

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). 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

City

Tehran

Province

Tehran

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,

Pitch-e-shemiran, Enghelab Ave., Tehran

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Email

Soleymaniz@sina.tums.ac.ir

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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Phone

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Email

Info@autismcharity.ir

Web page address

3

Recruitment center

Name of recruitment center

Second April Center

Full name of responsible person

Saeed Rezayi

Street address

No. 7, Hafez Shirazi St., Bani Hashim Sq., Bani Hashim St., Resalat HWY, Tehran

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Web page address

4

Recruitment center

Name of recruitment center

Iranian Autism Charity Association

Full name of responsible person

Saeedeh Saleh Gafari

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No.8, East Laleh St., Hemat Bridge, South Sattari HWY, Tehran.

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Web page address

http://www.irautism.org/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Adjutancy Chancellor for Research and Technology, Sixth Floor, Qods Ave., Keshavarz Blvd., Tehran

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zahra Soleymani

Position

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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

Tehran University of Medical Sciences

Full name of responsible person

Elham Masumi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

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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