

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

A clinical trial to comparison the effectiveness of choice theory on behavioral problems in attention deficit hyperactivity disorder (ADHD) with oppositional defiant disorder (ODD) patients

Protocol summary

Summary

Objective: To comparison the effectiveness of choice theory on behavioral problems in attention deficit hyperactivity disorder (ADHD) with oppositional defiant disorder (ODD) patients. Design: A single-blind block randomized clinical trial. Study population: Attention deficit hyperactivity disorder (ADHD) and oppositional defiant disorder (ODD) patients. Inclusion criteria: Attention deficit hyperactivity disorder (ADHD) and oppositional defiant disorder (ODD) patients base on DSM-V criteria; aged between 12 and 18 years; no signs of systemic diseases and other psychological diseases; history of normal IQ; have the standard drug treatment in the last of 3 to 12 months. Exclusion criteria: Unwillingness to continue the study; incidence of systemic diseases and other psychological diseases. Sample size: 32 cases. Study intervention: The intervention group received the standard treatment for ADHD (1-10 mg/kg ritalin and 10 mg risperidone per day) and received five 120-minute sessions of training based on choice theory for five consecutive weeks. The control group received the standard treatment for ADHD (1-10 mg/kg ritalin and 10 mg risperidone per day) along with group sessions similar to the intervention group, but without any special theoretical basis. Study outcome: Evaluation and comparison of the results obtained from SDQ and ODD questionnaires in the intervention and control groups before, as well as 1 and 4 weeks after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011431920N1**

Registration date: **2017-05-21, 1396/02/31**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-05-21, 1396/02/31

Registrant information

Name

Mahdieh Fatemi Naeri

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to comparison the effectiveness of choice theory on behavioral problems in attention deficit hyperactivity disorder (ADHD) with oppositional defiant disorder (ODD) patients

Public title

The effects of choice theory on behavioral problems

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Attention deficit hyperactivity disorder (ADHD) and oppositional defiant disorder (ODD) patients base on DSM-V criteria; aged between 12 and 18 years; no signs of systemic diseases and other psychological diseases; history of normal IQ; have the standard drug treatment in the last of 3 to 12 months. Exclusion criteria: Unwillingness to continue the study; incidence of systemic diseases and other psychological diseases.

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Postal code

Approval date

2016-07-13, 1395/04/23

Ethics committee reference number

IR.FM.REC.1395.109

Health conditions studied

1

Description of health condition studied

Attention deficit hyperactivity disorder (ADHD)

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

2

Description of health condition studied

Oppositional defiant disorder (ODD)

ICD-10 code

F91.3

ICD-10 code description

Oppositional defiant disorder

Primary outcomes

1

Description

Strengths and difficulties

Timepoint

Before, 1 and 4 weeks after the intervention

Method of measurement

Strengths and Difficulties Questionnaire (SDQ)

2

Description

Oppositional defiant disorder

Timepoint

Before, 1 and 4 weeks after the intervention

Method of measurement

Oppositional Defiant Disorder (ODD) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Who received the standard treatment for ADHD (1-10 mg/kg ritalin and 10 mg risperidone per day) and received five 120-minute sessions of training based on choice theory for five consecutive weeks

Category

Treatment - Other

2

Description

Control group: Who received the standard treatment for ADHD (1-10 mg/kg ritalin and 10 mg risperidone per day) along with group sessions similar to the intervention group, but without any special theoretical basis.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebn'e Sina Hospital

Full name of responsible person

Mahdiea Fatemi Naeri

Street address

Side of Astan Quds Vehicles, Horr Ameli Boulevard

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

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Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahdieh Fatemi Naeri

Position

Psychiatrist

Other areas of specialty/work

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Mashhad University of Medical Sciences

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code
empty
Data Dictionary
empty