

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### The comparison of the effectiveness of Enhanced Milieu Teaching (EMT) delivered in face-to-face and telepractice formats on improving communication skills of children with Autism spectrum disorder

#### Protocol summary

##### Study aim

The comparison of the effectiveness of Enhanced Milieu Teaching (EMT) delivered in face-to-face and telepractice formats on improving communication skills of children with Autism spectrum disorder

##### Design

Clinical trial with control group, one-way blind, using simple randomization method for 20 patients

##### Settings and conduct

Children with autism are the study population and autistic children referred to speech therapy clinics in Tehran are the study sample. Random sampling method will be used to select the subjects. To determine the sample size, in a pilot study, we will implement intervention programs on 20 children with autism spectrum disorder (two groups of 10 children). After collecting and analyzing the information, the sample size will be determined. This study will be conducted as a one-way randomized clinical trial in which the evaluators do not know the status of intervention groups.

##### Participants/Inclusion and exclusion criteria

Having definitive diagnosis of autism based on the psychiatrist's clinical judgment and the Gilliam Autism Diagnostic Scale - Second Edition (Garz-2). Being 3-6 years old. Having verbal imitation skill. Having less than a hundred functional words. Having no neurological problems such as cerebral palsy, seizures, and brain injuries. Having no sensory problems such as obvious hearing loss or visual impairment that cannot be compensated by assistive devices. Being a monolingual Farsi-speaking

##### Intervention groups

The intervention group receives EMT online via video call and the control group receives EMT in person through routine treatments.

##### Main outcome variables

Children's communication skills including communication

intentions, frequency of communication, means of communication, non-verbal communication, mean length of utterance, expressive and receptive vocabulary.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210507051213N1**

Registration date: **2021-07-07, 1400/04/16**

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

Last update: **2021-07-08, 1400/04/17**

Update count: **1**

##### Registration date

2021-07-07, 1400/04/16

##### Registrant information

##### Name

Salman Abdi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3270 8659

##### Email address

salmanabdi.slp@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-05, 1400/03/15

##### Expected recruitment end date

2021-12-06, 1400/09/15

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The comparison of the effectiveness of Enhanced Milieu Teaching (EMT) delivered in face-to-face and telepractice formats on improving communication skills of children with Autism spectrum disorder

**Public title**

The comparison of the effectiveness of Enhanced Milieu Teaching (EMT) delivered in face-to-face and telepractice formats on improving communication skills of children with Autism spectrum disorder

**Purpose**

Treatment

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

Having definitive diagnosis of autism based on the psychiatrist's clinical judgment and the Gilliam Autism Diagnostic Scale - Second Edition (Garz-2). Being 3-6 years old. Having verbal imitation skill. Having less than a hundred functional words.

**Exclusion criteria:**

Having neurological problems such as cerebral palsy, seizures, and brain injuries that are identified through observation, examination as well as the use of the child's history and medical records. Having sensory problems such as obvious hearing loss or visual impairment that cannot be compensated by assistive devices. Being Bilingual.

**Age**

From **3 years** old to **6 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **20**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

We use an online random number sequence generator (random.org; Haahr, 2010) to randomly allocate participants to intervention group (receiving online EMT) or control group (receiving face-to-face EMT). Haahr M. (2010). Random.org: True Random Number Service. Available at: <http://www.random.org> (accessed July 3, 2021)

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, assessors evaluate the clients before, during, and after follow-up, without knowing which treatment group each child is assigned to. Evaluators are not among the researchers in this study.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics Committee of Iran University of Medical Sciences

**Street address**

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

3136776558

**Approval date**

2021-03-15, 1399/12/25

**Ethics committee reference number**

IR.IUMS.REC.1399.1423

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

Autism Spectrum Disorder

**ICD-10 code**

F84.0

**ICD-10 code description**

Autistic disorder

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

Children's communication skills including communication intentions, frequency of communication, means of communication, non-verbal communication, mean length of utterance, expressive and receptive vocabulary.

