Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of SCT- based parental behavioral training on improving the behavior of 6-12- year- old children with attention deficit-hyperactivity disorder; A randomized controlled trial

Protocol summary

Study aim

Determining the effect of parent behavioral training on improving the behavior of 6-12 year old children with adhd

Design

A randomized clinical trial with a control and an intervention group, with parallel groups, was conducted on 50 parents. Pass software was used for randomization.

Settings and conduct

Research setting: Imam Reza Clinic, Shiraz After obtaining the necessary permits, the researcher began to collect samples based on the medical records. First, the informed consent form will be signed by the parents, and in the next stage, information related to the Connors and researcher-made hyperactivity questionnaires will be collected. Parents will be divided into small groups of 8 people. The parent training program will consist of at least 6 60-minute training sessions. One month after the end of the intervention period, the relevant questionnaires will be distributed and collected again for both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Age of the child 2- Confirmation of the child's disorder 3- Parental consent to participate in the study 4- Parental literacy 5- No disability of the child 6- Child and parent's lack of participation in similar programs 7- Affected child under the direct care of the parents 8- Time of diagnosis and start of treatment Exclusion criteria: 1. Withdrawal of the study subjects 2. Failure of the participant to participate in the tests 3. Absence of more than two sessions

Intervention groups

-The intervention group includes parents of children with ADHD who receive a 6-session educational intervention prepared. -The comparison group includes parents of children with ADHD who receive educational intervention from a doctor according to the clinic routine.

Main outcome variables

Knowledge; Outcome expectations; Self-efficacy; Goal setting ; Emotional coping; Child behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250315065082N1**
Registration date: **2025-05-05, 1404/02/15**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-05, 1404/02/15**
Update count: **0**

Registration date

2025-05-05, 1404/02/15

Registrant information

Name

Mohadeseh Mardaneh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 902 738 9240

Email address

m.mardane_74@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-03, 1404/02/13

Expected recruitment end date

2025-06-03, 1404/03/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of SCT- based parental behavioral training on improving the behavior of 6-12-year- old children with attention deficit- hyperactivity disorder; A randomized controlled trial

Public title

Investigating the effect of parental behavioral training on improving the behavior of 6-12 year old children with attention deficit hyperactivity disorder

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The child being studied must be at least 6 years old and no more than 12 years old The child's attention deficit hyperactivity disorder has been confirmed by the clinic's psychiatrist The child's parents (at least the mother) must give their consent to participate in the study The child's parents (at least the mother) must be at least literate (end of third grade of primary school) The child under study should not have severe physical or motor disabilities or severe hearing or visual impairments The child and his/her parents (at least the mother) are not participating in an educational program similar to the one that will be implemented in this project The affected child is under the direct care of the parents (mother, father, or both) At least 3 months have passed since the child was diagnosed and started treatment

Exclusion criteria:

The child under study has severe physical-motor disabilities or severe hearing and visual impairments. The child being studied has a specific disease, such as diabetes, that requires special care. The native language of the child being studied is other than Persian.

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the permutation block method to randomly assign participants (parents of hyperactive children) to two control and comparison groups. First, a list of all participants is prepared (50 people). Then, the parents are divided into blocks such that each block contains a certain number of participants. In this study, the size of each block is set to 4 (2 people for the control group and 2 people for the comparison group). NCSS-PASS version 15 software is used to create random sequences. In each block, all possible combinations for assigning participants to two groups (control and comparison) will be listed. One sequence is randomly selected from among the permutation sequences. Participants are assigned to blocks based on the selected random sequence and are assigned to one of the two control and comparison groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand Street

City

Shiraz

Province

Fars

Postal code

-

Approval date

2025-03-04, 1403/12/14

Ethics committee reference number

IR.SUMS.REC.1403.550

Health conditions studied

1

Description of health condition studied

Attention-deficit hyperactivity disorder

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes

1

Description

Children's behavior

Timepoint

Measuring children's behavior once before the start of

the study and once one to two months after the intervention.

Method of measurement

Connors Parent Hyperactivity Questionnaire

Secondary outcomes

1

Description

-Knowledge: Learning facts and gaining insight related to an action, idea, object, person, or situation; information and facts about a subject.

