

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 (envelopes 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

Masoomah Salmani

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Majid Mir Mohammadkhani

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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

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

Masoomah Salmani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

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Person responsible for updating data

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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_masoomo@yahoo.com

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

Proposal or ID card photo

Comments