Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of the "cognitive orientation to daily occupational performance" (CO-OP) approach on occupational and motor performances in 7-12 year old children with Autism spectrum disorder

Protocol summary

Study aim
Determining the effect of the "cognitive orientation to daily occupational performance" (CO-OP) approach on occupational and motor performances performances in children with Autism spectrum disorder (ASD).

Design
Clinical trial with control group, parallel groups, double-blind, randomized with SPSS software, on 30 patients.

Settings and conduct
Occupational Therapy Clinic - Autism Special Schools

Participants/Inclusion and exclusion criteria
In this study, the main inclusion criteria include children aged 7 to 12 years with a diagnosis of high-functioning ASD, the ability to communicate verbally in Persian. The main exclusion criteria include children with intellectual disabilities or progressive neurological disorders, children whose parents do not cooperate or withdraw from the study, and children who are unable to complete interventions or assessments for medical reasons.

Intervention groups
This study will be a clinical trial and will include two intervention and control groups: 1. Control group: Children in this group will receive routine occupational therapy treatment at the center, which will be assessed in two sessions (pre-test and post-test) with research tools. Routine treatment in this study refers to a set of common occupational therapy interventions that are typically provided in rehabilitation centers for children with ASD. 2. Intervention group: Children in this group will receive routine treatment along with a CO-OP-based intervention. This intervention is designed based on the standard protocol developed by Polatajko et al. and is structured and based on cognitive learning. The CO-OP-based intervention is designed as a structured 12-session protocol (45-60 minute sessions) in children aged 7 to 12 years. The sessions will be held 2 days a week.

Main outcome variables
Occupational performance; Performance satisfaction; Motor skills

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260207068781N1**
Registration date: **2026-03-15, 1404/12/24**
Registration timing: **prospective**

Last update: **2026-03-15, 1404/12/24**
Update count: **0**

Registration date
2026-03-15, 1404/12/24

Registrant information

Name
Seifolah Jahantabi Nejad

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-04-09, 1405/01/20

Expected recruitment end date
2026-06-21, 1405/03/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the "cognitive orientation to daily occupational performance" (CO-OP) approach on occupational and motor performances in 7-12 year old children with Autism spectrum disorder

Public title

The effect of CO-OP approach on occupational and motor performances in children with Autism spectrum disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children must be between the ages of 7 and 12. Having high-functioning autism spectrum disorder (based on the ASSQ questionnaire) and a diagnosis from a pediatric psychiatrist. Have the ability to communicate verbally in Persian. An IQ greater than or equal to 70 (based on the WISC Children's Test or its equivalent in the medical record). No intellectual disability or progressive neurological disorders. Completion of informed consent by the child or parent.

Exclusion criteria:

Unwillingness of the child or parent to continue participation at any stage prior to randomization.

Age

From **7 years** old to **12 months** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

After meeting the entry requirements, obtaining written informed consent, and completing a pre-test assessment, participants will be randomly assigned to two intervention and control groups with a 1:1 allocation ratio. In this study, a block randomization method with variable block sizes will be used to maintain a balance in the number of samples in the two groups and reduce the predictability of the allocation sequence. The randomization unit will be individual, and the random sequence will be generated using SPSS version 25 software by a member of the research team who has no role in implementing the intervention and evaluating the outcomes. In order to reduce allocation bias, allocation concealment will be performed sequentially through the use of opaque, sealed, numbered, and sealed envelopes, such that after completing the baseline assessment of each participant, the relevant envelope will be opened and his or her group will be determined. The outcome assessor will be blind to the group allocation of the participants and will not interfere in the randomization and intervention allocation process.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, pre-test and post-test assessments are conducted by an independent, blinded evaluator who has no knowledge of the children's allocation to the intervention or control group. The principal investigator is also blinded to the children's grouping during data collection. The occupational therapist conducting the intervention sessions is aware of the CO-OP method for operational purposes, but is not responsible for data evaluation. Due to the nature of the CO-OP-based occupational therapy intervention, blinding of participants was not possible. The staff of the treatment centers and schools also have only the necessary information for operational support and are blinded to the group allocation. This design reduces assessment bias and increases the validity of the study results.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz - University City - Ahvaz Jundishapur University of Medical Sciences - Vice Chancellor for Research and Technology - First Floor - University Research Ethics Working Group Unit

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2026-01-31, 1404/11/11

Ethics committee reference number

IR.AJUMS.REC.1404.585

Health conditions studied

1

Description of health condition studied

Children with high-functioning Autism Spectrum disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Comparison of occupational performance scores in children with Autism spectrum disorder.

Timepoint

At the beginning of the study (before the intervention) and immediately after the end of the intervention (post-test).

Method of measurement

Canadian Occupational Performance Measure

2

Description

Comparing satisfaction with occupational performance of children with Autism spectrum disorder.

Timepoint

At the beginning of the study (before the intervention) and immediately after the end of the intervention (post-test).

Method of measurement

Canadian Occupational Performance Measure

3

Description

Comparison of motor skills scores of children with Autism spectrum disorder.