Timepoint

Primary outcome measurements once before the start of the study and one to two months after the intervention

Method of measurement

-Researcher-made questionnaire

2

Description

Outcome expectations refer to the value that an individual places on the possible outcomes of performing a behavior.

Timepoint

Primary outcome measurements once before the start of the study and one to two months after the intervention

Method of measurement

-Researcher-made questionnaire

3

Description

Self-efficacy: confidence in one's ability to follow a behavior (confidence in behavior)

Timepoint

Primary outcome measurements once before the start of the study and one to two months after the intervention

Method of measurement

Researcher-made questionnaire

4

Description

Goal setting or self-control: setting goals and planning to carry out chosen behaviors (goal setting)

Timepoint

Primary outcome measurements once before the start of the study and one to two months after the intervention

Method of measurement

-Researcher-made questionnaire

5

Description

Emotional coping: Techniques a person uses to control emotional and physiological states.

Timepoint

Primary outcome measurements once before the start of the study and one to two months after the intervention

Method of measurement

-Researcher-made questionnaire

Intervention groups

1

Description

In the first session: A class for educational intervention will be held at Imam Reza Clinic. Initially, after familiarization, questionnaires will be distributed and collected, and the disease of attention deficit/hyperactivity disorder and the importance of the disease in improving children's behavior will be explained to increase the knowledge structure for 60 minutes using interactive lectures, questions and answers, and PowerPoint educational media and educational clips. In the second session: After reviewing the points of the previous session and announcing the results of the questionnaire, the characteristics and symptoms of the disease, the definition of attention and concentration, the strategy for increasing attention and concentration in order to increase the knowledge structure will be done for 60 minutes using the brainstorming method, interactive lectures, PowerPoint educational media, educational clips, and brochures. In the third session: After reviewing the points of the previous sessions, a description of the principles of behavior change at home and school in order to increase the knowledge structure and improve and change the self-control structure will be done for 60 minutes using interactive lectures, group discussions, PowerPoint educational media, and educational clips. In the fourth session: After reviewing the points of the previous sessions, the treatment of attention deficit/hyperactivity disorder including (drug therapy and behavioral therapy) and the importance of Behavior therapy will be conducted for 60 minutes using interactive lectures and questions and answers, with the help of PowerPoint educational media and educational clips. In the fifth session: After reviewing the points of the previous sessions on the impact of parental behavior and the family system on the treatment process and teaching appropriate behavior between parents and children and the appropriate communication between parents in order to increase the two knowledge structures and self-efficacy, it will be conducted for 60 minutes using interactive lectures and group discussions, with the help of PowerPoint educational media and educational clips. In the sixth session: After reviewing the points of the previous sessions, by defining parenting styles and defining reinforcement patterns (positive reinforcement and negative reinforcement) in order to change the outcome expectation structure for 60 minutes, parents will also be taught the 14 guiding principles for raising children with ADHD in sessions 6 and 7 using interactive lectures and questions and answers, with the help of PowerPoint educational media, educational clips and brochures. In the seventh session: After reviewing the points of the previous sessions, relaxation techniques for parents will be taught for 60 minutes using practical demonstrations and PowerPoint educational media and educational clips. In the eighth session: In this session, by summarizing the material, the success of the program will be examined for 60 minutes using group discussion

and PowerPoint media with the aim of resolving problems and answering ambiguities. The educational content has been prepared from reliable sources such as the book Managing the Behavior of Hyperactive Children by Rossella Barclay, which was mentioned in the study. No pharmaceutical, chemical, etc. interventions will be used in this plan.

Category

Behavior

2

Description

Control group: Control group: Initially, after the control group completes the existing questionnaires, this group will proceed according to the educational protocol they receive from the clinic's pediatric psychiatrist. At the end of the intervention, we will provide the control group with the educational content that was taught to the intervention group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Clinic, Shiraz

Full name of responsible person
Dr. Mohammad Hossein Kaveh

Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Hamid Mohammadi

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Email
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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
mohadeseh mardaneh

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Health Promotion

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Position
full professor

Latest degree

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Person responsible for updating data

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Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available