Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of “Cognitive Orientation to daily Occupational Performance (CO-OP)” with Current Treatment Approach (CTA) on motivation and participation of 8-12 years old children with cerebral palsy

Protocol summary

Study aim

The comparison of (CO-OP)” with current treatment approach (CTA) on motivation and participation

Design

Clinical, Randomized, Tripple-blind trial with two parallel group

Settings and conduct

consent form will obtain from parents. children who eligible are randomly assigned to CO-OP and CTA groups. partcipant choose their three treatment goals based on COPM. pediatric volitional questionnaire in children are administered by an unaware therapist through video recording pre/post-test and follow-up. On thePediatric motivation" (PMOT) is completed by the child in sessions 1, 3, 7, 12 during intervention. "Dimensions of mastery questionnaire(DMQ), "Life habit questionnaire" (LIFE_H) GAS and COPM will be filled in pre/post test and follow-up. " ,

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 8 and 12 years of age a; diagnosis of cerebral palsy that is determined by neurologist; level 1- 3 on the Gross Motor Function Classification Scale (GMFCS); level 1- 3 on The Manual Ability Classification System (MACS); normal intelligence that is determined by Raven test; normal or corrected to normal hearing and vision; sufficient language ability Exclusion criteria: dissuasion of parents and child ; child had previously received a cognitive treatment.

Intervention groups

CO-OP group: Children choose three goals based on COPM and with the approach of CO-OP", acquire skills, learn general problem-solving strategies (goal, planning, implementation, review and identification of strategies specific to the CO-OP). This study will be presented in 45 to 1 hour sessions twice a week for 12. CTA : 45- to 1-hour sessions will be offered twice a week for 12 sessions.

Main outcome variables

Primary outcomes: Participation, motivation during rehabilitation,Mastery motivation to master, Volition Secondary Outcomes: Satisfaction and Performance Score of COPM, Goal Attainment Scale(GAS)

General information

Reason for update

The results of the pilot study showed that the evaluation of the second stage (sixth session) is indeterminate due to interfere with intervention programs for performing second activity goals (we had three goals, each goal approximately required 4 sessions of intervention, the sixth session is one of the goals in the middle of which the results could not be analyzed) Therefore, the evaluation of the second stage was removed and replaced with a follow-up evaluation two months after the last session. In order to assess the achievement of children's goals in the study, with a top-down approach and a client-centered approach, the Assessment of Goal Attainment Scale (GAS) and the Canadian occupational Performance Measurement(COPM) were included to the study as secondary outcomes. The main reasons for not updating on time are: 1- Training of the therapist "Cognitive to daily work performance (CO_OP)" which lasted about four months, 2- The need to run a pilot, the results of which lasted six months, 3- Consequences of the Covid 19 pandemic.4: Edit and summerize the abstract due to word count limitation

Acronym

IRCT registration information

IRCT registration number: **IRCT20120910010806N5**
Registration date: **2018-02-14, 1396/11/25**
Registration timing: **prospective**

Last update: **2021-02-24, 1399/12/06**
Update count: **1**

Registration date
2018-02-14, 1396/11/25

Registrant information

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Iran University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-12, 1396/11/23

Expected recruitment end date
2018-06-21, 1397/03/31

Actual recruitment start date
2018-12-22, 1397/10/01

Actual recruitment end date
2020-01-20, 1398/10/30

Trial completion date
2020-01-30, 1398/11/10

Scientific title
The comparison of “Cognitive Orientation to daily Occupational Performance (CO-OP)” with Current Treatment Approach (CTA) on motivation and participation of 8-12 years old children with cerebral palsy

Public title
The effect of “Cognitive Orientation to daily Occupational Performance (CO-OP)” on motivation and participation of 8-12 years old children with cerebral palsy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 8 and 12 years at the time of sampling Diagnosis of cerebral palsy that is determined by a neurologist Level 1, 2, or 3 on the Gross Motor Function Classification Scale (GMFCS) Level 1,2 or 3 on The Manual Ability Classification System (MACS) Normal intelligence Normal or near to normal in hearing and vision Sufficient language ability to communicate with the therapist and be understood during treatment

Exclusion criteria:
Dissuasion of parents in making response to questions of measurements or bringing students to the intervention sessions Dissuasion of students in making response to questions of measurements or coming to the intervention sessions Child had previously received, or is presently receiving, a cognitive treatment

Age
From **8 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **9**
Actual sample size reached: **9**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will select by covenience sampling. Randomizing participants in CO-OP & CTA groups will done with randomization digits table by a blind person to the study.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participants will not aware of the group that are randomized. In this study the assesments will performed by parent, the child and trained assessor who are blind to the study. The data will enter in SPSS and statistically analysis by a blind statistician.

