

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparing the effectiveness of focused stimulation and enhanced milieu teaching (mand-model strategy) on the expressive vocabulary size of Persian-speaking late-talking toddlers aged 18 to 36 months.

Protocol summary

Study aim

Determining the effectiveness of focused stimulation and enhanced milieu teaching (mand-model strategy) on the expressive vocabulary size of Persian-speaking late-talking toddlers

Design

The single subject study is matched with the Adapted alternating treatment design, only one intervention group and no control group, from the available samples, will be conducted on 4 children with late talker.

Settings and conduct

This study will be conducted at the hospital clinic, 3 sessions a week for 12 sessions, and the selected target words will be taught to children with late talker with two therapeutic methods, focused stimulation and enhanced milieu teaching (mand-model strategy).

Participants/Inclusion and exclusion criteria

18-36-month-old Persian-speaking children who have a delay in expressive language and do not have accompanying problems such as vision, hearing, psychiatry, oral and movement defects

Intervention groups

In this study, the target expressive vocabulary will be taught to 4 children with late talker without the presence of a control group with two therapeutic methods of focused stimulation and enhanced milieu teaching (mand-model strategy) in order to determine which of the two methods these children were taught. Vocabulary conveys more purpose.

Main outcome variables

increasing expressive vocabulary; increasing the mean length of speech; increasing binary combinations; increasing phonetic vocabulary; increasing the mean length of phonetic utterances; increasing the total number of words, the number of different words and the ratio of type to number of words in a speech sample; The increase in the percentage of vowels, consonants and

phonemes is a speech pattern and syllabic structure.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230812059124N1**

Registration date: **2023-08-21, 1402/05/30**

Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**

Update count: **0**

Registration date

2023-08-21, 1402/05/30

Registrant information

Name

Zakieh Nakhaei fuzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4431 9402

Email address

nakhaeizakieh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2025-03-19, 1403/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of focused stimulation and enhanced milieu teaching (mand-model strategy) on the expressive vocabulary size of Persian-speaking late-talking toddlers aged 18 to 36 months.

Public title

Comparing the effect of focused stimulation and enhanced milieu teaching (mand-model strategy) late-talking toddlers.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a delay in the development of expressive language Between the ages of 18 and 36 months Being monolingual in Persian Not having non-verbal cognitive problems Not having hearing and vision defects and emotional behavioral problems (psychiatry) Not having oral-motor defects (structural and functional) The mean length of the child's utterances is between 1 and 3.5 Have at least 10 expressive words Having the ability to imitate words

Exclusion criteria:

The unwillingness of the family to cooperate or to carry out further evaluations during the stages of longitudinal examination of the child The patient should use other speech therapy services at the same time as the research The child suffering from convulsions or diseases during the study that lead to vision, hearing, neuro-motor or permanent structural problems.

Age

From **18 months** old to **36 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **4**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

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

No. 58 , SHahid Balangi Ave5, SHahid Bahonar Blvd, Bam Town

City

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Province

Kerman

Postal code

7661654542

Approval date

2023-07-31, 1402/05/09

Ethics committee reference number

IR.SEMUMS.REC.1402.090

Health conditions studied**1****Description of health condition studied**

Late talker

ICD-10 code

F80.1

ICD-10 code description

Expressive language disorder

Primary outcomes**1****Description**

Expression of trained words with each of the treatment methods

Timepoint

At the beginning of all three stages of the study (baseline, intervention, withdrawal), at the beginning of each session, the ability of the child with late speech to express therapeutic words is measured for each method.

Method of measurement

Name the object or image of each word

Secondary outcomes**1****Description**

Expression of untrained words

Timepoint

At the beginning of the baseline phase and once every 3 sessions in the intervention phase and in the withdrawal phase

Method of measurement

Name the object or image of each word

Intervention groups

1

Description

Persian-speaking late-talking toddlers aged 18 to 36 months

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Speech therapy clinic of Pastor Bam Hospital

Full name of responsible person

Zakieh Nakhaei fuzi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

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Rehabilitation Faculty, Semnan Medical Sciences, 5 km of Damghan road, Semnan Town

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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

Zakieh Nakhaei fuzi

Position

Masters student

Latest degree

Bachelor

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)

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available