Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effect of family management training (PMT) and attention process training (APT) in children with attention deficit and ADHD disorder under drug treatment

Protocol summary

Study aim

Comparing the effect of family management treatment (PMT) and attention process therapy (APT) in Children with hyperactivity disorder and attention deficit

Design

In this interventional study, 45 patient with ADHD will be selected and divided into three groups using block randomization method (n=15 each group). Proper counseling will be done and a written informed consent will be obtained before starting the treatment regimen.

Settings and conduct

In this study children with ADHD who will be referred to the psychiatric clinic of Fatemi Hospital in Ardabil will be investigated. At the beginning of the study, all patients will be evaluated in terms of degree of ADHD. After the end of treatment scores of the last assessment will be considered as a post-test scores and results will be compared.During the study participants and data analyser will be not aware of the type of medication.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ADHD, no drug intake. Exclusion criteria: Presence of mental illness, failure to cooperate due to hearing impairment, visual acuity, and movement, psychosis in the child and mother، Absence for maximum two sessions.

Intervention groups

Intervention group 1: In this group parents of subjects will be received parenting management training (PMT) treatment beside drug therapy. Intervention group 2: In this group, the child with ADHD will be trained by a psychologist with attention process training technique (APT) beside drug therapy. Intervention group 3: patients will be received only drug therapy same as other groups.

Main outcome variables

Decreased ADHD symptom

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171104037215N2**
Registration date: **2018-06-08, 1397/03/18**
Registration timing: **prospective**

Last update: **2018-06-08, 1397/03/18**
Update count: **0**

Registration date

2018-06-08, 1397/03/18

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3371 6616

Email address

p.bakhshi@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-06, 1397/04/15

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the effect of family management training (PMT) and attention process training (APT) in children with attention deficit and ADHD disorder under drug treatment

Public title
Effect of family management training (PMT) with attention process training (APT) in ADHD children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having ADHD disorder No drug intake
Exclusion criteria:
Absence for maximum two sessions The presence of mental illness, depression, psychosis in the child and mother Failure to cooperate due to hearing impairment, visual acuity, and movement
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **45**
More than 1 sample in each individual
Number of samples in each individual: **15**
Everyone is in the sample as a person and has an equal likelihood of selection
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are assigned randomly by blocking in one of the three specified groups and after selecting the envelope for each patient, before starting the treatment regimen envelope will be opened and based on the protocol, one of three methods will be selected.
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 Ardabil University of Medical Sciences
Street address
Ardabil University of Medicine Sciences, Daneshgah street, Ardabil
City
Ardabil
Province
Ardabil
Postal code
5615783134
Approval date
2018-01-28, 1396/11/08
Ethics committee reference number
IR.ARUMS.REC.1396.108

Health conditions studied

1

Description of health condition studied
Disturbance of activity and attention
ICD-10 code
F90.0
ICD-10 code description
Disturbance of activity and attention

Primary outcomes

1

Description
concentration
Timepoint
Before beginning of intervention and three times (end of first, second and third months) after intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Hyper Active disorder
Timepoint
Before beginning of intervention and three times (end of first, second and third months) after intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: In this group parents of subjects will be received parenting management training (PMT) treatment and Ritalin 10 mg, three times a day (Exir Co).
Category
Behavior

2

Description
Intervention group: The child with ADHD will be trained by a psychologist with attention process training technique (APT) and Ritalin 10 mg, three times a day (Exir Co).

Category
Behavior

3

Description
Control group: patients will be received Ritalin 10 mg, three times a day (Exir Co)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemi Hospital

Full name of responsible person
Mehriar Nadrmohamadi

Street address
Fatemi Hospital, Shariati Square, Ardabi

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Ardabil

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Ardabil

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5614733775

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+98 45 3323 2520

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M.nadermohammadi@arums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ardabil University of Medical Sciences

Full name of responsible person
Shahab Bohlooli

Street address
Ardabil University of Medical Science, Daneshgah street, Ardabil, Iran

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Phone
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Email
Shahab.bohlooli@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ardabil 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
Ardabil University of Medical Sciences

Full name of responsible person
Mehriar Nadrmohamadi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychiatrics

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Person responsible for scientific inquiries

Contact

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Ardabil University of Medical Sciences

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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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