Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness of parent management training sessions through internet based, live, intractive with face-to-face sessions on reducing the symptoms of children with attention deficit hyperactivity disorder.

Protocol summary

Study aim

Determining and comparing the average score of behavior problems, social problems, psychosomatic problems, social phobia, Attention Deficit Disorder (ADD), hyperactivity disorder (HD), attention deficit hyperactivity disorder (ADHD) in two methods of live communication through the Internet and face-to-face through interactive parent management training sessions.

Design

A clinical trial with a control group, with a parallel group, without blinding, randomized, on 92 patients, which is used for randomization using the rand function of Excel software.

Settings and conduct

Randomized clinical trial study method. Parents of children suffering from attention deficit and hyperactivity disorder are receiving drug treatment in Amin and Khurshid Educational Center, Isfahan University of Medical Sciences and Health Services, Department of Psychiatry.

Participants/Inclusion and exclusion criteria

The inclusion criteria included student aged 3 to 12 years referred to Khorshid and Amin Psychiatric Clinic, attentions deficit hyperactivity disorder based on DSM-5, and medication therapy. Exclusion criteria included having any chronic illness, no internet access, and any inability to communicate.

Intervention groups

Intervention group1: This group is comprised of parents who attend online classes. The subject of the course would be PMT (parent management training). The six sessions of this course are held once a week.
Intervention group2: This group is comprised of parents who attend face-to-face classes. The subject of the course would be PMT (parent management training). The six sessions of this course are held once a week.

Main outcome variables

Severity of Attention Deficit Hyperactivity Disorder.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211004052670N4**
Registration date: **2022-10-24, 1401/08/02**
Registration timing: **retrospective**

Last update: **2022-10-24, 1401/08/02**
Update count: **0**

Registration date

2022-10-24, 1401/08/02

Registrant information

Name

afsaneh karbasi amel

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-06, 1401/06/15

Expected recruitment end date

2022-09-20, 1401/06/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of parent management training sessions through internet based, live, intractive with face-to-face sessions on reducing the symptoms of children with attention deficit hyperactivity disorder.

Public title
Comparing the effectiveness of face-to-face and online parent management training classes for parents of children with hyperactivity.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Child 3-12 years old Diagnosis of ADHD according to DSM-V
Exclusion criteria:
Intellectual disability or borderline intelligence Concomitant physical disorder Psychological comorbidities Parents' unwillingness to participate in the study
Age
From **3 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **92**
Randomization (investigator's opinion)
Randomized
Randomization description
The method is premature mature block randomization. In this way, first we using online software (sealedenvelope), a sequence of random numbers will be created and by the same software, the generated number will be divided in to 46 block of 2. Which is an equal number in which block will be 1 item from the intervention group and 1 item from control group. So by doing each block, 1 patien (equal) will be assigned to each group.
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
Research Research Ethics Committees of School of Medicine - Isfahan University of Medical SciencesRe
Street address
Isfahan, Hazar Jarib Street, Isfahan University of Medical Sciences, Building No. 3, Faculty of Medicine, Ground Floor, Department of Medical Ethics
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Approval date
2022-08-14, 1401/05/23
Ethics committee reference number
IR.MUI.MED.REC.1401.194

Health conditions studied

1

Description of health condition studied
Attention deficit and hyperactivity disorder
ICD-10 code
F90
ICD-10 code description
Attention-deficit hyperactivity disorders

Primary outcomes

1

Description
Severity of Attention Deficit hyper Activity Disorder.
Timepoint
Before the intervention, Immediately after the end of the intervention and tow months after the end of the intervention.
Method of measurement
Using Connors 3rd edition and SNAP-IV questionnaires.

Secondary outcomes

1

Description
Severity of attention deficit hyperactivity disorder.
Timepoint
Two months after the end of the sessions.
Method of measurement
Using Connors 3rd edition and SNAP-IV questionnaires.

2

Description

Severity of attention deficit.

Timepoint

Two months after the end of the sessions.

Method of measurement

Using Connors 3rd edition and SNAP-IV questionnaires.

3

Description

Severity of hyperactivity.

Timepoint

Two months after the end of the sessions.

Method of measurement

Using Connors 3rd edition and SNAP-IV questionnaires.

4

Description

Severity of conduct disorder.

Timepoint

Two months after the end of the sessions.

Method of measurement

Using Connors 3rd edition and SNAP-IV questionnaires.

5

Description

Severity of social problems.

Timepoint

Two months after the end of the sessions.

Method of measurement

Using Connors 3rd edition and SNAP-IV questionnaires.

6

Description

Severity of psychosomatic problems.

Timepoint

Two months after the end of the sessions.

Method of measurement

Using Connors 3rd edition and SNAP-IV questionnaires.

7

Description

Severity of generalized anxiety disorder.

Timepoint

Two months after the end of the sessions.

Method of measurement

Using Connors 3rd edition and SNAP-IV questionnaires.

Intervention groups

1

Description

Intervention group: This group is comprised of parents who attend online classes. The subject of the course would be PMT (parent management training). The six sessions of this course are held once a week. The first session is on children psychology and familiarizing with attention deficit hyperactivity disorder, its etiology, prognosis and treatments. The second session is on commanding. The third one is on strengthening the communication with the child in order to achieve better obedience. The forth and the fifth sessions are about types of encouragement and discipline respectively. The sixth session is on the negative impact of certain situations on child’s misbehavior (e.g., hunger and peer effect). At the beginning of each session, the parents can ask questions about the last sessions and at the end of the session they are guided on specific homework that they are supposed to send to the instructor for review.

Category

Behavior

2

Description

Control group: This group is comprised of parents who attend face-to-face classes. The subject of the course would be PMT (parent management training). The six sessions of this course are held once a week. The first session is on children psychology and familiarizing with attention deficit hyperactivity disorder, its etiology, prognosis and treatments. The second session is on commanding. The third one is on strengthening the communication with the child in order to achieve better obedience. The forth and the fifth sessions are about types of encouragement and discipline respectively. The sixth session is on the negative impact of certain situations on child’s misbehavior (e.g., hunger and peer effect). At the beginning of each session, the parents can ask questions about the last sessions and at the end of the session children’s homework is checked.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin Educational and Therapeutic Center

Full name of responsible person

Afsane Karbassi Amel

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Amin Medical Education Center, Ibn Sina St., Shahada square, Isfahan

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2

Recruitment center

Name of recruitment center
Khorshid Medical Educational Research Complex

Full name of responsible person
Afsane Karbasi Amel

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Isfahan University of Medical Sciences Research Assistant

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
Esfahan University of Medical Sciences

Full name of responsible person
Afsane Karbassi Amel

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Psychiatrics

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Person responsible for scientific inquiries

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Position
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Latest degree
Subspecialist

Other areas of specialty/work
Psychiatrics

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available