

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### **Determining & comparing the immediate and long term effects of speech therapy services through the consultative-collaborative, classroom-based, & pull-out models on the language outcomes of students in regular and exceptional schools**

#### **Protocol summary**

##### **Study aim**

Determining & comparing the immediate effects and long term effects of the consultative-collaborative model, class-based model, & pull-out models on the language outcomes of students in regular and exceptional schools

##### **Design**

A clinical-controlled, parallel-group, double-blind, phase 3 trial of 400 students, with simple randomization by letter shuffling.

##### **Settings and conduct**

Normal and exceptional schools of Semnan city, where speech therapy services are assigned in the intervention group through three different models. Evaluators and recipients of services are completely unaware of the type of model and the allocation of groups.

##### **Participants/Inclusion and exclusion criteria**

Students with intellectual disability: intellectual disability without known cause, registered in Semnan exceptional schools, Have an effective presence during the academic year, receive speech therapy during education. children without intellectual disability: have not received any recommendation for any type of supportive service in the pre-school screening, registered in regular schools in areas with high socio-economic level and use the services of the same school throughout the academic year. Exclusion: if the student is removed from the list of school services or its rehabilitation team for any reason; suffering from diseases that endanger his education and rehabilitation process; Schools with speech therapist is present part-time or not at all; Non-cooperation of child, teacher and family

##### **Intervention groups**

Pull-out, consultative-collaborative and class-based speech therapy services will be provided to the group receiving services based on their needs. The control group will not receive any speech therapy services.

#### **Main outcome variables**

language outcomes

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20180612040069N2**

Registration date: **2022-10-19, 1401/07/27**

Registration timing: **prospective**

Last update: **2022-10-19, 1401/07/27**

Update count: **0**

##### **Registration date**

2022-10-19, 1401/07/27

##### **Registrant information**

##### **Name**

Masoomeh Salmani

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 23 3346 8920

##### **Email address**

salmani\_masoom@yaho.com

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2022-10-23, 1401/08/01

##### **Expected recruitment end date**

2023-04-20, 1402/01/31

##### **Actual recruitment start date**

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Determining & comparing the immediate and long term effects of speech therapy services through the consultative-collaborative, classroom-based, & pull-out models on the language outcomes of students in regular and exceptional schools

**Public title**  
speech therapy service delivery models

**Purpose**  
Health service research

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
In children with intellectual disability (ID): non-specified intellectual disability should have been confirmed by a psychologist using Leiter test, , and , . For typical children: They , they , and children with ID registered in special needs schools of Semnan city for 2022-2023 children with ID should have effective presence during educational year children with ID should be in the confirmed list to receive speech therapy services typical children should not have received any recommendation for any type of services (medical, educational and/or rehabilitative) in the screening for school inattentiveness. typical children should have been registered in highly socio-economic private or mainstream schools typical children should remain on that schools for the whole of the educational year (2022-2023)  
**Exclusion criteria:**  
for the children with Intellectual disability, if the child -for any reason- has been eliminated from the schooling service or rehabilitation program. In both groups, if the child suffers from diseases that jeopardize her education and / or rehabilitation process. Schools where the speech therapy staff is present part-time or not at all will be excluded from the study. In both groups, the lack of cooperation of the child, teacher and family A child without intellectual disability, if the student leaves the school for any reason and uses the educational services of other schools.

**Age**  
From **6 years** old to **7 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**  
Target sample size: **400**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, schools will be divided into intervention and

control based on a simple random method (envelops shuffling). In the school receiving the intervention, the classes will be assigned in the same way to receive speech therapy services based on three different models - pull-out, classroom-based and collaborative-consultative.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In the present study, students with intellectual disability are unaware of which model they receive speech therapy services. Students without intellectual disabilities are unaware not only of the delivery model, but even that they are receiving speech therapy services. Before, immediately after the intervention and at the end of the academic year, 5 speech therapists will assess the children. These evaluators will not be aware of the allocation of services, type of model, etc.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Semnan University of Medical Sciences

**Street address**

5km. of Damghan road, Pardis campus of Semnan University of Medical Sciences, Faculty of Rehabilitation, Department of Speech therapy

**City**

Semnan

**Province**

Semnan

**Postal code**

3513138111

**Approval date**

2022-10-10, 1401/07/18

**Ethics committee reference number**

IR.SEMUMS.REC.1401.163

**Health conditions studied**

**1**

**Description of health condition studied**

typical children with the risk of language problems & children with intellectual disability

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

1

### Description

Language outcomes

### Timepoint

Measure language outcomes at week 1, 12, and 28

### Method of measurement

test of language development-p 3

## Secondary outcomes

empty

## Intervention groups

1

### Description

The first intervention group: receiving speech therapy services based on the pull-out model; The second intervention group: receiving speech therapy services based on the consultation-collaboration model; The third intervention group: receiving speech therapy services based on the class-based model

### Category

Rehabilitation

2

### Description

Control group: This group will not have any speech therapy services.

### Category

Rehabilitation

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

regular and exceptional schools

#### Full name of responsible person

Masoomeh Salmani

#### Street address

5 km. of Damghan road, Pardis campus of Semnan university of medical sciences, Semnan, Iran

#### City

Semnan

#### Province

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#### Postal code

3513138111

#### Phone

+98 23 3365 4180

#### Email

salmani\_masoom@yaho.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Semnan University of Medical Sciences

#### Full name of responsible person

Dr Majid Mir Mohammadkhani

#### Street address

Deputy of research and technology, Semnan University of Medical Sciences, Amirkabir square, SemnanSemnan

#### City

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#### Province

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#### Postal code

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#### Phone

+98 23 3345 1336

#### Email

majidmirmohammadkhani@yahoo.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Semnan 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

Semnan University of Medical Sciences

#### Full name of responsible person

Masoomeh Salmani

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Speech therapy

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5 km. of Damghan Road, Semnan University of Medical Sciences, Rehabilitation Faculty, Speech and Language Therapy Department

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#### Province

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Semnan University of Medical Sciences  
**Full name of responsible person**  
Masoomeh Salmani  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Speech therapy  
**Street address**  
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Medical Sciences, Rehabilitation Faculty, Speech and  
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**City**  
Semnan  
**Province**  
Semnan  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Semnan University of Medical Sciences  
**Full name of responsible person**  
Masoomeh Salmani  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**

Speech therapy  
**Street address**  
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## 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

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

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

All data is potentially shareable after de-identifying  
individuals.

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

The access period starts 6 months after the results are  
published

### To whom data/document is available

Only for researchers working in academic and scientific  
institutions and department of education

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

As a pilot for further studies or for educational policies or  
as basic data

### From where data/document is obtainable

by sending email to the salmani\_masooome@yahoo.com

### What processes are involved for a request to access data/document

Proposal or ID card photo

### Comments