

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### **Social cognition dysfunction in children with high functioning autism disorder: evaluation, developing program based on remediation and compensation strategies and study on its effectiveness on theory of mind ability and executive function**

#### **Protocol summary**

##### **Study aim**

Investigating and comparing cognitive rehabilitation based on remediation and compensation strategies and study on its effectiveness on theory of mind ability and executive function

##### **Design**

the present study was on sub-experimental study with pretest and posttest design and a control group. Individuals who were diagnosed with autism were randomly divided into two intervention groups and one control group. The size of each group is 20 people.

##### **Settings and conduct**

Among children with autism in autistic children centers in Tehran, 80 children were selected using screening tests. participants are randomly assigned to one of three study groups (remediation, compensation, remediation-compensation ) and receive the intervention of the same groups.

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria: **گروه**Diagnosis of autism according to the Gilliam test, clinical interview based on DSM-5. Age (in the age range of 4 to7 years).above 80 according to Wechsler 3don't poor vision or hearing based on the child's record Parent consent to participate in the study. Exclusion criteria Attending therapeutic sessions or psychotherapy training concurrently, Absence of more than two sessions, Not willing to continue attending meetings.

##### **Intervention groups**

first group: cognitive rehabilitation based on remediation and compensation strategies second group: cognitive rehabilitation based on remediation strategies third group: cognitive rehabilitation based on compensation strategies

##### **Main outcome variables**

capacity of theory of mind executive functions

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20210619051618N1**

Registration date: **2021-11-01, 1400/08/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-11-01, 1400/08/10**

Update count: **0**

##### **Registration date**

2021-11-01, 1400/08/10

##### **Registrant information**

##### **Name**

Fatemeh Abadi

##### **Name of organization / entity**

Institute for Cognitive Science Studies

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Iran (Islamic Republic of)

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##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2021-10-24, 1400/08/02

##### **Expected recruitment end date**

2021-12-23, 1400/10/02

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Social cognition dysfunction in children with high functioning autism disorder: evaluation, developing program based on remediation and compensation strategies and study on its effectiveness on theory of mind ability and executive function

**Public title**

Comparison of effectiveness of cognitive rehabilitation based on remediation and compensation strategies on theory of mind and executive function in preschool children with autism

**Purpose**

Treatment

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

used participants between the ages of 4 and 7 years with autism spectrum disorder diagnosis of autism based on DSM-V criteria IQ above 80 according to Wechsler 3 don't poor vision or hearing based on the child's record Parent consent to participate in the study

**Exclusion criteria:**

history of seizures Receive simultaneous study  
Reluctance to continue attending meetings

**Age**

From **4 years** old to **7 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

participant who met the inclusion and exclusion criteria were randomly divided into three groups of first intervention, second intervention and control by online generating random numbers (calculator.net/random-number-generator). In the random numbers program, the numbers range was set from 1 to 60, and by choosing no duplicates, we request the production of three sets of random numbers, which are assigned to each group according to visit number of the people. This allocation is concealed from researchers and participant.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Not blinded

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of kharazmi university

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KhU, No. 43. South Mofatteh Ave., Tehran, Iran

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۱۴۹۱۱-۱۵۷۱۹

**Approval date**

2021-02-13, 1399/11/25

**Ethics committee reference number**

IR.UT.IRICSS.REC.1399.011

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

Autism

**ICD-10 code**

F84.0

**ICD-10 code description**

Autistic disorder

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

Mind Theory score, which is measured through the Mind Theory Scale, Stirman et al.'S Mind Theory, and Mind Theory Stories questionnaires.

**Timepoint**

Components of theory of mind at the beginning of the study before the intervention and will be measured three months after the start of the study after the intervention and one month after the last intervention

**Method of measurement**

theory of mind is measured through the theory of mind Scale Questionnaire, the theory of mind Test, theory of mind stories.

**2****Description**

Executive functions score, which is measured through the dimond's shape span, Missing scan test, shape school, day and night stroop,TRAIL-P.

**Timepoint**

executive functions at the beginning of the study before the intervention and will be measured three months after

the start of the study after the intervention and one month after the last intervention.

**Method of measurement**

executive function is measured dimond's shape span, Missing scan test, shape school, day and night stroop,TRAIL-P.

**Secondary outcomes**

**1**

**Description**

Behavioral dimensions of theory of mind

**Timepoint**

Behavioral dimensions of theory of mind at the beginning of the study before the intervention and will be measured three months after the start of the study after the intervention and one month after the last intervention.

**Method of measurement**

Behavioral dimensions of theory of mind is measured Theory of Mind Inventory.

**2**

**Description**

Behavioral dimensions of executive function

**Timepoint**

Behavioral dimensions of executive function at the beginning of the study before the intervention and will be measured three months after the start of the study after the intervention and one month after the last intervention.

**Method of measurement**

Behavioral dimensions of executive function is measured Behavioral Rating Executive Function Questionnaire Preschool(BRIEF-P).

**Intervention groups**

**1**

**Description**

Intervention group 1 : program based on remediation strategies. The treatment protocol consists of 18 one-hour sessions. The theory of mind training package based on the basics of mind theory and is designed according to the evolutionary and multidimensional approach of "theory of mind". training package is designed according to the evolutionary and multidimensional approach of "theory of mind".

**Category**

N/A

**2**

**Description**

Intervention group 2 : program based on compensation strategies. Rehabilitation package for executive functions in children with autism: In this program, based on theories, the basis of executive functions and cognitive rehabilitation, inhibitory control, working memory and

cognitive flexibility are targeted.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Brain and Cognition Clinic

**Full name of responsible person**

Alireza Moradi

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Cognitive Sciences and Technologies Council

**Full name of responsible person**

Majid Nili Ahmadabadi

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No 35, CSTC Building, Alvand St, Argentina Sq, Tehran, Iran

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**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**  
cognitive sciences and technologies council  
**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**  
Institute for Cognitive Science Studies  
**Full name of responsible person**  
Alireza Moradi  
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Ph.D, Professor  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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

Not applicable

### 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

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

data file, study protocol, informed consent form and clinical study reports after unidentifiable people is shareable

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

The beginning of the access period is 1 year after the

publication of the results.

**To whom data/document is available**

data of this research will be available only for researchers that working in universities.

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

Use of the data is allowed only for review articles.

**From where data/document is obtainable**

fateme abadi Mobile number: 00 98 9123138621

Email:psy.abadi@gmail.com Address:Phase 4 of Pardis

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

Researchers who want to access the data must get a letter from the university at their place of work and send to the responsible person's email address, then the data will be available in less than 1 month.

**Comments**