Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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
Street address
No. 216, between Aban & Azar, khordad Ave, Golestan Blvd, Ahvaz Town
City
Ahvaz
Province
Khouzestan
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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Province
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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
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

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

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Assistant Professor

Latest degree
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Other areas of specialty/work
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Associate professor

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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