

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effectiveness of Non-Directive Play Therapy Training on Loneliness, Social Anxiety, and Aggression in Children with Attention Deficit Hyperactivity Disorder

#### Protocol summary

##### Study aim

Determining the effectiveness of non-directive play therapy training on loneliness, social anxiety, and aggression in children with attention deficit hyperactivity disorder

##### Design

The clinical trial will use a pretest-posttest design with experimental and control groups, and individuals will be randomly assigned to the experimental and control groups.

##### Settings and conduct

This study is an experimental study with a pretest-posttest design and a control group. The statistical population consists of children with hyperactivity who refer to a psychological treatment center in Ahvaz. Thirty children are randomly selected and assigned to two groups: experimental (15 participants) and control (15 participants). The experimental group receives 8 sessions of non-directive play therapy based on the Kaduson and Schaefer (2001) protocol.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria Be between 7 and 11 years old. Have a diagnosis of Attention Deficit/Hyperactivity Disorder (ADHD) confirmed by a clinical psychologist or psychiatrist based on DSM-5 criteria. Be enrolled in elementary school (grades one to five). Exclusion Criteria Have a severe physical problem that interferes with the research process. Have a confirmed diagnosis of another disorder besides ADHD, such as severe anxiety disorders, other unrelated behavioral disorders, or neuropsychological disorders that may affect the results. Have severe physical or psychological problems that impair participation in sessions, such as severe motor disability, speech impairment, or serious cognitive disorders.

##### Intervention groups

Intervention Group: Non-directive play therapy; participants will receive non-directive play therapy sessions over 8 sessions, according to the Kaduson and Schaefer (2001) protocol. Control Group: They will not receive any intervention.

##### Main outcome variables

Loneliness; Social Anxiety; Aggression.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20260501069223N1**

Registration date: **2026-05-05, 1405/02/15**

Registration timing: **prospective**

Last update: **2026-05-05, 1405/02/15**

Update count: **0**

##### Registration date

2026-05-05, 1405/02/15

##### Registrant information

##### Name

Mahsa Heidari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 930 749 8065

##### Email address

mahsaheidari980000@yahoo.com

##### Recruitment status

**recruiting**

##### Funding source

##### Expected recruitment start date

2026-06-05, 1405/03/15

**Expected recruitment end date**

2026-07-06, 1405/04/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effectiveness of Non-Directive Play Therapy Training on Loneliness, Social Anxiety, and Aggression in Children with Attention Deficit Hyperactivity Disorder

**Public title**

The Effectiveness of Play Therapy Training

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Be between 7 and 11 years old. Have a diagnosis of Attention Deficit/Hyperactivity Disorder (ADHD) confirmed by a clinical psychologist or psychiatrist based on DSM-5 criteria. Be enrolled in elementary school (grades one to five). Have the cognitive and communicative ability to participate in group or individual play therapy sessions.

**Exclusion criteria:**

Have a severe physical problem that interferes with the research process. Have a confirmed diagnosis of another disorder besides ADHD, such as severe anxiety disorders, other unrelated behavioral disorders, or neuropsychological disorders that may affect the results. Participate in other therapeutic, psychological training, or play therapy programs during the study period. Have severe physical or psychological problems that impair participation in sessions, such as severe motor disability, speech impairment, or serious cognitive disorders. Have sensory problems or specific disabilities that interfere with play therapy activities (such as visual or hearing impairments, or severe physical disabilities without possible adaptation).

**Age**From **7 years** old to **11 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Care provider
- Outcome assessor
- Data analyser

**Sample size**Target sample size: **30****Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, in order to achieve completely random allocation and eliminate any researcher involvement or bias, the simple randomization method will be used. First, a complete list of children referred to the

counseling center who meet the inclusion criteria for the study will be prepared. Then, an initial numerical identification code will be assigned to each of these individuals. These codes will be entered into a Random Number Generator software. The software will generate a unique random number for each individual. After the numbers are generated, the participants will be listed in ascending order based on the value of the random number. Then, sequentially, the first to the fifteenth individuals on the list will be assigned to the experimental group and the sixteenth to the thirtieth individuals will be assigned to the control group. This process will be designed in such a way that the order of entry or the researcher's familiarity with the participants will have no role in the allocation process, and it will not be possible to predict the group of any individual before the completion of randomization.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, clinical caregivers, the outcome assessor, and data analysts are blinded to the study group allocation, and the information will be coded.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Islamic Azad University of Ahvaz

**Street address**

Islamic Azad University of Ahvaz, Farhang Shahr.

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6134937333

**Approval date**

2026-02-28, 1404/12/09

**Ethics committee reference number**

IR.IAU.AHVAZ.REC.1405.007

**Health conditions studied****1****Description of health condition studied**

Hyperactivity

**ICD-10 code**

F90

**ICD-10 code description**

Attention-deficit hyperactivity disorders

## Primary outcomes

### 1

#### Description

Loneliness

#### Timepoint

before performing the intervention and two weeks after completion of the intervention

#### Method of measurement

Asher and Wheeler's Loneliness Questionnaire (1985)

### 2

#### Description

Social anxiety

#### Timepoint

before performing the intervention and two weeks after completion of the intervention

#### Method of measurement

Reynolds and Richmond Social Anxiety Questionnaire (1978)

### 3

#### Description

Aggression

#### Timepoint

before performing the intervention and two weeks after completion of the intervention

#### Method of measurement

Eysenck and Wilson Aggression Questionnaire (1975)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Non-directive play therapy is an approach that allows the child to freely express his or her feelings and problems during play without direct guidance from the therapist. In this method, the therapist mainly plays the role of an observer and supporter and only provides a safe and accepting environment so that the child can express himself or herself in a natural way. The aim of this method is to strengthen the child's self-confidence, self-awareness, and resolution of psychological problems through experience and free expression in the play setting. In this study, non-directive play therapy sessions will be conducted in 8 sessions, according to the Kaduson and Schaefer (2001) protocol.

#### Category

Behavior

### 2

#### Description

Control group: They do not receive any intervention or treatment.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rayan Counseling and Psychological Center

##### Full name of responsible person

Mahsa Heidari

##### Street address

1st floor, Mahtab Complex, between East 4th and 5th Streets, Kianpars.

##### City

Ahvaz

##### Province

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##### Postal code

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##### Phone

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##### Email

mahsaheidari980000@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Aslan Aghdarnajad

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Islamic Azad University of Ahvaz, Farhang Shahr.

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##### Email

a\_eigder@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Islamic Azad University

#### Proportion provided by this source

100

#### Public or private sector

Public  
**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**  
Islamic Azad University  
**Full name of responsible person**  
Mahsa Heidari  
**Position**  
Master's student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Psychology  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

Participant data is completely confidential and I do not intend to publish it.

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available