Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 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)

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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.

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2

Recruitment center

Name of recruitment center
education and rehabilitation center for specific Learning Disabilities No. 3

Full name of responsible person

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3

Recruitment center

Name of recruitment center
education and rehabilitation center for specific Learning Disabilities No. 2

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Hosein Keyvani

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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
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.

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Full name of responsible person
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Other areas of specialty/work
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Person responsible for updating data

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

Occupational Therapy

Street address

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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

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