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

Registrant information
Name
Akram Azad
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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)

Secondary outcomes

1

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)

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 number 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 Exceptional
Full name of responsible person
Akram Azad
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Sponsors / Funding sources

1 Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seied Abas Motavalian-Vice-Chancellor's Office for Research
Street address
Mirdamad Blvd., Modar Sq., Shahnazari Ave., School of Rehabilitation
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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
Akram Azad
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
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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