

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

##### **Street address**

Ahmad Abad Blvd., Nurse St., 2

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9177949025

##### **Phone**

+98 51 3189 2001

##### **Email**

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

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

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##### **Phone**

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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

**Street address**

Department of Speech Therapy, Kharazmi building,  
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## Person responsible for scientific 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.

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## Person responsible for updating data

### Contact

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Mashhad University of Medical Sciences

**Full name of responsible person**

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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