

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

The effect of signing education on speech and language skills of patients with autism spectrum disorders: A clinical trial

Protocol summary

Study aim

Determining the effect of reference education on speech and language skills of patients with autism spectrum disorders

Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, on 90 patients. Excel software will be used for randomization.

Settings and conduct

The present study is performed on all available samples that have been referred to rehabilitation and speech therapy centers in Tabriz during the research period and have inclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of autism spectrum disorders by a neurologist / Age of subjects is three to ten calendar years / Absence Other psychological and psychiatric disorders with the exception of autism/living with both parents/level of education of parents at least diploma/place of residence in Tabriz. Exclusion criteria: Receiving other parallel rehabilitation and educational interventions during the intervention/absence of more than one session/presence of speech or number of words more than three or four words / sensory and Motor defects.

Intervention groups

All selected patients will be tested for Newsha and verbal imitation. These tests will also be performed on normal children. The results will be evaluated and compared with the results obtained from children on the autism spectrum. After the test, autism spectrum subjects will be randomly divided into intervention and control groups. Finally, the training intervention session will refer to the members of the intervention group.

Main outcome variables

speech and language skills

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220311054258N1**

Registration date: **2022-05-29, 1401/03/08**

Registration timing: **retrospective**

Last update: **2022-05-29, 1401/03/08**

Update count: **0**

Registration date

2022-05-29, 1401/03/08

Registrant information

Name

mahsa mehdizadeh behtash

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3320 4202

Email address

mahsamehdizadeh.slp@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-12, 1400/12/21

Expected recruitment end date

2022-03-15, 1400/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of signing education on speech and language skills of patients with autism spectrum disorders: A clinical trial		Other design features	
Public title	The effect of signing education on speech and language skills of patients with autism spectrum disorders	Secondary Ids	empty
Purpose	Treatment	Ethics committees	
Inclusion/Exclusion criteria	Inclusion criteria: Diagnosis of autism spectrum disorders by a neurologist Confirmation of the diagnosis of autism spectrum disorders by the screening form of children with autism spectrum disorder Absence of other psychological and psychiatric disorders except autism Living with both parents Level of education of parents at least a diploma The place of residence is the city of Tabriz The subject belongs to the autism spectrum disorders with low performance and non-verbal. Age of entry at least 3 to a maximum of 10 years Exclusion criteria: Receive other parallel rehabilitation and training interventions during the intervention Absence of one of the conditions of inclusion criteria Absence of more than one session Existence of speech or number of words more than three or four words Suffering from sensory defects Having motor defects	<u>1</u>	
Age	From 3 years old to 10 years old	Ethics committee	
Gender	Both	Name of ethics committee	Ethics committee of Tabriz University of Medical Sciences
Phase	N/A	Street address	Tabriz / 29 Bahman Blvd. / University of Tabriz / Next to Vahdat Hall, Faculty of Rehabilitation Sciences
Groups that have been masked	Outcome assessor	City	Tabriz
Sample size	Target sample size: 90	Province	East Azarbaijan
Randomization (investigator's opinion)	Randomized	Postal code	5157658134
Randomization description	Each participant was assigned a code Using a simple random allocation strategy and using a random number table method, eligible participants were divided into intervention or control groups. In this random method, a table without a specific pattern or order is used. With the help of a table of random numbers, one digit is assigned to each person. Numbers with even numbers are assigned to the control group and odd numbers to the actual intervention group. Participants did not know the true purpose of the study.	Approval date	2022-03-01, 1400/12/10
Blinding (investigator's opinion)	Single blinded	Ethics committee reference number	IR.TBZMED.REC.1400.1191
Blinding description	Participants were randomized by the research team in their absence and none of them was aware of the intervention group they were in.	Health conditions studied	
Placebo	Used	<u>1</u>	
Assignment	Parallel	Description of health condition studied	Autism spectrum
		ICD-10 code	F84.0
		ICD-10 code description	Autistic disorder
		Primary outcomes	
		<u>1</u>	
		Description	Speech and language skills changes in children with autism spectrum after receiving sign education
		Timepoint	Newsha test and the verbal imitation will be calculated at the beginning of the study and finally, after the intervention, the language skills test will be performed again.
		Method of measurement	Nyusha Hearing, Language, and Speech Development Test: Subtests related to spoken, received, and spoken language of this test will be used and the results will be recorded in special forms. Verbal imitation test: A test used by Dr. Rafiei in his master's thesis is used for this purpose.
		Secondary outcomes	empty

Intervention groups

1

Description

Intervention group: only for this group, reference therapies will be used. In this study, 7 objects (mirror, comb, automatic, house, spoon, umbrella and glass) up to 7 verb images (driving, sleeping, smelling) , Reading, calling, licking and cuddling) are selected. 7 objects and pictures are taught for three months and three half-hour sessions per week. And then, without the examiner's knowledge of their group, they are examined by the Newsha test.

Category

Rehabilitation

2

Description

Control group: No special intervention will be performed for the control group and only the usual and traditional therapies available for speech therapy will be used.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Atieh Under-15 Training and Rehabilitation Center

Full name of responsible person

Zahra Nik Nafs Bagheri

Street address

Imam Street, Bafghi Wild Street

City

ilkhichi

Province

East Azarbaijan

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5157658134

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Mta1386@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

Tabriz / Azadi St. / Golgasht St. / Central Building of University of Medical Sciences

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parvizshahabi@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Jafar Masumi Komanj

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

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Tabriz / 29 Bahman Blvd. / University of Tabriz / Next to Vahdat Hall, Faculty of Rehabilitation Sciences

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Jafar Masumi Momanj

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

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Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mahsa Mehdizadeh behtash

Position

Master of speech therapy- faculty of rehabilitation

Latest degree

Master

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Speech therapy

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Fax**Email**

mahsamehdizadeh.slp@gmail.com

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

Due to the lack of permission of the moral code

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable