

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

the study of The effect of psychodrama on aggression, social anxiety and symptoms attention deficit and hyperactivity, in children with attention deficit and hyperactivity disorder

Protocol summary

Study aim

Determine the effect of psychodrama on aggression, social anxiety and symptoms of attention deficit and hyperactivity in children with attention deficit / hyperactivity disorder.

Design

Sample size contains 48 children who have inclusion criteria for research. 24 people receive Ritalin and 24 people receive Atomoxetine (Strattera). those who receive Ritalin are randomly assigned (according to the luck) to the control and experiment groups and those who receive Atomoxetine are randomly divided (according to the luck) into two groups: control and experiment. The control and experiment groups each included 12 members.

Settings and conduct

Our samples in this study are collected from the children who referred to the Baharan Hospital based on inclusion criteria and randomly assigned into the experiment and control groups. At first, groups are pretested, then 10 sessions, 90-minute group psychodrama are performed for children in two experiment groups for 10 weeks independently. control groups do not receive any interventions. At the end of the treatment sessions, Post-test is taken from all groups and after a month follow-up, the research variables are performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1)Having the attention deficit\ Hyperactivity Disorder 2)6 to 12 years old 3)Lack of mental retardation 4) Taking Ritalin 5)Taking Atomoxetine exclusion criteria 1)presence of another disorder

Intervention groups

10 sessions of group psychodrama are performed for 10 weeks and each session lasts for 90 minutes for the two experiment groups, while the two control groups do not receive any interventions.

Main outcome variables

Aggression grade; Social anxiety grade; Hyperactivity disorder symptoms grade

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181201041814N1**

Registration date: **2019-01-27, 1397/11/07**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-27, 1397/11/07**

Update count: **0**

Registration date

2019-01-27, 1397/11/07

Registrant information

Name

Yunes Zaheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5796

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zaheriyones@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-04-20, 1398/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the study of The effect of psychodrama on aggression, social anxiety and symptoms attention deficit and hyperactivity, in children with attention deficit and hyperactivity disorder

Public title

Evaluating The effect of psychodrama group psychotherapy on the symptoms associated with attention deficit / hyperactivity disorder.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having the attention deficit\ Hyperactivity Disorder 6 to 12 years old Lack of mental retardation Taking Ritalin Taking Atomoxetine

Exclusion criteria:

presence of another disorder

Age

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

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

24 people of those who receive Ritalin and 24 people of those who receive Atomoxetine will be categorized into 2 groups (control, experiment) randomly. the names of all subjects will be written separately on piece of papers. Then they are thrown into a box and members of both control and experiment groups are selected randomly . The control and experiment groups each included 12 members. This is done separately for those taking Ritalin and Atomoxetine.

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 Zahedan University of Medical Sciences

Street address

Research Deputy ,University Medical sciences,Dr Hasabi's Square,University Street

City

zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2018-06-17, 1397/03/27

Ethics committee reference number

IR.ZAUMS.REC.1397.138

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**

Aggression grade

Timepoint

Aggressive symptoms are measured before the first session of treatment, and after the end of treatment course. variables will be measured for the last time, a month after the last session of the treatment course.

Method of measurement

Child Behaviors checklist of Achenbach

2**Description**

Social Anxiety grade

Timepoint

Social anxiety symptoms are measured before the first session of treatment, and after the end of treatment course. variables will be measured for the last time, a month after the last session of the treatment course

Method of measurement

Spence Children's Anxiety Scale

3**Description**

attention deficit\hyperactivity grade

Timepoint

Attention deficit\hyperactivity symptoms are measured

before the first session of treatment, and after the end of treatment course. variables will be measured for the last time, a month after the last session of the treatment course

Method of measurement

The Conners Parent Rating Scales

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group:10 sessions of the psychodrama group therapy includes the use of Introduction, magical Store , mirrors for introducing themselves, family imaginations, role play, empty chair, use of body language, storytelling, The task of finding symbolic gifts techniques and methods(such as: assertiveness training, giving responsibility to the members of the group, giving the memoir assignment and challenging thoughts and beliefs of the members of the group that accompany examination of the feelings and experiences of the members during the therapeutic sessions). These sessions will be performed for the Ritalin consumer group within ten weeks, each session takes approximately 90 minutes.

Category

Behavior

2

Description

Second Intervention group: 10 sessions of the psychodrama group therapy includes the use of Introduction, magical Store , mirrors for introducing themselves, family imaginations, role play, empty chair, use of body language, storytelling, The task of finding symbolic gifts techniques and methods(such as: assertiveness training, giving responsibility to the members of the group, giving the memoir assignment and challenging thoughts and beliefs of the members of the group that accompany examination of the feelings and experiences of the members during the therapeutic sessions). These sessions will be performed for the Atomoxetine consumer group within ten weeks, each session takes approximately 90 minutes.

Category

Behavior

3

Description

Third Intervention group: Those who take Ritalin do not receive any type of intervention.

Category

Behavior

4

Description

control group: Those who take Atomoxetine (Strattera) do not receive any type of intervention

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Baharan Psychiatry hospital

Full name of responsible person

Azizullah Mujahid

Street address

Baharan Psychiatric Hospital,Imam Khomeini Street

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Noor Mohammad Bakhshani

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bakhsha@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Email

zaheriyones@zaums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Yunrs Zaheri

Position

Msc student

Latest degree

Master

Other areas of specialty/work

Psychology

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Yunes zaheri

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/documentThe outcome and conclusion of the data will be published
in article after the end of the interventions. All
questionnaires and scales that are used, are available.**When the data will become available and for how long**The beginning of availability period will be Summer of
1398**To whom data/document is available**

Will be available for everyone

Under which criteria data/document could be usedno analysis on data is allowed. Only the protocol can be
used and referenced.**From where data/document is obtainable**

Yunes Zaheri\ zzaheriyones@gmail.com

What processes are involved for a request to access

data/document

After requesting an email, it will be sent within a

maximum of two weeks

Comments