

# 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*