Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Designing Interventions based on occupation performance coaching with four quadrant model of facilities learning and its effect on the participation in activities outside of school in students with specific learning disorder

Protocol summary

Study aim

Designing Interventions based on occupation performance coaching with four Quadrant Model of facilities learning and its effect on the participation in activities outside of school in students with Specific learning disorder

Design

Randomized controlled trial with intervention and control group, double-blind

Settings and conduct

Sampling from training and rehabilitation centers for special learning problems (5 areas in Tehran) is done. After the eligible patients fill out the consent form, they will be randomly assigned to in two group.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: - The age of the student is between 7 and 12 years (both sexes) - The participating families must live in Tehran - The student has a diagnosis of a specific learning disorder. - The student has no physical, vision, or hearing problems; - The student should not have comorbidities such as Coping Behavior Disorder, Disseminated anxiety disorder, Depressive disorder, Separation Anxiety Disorder, and Social phobia through the Child Symptoms Questionnaire-4 - The student must score lower than the chronological age on the Vineland Adaptive Behavior Scale - The participating parent must have a diploma or higher Exclusion Criteria: - Parents should not cooperate in answering questionnaires or attending intervention sessions.

Intervention groups

Two groups: 1) control group (interventions based on occupation performance coaching), 2) intervention group (interventions based on occupation performance coaching with four Quadrant Model of facilities learning)

Main outcome variables

Participation in extracurricular activities, educational status, quality of student performance in the priorities set by the family, the degree of achievement of goals set by the family, the degree of family satisfaction with the child's performance, parental involvement, parent-child relationship, executive functions

General information

Reason for update

1- Since in the inclusion criteria in the study for children only the Child Symptoms Questionnaire (CSI-4) is sufficient to evaluate the comorbidities, there was no need for the Vinland Adaptive Behavior Scale and it was omitted. 2- Due to the importance of the parent's participation in the study, it was necessary to assess the parent's mental health status. Therefore, in the exclusion criteria, the Depression, Anxiety, and Stress Scale-21(DASS-21) were added for parents. 3- In the section of primary outcomes, at the same time as examining participation in activities outside of school, The quality of student performance in the priorities set by the family, the degree of family satisfaction with the child's performance, and the rate of achievement of goals set by the family Is also measured, so the above three items were moved from the secondary outcomes section to the primary outcomes section. 4- In secondary outcomes, due to the importance of parental cooperation in this study, numerous questionnaires and the absence of students from school due to COVID-19, the questionnaire of Parent-Teacher Involvement Questionnaire (PTIQ) and the Child-Parent Relationship Scale (CPRS) were removed and the parent self-efficacy questionnaire was replaced.

Acronym

IRCT registration information

IRCT registration number: **IRCT20140416017301N9**
Registration date: **2021-06-24, 1400/04/03**
Registration timing: **prospective**

Last update: **2022-04-20, 1401/01/31**
Update count: **1**

Registration date
2021-06-24, 1400/04/03

Registrant information

Name
Akram Azad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2226 2450

Email address
azad.a@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-06, 1400/04/15

Expected recruitment end date
2022-02-22, 1400/12/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Designing Interventions based on occupation performance coaching with four quadrant model of facilities learning and its effect on the participation in activities outside of school in students with specific learning disorder

Public title
Designing Interventions Based on Occupation performance with facilities learning and its effect on the participation in activities outside of school in students with specific learning disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The age of the student is between 7 and 12 years (both sexes) The participating families must live in Tehran The student has a diagnosis of a specific learning disorder. Diagnosis is made by experts from Exceptional Education Learning Disabilities Centers through the Wechsler Intelligence Test for Children, the Stanford-Binet Intelligence Test and the Woodcock Johnson Cognitive Ability Test. The student has no physical, vision or hearing problems; The student should not have comorbidities such as Coping Behavior Disorder, Disruptive Disorders, Disseminated anxiety disorder, Depressive disorder, Separation Anxiety Disorder, and Social phobia through the Child Symptoms Questionnaire (CSI-4). The participating parent must have a diploma or higher

Exclusion criteria:
Parents cancel their cooperation in answering the questionnaires or referring to the intervention sessions; Parent's unwillingness to participate in intervention sessions or answering a questionnaire; Occurrence of problems, illnesses, life changes or events for the parent that affect the behaviors being evaluated or seriously affect the results of the study. Lack of severe depression for the participating parent based on the Depression, Anxiety, and Stress Scale-21(DASS-21)

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Available samples of parents of 7 to 12-year-old students referring to education and rehabilitation centers for special learning problems in Tehran, related to exceptional education (5 areas in Tehran: 1, 6, 8, 14, 18) According to the selected inclusion criteria and after agreeing to participate in this study and signing the consent form, they will be divided into two groups of control and intervention by complete randomization method (sealed envelope method). In absolute random method (envelope and paper method), the name of groups will be written on a piece of paper and put in an envelope and the participants will be asked to choose one of the papers randomly then the patient will be placed in the intervention or control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. Participants (in both intervention and control groups) and the examiner (outcome assessor) are also blind (all assessments at all stages of the study by an experienced occupational therapist working with the child and their family who have previously been tested by the researcher. They are trained and done completely blind to the type of intervention in each family). Also, after the interventions in both groups, the test results will be analyzed by a blind statistician from both groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Shahid Hemmat Highway between Sheikh Fazl ... Nouri and Shahid Chamran Iran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2021-04-18, 1400/01/29