Placebo
Not used

Assignment
Parallel

Other design features
Cognitive Orientation to Daily Occupational Performance (CO-OP): is a well-explicated top-down, problem solving approach that has been shown to support skill acquisition and a client-centered approach. The CO-OP approach differ from traditional bottom-up interventions in that it is situated in a learning paradigm and use cognitive strategies to facilitate skill acquisition at the ICF activity rather than structure and function level, and draw on motor learning principle to help children discover how to perform everyday activities. The main objective of CO-OP are skill acquisition, the learning of global problem solving strategy (goal, plan, do, check) and the identification of domain-specific strategies to support generalization to the other environment and transfer to other motor-based tasks. CO-OP can be used to enable the achievement of occupation-based goal while simultaneously promoting self-efficacy. “9 child with inclusion criteria will enter to CO-OP group., Each sample will receive the intervention two days a week and 2 hours in every day. Each sample will receive 12 hours treatment. Current Treatment Approach(CTA) for children with cerebral palsy: this treatment typically focus on remediation or bottom-up approaches. Many of this therapeutic approaches to managing cerebral palsy are based on neuromaturational models of motor development which focus on improving motor movement (bottom-up approaches) and do not emphasize performance in every day activities. Other approaches

implementing these bottom-up strategies, such as casting and positioning techniques, can be effective in achieving in anatomical goals such as increase range of motion and enhancing postural tone. Little evidence exists that achieving these anatomical goals translates into improved task performance or motor-based skill acquisition among children with cp.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی و خدمات درمانی ایران

Street address

iran univercity of medical science- shahid Hemmat highway- Tehran- Iran

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Approval date

2018-01-18, 1396/10/28

Ethics committee reference number

IR.IUMS.REC1396.9511355001

Health conditions studied

1

Description of health condition studied

Cerebral Palsy (CP)

ICD-10 code

G80

ICD-10 code description

Cerebral palsy

Primary outcomes

1

Description

participation

Timepoint

pretest , post test and follow-up (two months after last session)

Method of measurement

Life habit questionnaire(LIFE_H) for 5-13 years children with cerebral palsy

2

Description

Motivation during therapy

Timepoint

sessions 1, 3,7,11 and 12

Method of measurement

The Pediatric motivation scale for children rehabilitation

3

Description

Mastery motivation

Timepoint

pretest , post test and follow-up (two months after last session)

Method of measurement

Dimensions of mastery questionnaire (DMQ) The DMQ parent proxy-report

4

Description

Volition

Timepoint

pretest , post test and follow-up (two months after last session)

Method of measurement

Pediatric volitional questionnaire (PVQ)

Secondary outcomes

1

Description

Goal achievement

Timepoint

Pretest, post test and follow-up

Method of measurement

Goal Attainment scale (GAS)

2

Description

Performance and satisfaction scores of child-chosen goal

Timepoint

Pretest, post test and follow-up

Method of measurement

Canadian Occupational Performance Measurement (COPM)

Intervention groups

1

Description

Intervention group: Cognitive orientation to daily occupational performance (CO-OP): is a well-explicated top-down, problem solving approach that has been shown to support skill acquisition and a client-centered approach. The CO-OP approach differ from traditional bottom-up interventions in that it is situated in a learning paradigm and use cognitive strategies to facilitate skill acquisition at the ICF activity rather than structure and function level, and draw on motor learning principle to help children discover how to perform everyday activities. The main objective of CO-OP are skill

acquisition, the learning of global problem solving strategy (goal, plan, do, check) and the identification of domain-specific strategies to support generalization to the other environment and transfer to other motor-based tasks. CO-OP can be used to enable the achievement of occupation-based goal while simultaneously promoting self-efficacy. in this study participant will choose three treatment goals by use of Candian Occupational Performance Model (COPM). Primary sessions of CO-OP include to review the child's "daily activity log", setting goals and teaching general strategies. Middle sessions include facilitating the learning and use of domain specific strategy and family education . In the final sessions, the suppportive role of therapist is reduced and the child is prepared for the transfer of general and specific strategies to other tasks.

Category

Rehabilitation

2

Description

Control group: Current treatment approach (CTA)Current approach for children with cerebral palsy: this treatment typically focus on remediation or bottom-up approaches. Many of this therapeutic approaches to managing cerebral palsy are based on neuromaturational models of motor development which focus on improving motor movement (bottom-up approaches) and do not emphasize performance in every day activities. Other approaches implementing these bottom-up strategies, such as casting and positioning techniques, can be effective in achieving in anatomical goals such as increase range of motion and enhancing postural tone. Little evidence exists that achieving these anatomical goals translates into improved task performance or motor-based skill acquisition among children with cp. 9 children between age 8-12 will receive twelve 45-minute sessions of intervention on average twice per week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

sourosh school (for physical disabilities)

Full name of responsible person

Mr saeid reisi

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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

Research deputy of Iran university of medical sciences

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

Zahra Poorzamani Dehkordi

Position

master candidate of Occupational Therapy

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

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Person responsible for scientific inquiries

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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
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Article puplished
When the data will become available and for how long
March 2019
To whom data/document is available
The researcher and occupational therapists
Under which criteria data/document could be used
Other research, critics, check and clinical usage
From where data/document is obtainable
First person in article
What processes are involved for a request to access data/document
Send request by email
Comments