Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of adapted Cognitive Orientation to daily Occupational Performance (CO-OP) approach by adding self-controlled video feedback on the upper limb Occupational Performance of children with spastic cerebral palsy

Protocol summary

Study aim
The Adaptation of Cognitive Orientation to daily Occupational Performance (CO-OP) approach by adding self-controlled video feedback and investigating its effect on the upper limb Occupational Performance of children with spastic cerebral palsy

Design
This is a randomized controlled trial with blinded assessors and is a superiority trial. 39 participants in this study will be assigned to one of three groups after stratified block randomization: control group, CO-OP approach, and adapted CO-OP approach.

Settings and conduct
Interventions will be carried out in governmental and non-governmental occupational therapy clinics and exceptional schools in Zanjan. All assessments will be conducted by an occupational therapist and blinded to the allocation of participants.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of spastic cerebral palsy by a neurologist Age range between 8 and 11 years A level 3-1 on the GMFCS, MACS, BFMF, VFCS, CFCS Achieving an age-appropriate educational level or a score above 70 on the Sparkle Intelligence Estimation Scale Exclusion criteria History of orthopedic-reconstructive surgeries within the past six months History of Botox injections within the past three months Hearing impairments that cannot be corrected with assistive devices.

Intervention groups
Control group: conventional occupational therapy treatments (such as various techniques such as Neurodevelopmental treatment, positioning, etc.). Interventions Group One: Occupational therapy Cognitive Orientation to daily Occupational Performance Approach Interventions Group Two: Occupational therapy with an adapted Cognitive Orientation to daily Occupational Performance Approach

Main outcome variables
Canadian Occupational Performance Measure Performance Quality Rating Scale Operational definition Goal Attainment Scaling Box and Block Test ABILHAND-Kids Pediatric Motivation Scale

General information

Reason for update
The location of sample collection has been changed from Tehran to Zanjan. Other details of the study remain unchanged.

Acronym

IRCT registration information
IRCT registration number: **IRCT20241123063805N1**
Registration date: **2024-12-08, 1403/09/18**
Registration timing: **prospective**

Last update: **2025-10-07, 1404/07/15**
Update count: **1**

Registration date
2024-12-08, 1403/09/18

Registrant information

Name
Amin Rezaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 56 3246 8349

Email address
rezaei.amin@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-20, 1403/11/01
Expected recruitment end date
2026-05-21, 1405/02/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of adapted Cognitive Orientation to daily Occupational Performance (CO-OP) approach by adding self-controlled video feedback on the upper limb Occupational Performance of children with spastic cerebral palsy

Public title
Effect of adapted Cognitive Orientation to daily Occupational Performance approach on spastic cerebral palsy children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of spastic cerebral palsy by a neurologist The age range is between 8 and 11 years level 1-3 of gross motor function based on GMFCS scale level 1-3 of hand function based on MACS scale level of 1-3 of bimanual fine motor function on BFMF scale level of 1-3 of visual function on the VFCS scale level of 1-3 of verbal communication ability using Persian language based on the CFCS scale Placement in the education level according to age or a score higher than 70 based on Sparkle's IQ estimation criteria
Exclusion criteria:
History of orthopedic-reconstructive surgeries within the past six months History of botox injection during the last three months Hearing impairments that cannot be corrected with the use of assistive devices.
Age
From **8 years** old to **11 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **39**
Randomization (investigator's opinion)
Randomized
Randomization description
Considering that Manual Ability Classification System (MACS) levels one to three have been determined as the criteria for entering the research, and on the other hand, it is the main dependent variable of studying the occupational performance of the upper limb therefore for the random allocation of samples, stratified block randomization method will be used. (MACS 1), (MACS 2) and (MACS 3) are considered as randomization layers. In this regard, a random sequence will be created using blocks of 6 (proportion of sample sizes in three groups during the sampling period) and the online program randomization.com. In fact, for each class, there is a specific blocked sequence in which the samples are entered into the desired sequence after evaluation according to the MACS level. To conceal the random sequence, the SNSOE method (Sequentially Numbered, Selected, Opaque Envelops) will be used, and in the implementation, the person who creates the random sequence process is separate from the person who assigns the participants to the groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
All assessments (primary, secondary, and follow-up) in all three intervention groups (intervention one, intervention two, and control group) will be conducted by an experienced and trained occupational therapist (with at least three years of clinical experience in children) outside the research group and blinded to the allocation of participants to the control and intervention groups (intervention one and two).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, 5th floor of the central headquarters, Hemat Highway, next to Milad Tower, Deputy of research and technology
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2024-11-09, 1403/08/19
Ethics committee reference number
IR.IUMS.REC.1403.682

