

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Designing and evaluating the effect of school-based occupational therapy interventions via tele-rehabilitation method on education in students with specific learning disorder aged 8 to 12 years old based on the Canadian Model of Occupational Performance

#### Protocol summary

##### Study aim

Designing and evaluating the effect of school-based occupational therapy interventions with distance rehabilitation method on the acupuncture of education in students with special learning disabilities 8 to 12 years old based on the Canadian model of work performance

##### Design

A single-blind clinical trial with three groups with a simple random distribution method using software, 30 people

##### Settings and conduct

For sampling, refer to all government centers for learning disorders in Tehran. Interventions are performed in these centers or in the clinic of the Faculty of Rehabilitation. Using the convenience sampling method, children with inclusion criteria are invited to study and after signing the consent form, they are randomly divided into two intervention groups and a control group. Participants and evaluators are blind. The intervention group with tele rehabilitation method receives interventions online, the intervention group with in person method receives similar interventions in person and the control group receives common therapies. At the end, the re-evaluation is done.

##### Participants/Inclusion and exclusion criteria

inclusion: 1. Age range 8 to 12 years 2. Diagnosis of a specific learning disorder by a psychiatrist 4. Internet and computer access 6. At least a diploma for parents  
exclusion: Existence of other psychiatric disorders

##### Intervention groups

Intervention group with tele rehabilitation method: sensorimotor and cognitive interventions in the form of video calls and assignments in the form of worksheets and tool kits for the home. Intervention group with the method of attending the clinic: A protocol similar to the method of tele rehabilitation in the presence of the clinic

Control group: Common interventions of learning disorders

##### Main outcome variables

academic educational performance

#### General information

##### Reason for update

Due to the completion of this clinical trial, additional information was added regarding the actual recruitment start date, actual recruitment start date and the trial completion date. Also, the sample size obtained based on the pilot study was also corrected. The section related to primary and secondary outcomes was also corrected in terms of writing.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180521039770N1**  
Registration date: **2022-03-25, 1401/01/05**  
Registration timing: **prospective**

Last update: **2023-08-16, 1402/05/25**

Update count: **1**

##### Registration date

2022-03-25, 1401/01/05

##### Registrant information

##### Name

Mehdi Alizadeh Zarei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 8051

##### Email address

alizadeh.m@iums.ac.ir

##### Recruitment status

**Recruitment complete****Funding source****Expected recruitment start date**

2022-04-21, 1401/02/01

**Expected recruitment end date**

2022-06-22, 1401/04/01

**Actual recruitment start date**

2022-04-21, 1401/02/01

**Actual recruitment end date**

2022-06-22, 1401/04/01

**Trial completion date**

2023-02-03, 1401/11/14

**Scientific title**

Designing and evaluating the effect of school-based occupational therapy interventions via tele-rehabilitation method on education in students with specific learning disorder aged 8 to 12 years old based on the Canadian Model of Occupational Performance

**Public title**

The effect of Tele occupational therapy interventions on educational performance of students with learning disorder

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age range 8 to 12 years for both girls and boys Definitive diagnosis of a specific learning disorder by a psychiatrist or learning disorder experts Living in the city of Tehran Internet access; Home or mobile internet with a minimum speed of 128 kbps Access to smartphones, or personal computers, or laptops or tablets At least a diploma and basic computer literacy for a parent who is going to work with the research team in therapy sessions.

**Exclusion criteria:**

Presence of irreparable physical, visual and hearing problems with assistive devices Comorbidity of psychiatric disorders based on the contents of the student's medical and educational records. Refusal to sign informed consent by parents

**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: **30**Actual sample size reached: **31****Randomization (investigator's opinion)**

Randomized

**Randomization description**

After agreeing to participate in the study and signing the consent form, participants will be divided into two intervention groups and a control group by a simple

accident distribution method by someone other than the researcher, evaluator and intervener. The dice roll method will be used to perform a simple random distribution. The numbers 1 and 2 will be considered for the intervention group by remote rehabilitation method, the numbers 3 and 4 will be considered for the intervention group by the clinic method and the numbers 5 and 6 will be considered for the control group and individuals will be randomly assigned to three groups. They find. The central randomization method will be used to conceal random allocation. In this method, a random sequence is provided to a specific center and the researcher communicates with the relevant center based on the order in which the participants enter the study and asks about the random assignment of the participant to a specific group. Communication methods include the use of telephone and SMS.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, both participants and outcome assessors are unaware of the allocation of study groups.

