Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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
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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
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

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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 Teimurian 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