Health conditions studied

1

Description of health condition studied
Cerebral palsy
ICD-10 code
G80
ICD-10 code description
Cerebral palsy

2

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

3

Description of health condition studied
Spastic quadriplegic cerebral palsy
ICD-10 code
G80.0
ICD-10 code description
Spastic quadriplegic cerebral palsy

4

Description of health condition studied
Spastic hemiplegic cerebral palsy
ICD-10 code
G80.2
ICD-10 code description
Spastic hemiplegic cerebral palsy

Primary outcomes

1

Description
Occupational performance, which is the score that participants report on the performance and satisfaction of their chosen occupations based on a semi-structured interview based on the Canadian Occupational Performance Measure.
Timepoint
Occupational performance will be assessed at the beginning of the study (before the start of the interventions), after the end of the intervention sessions, and in order to assess the follow-up period six weeks after the end of the interventions.
Method of measurement
Canadian Occupational Performance Measure

2

Description
The actual performance of the selected occupations is determined from the score that participants obtain from a video-based observational tool called the Performance Quality Rating Scale (operational definition), which is intended to measure the actual performance of the selected activities of the subjects.
Timepoint
The actual performance of the selected occupations will be assessed at the beginning of the study (before the start of the interventions), after the end of the intervention sessions, and in order to assess the follow-up period six weeks after the end of the interventions.
Method of measurement
Performance Quality Rating Scale (Operational Definition)

3

Description
Goal attainment is a method of assessing progress toward individual goals that is used in occupational therapy, physiotherapy, and speech therapy across a wide range of clinical populations, including children, adults, and the elderly.
Timepoint
Goal attainment will be assessed at the beginning of the study (before the start of the interventions), after the end of the intervention sessions, and in order to assess the follow-up period six weeks after the end of the interventions.
Method of measurement
Goal Attainment Scaling

Secondary outcomes

1

Description
Manual ability
Timepoint
Manual ability will be assessed at the beginning of the study (before the start of the interventions), after the end of the intervention sessions, and in order to assess the follow-up period six weeks after the end of the interventions.
Method of measurement
ABILHAND-Kids

2

Description
Gross manual dexterity
Timepoint
Gross manual dexterity will be assessed at the beginning of the study (before the start of the interventions), after the end of the intervention sessions, and in order to assess the follow-up period six weeks after the end of the interventions.
Method of measurement
Box and Block Test

3

Description
Pediatric Motivation
Timepoint
To measure changes in motivation during the implementation of interventions, the test was repeated

in sequence every three sessions (first, fourth, seventh, and tenth sessions).

Method of measurement

Pediatric Motivation Scale

Intervention groups

1

Description

Control group: Conventional occupational therapy treatments (such as a variety of techniques such as Neurodevelopmental treatment, positioning, etc.). Therefore, these children were exposed to a broad range of intervention modalities. Intervention techniques included those aimed at improving impairment (eg, stretching) and enhancing activities (eg, motor learning exercises). In control group, as in the other two groups, the child sets four goals using the Canadian Occupational Performance Measure and work on the set treatment goals continues based on the clinical reasoning of the control group therapist who has no training in Cognitive Orientation to Daily Occupational Performance. The number and duration of conventional occupational therapy sessions in the control group will include at least 2 sessions per week for at least 45 minutes. Treatment in the control group will be provided by occupational therapists with at least two years of clinical experience in the field of children with cerebral palsy and outside the research group and will not be aware of the allocation of samples to the control and intervention groups.

