

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The effect of narrative discourse intervention based on the Supporting Knowledge in Language and Literacy (SKILL) program on discourse production and reading comprehension abilities in children with autism spectrum disorders in elementary schools

#### Protocol summary

##### Study aim

Determine the effect of narrative discourse intervention based on the Supporting Knowledge in Language and Literacy (SKILL) program on discourse production and reading comprehension abilities in children with autism spectrum disorders in elementary schools

##### Design

This study is a two-blind clinical trial with parallel group. 24 children with autism are assigned in one of the two treatment groups using random blocks.

##### Settings and conduct

In this study, 30 children with autism were randomly divided into two groups. The first group receives the SKILL program and the second group receives the conventional speech therapy. Intervention is performed in centers and clinics affiliated to Tehran University of Medical Sciences. Intervention is provided individually, 3 sessions per week for two months. The ability of children to produce narrative speech and reading comprehension before and after treatment is evaluated, and the effectiveness of the SKILL program compared to conventional speech therapy is examined. In this study, trained assessors are not aware of the children's grouping, their demographic characteristics, the time of research, and the type of intervention received by each child. The participants and their families are unaware of intervention of the groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteris: Having ages 8 to 12 years; Having Diagnosis of Autism Spectrum Disorders Persian speaking; Having a nonverbal intelligence score 70 and above; Having verbal fluent; Having the ability to decode words appropriate to age but weakness in reading comprehension; Exclusion criteria: If they have already received SKILL intervention program

##### Intervention groups

Group 1 receives SKILL program and group 2 receives the program of conventional speech therapy.

##### Main outcome variables

Macrostructure score; microstructure score; Index of narrative complexity

#### General information

##### Reason for update

\*\*\* The surveys showed that 12-year-old children are studying in the sixth or seventh grade. \*\*\*Sampling began in 2019, due to the prevalence of the corona virus and the closure of rehabilitation centers and the lack of families cooperation to participate in the research, the issue was discussed with the supervisors and the statistics consultant, and according to the letter sent from the Ministry of health Affairs to the universities in order to reduce the sample size during the corona period, the sample size was calculated again. Taking into account the dropout, a sample size of 24 was obtained. Three subjects withdrew from the intervention. Finally significant results were obtained with 21 samples (10 samples in the intervention group and 11 samples in the control group). \*\*\*Sampling began in 2019, which coincided with the Corona pandemic. Due to the prevalence of the corona virus and the risk of infection, no one was willing to do the evaluations. For this reason, the method of blinding was changed.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190505043477N1**  
Registration date: **2019-10-31, 1398/08/09**  
Registration timing: **prospective**

Last update: **2023-02-02, 1401/11/13**

Update count: **1**

##### Registration date

2019-10-31, 1398/08/09

## Registrant information

### Name

Elham Masumi

### Name of organization / entity

### Country

Iran (Islamic Republic of)

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## Recruitment status

### Recruitment complete

## Funding source

## Expected recruitment start date

2019-09-23, 1398/07/01

## Expected recruitment end date

2020-03-14, 1398/12/24

## Actual recruitment start date

2019-11-20, 1398/08/29

## Actual recruitment end date

2022-07-05, 1401/04/14

## Trial completion date

2022-07-05, 1401/04/14

## Scientific title

The effect of narrative discourse intervention based on the Supporting Knowledge in Language and Literacy (SKILL) program on discourse production and reading comprehension abilities in children with autism spectrum disorders in elementary schools

## Public title

"Narrative discourse intervention in children with autism"

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Be in the age range of 8 to 12 years Be in the second to seventh grade of elementary schools Have autism spectrum disorders; they have received a diagnosis of autism by a psychiatrist based on the DSM-V criteria and the diagnosis of autism should be supported by a speech and language pathologist using the GARS-2 questionnaire Be monolingual and Persian language Have be standard scores 70 and above on nonverbal portion of Wechsler Intelligence Test Have be verbal fluent Have be the ability to produce at least 100 spoken that is evaluated using the Farsi Narrative Norms Instrument guide Stories by speech and language pathologist Have be the ability to sit behind the table and keep the attention Have be the ability to decode words appropriate to age but weakness in reading comprehension; This is diagnosed by speech and language pathologists using reading and dyslexic tests (NEMA)

### Exclusion criteria:

If they have already received SKILL intervention program Have be sensory damage (not compensated) for visual and auditory sensations Have be neurological problems

(epilepsy, cerebral palsy) and other psychiatric disorders except autism

## Age

From **8 years** old to **12 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Data analyser

## Sample size

Target sample size: **24**

Actual sample size reached: **21**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Taking into account the dropout, 24 children with autism are assigned in one of the two treatment groups using random blocks. To randomize the size of blocks will be 4. According to the sample size of 24, which has been determined, 6 blocks will be produced using the online site ([www.sealedenvelope.com](http://www.sealedenvelope.com)). Group 1 received the Supporting Knowledge in Language and Literacy (SKILL) program and group 2 received the program of conventional speech therapy.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

At first, the people who analyzed the data learn about how to analyze data, Then, they are asked to analyze the per-treatment data. It should be noted that these people are unaware of the grouping of children, their demographic characteristics, the timing of the research, and the type of intervention received by each child. Subsequently, these individuals will be asked to analyze the post-treatment data. The participants and their families are unaware of the compositions of the groups and do not visit each other during the trial sessions and outside the treatment environment..

