Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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: گروهDiagnosis 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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Institute for Cognitive Science Studies

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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

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

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Province
Tehran

Postal code
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
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Full name of responsible person
Alireza Moradi
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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