Category

Rehabilitation

2

Description

Intervention group: Occupational therapy with Cognitive Orientation to daily Occupational Performance (CO-OP) Approach. According to the established format, (CO-OP) will be conducted in a clinic setting over eleven sessions (one preparatory session followed by ten therapy sessions), twice a week (each session 45 minutes). In the initial introductory session, the therapist will introduce the child to the global problem-solving strategy (goal-plan-do-check), which will be used when working to achieve the goals. Therefore, in the interventions of this group, each child will be taught a Global Cognitive Strategy, and then the therapist will guide to discover Domain Specific Strategies (DSSs) to improve motor-based occupational performance problems. The therapist will guide the child in discovering his/her plan for functioning, and the child will implement this plan and then check whether the action taken is effective or needs to be modified. Intervention will be done on a single goal first (the goal selected by the child as the first priority during the goal-setting phase), and then second and third goals will be gradually added. The interventions in this group will be conducted by an occupational therapist experienced in using CO-OP in the treatment of children with cerebral palsy.

Category

Rehabilitation

3

Description

Intervention group: Occupational therapy with an adapted Cognitive Orientation to daily Occupational Performance (CO-OP) Approach. After preparing an adapted version of the (CO-OP) Approach with the addition of self-controlled video feedback, in the preparation session of this group, in addition to explanations about the (CO-OP) approach and the strategies used, necessary training will be provided on how to use self-controlled video feedback. The training provided will be about the importance of benefiting from video feedback and its impact on performance, determining the appropriate time to receive video feedback, how to work with the user interface and manage images, and giving real and practical examples in the form of a case study, and finally the participant will practice how to use it in practice. In the preparation session and before each session, the therapist will remind the participant that at least two or more times should be used self-controlled video feedback and naturally, determining its time, sequence, and number is up to the participant. In fact, participants in this group are able to use elf-controlled video feedback to obtain appropriate cognitive solutions to solve upper limb occupational performance problems. The number of times self-controlled video feedback is received during the sessions will be recorded by the intervention provider. The interventions of this group will be conducted by the main researcher.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Government Occupational Therapy Centers in Zanjan

Full name of responsible person

Amin Rezaei

Street address

Government Occupational Therapy Centers in Zanjan

City

Zanjan

Province

Zanjan

Postal code

1348715459

Phone

+98 937 370 4662

Email

aminrezaei402@yahoo.com

2

Recruitment center

Name of recruitment center

Non-governmental centers of occupational therapy in Zanjan

Full name of responsible person
Amin Rezaei

Street address
Private Occupational Therapy Centers

City
Zanjan

Province
Zanjan

Postal code
1348715459

Phone
+98 992 348 0281

Email
aminrezaei402@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Dr. Reza Falak

Street address
Iran University of Medical Sciences, 5th floor of the central headquarters, Hemat Highway, next to Milad Tower, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8670 2503

Email
falak.r@iums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Iran University of Medical Sciences

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
Iran University of Medical Sciences

Full name of responsible person
Amin Rezaei

Position
PhD candidate in Occupational Therapy

Latest degree
Master

Other areas of specialty/work
Occupational Therapy

Street address
Tehran, Mirdamad, Madar Square, Shah Nazari Street, Madakaran Street, Faculty of Rehabilitation Sciences, Iran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1545913487

Phone
+98 21 2222 8051

Email
aminrezaei402@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Amin Rezaei

Position
PhD candidate in Occupational Therapy

Latest degree
Master

Other areas of specialty/work
Occupational Therapy

Street address
Tehran, Mirdamad, Madar Square, Shah Nazari Street, Madakaran Street, Faculty of Rehabilitation Sciences, Iran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1545913487

Phone
+98 21 2222 8051

Email
aminrezaei402@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Amin Rezaei

Position

PhD candidate in Occupational Therapy

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

Street address

Tehran, Mirdamad, Madar Square, Shah Nazari Street, Madakaran Street, Faculty of Rehabilitation Sciences, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 8051

Email

aminrezaei402@yahoo.com

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

.

When the data will become available and for how long

.

To whom data/document is available

.

Under which criteria data/document could be used

.

From where data/document is obtainable

.

What processes are involved for a request to access data/document

.

Comments