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

Public title
The effect of signing education on speech and language skills of patients with autism spectrum disorders

Purpose
Treatment

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

Age
From **3 years** old to **10 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

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.

Blinding (investigator's opinion)
Single blinded

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.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

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

City
Tabriz

Province
East Azarbaijan

Postal code
5157658134

Approval date
2022-03-01, 1400/12/10

Ethics committee reference number
IR.TBZMED.REC.1400.1191

Health conditions studied

1

Description of health condition studied
Autism spectrum

ICD-10 code
F84.0

ICD-10 code description
Autistic disorder

Primary outcomes

1

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

Postal code
5157658134

Phone
+98 41 3341 7458

Email
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

City
Tabriz

Province
East Azarbaijan

Postal code
5157658134

Phone
+98 41 3335 5921

Email
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

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

City
Tabriz

Province
East Azarbaijan

Postal code
5157658134

Phone
+98 41 3337 2072

Email
masumij@tbzmed.ac.ir

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
Street address
Tabriz / 29 Bahman Blvd. / University of Tabriz / Next to Vahdat Hall, Faculty of Rehabilitation Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5157658134
Phone
+98 41 3337 2072
Email
masumij@tbzmed.ac.ir

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
Other areas of specialty/work
Speech therapy
Street address
Valiasr/ negin park street/ shaqayeq alley/ no22 5th floor
City
Tabriz
Province
East Azarbaijan
Postal code
5157658134
Phone
+98 41 3320 4202
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