

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of increasing parental involvement in the transfer process in CO-OP approach on motor-based trained and untrained occupational performance in 7 to 12 -year-old children with Specific Learning Disorders (SLD).

Protocol summary

Study aim

The effectiveness of increasing parental involvement in the transfer process in the Cognitive orientation to daily occupational performance Approach on motor-based occupational performance in untrained task in children with Specific Learning Disorders.

Design

single blind randomized controlled clinical trial

Settings and conduct

Children with Specific Learning Disabilities who meet the inclusion criteria will be selected, then randomly assigned to intervention and control groups using the randomization Block method. In both groups, the evaluation of Occupational performance of daily activities was performed by an independent assessor who was blind to the participants of the intervention and control group. In the intervention group, the CO-OP intervention will be presented to children along with the parents training protocol by the trained therapist, and in the control group, the CO-OP intervention will be presented according to the traditional protocol. At the end of the intervention, the occupational performance of daily activities will be assessed in both groups.

Participants/Inclusion and exclusion criteria

aged between 7 and 12 years; diagnosed as Specific Learning Disorders (SLD) by a pediatrician according to DSM V criteria for SLD, had problems in motor-based occupational performance; and had no other diagnosis or signs of neurological or neuromuscular disease.

Intervention groups

CO-OP approach will be conducted in 12 sessions of one hours over a period of 6 weeks. The intervention group will receive a CO-OP intervention and parent education.

Main outcome variables

Canadian Occupational Performance Measures
Performance Quality Rating Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201019049080N1**

Registration date: **2021-01-11, 1399/10/22**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-11, 1399/10/22**

Update count: **0**

Registration date

2021-01-11, 1399/10/22

Registrant information

Name

Soraya Gharebaghy

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2222 7124

Email address

gharebaghy_ot@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-04, 1399/09/14

Expected recruitment end date

2021-05-19, 1400/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of increasing parental involvement in the transfer process in CO-OP approach on motor-based trained and untrained occupational performance in 7 to 12 -year-old children with Specific Learning Disorders (SLD).

Public title

Effectiveness Increasing parental involvement in the transfer process in CO-OP approach on motor-based occupational performance in 7 to 12 -year-old children with Specific Learning Disorders (SLD).

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with an SLD diagnosis aged between 7 and 12 years old Normal or correct to normal hearing and vision. Sufficient language ability to communicate with and be understood during treatment. Report at least 5 occupational performance problems.

Exclusion criteria:

had other diagnosis or signs of neurological or neuromuscular disease.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced (permuted) block randomization: In this method, the number of participants in each group is the same and the size of all blocks is equal. In this study, 8 blocks with 4 participants were assigned to the intervention group and 4 participants to the control group. In this study, there are two intervention groups, we define 6 modes for quadruple blocks and we define 6 cards. Given that the sample number is 20 participants, we select 5 of the above cards by replacement. Sample defined cards: Intervention group (A), control group (B) AABB-ABAB-BABA-BBAA-ABBA-BAAB

Blinding (investigator's opinion)

Single blinded

Blinding description

single blind: Outcome assessor: The person or persons conducting the assessment are unaware of assigning participants to intervention and control groups.

Placebo

Not used

Assignment

Parallel

Other design features

A qualitative study will be conducted to design a guideline to increasing parental involvement in the transfer process in the CO-OP intervention, and given that the number of children receiving CO-OP intervention has been limited. In the qualitative phase for designing the guideline, if we do not have access to an enough amount of information, the CO-OP intervention will be presented to a number of children as pre-test and post-test without control group. And the parents of these children will be involved in the qualitative phase of the interview and the design of the intervention guide.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences-Ethical Committee

Street address

Maddadkaran St., Shahid Nazari St., Mother Square, Mirdamad Blvd, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran.

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1545913487

Approval date

2019-08-23, 1398/06/01

Ethics committee reference number

IR.IUMS.REC.1398.062

Health conditions studied

1

Description of health condition studied

Specific Learning Disorders

ICD-10 code

F81.0

ICD-10 code description

Specific reading disorder

2

Description of health condition studied

Disorder of written expression

ICD-10 code

F81.81

ICD-10 code description

Disorder of written expression

3

Description of health condition studied

Mathematics disorder

ICD-10 code

F81.2

ICD-10 code description

Mathematics disorder

Primary outcomes**1****Description**

motor-based occupational performance and satisfaction of performance in trained and untrained tasks

Timepoint

pre intervention- post intervention and two month after intervention (follow-up)

Method of measurement

Canadian Occupational Performance Measure (COPM)

2**Description**

motor-based occupational performance in trained and untrained tasks

Timepoint

pre intervention- post intervention and two month after intervention (follow-up)

Method of measurement

Performance Quality Rating Scale (PQRS)

Secondary outcomes**1****Description**

Motor skills

Timepoint

Pre intervention, Post intervention

Method of measurement

Bruninks Oseretsky Test of Motor Proficiency Measure

Intervention groups**1****Description**

Intervention group: CO-OP intervention with increasing parental involvement guideline. Over 12 individualized sessions (10 treatment and one pre and post test session), at the rate of one or two a week, each child will learn the Goal-Plan-Do-Check strategy and then apply it in learning to perform the target skills. Through guided discovery, the therapist will enable the child to discover the domain-specific strategies required for task performance. Verbalization, by both therapist and child, of discovered strategies will be used to guide performance and to promote strategy learning. Bridging techniques will be used to promote transfer and generalization. Treatments will be administered by qualified occupational therapists who will receive specific CO-OP training. All treatment sessions will last approximately 60 minutes. This intervention will be done along with two sessions of direct teaching of the basic

principles of the CO-OP approach to parents and practicing these principles during the child intervention sessions. Parents at home will then help the child with additional goals chosen by the child. And are present during the sessions and practice and observe a variety of guided detection methods as scheduled. Two parent training sessions last 60 minutes. And at the end of the child's educational sessions, the parents will review the session and learn for 15 minutes.

Category

Rehabilitation

2**Description**

Control group: CO-OP intervention. Over 12 individualized sessions (10 treatment and one pre and post test session), at the rate of one or two a week, each child will learn the Goal-Plan-Do-Check strategy and then apply it in learning to perform the target skills. Through guided discovery, the therapist will enable the child to discover the domain-specific strategies required for task performance. Verbalization, by both therapist and child, of discovered strategies will be used to guide performance and to promote strategy learning. Bridging techniques will be used to promote transfer and generalization. Treatments will be administered by qualified occupational therapists who will receive specific CO-OP training. All treatment sessions will last approximately 60 minutes.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Exceptional education in Mashhad

Full name of responsible person

Soraya Gharebaghy

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Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Narges Shafaroodi

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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

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

Narges Shafaroodi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Soraya Gharebaghy

Position

Student

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

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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

Part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Occupational Therapist, and researcher in the Occupational therapy

Under which criteria data/document could be used

Use the reported results for clinical work

From where data/document is obtainable

Iran university of Medical Science, School of Rehabilitation Sciences, Occupational Therapy department

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

The data and results of the study are available in the final version of the dissertation and are available at the Faculty of Rehabilitation.

Comments