

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The effect of group play therapy on emotional behavioral problems of children with attention deficit hyperactivity disorder (ADHD) aged 6-12 years

#### Protocol summary

##### Study aim

The effect of group play therapy on emotional behavioral problems in children with attention deficit hyperactivity disorder (ADHD) aged 6-12 years

##### Design

Clinical trial with control group

##### Settings and conduct

After obtaining the necessary permits from the University of Social Welfare and Rehabilitation Sciences, children with a diagnosis of attention deficit hyperactivity disorder were selected by a psychiatrist who was referred to the TOHID Child Care Clinic in Isfahan. The parents first filled out the child morbidity questionnaire. Children with ADHD were selected for the intervention. After completing the consent form, the selected subjects filled out a demographic questionnaire and were initially evaluated for child behavioral logs and the results were recorded by the researcher. By random selection, indoor cards were divided into two intervention or control groups. Intervention group in addition to receiving daily educational services, participated in 12 sessions of group play intervention (6 weeks, 2 sessions per week and 45-60 minutes per session), but the control group received only daily educational and mental health services (subjective occupational therapy). And physical, speech therapy). After 12 sessions, the parents' questionnaire was again filled out by the parents.

##### Participants/Inclusion and exclusion criteria

6-12 year old children with attention deficit hyperactivity disorder

##### Intervention groups

Intervention group in addition to receiving daily educational services, participated in 12 sessions of group play intervention (6 weeks, 2 sessions per week and 45-60 minutes per session), but the control group received only daily educational and mental health services (subjective occupational therapy). And physical,

speech therapy).

##### Main outcome variables

Reducing emotional and behavioral problems in children with attention deficit hyperactivity disorder

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190924044875N1**

Registration date: **2019-10-14, 1398/07/22**

Registration timing: **prospective**

Last update: **2019-10-14, 1398/07/22**

Update count: **0**

##### Registration date

2019-10-14, 1398/07/22

##### Registrant information

##### Name

Sepide Teimourian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3629 2578

##### Email address

sepide.teimourian@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-21, 1398/07/29

##### Expected recruitment end date

2019-11-27, 1398/09/06

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The effect of group play therapy on emotional behavioral problems of children with attention deficit hyperactivity disorder (ADHD) aged 6-12 years

**Public title**  
The effect of group play therapy on emotional behavioral problems

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) by a child psychiatrist (based on medical records). Completion of written consent of parents to participate in the research. Age between 6 and 12 years based on year of birth listed in the file Higher score of child behavioral inventory questionnaire than cut-off point (score 65) (completed by therapist). Absence of psychotic symptoms in the child (CSI-4 test) (performed by the therapist). Absence of obvious physical, sensory, or motor disorders (based on medical records) Lack of history of seizures and use of related drug therapy (based on medical records). No previous record of participation in similar studies.  
**Exclusion criteria:**

**Age**  
From **6 years** old to **12 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **28**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Using a simple randomization method using a sealed envelope.

**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 university of Social Welfare and Rehabilitation Sciences

##### Street address

Kodakyar, Daneshjo Boulevard, Evin, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985713834

#### Approval date

2018-10-29, 1397/08/07

#### Ethics committee reference number

IR.USWR.REC.1397.089

## 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

Emotional Behavior Problem Score in Child Behavior Check List

#### Timepoint

Evaluation of emotional behavior problems score at baseline (before intervention) and 6 weeks after intervention in group play therapy.

#### Method of measurement

Child Behavioral Check List

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In addition to individual occupational therapy and speech therapy, the group received group play intervention for 12 sessions, twice a week, each session lasting between 45 and 60 minutes. Each session is played in groups to control emotional-behavioral problems.

#### Category

Behavior

## 2

### Description

Control group: the group does not receive group play intervention but attend other sessions including occupational therapy and speech therapy if needed.

### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dostdaran kodak Tohid clinic

##### Full name of responsible person

Mahdi Parsa

##### Street address

Khaghani Crossroad, Middle Vahid Ave

##### City

esfahan

##### Province

Isfahan

##### Postal code

8175800000

##### Phone

+98 31 9501 0222

##### Email

tohidclinic@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

University of social welfare and rehabilitation sciences

##### Full name of responsible person

Mohammad Reza Khodaei Ardakani

##### Street address

University of social welfare and rehabilitation sciences, Koodakyar End, Daneshjoo Blv, Evin, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985713834

##### Phone

+98 21 7173 2832

##### Email

kh.ardakani@uswr.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

University of social welfare and rehabilitation sciences

### 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

University of social welfare and rehabilitation sciences

#### Full name of responsible person

Sepide Teimourian

#### Position

Student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Occupational Therapy

#### Street address

No. 78, Rashtchi Alley, Niknafs Alley, Vahid Ave

#### City

Esfahan

#### Province

Isfahan

#### Postal code

8175836461

#### Phone

+98 31 3629 2578

#### Fax

#### Email

sepide.teimourian@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

University of social welfare and rehabilitation sciences

#### Full name of responsible person

Houshang Mirzaie

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Occupational Therapy

#### Street address

Koodakyar End, Daneshjoo Blv, Evin, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1985713834

#### Phone

+98 21 2218 0037

**Email**

ho.mirzaie@uswr.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Houshang Mirzaie

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Therapy

**Street address**

Koodakyar End, Daneshjoo Blv, Evin, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985713834

**Phone**

+98 21 2218 0037

**Email**

ho.mirzaie@uswr.ac.ir

## 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**

Only for general study data, including its main implications, can be shared.

**When the data will become available and for how long**

Start of access period 6 months after printing results

**To whom data/document is available**

Study data will be available only to researchers working in academic institutions.

**Under which criteria data/document could be used**

Use of data is permitted solely for the purposes of further study and information of applicants.

**From where data/document is obtainable**

Responsive Name: Sepideh Teimourian Email address: sepide.teimourian@yahoo.com

**What processes are involved for a request to access data/document**

The applicant sends his application to the above mentioned email address and receives his reply within 2 weeks.

**Comments**