Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effectiveness of remote training of the theory of mind in improving the social interactions of children with autism spectrum disorder level 1 compared to face-to-face training

Protocol summary

Study aim

Main Objective: To determine the effectiveness of in-person training compared to remote training in Theory of Mind on improving social interactions in children with Autism Spectrum Disorder level 1.

Design

Clinical trial with 2 parallel groups, without blinding, randomized, on 28 patients. The closed envelope method will be used for randomization.

Settings and conduct

Theory of Mind (TOM) training for children with Autism Spectrum Disorder (ASD) will be conducted in government hospitals and centers, under the cover of Mashhad University of Medical Sciences. The effect of this training on the social skills of those who have been blinded in the research path of the evaluator and statistician and do not know which group the examined subjects belong to.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Be in the autistic range according to the GARS-3 questionnaire 2. The age of children should be between 6 and 9 years 3. Do not have any intelligence, hearing, vision or neurological problems other than ASD Exclusion criteria: 1. Parents' lack of consent for their child's participation in the study 2. Observing signs of parents' inability to participate in exercises and perform them at home

Intervention groups

Two groups, one in-person and the other remote, will undergo a 20-session training over a 10-week period in Mind Reading concepts at 10 therapeutic levels, based on a reputable source (Hawkins et al., 1999; translated by Rezaei, 2020). The training sessions will be conducted individually.

Main outcome variables

social interactions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240305061172N1**
Registration date: **2024-04-08, 1403/01/20**
Registration timing: **prospective**

Last update: **2024-04-08, 1403/01/20**
Update count: **0**

Registration date

2024-04-08, 1403/01/20

Registrant information

Name

Fatemeh Haresabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3189 2001

Email address

haresabadif@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-20, 1403/02/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effectiveness of remote training of the theory of mind in improving the social interactions of children with autism spectrum disorder level 1 compared to face-to-face training

Public title
Investigating the effectiveness of training of the theory of mind in improving the social interactions of children with autism spectrum disorder level 1

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Receiving a diagnosis of Autism Spectrum Disorder, level 1 by a psychiatrist Being within the autistic range according to the GARS-3 questionnaire Monolingual Persian speaker The age of children should be between 6 and 9 years old no presence of any intellectual, auditory, visual, or other neurocognitive problems except ASD, as determined through observation and reviewing files at centers, as well as interviews with parents

Exclusion criteria:
Parents' lack of consent for their child's participation in the study Observing the signs of parents' inability to participate in exercises and perform them at home

Age
From **6 years** old to **9 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
Due to the necessity of equal number of participants in two study groups, randomization will be done based on the blocked randomization method. For this, using the Randomization menu of the website of https://www.sealedenvelope.com (which provides researchers with a web-based block randomization tool) and considering random blocks of 2, 4 and 6 participants, the allocation of subjects to groups will be determined. For allocation concealment, Sequentially numbered, sealed, opaque envelopes (SNOSE) will be used.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
According to the nature of the study, blinding is not possible. However, the evaluator and statistician will not know about the allocation of the subjects.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Speech therapy department, 2nd floor, Shahid Kharazmi educational building, University campus, Vakil Abad Blvd., Bahnar Blvd.

City
Mashhad

Province
Razavi Khorasan

Postal code
9177949025

Approval date
2024-03-11, 1402/12/21

Ethics committee reference number
IR.MUMS.FHMPM.REC.1402.238

Health conditions studied

1

Description of health condition studied
Autism spectrum disorders

ICD-10 code
F84.0

ICD-10 code description
Autistic disorder

Primary outcomes

1

Description
The score of an autistic child on the Sternberg Theory of Mind Test.

Timepoint
Evaluation before and after the intervention

Method of measurement
Theory of Mind Test - Sternmen

Secondary outcomes

1

Description
The score of an autistic child on the Garshasebi and Elliot (1990) Social Skills Questionnaire

Timepoint
Evaluation before and after the intervention

Method of measurement
The Garshasebi and Elliot (1990) Social Skills Questionnaire

2

Description
The score of an autistic child on the Communication Skills Checklist - Second Edition
Timepoint
Evaluation before and after the intervention
Method of measurement
The Communication Skills Checklist - Second Edition

3

Description
the assessment of informal social interaction behaviors
Timepoint
Evaluation before and after the intervention
Method of measurement
The assessment of informal social interaction behaviors

Intervention groups

1

Description
Intervention group: distance learning (online): Participants will be trained in mind reading concepts in 10 treatment levels for 20 sessions in 10 weeks based on a reliable source (Havlin et al., 1999; translated by Rezaei, 2019). (Number of sessions per week: 2 - Duration of each session: 20 minutes - Session audience: child + mother - Executive measures in each session: 1. Teaching exercises to the mother to guide the child in the online session and perform at home (daily for at least 45 minutes)2. Examining the video of the exercises and the mother's report on the exercises and the child's conditions at home3. Answering the mother's questions - mandatory items of each session: Mother's verbal report and at least 3 videos of 40-60 seconds (one of the best, one of the worst, and one of the usual) of performing exercises at home.
Category
Rehabilitation

2

Description
control group: face-to-face training (traditional method): Participants will be trained in mind reading concepts in 10 treatment levels for 20 sessions in 10 weeks based on a reliable source (Havlin et al., 1999; translated by Rezaei, 2019). (number of sessions per week: 1 - duration of each session: 40 minutes - session audience: mother + child - implementation measures in each session: 1. Performing exercises with the child2. Providing explanations of the exercises to the mother to perform at home3. Examining the mother's verbal report of the child's activity in the interval between sessions4. Answering mother's questions - the mandatory items of each session: Mother's verbal report of performing exercises at home
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive rehabilitation center
Full name of responsible person
Fatemeh Haresabadi
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Ahmad Abad Blvd., Nurse St., 2
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haresabadif@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Fatemeh Haresabadi
Street address
Department of Speech Therapy,Kharazmi building, university campus, Vakilabad Blvd, Bahonar Blvd, Mashhad, Iran
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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
Mashhad University of Medical Sciences
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
Mashhad University of Medical Sciences

Full name of responsible person
Fatemeh Haresabadi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Speech therapy

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Person responsible for scientific inquiries

Contact

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Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Speech therapy

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Person responsible for updating data

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Full name of responsible person
Fatemeh Haresabadi

Position
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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available