Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Cognitive Orientation to daily Occupational Performance (CO-OP) Approach in improving handwriting performance of children with specific learning disorder 8-12 years old

Protocol summary

Study aim

Determining the effectiveness of the cognitive orientation to daily occupational performance approach (CO-OP) in the handwriting of children with specific learning disabilities aged 8 to 12 years, such as dyslexia and dysgraphia

Design

Randomised, parallel group trial design of 15 samples in each group with blinded outcome assessment. Random allocation was centralised and computerised with block randomization with both boys and girls in each group.

Settings and conduct

The intervention in both groups is carried out in ten sessions by a common therapist in 40 minutes, and for checking the results of the interventions, an evaluator who is blind to the people in the groups and the process of the interventions evaluates the results.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with specific learning disabilities such as dyslexia and dysgraphia 8-12 years old Children who have been diagnosed with a learning disorder based on the patient's profile by a psychiatrist and those who study in schools or learning disorder centers. Do not have visual and auditory processing problems Do not have another medical diagnosis such as autism spectrum disorder Exclusion criteria: If the participants have already received the co-op approach If the family or the child does not want to collaborate for any reason.

Intervention groups

In the intervention group, CO-OP is implemented, and the control group receives typical interventions in occupational therapy (perceptual-motor interventions most used by occupational therapists in studies are visual-motor integration (VMI) interventions).

Main outcome variables

Legibility in dictation and copy; speed in copy; occupational performance; executive functions; reading skills

General information

Reason for update

Acronym

CO-OP

IRCT registration information

IRCT registration number: **IRCT20240822062837N1**
Registration date: **2024-09-05, 1403/06/15**
Registration timing: **prospective**

Last update: **2024-09-05, 1403/06/15**
Update count: **0**

Registration date

2024-09-05, 1403/06/15

Registrant information

Name

Sara Zamiran

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 918 520 1519

Email address

sarazamiran@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-22, 1403/07/01

Expected recruitment end date

2024-12-20, 1403/09/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Cognitive Orientation to daily Occupational Performance (CO-OP) Approach in improving handwriting performance of children with specific learning disorder 8-12 years old

Public title
The Effect of Cognitive Orientation to daily Occupational Performance (CO-OP) Approach in improving handwriting performance of children with specific learning disorder 8-12 years old
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children with specific learning disabilities such as dyslexia and dysgraphia 8-12 years old Children who have been diagnosed with a learning disorder based on the patient's profile by a psychiatrist and those who study in schools or learning disorder centers. Do not have visual and auditory processing problems Do not have another medical diagnosis such as autism spectrum disorder.
Exclusion criteria:
If the participants have already received the co-op approach If the family or the child does not want to collaborate for any reason.
Age
From **8 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **15**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of allocating the samples to the control and intervention groups is by random allocation and using the block randomization method, in which there are boys and girls in each group.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, both intervention and control groups have a common therapist who is aware of the intervention process, and both groups have a common evaluator who is blind to the process of the intervention and the people in the groups.
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Science
Street address
Damavand street, across from Buali hospital, Tehran, Iran. SBMU School of Rehabilitation Sciences
City
Tehran
Province
Tehran
Postal code
1616913111
Approval date
2024-08-18, 1403/05/28
Ethics committee reference number
IR.SBMU.RETECH.REC.1403.201

Health conditions studied

1

Description of health condition studied
Specific learning disorder
ICD-10 code
F81
ICD-10 code description
Specific developmental disorders of scholastic skills

Primary outcomes

1

Description
Legibility in dictation and copy; speed in copy; occupational performance;
Timepoint
The beginning and the end of the intervention
Method of measurement
Legibility and speed is measured by "Persian Handwriting Assessment Tool"; occupational performance is measured by "Canadian Model of Occupational Performance" and "Performance Quality Rating Scale".

Secondary outcomes

1

Description
Executive functions; reading skill
Timepoint

The beginning and the end of the intervention.

Method of measurement

executive functions is measured by "Behavioral rating inventory of executive function". reading skill is measured by "KHANA".

Intervention groups

1

Description

Intervention group: The intervention group will receive the Co-op cognitive approach for 10 sessions of 40 minutes. These sessions are held once a week and last for 10 weeks. between sessions, students get homeworks to do till the next session.

Category

Rehabilitation

2

Description

Control group: The selected intervention for the control group is a perceptual-motor approach called visual-motor integration. This intervention is implemented according to the established protocol of 10 sessions of 40 minutes and continues for 10 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

SBMU School of Rehabilitation Sciences

Full name of responsible person

Sara zamiran

Street address

SBMU School of Rehabilitation Sciences, across from Buali hospital, Damavand street, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 7756 1721

Email

saraazamiran@gmail.om

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zerghi

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1467664961

Phone

+98 21 8145 5618

Email

ethics@behdasht.gov.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sara Zamiran

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

Street address

SBMU School of Rehabilitation Sciences, across from Buali hospital, Damavand street, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 918 520 1519

Fax

Email

sarazamiran@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Sara Zamiran

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Occupational Therapy

Street address
SBMU School of Rehabilitation Sciences, across from Buali hospital, Damavand street, Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
1616913111

Phone
+98 918 520 1519

Fax

Email
sarazamiran@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Sara Zamiran

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Occupational Therapy

Street address
SBMU School of Rehabilitation Sciences, across from Buali hospital, Damavand street, Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
1616913111

Phone
+98 918 520 1519

Fax

Email
sarazamiran@sbmu.ac.ir

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
Data about primary and secondary outcome measures; statical analysis of outcomes and the study protocol

When the data will become available and for how long
Available after publishing the results

To whom data/document is available
Researchers and therapists

Under which criteria data/document could be used
Using the study protocol for use in the clinic as a new approach and other similar researches

From where data/document is obtainable
First author: saraazamiran@gmail.com

What processes are involved for a request to access data/document
The information will be available by the first author or the corresponding author within one week after sending the email.

Comments