

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

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Name of organization / entity

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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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Province

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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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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
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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

City, Tehran, Iran

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