Timepoint

At the beginning of the study (before the intervention) and immediately after the end of the intervention (post-test).

Method of measurement

Bruininks-Oseretsky Test Of Motor Proficiency, Second Edition

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: In addition to receiving routine treatment, children in the intervention group will receive an intervention based on the Cognitive Orientation to daily Occupational Performance (CO-OP) approach. This intervention is designed based on the standard protocol developed by Helen Polatajko et al. and has a specific, staged structure and is based on cognitive learning. The intervention consists of 12 sessions of 45 to 60 minutes, two days a week for six weeks. The sessions are held in a controlled environment of occupational therapy centers or special schools for autism, and each session consists of three stages: review of goals and planning (5 minutes), active practice with the “goal-plan-do-check” cycle (30 minutes), and final feedback (10 minutes). To maintain motivation and prevent fatigue, activities are divided into shorter intervals and 2–3 minute breaks, symbolic games, and a reward system are applied. Parents will also be present at some sessions to observe the intervention process and receive the necessary training to transfer the strategies to the home and school environment. The CO-OP intervention consists of three main phases: 1. Preparation (sessions 1 and 2): Includes an initial assessment with COPM and BOT-2 to identify person-centered goals and training in the general CO-OP strategy and self-talk. 2. Skill acquisition and intervention (sessions 3 to 11): Practicing strategies on the child's chosen goals using guided discovery and dynamic performance analysis, along with training parents to transfer the strategies. 3. Reassessment (session 12): Measuring changes in performance and satisfaction with COPM and changes in motor skills with BOT-2 and providing feedback and guidance to parents to generalize the strategies in the child's daily life.

Category

Treatment - Other

2

Description

Control group: Children in the control group will receive routine occupational therapy at the center. This treatment includes a set of standard and common occupational therapy interventions that are usually provided in rehabilitation centers for children with autism spectrum disorder and aims to improve motor function, participation in daily activities, and increase social and play skills. Routine therapy interventions include sensory-motor activities, gross and fine motor skill practice, activities related to personal care and daily living, and play therapy. In this group, unlike the CO-OP intervention group, explicit training in cognitive strategies and systematic use of the “goal-plan-do-control” cycle will not be provided. Pre-test and post-test assessments will be conducted for all participants in the control group using the COPM and BOT-2 research instruments to measure changes in occupational performance, satisfaction with performance, and motor skills.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Saifollah Jahantabi-nejad

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Iran-Ahvaz-Golestan Highway-Ahvaz Jundishapour University

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Dr. Abdollah Rafiei

Street address
Ahvaz, University City - Vice President for Research and Technology, Ahvaz Jundishapur University of Medical Sciences and Health Services - Ground Floor

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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
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Seifolah Jahantabi Nejad

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

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Person responsible for scientific inquiries

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Position
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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)
Undecided - It is not yet known if there will be 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
Not applicable

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
Individual participant data (IPD) and related study documents from the clinical trial on occupational therapy in children with Autism Spectrum Disorder. The dataset includes de-identified participant-level information for all study variables, including primary outcomes (occupational performance, satisfaction with performance, motor skills) and relevant demographic characteristics. All personal identifiers have been removed to ensure confidentiality. The shared documents also include the study protocol, statistical analysis plan, and informed consent forms

When the data will become available and for how long
Individual participant data and study-related documentation will be available for sharing for six months after the publication of the main study results. The access period will be from 1405 AH after the access start date.

To whom data/document is available
Access to the individual participant data and related study documents will be granted only to researchers affiliated with academic or scientific institutions who submit a reasonable request. Researchers from industry may also request access if their proposed analysis aligns with the scientific objectives of the study and is approved by the study steering committee.

Under which criteria data/document could be used
The provided data and documents are intended solely for research and scientific purposes by academic researchers and investigators affiliated with scientific institutions. Any secondary analysis of the data must ensure participant confidentiality, with all identifying information removed. Commercial use or publication of the data without written permission from the research team is prohibited. Requesting researchers must specify the purpose and type of analysis in their application, and access will be granted upon approval by the research team.

From where data/document is obtainable
To receive the study data and documents, applicants can send their request via email to the principal investigator, "Dr. Seifollah Jahantabi-nejad", at the email address "jahantabi-s@ajums.ac.ir". If necessary, it is also possible to send a postal correspondence to the address "Khuzestan-Ahvaz-Golestan-Ahvaz Jundishapur University of Medical Sciences-Faculty of Rehabilitation Sciences". After being reviewed and approved by the research team, the requests will be submitted to the applicant within a specified period of time.

What processes are involved for a request to access data/document
The applicant must first submit a written or emailed request to the principal investigator, including the purpose of data use and research details. The research team will review the request and, if the documentation is complete and ethical and privacy requirements are met, approve it. After approval, de-identified data or documents will be provided to the applicant in electronic or printed format. The review and provision process is usually completed within 2 to 4 weeks after receiving a complete request.

Comments