Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

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)
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+98 930 749 8065
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mahsaheidari980000@yahoo.com

Recruitment status

Recruitment complete

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 Disorde

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
Khouzestan
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.
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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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Phone
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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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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