**Timepoint**

Evaluation of communication variables before the intervention, after the intervention and two months after the intervention (the follow-up stage)

**Method of measurement**

Structured observation and MacArthur-Bates Communicative Development Inventories

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Arranging the environment: Providing online parent training to structure the child's daily routine in order to form routines, limiting the environment, waiting for the child to ask for help, giving the child what he/she needs, and talking about the object's features.

#### Category

Rehabilitation

### 2

#### Description

Play and participation: Providing online parent training to choose interesting and fun toys, to join the child through active play with toys of his/her choice, and to teach activities and stages of the target play level to the child

#### Category

Rehabilitation

### 3

#### Description

Intervention group: Attention and responsiveness: Providing online parent training to sit face to face with the child, to follow the child's inner driver and to respond to all the child's communication

#### Category

Rehabilitation

### 4

#### Description

Intervention group: imitating and modeling: Providing online parent training to imitate the child's non-verbal activities and to provide language modeling through verbal description of the child's activities

#### Category

Rehabilitation

### 5

#### Description

Control group: Arranging the environment: Providing in-person parent training to structure the child's daily routine in order to form routines, limiting the environment, waiting for the child to ask for help, giving the child what he/she needs, and talking about the object's features.

#### Category

Rehabilitation

### 6

#### Description

Control group: Providing in-person parent training to

choose interesting and fun toys, to join the child through active play with toys of his/her choice, and to teach activities and stages of the target play level to the child

#### Category

Rehabilitation

### 7

#### Description

Control group: Attention and responsiveness: Providing in-person parent training to sit face to face with the child, to follow the child's inner driver and to respond to all the child's communication

#### Category

Rehabilitation

### 8

#### Description

Control group: Intervention group: imitating and modeling: Providing in-person parent training to imitate the child's non-verbal activities and to provide language modeling through verbal description of the child's activities

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faculty of Rehabilitation Sciences - Iran University of Medical Sciences

##### Full name of responsible person

Salman Abdi

##### Street address

Maddakaran Alley, Shah Nazari St., Madar Square, Mirdamad Blvd., Tehran.

##### City

Tehran

##### Province

Tehran

##### Postal code

1545913487

##### Phone

+98 21 2222 7124

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##### Email

rehab@iums.ac.ir

##### Web page address

<https://rehab.iums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Salman Abdi

**Street address**

Madadkaran Ave., Shahnazari Ave., Madar Square.,  
Mirdamad

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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**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Salman Abdi

**Position**

PhD candidate in speech and language pathology

**Latest degree**

Master

**Other areas of specialty/work**

Speech therapy

**Street address**

DolatAbad, Abu Saeed Street 24 meters, Abu Saeed  
39, No. 28

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**Province**

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**Postal code**

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**Phone**

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**Email**

salmanabdi.slp@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Leila Ghelichi

**Position**

Assistant Professor of Speech Therapy

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Speech therapy

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Maddakaran Alley, Shah Nazari St., Madar Square,  
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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Salman Abdi

**Position**

PHD candidate of speech and language pathology

**Latest degree**

Master

**Other areas of specialty/work**

Speech therapy

**Street address**

No. 28, abosaid 39 Allay, 24metri abosaid Blvd,  
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**Province**

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**Postal code**

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**Phone**

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**Fax**

**Email**

salmanabdi.slp@gmail.com

**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**  
Yes - There is a plan to make this available  
**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**  
Yes - There is a plan to make this available  
**Data Dictionary**  
Yes - There is a plan to make this available  
**Title and more details about the data/document**  
Individual Participant Data (IPD) Study protocol Statistical  
analysis map Informed consent form Clinical study report  
**When the data will become available and for how  
long**

Documentation will be available 3 months after the  
results are published.  
**To whom data/document is available**  
Academic Researchers Speech Therapists  
**Under which criteria data/document could be used**  
Data, analyzes, clinical study reports and treatment  
protocols for academic studies Therapeutic protocol for  
use in clinical work  
**From where data/document is obtainable**  
Salman Abdi Iran School of Rehabilitation Sciences  
salmanabdi.slp@gmail.com 09013213415  
**What processes are involved for a request to access  
data/document**  
Electronic correspondence or telephone call with the  
researcher, providing reasons for accessing the data or  
protocol  
**Comments**