Ethics committee reference number
IR.IUMS.REC.1400.060

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
Participate in extracurricular activities including basic activities of daily living, instrumental activities of daily living, play, leisure, social participation and sleep performance

Timepoint
Before intervention, after intervention , follow up after 1/5 month of intervention

Method of measurement
Children Participation Assessment Scale -Parent Version (CPAS-P)

2

Description
The quality of student performance in the priorities set by the family

Timepoint
Before intervention, after intervention , follow up after 1/5 month of intervention

Method of measurement
Canadian Occupational Performance Measure (COPM)

3

Description
Degree of family satisfaction with the child's performance

Timepoint
Before intervention, after intervention , follow up after 1/5 month of intervention

Method of measurement
Canadian Occupational Performance Measure (COPM)

4

Description
Rate of achievement of goals set by the family

Timepoint
Before intervention, after intervention , follow up after 1/5 month of intervention

Method of measurement
Goal Attainment Scale (GAS)

Secondary outcomes

1

Description
Student's educational status (grades obtained in school, which are obtained by the student and entered in the school transcript)

Timepoint
Before intervention, after intervention , follow up after 1/5 month of intervention

Method of measurement
Shades of Academic Adequacy of the Ministry of Education

2

Description
Executive functions include two parts: behavior regulation index (inhibit, shift, emotional control) and metacognition index (working memory, initiation, plan, organization of materials, monitor)

Timepoint
Before intervention, after intervention , follow up after 1/5 month of intervention

Method of measurement
Behavior Rating Inventory of Executive Function (BRIEF)

3

Description
Self-efficacy of parent

Timepoint
Before intervention, after intervention , follow up after 1/5 month of intervention

Method of measurement
The Sherer General Self-Efficacy Scale (SGSES)

Intervention groups

1

Description

Intervention group: Occupation performance coaching interventions are presented to the intervention group in the form of three areas of structural process, emotional support, and information exchange along with the Four Quadrant Model of Facilitated learning. The content of the sessions based on the inventor of this method and Dr. Kessler, in general, is as follows. Also, the necessary changes will be applied after the pilot phase of the study: Session 1: Introducing and explaining the details of the intervention and setting goals by completing questionnaires (initial assessments). Objectives as specific as possible, measurable, and achievable in 10 to 12 sessions. Session 2: Start the problem-solving process for one of the goals and provide a printout of the problem-solving process. In this session, the parent determines that he or she will perform at least two different actions during the next week regarding the goal. Session 3: Review the first goal and start the next goals (one to two actions for each goal). Sessions 4 to 8: Assessing progress in all goals by considering the learning needs of parents and adding the Four Quadrant Model of Facilitated Learning to them to get acquainted with the structure and method of teaching goals to their child. session 9: Review of goals and aggregation to end the of sessions. Session 10 to 12: Deciding on goals that have not been achieved and ending the intervention with completing secondary evaluations

Category

Rehabilitation

2

Description

Control group: Occupation performance coaching interventions are presented to the control group in the form of three areas of structural process, emotional support, and information exchange. The content of the sessions based on the inventor of this method and Dr. Kessler, in general, is as follows. Also, the necessary changes will be applied after the pilot phase of the study: Session 1: Introducing and explaining the details of the intervention and setting goals by completing questionnaires (initial assessments). Objectives as specific as possible, measurable, and achievable in 10 to 12 sessions. Session 2: Start the problem-solving process for one of the goals set and provide a printout of the problem-solving process. In this session, the parent determines that he or she will perform at least two different actions regarding the goal in the coming week. Session 3: Review the first goal and start the next goals (one to two actions for each goal). Sessions 4 to 8: Examining progress on all goals. Session 9: Review of goals and aggregation to end of sessions. Session 10 to 12: Deciding on goals that have not been achieved and ending the intervention with completing secondary evaluations

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Training and Rehabilitation Centers for Special Learning Disabilities in Tehran, Related to Exceptio

Full name of responsible person
Akram Azad

Street address
Shahnazari Ave., Moder Square,. Mirdamad Blvd

City
Tehran

Province
Tehran

Postal code
1545913187

Phone
+98 21 2222 8051

Email
azad.a@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Seeid Abas Motavalian-Vice-Chancellor's Office for Research

Street address
Mirdamad Blvd., Modar Sq., Shahnazari Ave., School of Rehabilitation

City
Tehran

Province
Tehran

Postal code
1545913187

Phone
+98 21 2222 8051

Email
azad.a@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
Akram Azad
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Occupational Therapy
Street address
Mirdamad Blv., Modar Sq., Shahnazari Ave., School of Rehabilitation
City
Tehran
Province
Tehran
Postal code
1545913187
Phone
+98 21 2222 8051
Email
azad.a@iums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Akram Azad
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Occupational Therapy
Street address
Mirdamad Ave, Modar Blvd, Nazari St, School of Rehabilition
City
Tehran
Province
Tehran
Postal code
154513187
Phone
+98 21 2222 8051
Email
azad.a@iums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Akram Azad
Position
Associat Professor
Latest degree
Ph.D.
Other areas of specialty/work
Occupational Therapy
Street address
Mirdamad St., Mirdamad Blvd., Shahnazari St., School of Rehabilition
City
Tehran
Province
Tehran
Postal code
158754391
Phone
+98 21 2222 8051
Email
azad.a@iums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Not Decided
When the data will become available and for how long
Not Decided
To whom data/document is available
Not Decided
Under which criteria data/document could be used
Not Decided
From where data/document is obtainable
Not Decided
What processes are involved for a request to access data/document
Not decided
Comments