Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Iran (Islamic Republic of)

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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

City

Zahedan

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Sistan-va-Balouchestan

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9819713955

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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

Street address

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

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Email

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

Person responsible for general inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Yunes zaheri
Position
Msc Student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Room 213, Block 3, Kaykha dormitory, University Medical sciences, Dr Hasabi Square, University Street
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Person responsible for scientific inquiries

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Zahedan University of Medical Sciences
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Person responsible for updating data

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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/document
The 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 used
no 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