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethcs committee of Tehran University of Medical Sciences.

##### Street address

Adjutancy Chancellor for Research and Technology,

Sixth Floor, Qods Ave., Keshavarz Blvd., Tehran

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Tehran

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**Postal code**

1148965141

**Approval date**

2019-07-25, 1398/05/03

**Ethics committee reference number**

IR.TUMS.FNM.REC.1398.087

## 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 macrostructures of narrative discourse score

**Timepoint**

Before intervention and after intervention

**Method of measurement**

The Farsi Narrative Norms Instrument will be used to evaluate Narrative discourse production ability. The Monitoring Indicators of Scholarly Language will be used to obtain the macrostructures scores.

### 2

**Description**

The microstructures of narrative discourse score

**Timepoint**

Before intervention and after intervention

**Method of measurement**

The Farsi Narrative Norms Instrument will be used to evaluate Narrative discourse production ability. The Monitoring Indicators of Scholarly Language will be used to obtain the microstructures scores.

### 3

**Description**

Index of narrative complexity

**Timepoint**

Before intervention and after intervention

**Method of measurement**

The Farsi Narrative Norms Instrument will be used to evaluate Narrative discourse production ability. The Monitoring Indicators of Scholarly Language will be used to obtain the index of narrative speech complexity.

## Secondary outcomes

### 1

**Description**

Reading comprehension score

**Timepoint**

Before intervention and after intervention

**Method of measurement**

The reading and dyslexic tests will be used to evaluate children's reading ability and reading comprehension.

## Intervention groups

### 1

**Description**

Intervention group: The group receiving the Supporting Knowledge in Language and Literacy (SKILL) program, the intervention is provided individually, 3 sessions per week, and 50 minutes each session by a speech and language pathologist. The intervention period is two months and the program is provided in 24 sessions. The intervention program contains of three phases, phase 1: Teaching Story Structure and Causal Language, phase 2: Teaching Strategies for Creating a Situation Model, and phase 3: Teaching Strategies for Integration into Long Term Memory. The first phase of intervention consists of 17 lessons, the second phase is 11 lessons, and the third phase is 8 lessons.

**Category**

Rehabilitation

### 2

**Description**

Control group: The group receiving conventional speech therapy, the intervention is provided individually, 3 sessions per week, and 50 minutes each session by a speech and language pathologist. The intervention period is two months and the program is provided in 24 sessions. This group of children with autism does not teach narratives intervention according to the SKILL program. They receive conventional speech therapy by 3 speech and language pathologists in centers and autism schools.

**Category**

Rehabilitation

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Speech Therapy Clinic, Tehran University of Medical Sciences

**Full name of responsible person**

Zahra Soleymani

**Street address**

Department of Speech Therapy, School of Rehabilitation, Tehran University of Medical Sciences,

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**Web page address**

**2**

**Recruitment center**

**Name of recruitment center**

Autism Charity Foundation

**Full name of responsible person**

Nasser Zojaji

**Street address**

No. 25, 4st Floor, Building 76, Kalantari Ave, Garani St., Tehran

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**3**

**Recruitment center**

**Name of recruitment center**

Second April Center

**Full name of responsible person**

Saeed Rezayi

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**4**

**Recruitment center**

**Name of recruitment center**

Iranian Autism Charity Association

**Full name of responsible person**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Sahraiyani

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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**

Tehran 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**

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Zahra Soleymani

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Speech therapy

**Street address**

Department of Speech Therapy, School of Rehabilitation, Tehran University of Medical Sciences, Pitch-e-shemiran, Enghelab Ave., Tehran

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Tehran University of Medical Sciences

**Full name of responsible person**

Elham Masumi

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PhD student

**Latest degree**

Master

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

No - There is not a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The results for the primary and secondary outcomes are published.

**When the data will become available and for how long**

The access period begins 12 months after publishing results.

**To whom data/document is available**

It will be available to speech therapy researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

It can be used for research and treatment in children with autism.

**From where data/document is obtainable**

By email to Dr. Zahra Soleymani and Elham Masoumi

Soleymaniz@sina.tums.ac.ir, e-masumi@razi.tums.ac.ir  
**What processes are involved for a request to access data/document**

It will be sent within two weeks of receiving the email.  
**Comments**