

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Effects of the Family Centered Approach on the Communication Skills of Typical Toddlers from Low Socioeconomic Status (SES) Families: A Pilot Study

Protocol summary

Study aim

The effect of Family Centered Therapy on Communication Skills of Persian Toddlers, Aged 12-14 Month

Design

It will be a randomized controlled trial, with a control group, permuted block randomization, single blind. children will be divided in three different groups based on pretest on their vocabulary: 1) with less than 10 words, 2) between 10 and 20 words and 3) more than 20 words. Group 3 will be excluded. The statistician will divide the group 1 and 2 in two groups of control and experimental. Families do not know what group they are going to be, only the speech therapist knows.

Settings and conduct

This study will be done in different health centers located in low SES residency areas such as Maskan Mehr, Jahadiyeh, & Abuzar in Semnan.

Participants/Inclusion and exclusion criteria

1- Families who have children aged between 12 and 14 months 2- Children who have a typical history in their milestones based on ASQ 3- Families who present a signed consent form 4- Mothers without history of depression 5- Parents speak Persian 6- Children who have less than 20 words in their expressive lexicon 7- Parents will not reveal any specific developmental, medical or family problems during the interviews 8- Mothers report a safe pregnancy and delivery

Intervention groups

The experimental group will participate in 4 workshops, each two hours, during 8 weeks. The control group will not have any workshop. In these workshops, mothers will receive education on their children's communication skills in this age, how they can support their toddlers and help them to develop their language, communicative and cognitive skills. Both groups will report their children's lexicons on MC-Arthur Bates form before, in the middle

and at the end of the intervention.

Main outcome variables

The workshops content can be used to prevent developmental language disorders.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180612040069N1**

Registration date: **2018-07-04, 1397/04/13**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-04, 1397/04/13**

Update count: **0**

Registration date

2018-07-04, 1397/04/13

Registrant information

Name

Masoomah Salmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3346 8920

Email address

salmani_masooma@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-09-06, 1397/06/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effects of the Family Centered Approach on the Communication Skills of Typical Toddlers from Low Socioeconomic Status (SES) Families: A Pilot Study

Public title
Family Centered Approach for Toddlers from Low SES

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Children should be in the age limit (12-14 months)
 Children had a history of typical milestones confirmed by the health staff Children's expressive lexicon contains 20 or less words Children without any history of delay, or disorders, based on ASQ children have typical development parents signed the consent form No history of depression in mothers only Persian language (no other dialects such as Gilaki, or language ex. English) A history of a safe pregnancy-delivery
Exclusion criteria:

Age
From **12 months** old to **14 months** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
It will be a randomized controlled trial, with a control group, permuted block randomization

Blinding (investigator's opinion)
Single blinded

Blinding description
children will be divided in three different groups based on pretest on their vocabulary: 1) with less than 10 words, 2) between 10 and 20 words and 3) more than 20 words. Group 3 will be excluded. The statistician will divide the group 1 and 2 in two groups of control and experimental. Families do not know what group they are going to be, only the speech therapist knows.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Semnan University of Medical Sciences

Street address

Research Affairs, Main Campus of Semnan University of Medical Sciences, Amirkabir Square, Semnan, Iran

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Semnan

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Postal code

35147-99442

Approval date

2018-06-12, 1397/03/22

Ethics committee reference number

IR.SEMUMS.REC.1397.005

Health conditions studied

1

Description of health condition studied

The Effect of Family Centered Approach on Children's Lexicons from Low SES Families

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Changes in children's expressive and receptive scores

Timepoint

The evaluation will happen in week1, 5 and 9.

Method of measurement

Mc-Arthur Bates Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 50 mothers who have children aged between 12 and 14 months, with education at or below high school diploma from low SES residency areas will participate in 4 workshops during 8 weeks.

Category

Prevention

2

Description

Control group: 50 mothers who have children aged between 12 and 14 months, with education at or below high school diploma from low SES residency areas will report their children's lexicons on Mc-Arthur Bates in the first week and eight weeks later.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohaghegh

Full name of responsible person

Masoomeh Salmani

Street address

Speech and Language Therpay Deptment,
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Recruitment center

Name of recruitment center

17 Shahrivar

Full name of responsible person

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Recruitment center

Name of recruitment center

Jahadiyeh

Full name of responsible person

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Recruitment center

Name of recruitment center

Maskan Mehr

Full name of responsible person

Masoomeh Salmani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Parviz Kokhayi

Street address

Research Affaires, Main Campus of Semnan University
of Medical Sciences, Amirkabir Square, Semnan, Iran.

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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

Masoomeh Salmani

Position

Assistant 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**

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

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

Statistical Analysis Plan

Not applicable

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

Not applicable