**Placebo**

Not used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

14496145351

**Approval date**

2022-01-01, 1400/10/11

**Ethics committee reference number**

IR.IUMS.REC.1400.876

**Health conditions studied****1****Description of health condition studied**

Specific learning disorder

**ICD-10 code**

F81.0

**ICD-10 code description**  
Specific reading disorder

## 2

**Description of health condition studied**  
Specific learning disorder

**ICD-10 code**  
F81.81

**ICD-10 code description**  
Disorder of written expression

## 3

**Description of health condition studied**  
Specific learning disorder

**ICD-10 code**  
F81.2

**ICD-10 code description**  
Mathematics disorder

## **Primary outcomes**

### 1

**Description**  
academic school function

**Timepoint**  
Before the start of the 12 intervention sessions, after the end of the 12 intervention sessions, one month after the end of the 12 intervention sessions

**Method of measurement**  
Student assessment of academic self conception

## **Secondary outcomes**

### 1

**Description**  
academic school function

**Timepoint**  
Before the start of the 12 intervention sessions, after the end of the 12 intervention sessions, one month after the end of the 12 intervention sessions

**Method of measurement**  
Academic adequacy lists of the Ministry of Education

### 2

**Description**  
non academic school function: physical activity performance

**Timepoint**  
Before the start of the 12 intervention sessions, after the end of the 12 intervention sessions, one month after the end of the 12 intervention sessions

**Method of measurement**  
school function assessment

### 3

**Description**

non academic school function: hand writing

### **Timepoint**

Before the start of the 12 intervention sessions, after the end of the 12 intervention sessions, one month after the end of the 12 intervention sessions

### **Method of measurement**

Persian handwriting assessment tool

## 4

### **Description**

non academic school function: upper limb motor function

### **Timepoint**

Before the start of the 12 intervention sessions, after the end of the 12 intervention sessions, one month after the end of the 12 intervention sessions

### **Method of measurement**

Bruininks-Oseretsky Test of Motor Proficiency

## 5

### **Description**

non academic school function: cognitive activity performance

### **Timepoint**

Before the start of the 12 intervention sessions, after the end of the 12 intervention sessions, one month after the end of the 12 intervention sessions

### **Method of measurement**

school function assessment

## 6

### **Description**

non academic school function: visual perception

### **Timepoint**

Before the start of the 12 intervention sessions, after the end of the 12 intervention sessions, one month after the end of the 12 intervention sessions

### **Method of measurement**

test of visual perceptual skills

## 7

### **Description**

non academic school function: working memory

### **Timepoint**

Before the start of the 12 intervention sessions, after the end of the 12 intervention sessions, one month after the end of the 12 intervention sessions

### **Method of measurement**

N-back test

## 8

### **Description**

non academic school function: visual auditory integration

### **Timepoint**

Before the start of the 12 intervention sessions, after the end of the 12 intervention sessions, one month after the end of the 12 intervention sessions

### **Method of measurement**

integrated Visual and Auditory (IVA) Test

## 9

### **Description**

The quality and satisfaction of occupational performance in the priorities set by the parents

### **Timepoint**

Before the start of the 12 intervention sessions, after the end of the 12 intervention sessions, one month after the end of the 12 intervention sessions

### **Method of measurement**

Canadian occupational performance measure

## 10

### **Description**

Student assessment of self competence and the value of occupations

### **Timepoint**

Before the start of the 12 intervention sessions, after the end of the 12 intervention sessions, one month after the end of the 12 intervention sessions

### **Method of measurement**

Child Occupational Self-Assessment

## **Intervention groups**

### 1

#### **Description**

The Canadian Model of Occupational Performance (CMOP) is one of the occupational therapy models. According to this model, occupation is the result of dynamic interaction between the person and the environment, and each has different components. In this model, the occupation includes three domains: self-care, productivity and leisure, the person includes three main components: affective, physical, and cognitive abilities, and the environment including physical, social, cultural, and institutional environment of the client. This model is used in clinical setting by a tool called the Canadian Occupational Performance Measure (COPM). This tool is a semi-structured interview in which the clients determine their therapeutic goals in the field of occupational performance and give them points in terms of priority and satisfaction. The therapist designs treatment goals based on set priorities and provides appropriate treatments to each client based on evaluations. In this study, in both intervention groups, this method is used to determine the therapeutic interventions of each student and only the method of providing interventions is different in the two groups (one intervention group received the method of tele-rehabilitation and other intervention group received the in-person method).

#### **Category**

Rehabilitation

### 2

#### **Description**

Intervention group 2: Intervention group by attending the clinic: The interventions of this group will be performed by a trained occupational therapist with at least 2 years of experience in the field of learning disabilities. This

person is completely blind to reading. All intervention protocols in the intervention group will be presented to this group by remote rehabilitation method, with the difference that in this group, all evaluation and intervention steps will be performed in person.

