Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Nov 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
Zakiyeh Nakhaei fuzi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 34 4431 9402
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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
Bam

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
Zakiyeh Nakhaei fuzi
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Bam hospital, khalig fars Blvd, Bam Town
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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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Rehabilation 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
Zakiyeh 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