghorban Taghizadeh

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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Private budget
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
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Ghorban Taghizadeh
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The shared file will include de-identified data from study participants. Specifically, the dataset will contain general demographic information (age, gender), group allocation, and scores related to the primary outcome measures of the study. No personal identifiers such as names, contact details, or national ID numbers will be included. Only this specific part of the data will be available to other researchers upon formal request and after obtaining appropriate approvals. The complete dataset or other sensitive information will not be shared.
When the data will become available and for how long
One year after publishing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Researchers working in academic and scientific institutions
From where data/document is obtainable
Ghorban Taghizadeh Adsress: Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran Tel: 00982122227124 E-mail: taghizadeh.gh@iums.ac.ir
What processes are involved for a request to access data/document
Just sending a request by email and mentioning the explanation about the cause of the need for documentation is enough.
Comments