#### **Category**

Rehabilitation

### 3

#### **Description**

Control group: This group will receive common interventions in education and rehabilitation centers for special learning problems. Students with learning disorders are referred to these centers by the school. In these centers, the student is first evaluated with Wechsler Intelligence Scale for Children (WISC) and is accepted if the learning disorder is confirmed. After that, he attends individual classes for one or two days a week for one hour. In this session, a teacher evaluates the student's performance in reading, writing, math, and science based on his / her educational grade, and according to the results of his / her observations and evaluation, teaches lessons in which the child's performance will be poor. Sometimes, if necessary, lessons related to previous grades are also taught. Worksheets for repeating and practicing the taught items will also be provided as homework.

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

education and rehabilitation center for specific Learning Disabilities No. 5

##### **Full name of responsible person**

Fatemeh Palizgir

##### **Street address**

Fakhr Alley, between 12 Farvardin and Ordibehesht, Jomhoori St.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1316683595

##### **Phone**

+98 21 6695 5120

##### **Email**

seo@medu.ir

### 2

#### **Recruitment center**

##### **Name of recruitment center**

education and rehabilitation center for specific Learning Disabilities No. 3

##### **Full name of responsible person**

Somaye Hajzeinilabedin

**Street address**

No. 31, before Shoosh Square, West Shoosh St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1168818411

**Phone**

+98 21 5559 5100

**Email**

seo@medu.ir

**3**

**Recruitment center**

**Name of recruitment center**

education and rehabilitation center for specific Learning Disabilities No. 2

**Full name of responsible person**

Ahdiye Niknam

**Street address**

No. 3, Rose Alley, South Golestan St., Nobonyad Movahed Danesh St.,

**City**

Tehran

**Province**

Tehran

**Postal code**

1957646539

**Phone**

+98 21 2228 3888

**Email**

seo@medu.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Hosein Keyvani

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Phone**

+98 21 8670 2504

**Email**

research-m@iums.ac.ir

**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**

Mahsa Kheirollahzade

**Position**

Ph.D. candidate

**Latest degree**

Master

**Other areas of specialty/work**

Occupational Therapy

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۳۴۸۷ - ۱۵۴۵۹

**Phone**

009822222059

**Email**

kheirollahzade.m@iums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mehdi Alizadeh Zarei

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Therapy

**Street address**

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

**City**

Tehran  
**Province**  
Tehran  
**Postal code**  
۱۳۴۸۷ - ۱۵۴۵۹  
**Phone**  
009822222059  
**Email**  
alizadeh.m@iums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Mehdi Alizadeh Zarei  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Occupational Therapy  
**Street address**  
School of Rehabilitation Sciences, Iran University of  
Medical Sciences, Maddadkaran St., Shah Nazari St.,  
Mother Square, Mirdamad Blvd, Tehran, Iran.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۳۴۸۷ - ۱۵۴۵۹  
**Phone**  
009822222059  
**Email**  
alizadeh.m@iums.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

Some of the data can be shared after unidentifiable individuals such as age, gender and educational grade, as well as data related to the main outcome of the research.

### When the data will become available and for how long

It is possible to start accessing the results 6 months after the outcomes are published in the form of an article.

### To whom data/document is available

Researchers working in academic and scientific institutions, people working in educational center , decision makers in the field of health management

### Under which criteria data/document could be used

Researchers working in academic and scientific institutions, people working in educational center and decision makers in the field of health management can send their request for access to data by sending an email to the person is responsible for scientific response (principal researcher). Performing statistical analyzes different from the main research to extract other consequences is permitted by obtaining permission from the researcher and the supporting organization (Vice Chancellor for Research and Technology of Iran University of Medical Sciences).

### From where data/document is obtainable

1- Main researcher: Dr. Mehdi Alizadeh Zarei Email: alizadeh.m@iums.ac.ir Phone: Phone: 00982122222059 Internal: 333 Address: School of Rehabilitation Sciences, Iran University of Medical Sciences, Maddadkaran St., Shahid Nazari St., Mother Square, Mirdamad Blvd, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran. 2- Vice Chancellor for Research and Technology of Iran University of Medical Sciences Email: research-m@iums.ac.ir Tel: 00982186702503-00982186702504 Address: Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN

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

Applicants should send their request by sending email to the main researcher Dr. Mehdi Alizadeh Zarei or the Vice Chancellor for Research and Technology of Iran University of Medical Sciences. They can also refer to the address of the occupational therapy department of the Faculty of Rehabilitation sciences of Iran University of Medical Sciences or the Vice Chancellor for Research and Technology of Iran University of Medical Sciences and submit their written request. After reviewing the request, if the permission to access the data and documents is possible, it will be issued and provided to the applicant.

### Comments