

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

The effectiveness of play therapy on anxiety and aggression in preschool and elementary school children with Attention Deficit Hyperactivity Disorder

Protocol summary

Summary

The purpose of this study is to evaluate the efficacy of play therapy on anxiety and aggression in preschool and elementary school children with ADHD disorder. This is an interventional study with control group. Participants have diagnosed ADHD disorder aged 6-11 years that last at least 3 months of receiving them medication. Also participants should not have other significant disorders in physical and psychological conditions. Participants are divided into two groups, experimental and control based on randomization list. The method of sampling is in accessible and is among individuals who have been referring to the Motahhary clinic, Esfahan, Iran. The intervention in this study is playing therapy that include 4 types of individual play and 4 type of collection play at period 8 week, 1 session a week. Pre-test and post-test to measure scale children anxiety and aggression by Questionnaire. Pre-test is conduct for both groups then post-test is conduct for both groups also through 2 stage (8 week after to start intervention and 1 month after to end intervention).

General information

Acronym

ADHD

IRCT registration information

IRCT registration number: **IRCT2014090819086N1**

Registration date: **2014-11-20, 1393/08/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-11-20, 1393/08/29

Registrant information

Name

Parisa Doodman

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 5410

Email address

doodman@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of play therapy on anxiety and aggression in preschool and elementary school children with Attention Deficit Hyperactivity Disorder

Public title

Effect of play therapy on ADHD children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 6 to 11 years old; entry into preschool or elementary schools; diagnosis of attention deficit disorder / hyperactivity, according to

psychiatrist; willingness to participate in the study (by agreeing with parental consent); children who are going at least 3 months of drug treatment; at least a fifth grade education for parents of children and lack of significant psychiatric disorders in order to complete questionnaire. Exclusion criterion: child having any other significant disorder in physical or mental conditions.

Age

From **6 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand st.

City

Shiraz

Postal code

Approval date

2014-10-25, 1393/08/03

Ethics committee reference number

CT-9374-7184

Health conditions studied

1

Description of health condition studied

Attention Deficit Hyperactivity Disorder

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes

1

Description

Anxiety

Timepoint

Before the intervention, 8 weeks after the beginning of intervention, one month after the end of intervention.

Method of measurement

Questionnaire

2

Description

Aggression

Timepoint

Before the intervention, 8 weeks after the beginning of intervention, one month after the end of intervention.

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention in the intervention group is play therapy. 8 type individual and group plays are conducted with each child at period 8 week.

Category

Behavior

2

Description

Intervention in control group is no action.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari clinic

Full name of responsible person

Dr. Mojgan Karahmadi

Street address

Sepahsalar street, Esfahan

City

Esfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Ali Poostforosh Fard

Street address

Seventh floor, Shiraz University of Medical Sciences,
Zand street

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Parisa Doodman

Position

MSc Student

Other areas of specialty/work**Street address**

Shiraz University of Medical Sciences, front Felestine
Street, Zand Street

City

Shiraz

Postal code**Phone**

+98 71 3230 5410

Fax**Email**

doodman@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Ali Alavi Shooshtari

Position

Assistant prof.

Other areas of specialty/work**Street address**

Shiraz University of Medical Sciences, front Felestine
Street, Zand Street

City

Shiraz

Postal code**Phone**

+98 71 3230 5410

Fax**Email**

alialavi@sums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Parisa Doodman

Position

MSc Student

Other areas of specialty/work**Street address**

Shiraz University of Medical Sciences, front Felestine
Street, Zand Street

City

Shiraz

Postal code

71348 14336

Phone

+98 71 3230 5410

Fax

+98 71 3212 2430

Email

doodman@sums.ac.ir

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