

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)

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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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Institute for cognitive science studies

Full name of responsible person

Javad Hatami

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ICSS@iricss.org

Web page address

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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

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

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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

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