Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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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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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
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Exceptional education in Mashhad
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Sponsors / Funding sources

1

Sponsor

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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
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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