

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Examining the effect of training pretend play based on theory of mind in children with autism spectrum disorder

#### Protocol summary

##### Study aim

Examining the effect of training pretend play on theory of mind in children with autism spectrum disorder

##### Design

Clinical trial with a control group, double-blind, randomized, a sealed envelope will be used for randomization.

##### Settings and conduct

The study will be performed on 20 children with an autism spectrum disorder in Ahvaz. The assessor of the outcome measures will be blind about the groups that children will be allocated.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 9-5 years; Definitive diagnosis of autism spectrum disorder based on the opinion of a psychiatrist; Gilliam-Garz diagnostic test with a score of 30 or higher to diagnose mild to moderate autism spectrum disorder; Assessing the history of the child's play in the form of interviews with the mother and also observing the child's free play will be examined to assess the level of pretend to play in the child, the literacy of reading and writing in Persian for parents.

##### Intervention groups

The experimental group is a total of 20 people who will be divided into two groups of 10 people. The first intervention group, in addition to common interventions, will undergo 20 sessions of 45 to 60 minutes of pretend play training with a identiplay approach and relying on the theory of mind. The form is prepared from two series of play tools and after the scenario is done by the child researcher, the child must be able to imitate the play scenario and if the next level is done correctly, the next level will be presented to the child, but the second intervention group, receive pretend play without relying on theory of mind, while the control group, which is 10 people, only receive common interventions..

##### Main outcome variables

Improving the theory of mind in children with autism

spectrum disorder

#### General information

##### Reason for update

In the initial protocol, due to the fact that it was in the form of a thesis and coincided with the Corona situation, the families did not go to the clinic for the desired study due to the conditions, but considering that the thesis with a smaller number (6 people) in the defense group. Currently, there is an opportunity to include the third group in the study of this clinical trial in a more accurate and strong way and to answer the questions more precisely.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210227050518N1**  
Registration date: **2021-08-14, 1400/05/23**  
Registration timing: **prospective**

Last update: **2023-01-14, 1401/10/24**

Update count: **1**

##### Registration date

2021-08-14, 1400/05/23

##### Registrant information

###### Name

Fatemeh Rahmani

###### Name of organization / entity

Institute for Cognitive Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3321 3077

###### Email address

markazgolshan@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2021-08-23, 1400/06/01

**Expected recruitment end date**

2021-09-21, 1400/06/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Examining the effect of training pretend play based on theory of mind in children with autism spectrum disorder

**Public title**

Examining the effect of training pretend play based on theory of mind in children with autism spectrum disorder

**Purpose**

Education/Guidance

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

Age range 9-5 years Definitive diagnosis of autism spectrum disorder based on the opinion of a psychiatrist Gilliam-Garz diagnostic test with a score of 30 or higher to diagnose mild to moderate autism spectrum disorder Assessing the history of the child's play in the form of interviews with the mother and also observing the child's free play will be examined to assess the level of pretend to play in the child, performing 3 examples of pretend play that the child can show 3 consecutive or more pretending behaviors in the play the literacy of reading and writing in Persian for parents

**Exclusion criteria:**

Lack of normal hearing and vision

**Age**

From **5 years** old to **9 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Investigator
- Outcome assessor

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random sequencing will be done through a table of random numbers in such a way that from the second page of the third column of the table of random numbers with a sequence of 3 numbers whose last digit is even as an experimental group and numbers whose last digit is odd as a control group is selected. Concealment of random allocation is sealed through the envelope by preparing a number of envelopes and writing the numbers of the table, experimental group, and control on the sheet and placing them in the envelope, respectively, and in order to maintain a random sequence, on external surfaces. Envelopes are numbered in the same way.

Finally, the lids of the envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, according to the order of entry of eligible participants into the study, one of the envelopes will be opened in order and the assigned group of the participant will be revealed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Pre-test and post-test will be performed by a trained assessor who is not aware of the patients' group.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of Institute for Cognitive Sciences

**Street address**

No. 216, between Aban & Azar, khordad Ave, Golestan Blvd, Ahvaz Town

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6136939161

**Approval date**

2021-01-31, 1399/11/12

**Ethics committee reference number**

IR.UT.IRICSS.REC.1399.004

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

Autism spectrum disorder

**ICD-10 code**

F84.0

**ICD-10 code description**

Autistic disorder

**Primary outcomes****1****Description**

Theory of Mind

**Timepoint**

Beginning and end of the study

**Method of measurement**

Theory of mind inventory, Sally-Anne and smartiz task, penny-hiding game

## Secondary outcomes

### 1

#### Description

Task-based theory of mind

#### Timepoint

Beginning and end of the study

#### Method of measurement

penny-hiding game, Sally-Anne task and Smartiz task

### 2

#### Description

Level of theory of mind from family perspective

#### Timepoint

Beginning and end of the study

#### Method of measurement

Theory of mind inventory

## Intervention groups

### 1

#### Description

Intervention group: Children after pre-test will undergo 20 sessions of pretend play training with a identiplay approach based on theory of mind for 45 minutes and 4 times a week and the current treatment approach. Sessions will be held individually.

#### Category

Rehabilitation

### 2

#### Description

Control group: They will receive standard rehabilitation therapies such as occupational therapy, cognitive rehabilitation, and speech therapy.

#### Category

Rehabilitation

### 3

#### Description

Intervention group: After the pre-test, the children undergo 20 sessions of pretend play training without the theory of mind approach for 45 minutes, 4 times a week, and regular rehabilitation treatments. Meetings are held individually.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Autism Spectrum Disorder Treatment and Rehabilitation Centers

#### Full name of responsible person

Masoome Mohtasham

#### Street address

No. 101, Between Zamzam & Zomorod, Yosefi nejad Blvd, Zeyton karmandi Blvd

#### City

Ahvaz

#### Province

Khouzestan

#### Postal code

6163874641

#### Phone

+98 61 3445 6377

#### Fax

+98 61 3445 6377

#### Email

markazgolshan@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Institute for cognitive science studies

##### Full name of responsible person

Javad Hatami

##### Street address

Phase 4 of Pardis City, Tehran, Iran

##### City

Pardis

##### Province

Tehran

##### Postal code

1658344575

##### Phone

+98 21 7629 1130

##### Fax

+98 21 7629 1140

##### Email

ICSS@iricss.org

##### Web page address

<http://www.iricss.org>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Institute for cognitive science studies

#### 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

Other

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Samaneh Karamali Esmaili

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Therapy

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۳۴۸۷ - ۱۵۴۵۹

**Phone**

+98 21 2222 2059

**Email**

esmaeili.s@iums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Samaneh Karamali Esmaili

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Therapy

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۳۴۸۷ - ۱۵۴۵۹

**Phone**

+98 21 2222 2059

**Fax****Email**

esmaeili.s@iums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Samaneh Karamali Esmaili

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Therapy

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۳۴۸۷ - ۱۵۴۵۹

**Phone**

+98 21 2222 2059

**Email**

esmaeili.s@iums.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**

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

In the form of an article

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

In the form of an article

**To whom data/document is available**

In the form of an article

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

In the form of an article

**From where data/document is obtainable**

In the form of an article

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

In the form of an article

**Comments**