Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

Effects of community based intervention focused on the comprehensive nurturing care of the child on parent-child communicative styles and lexical development of 12-24 month old children

Protocol summary

Study aim

Effects of community-based intervention focused on the comprehensive nurturing care of the child on parent-child communicative styles and lexical development of 12-24 months old children

Design

Randomized, Community-based, parallel group trial on 140 children

Settings and conduct

The study field: Mashhad city. The tools used for the intervention included two mobile health applications, MAHAK and HAK and short educational videos produced by the research team to demonstrate appropriate techniques for mother-child interaction. The duration of the study for all subjects will be 6 months from the time of enrollment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 12- to 24-months old children who: are Monolingual speaker of Persian are from Middle or lower socio-economic class have poor language and communicative skills (Based on MacArthur-Bates CDI) are typical in all developmental areas except language and communication, based on ASQ and Bayley III. have literate parents. one parent has a smartphone and know how to work with it, and signed the consent form Exclusion criteria: Parents' not willing to participate in the study

Intervention groups

Intervention group 1: 12-24 months old children from lower class families who receive the intervention. Intervention group 2: 12-24 months old children from to the middle class families who receive the intervention. Control group 1: 12-24 months old children from lower class families who don't receive the intervention. Control group 2: 12-24 months old children from to the middle class families who don't receive the intervention.

Main outcome variables

Child Score on MacArthur-Bates Communicative Development Inventories- checklist 2 Scores obtained via coding and analyzing the interactive and linguistic samples

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191214045730N1**
Registration date: **2022-02-24, 1400/12/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-24, 1400/12/05**
Update count: **0**

Registration date

2022-02-24, 1400/12/05

Registrant information

Name

Toktam Maleki Shahmahmood

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 6710

Email address

malekist@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2023-08-21, 1402/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of community based intervention focused on the comprehensive nurturing care of the child on parent-child communicative styles and lexical development of 12-24 month old children

Public title

Effects of community based intervention focused on the comprehensive nurturing care of the child on parent-child communicative styles and lexical development of 12-24 month old children

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 12 to 24 months Having verbal and communication skills below the expected level for age, based on the scores in the Persian version of the MacArthur-Bates Communicative Development Inventories- checklist 1 / 2 Having age-appropriate performances in all developmental domains (except for verbal communication) based on the Persian version of the Ages and Stages Questionnaire (ASQ) and the Bayley Scales of Infant and Toddler Development Classified in middle or lower socioeconomic classes based on the researcher-made questionnaire of socio-demographics No history of neurological defects; problems such as low birth weight (less than 1500), hypoxia at birth, head trauma, sensory deficits (in vision/ hearing), seizures end, etc. Patients' parents are monolingual Persian speakers, literate, have a mobile phone to receive educational files and know how to work with it / be able to learn it

Exclusion criteria:

Parents' not willing to participate in the study

Age

From **12 months** old to **24 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

First, individuals would be allocated to one of middle or low socio-economic classes based on the information obtained from the socio-economic questionnaire. For random allocation of the subjects of each SES class to one of the intervention or control groups, block randomization method (4 blocks) will be used. In each block, 2 individuals are assigned to the intervention group and 2 people to the control group. For each block, random sequences will be generated by Random allocation software and then, concealed in sequentially numbered, sealed, opaque envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Mashhad University of Medical Sciences

Street address

Khorasan Razavi, Mashhad, East door of Ferdowsi University, Public Relations Department of the University (Tardarandshjoo), Website Unit

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948964

Approval date

2021-07-25, 1400/05/03

Ethics committee reference number

IR.MUMS.FHMPM.REC.1400.050

Health conditions studied

1

Description of health condition studied

late talker

ICD-10 code

R62.0

ICD-10 code description

Delayed milestone in childhood

Primary outcomes

1

Description

vocabulary size (comprehension and production scores)

Timepoint

Before study, after study

Method of measurement

Persian version of MacArthur-Bates Communicative Development Inventories

Secondary outcomes

1

Description
parent- child communicative behaviors
Timepoint
after intervention
Method of measurement
structural analysis of mother-child free play

Intervention groups

1

Description
Intervention group1: 12 to 24 months old late talkers from middle socioeconomic class whose parents receive 2 mobile health applications (named comprehensive child care application (MOHAK) and the art of communicate with the child through love, talking, playing and reading (HAK)), as well as 14 short educational videos about the appropriate mother-child interactions styles on their smart phone, in addition to common counselling interventions by speech therapists. Parents, will have 3 to 5 individual 45-minute sessions with the researchers to learn about working with the apps, scheduling files, and using from age-appropriate contents in daily routine situations. They will give weekly reports to researchers and will receive appropriate corrective/confirmatory feedbacks from them. The duration of the intervention period will be 6 months from the time of enrolment.
Category
Behavior

2

Description
Intervention group: 12 to 24 months old late talkers from lower socioeconomic class. These children will receive the same intervention as the intervention group 1.
Category
Behavior

3

Description
Control group1: 12 to 24 months old late talkers from middle socioeconomic class who receive no intervention other than common counselling interventions by speech therapists.
Category
Behavior

4

Description
Control group 2: 12 to 24 months old late talkers from lower socioeconomic class who receive no intervention other than common counselling interventions by speech therapists.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive health centers, State Health Center / Vice Health, Mashhad university of medical scie
Full name of responsible person
Dr Seyyed Javad Hosseini
Street address
Sanabad Ave.
City
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Province
Razavi Khorasan
Postal code
9185684538
Phone
+98 51 3841 5222
Email
health@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour Mobarhan
Street address
Daneshgah Ave., beside the Hoveyze movie theater, Ghoreiyshi building,
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 2081
Email
GhayourM@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Toktam Maleki Shahmahmood

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

Street address

East door of Ferdowsi University, Public Relations Department of the University

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9177899191

Phone

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Toktam Maleki Shahmahmood

Position

assistant professor

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

size of productive /comprehensive vocabulary of children lexical, semantic and communicative indexes extracted from language and interactive samples

When the data will become available and for how long

6 months after publication

To whom data/document is available

researchers and clinicians

Under which criteria data/document could be used

A variety of linguistic analyzes are allowed on the data

From where data/document is obtainable

Dr. Toktam Maleki Shahmahmood Email: malekist@mums.ac.ir

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

Data will be sent immediately after the request and stating the reason for the request.

Comments