

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of play therapy on the attention and concentration and active memory in children the attention deficit hyperactivity disorder

#### Protocol summary

##### Study aim

The effect of Play Therapy on the attention and concentration and active memory in children with the attention deficit hyperactivity disorder

##### Design

The samples of this research include children with ADHD and randomly will be divided into experimental and control groups (20 persons in each group) and will complete continuous performance scale, active memory scale. Play therapy will be conducted during 8 sessions in experimental group while the control group will not receive any training.

##### Settings and conduct

Research place : personal counselor office Play therapy will be conducted during 8 sessions in 2 months for experimental group while the control group will not receive any training. Finally, after the intervention course, results will be compared.

##### Participants/Inclusion and exclusion criteria

All Children with ADHD in Rasht city

##### Intervention groups

Play therapy, named "See and Say", will be attended 1 session in a week for about 2 months (totally 8 sessions). Control group will receive no intervention but after measurement, it will be done for control group too, morally.

##### Main outcome variables

attention, concentration and active memory

#### General information

##### Reason for update

##### Acronym

ADHD

##### IRCT registration information

IRCT registration number: **IRCT20190331043147N1**

Registration date: **2020-02-04, 1398/11/15**

Registration timing: **retrospective**

Last update: **2020-02-04, 1398/11/15**

Update count: **0**

##### Registration date

2020-02-04, 1398/11/15

##### Registrant information

###### Name

Manizheh Hasanipour fallah

###### Name of organization / entity

University payame noor

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 3334 3658

###### Email address

m.hasanipour94@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-04-04, 1398/01/15

##### Actual recruitment start date

2018-12-22, 1397/10/01

##### Actual recruitment end date

2019-04-04, 1398/01/15

##### Trial completion date

2019-04-04, 1398/01/15

##### Scientific title

The effect of play therapy on the attention and concentration and active memory in children the attention deficit hyperactivity disorder

##### Public title

play therapy in 6-years old children with attention deficit hyperactivity disorder

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

hyperactivity disorder and Attention deficit being 6 years old

### **Exclusion criteria:**

continuous attention Mental disability less than 6 years old

## **Age**

From **6 years** old to **6 years** old

## **Gender**

Both

## **Phase**

1-2

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **40**

Actual sample size reached: **40**

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

Randomized

## **Randomization description**

In this method, the researcher gives each individual in the community a special code or number (here the file number). (Some of the communities studied have numbered systems, such as students or students of a training center. Therefore, no coding is required and the researcher can base numbers on these lists.) Then use beads and plates on the numbers or write them on a small paper or cardboard; therefore, it will have the number of people in the community. Then they throw them into a bag or container and mess up. He then extracts the beads one by one, records their numbers, and continues this until they choose the number of sample numbers. Accordingly, here, 40 children with attention deficit hyperactivity disorder who were referred to the researcher's personal clinic were selected according to the inclusion criteria and randomly selected from a referral file number. They were divided into two experimental and control groups.

## **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**

Guilan University of Medical Sciences

##### **Street address**

Dorsa building, Noorbakhsh St, Sabze-Meydan Sq, Rasht

## **City**

Rasht

## **Province**

Guilan

## **Postal code**

4143775545

## **Approval date**

2018-12-15, 1397/09/24

## **Ethics committee reference number**

IR.GUMS.REC.1397.348

## **Health conditions studied**

### 1

#### **Description of health condition studied**

attention deficit hyperactivity

#### **ICD-10 code**

F90.9

#### **ICD-10 code description**

Attention-deficit hyperactivity disorder, unspecified type

## **Primary outcomes**

### 1

#### **Description**

attention and concentration

#### **Timepoint**

at the beginng, during the course and at the end after one month

#### **Method of measurement**

CPT

### 2

#### **Description**

active memory

#### **Timepoint**

at the beginng, during the course and at the end after one month

#### **Method of measurement**

WISC-IV

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

For Test group, The game "See and Say" which is a therapeutic package and includes a board game for hyperactive children, will be done. This game is suitable for treatment of attention and concentration problems. The time of hourglass is 30 seconds. The game will be played with 2 to 4 players and is suitable for children over 4 years. (Children who do not have the ability to read and write should also do it with an adult, because the questions behind the cards must be handled by

someone who can read). This game contains 160 cards and 960 questions.

**Category**

Treatment - Other

**2**

**Description**

Control group: no specific training but playing the game in one session just for being familiar with.

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Andisheh Novin

**Full name of responsible person**

Manizheh Hassani pourFallah Behdani

**Street address**

3rd floor, Pars Building, Motahari St

**City**

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**Postal code**

4184935174

**Phone**

+98 13 3334 3658

**Email**

m.hasanipour94@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Dr nemati

**Street address**

in front of 17 Shahrivar hospital

**City**

rasht

**Province**

Guilan

**Postal code**

4193893345

**Phone**

+98 13 3333 6394

**Email**

medjour@gums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Rasht University of Medical Sciences

**Proportion provided by this source**

1

**Public or private sector**

Private

**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**

Rasht University of Medical Sciences

**Full name of responsible person**

Manizheh Hassani pourFallah Behdani

**Position**

counselor

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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3rd floor, Pars building, Motahari St

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

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

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be 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**

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

**Data Dictionary**

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