Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

Development of Enhanced Milieu Teaching with Phonological Emphasis, Telepractice and Parent-Implemented Protocol and Investigating Its Effectiveness on Speech and Language Development of Persian Toddlers with Cleft Lip and /or Palate.

Protocol summary

Study aim

Development of EMT+PE, Telepractice Protocol and Investigating Its Effectiveness on Speech and Language Development of Persian Toddlers with Cleft palate.

Design

A clinical trial with a control group, parallel, randomized groups on 32 children with cleft lip or/and palate.

Settings and conduct

After developing protocol and providing educational videos sampling from CLP teams of Tehran, Shiraz, Isfahan and private clinics will be started and the participants will randomly assign into two groups; control and intervention. control group receives usual interventions in CLP teams and private clinics. parents of intervention group will receive and implement supportive speech and language strategies by therapists via telepractice in 3 months and 24 sessions. assessments will be repeated after 3 months intervention.2 months will be considered for follow-up of intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria; toddlers with CL/P between 16-36 months of age, no geneticist syndrome, palate primary repair about 12months,no sensorineural hearing loss, child joint attention with the parent, at least one type of articulated error during the language sample, at least 5 different spontaneous expressive words Exclusion criteria; bilingual and multilingual children, having other dysmorphic features.

Intervention groups

Control group will receive conventional interventions in CLP teams and private clinics. parents in experimental intervention group will accomplish the supportive speech and language strategies of experimental intervention via telepractice for 3 months by coaching educated therapists and 2 months follow-up without coaching.

Main outcome variables

Number of production words, mean length utterance, number of different words, number of total words, number of consonant inventory, percent of correct consonants, intelligibility.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220219054063N1**
Registration date: **2022-04-29, 1401/02/09**
Registration timing: **prospective**

Last update: **2022-04-29, 1401/02/09**
Update count: **0**

Registration date

2022-04-29, 1401/02/09

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-14, 1401/03/24

Expected recruitment end date

2023-01-14, 1401/10/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development of Enhanced Milieu Teaching with Phonological Emphasis, Telepractice and Parent-Implemented Protocol and Investigating Its Effectiveness on Speech and Language Development of Persian Toddlers with Cleft Lip and /or Palate.

Public title

Development of enhanced milieu teaching, parent-implemented and telepractice and investigating its effectiveness on speech and language toddlers with cleft palate.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All children will meet the following criteria: Persian Iranian children with CL/P between 18 and 36 months of age at pre-intervention. Non-existence a syndrome diagnosis from a geneticist and by referring medical records in cleft lip and palate teams. For children with clefts involving the palate, underwent primary palate repair by 12 months of age. Non-existence a sensorineural hearing loss or sound field hearing threshold over 30 dB HL by referring medical records in cleft lip and palate teams. Pre-intervention assessment of children with typical development by ages and stages questionnaires (ASQ). Child joint attention with the parent during collection of play-based language sample. At least one type of error during the language sample a) a compensatory error on at least one phoneme, b) a consonant inventory of fewer than five stop or nasal consonants in all positions and / or c) errors on at least two stop or nasal consonants. Child Can produce at least 5 different words per parent report on the MCDI.

Exclusion criteria:

Children will be bilingual or multilingual or non-Persian speaking on the basis of parent report. In addition to the CL/P, having other dysmorphic features that have effect on speech (such as short frenulum, short hard palate, deep palate, fistula in palate).

Age

From **18 months** old to **3 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

After primary assessment, the number of vocabulary and consonants inventory will be determined for each participant. then each participant is allocated into two intervention groups of I) EMT+PE or II) conventional interventions(consultative interventions) that in each age group randomization will be made for block random clinical trials by blockrand package in R 4.1.3 software. it is noted that randomization is performed according to age groups and intervention groups (i.e 32 participants were assigned in 2 intervention groups based on 3 age groups).

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

Ethics committee of university of social welfare and rehabilitation sciences

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University of social welfare and rehabilitation science, Kodakyar Ave., Daneshjo Blvd.,Evin,,Tehran,Iran

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Approval date

2022-02-15, 1400/11/26

Ethics committee reference number

IR.USWR.REC.1400.310

Health conditions studied

1

Description of health condition studied

Cleft palate with cleft lip

ICD-10 code

Q37

ICD-10 code description

Cleft palate with cleft lip

Primary outcomes

1

Description

Number of production words

Timepoint

Pre-intervention, post-intervention, after follow-up

Method of measurement

CDI

2

Description

Mean length utterance

Timepoint

Pre-intervention, post-intervention, after follow-up

Method of measurement

Language sample

3

Description

Number of different words

Timepoint

Pre-intervention, post-intervention, after follow-up

Method of measurement

Language sample

4

Description

Number of total words

Timepoint

Pre-intervention, post-intervention, after follow-up

Method of measurement

Language sample

5

Description

Number of consonant inventory

Timepoint

Pre-intervention, post-intervention, after follow-up

Method of measurement

Speech sample

6

Description

Percent of correct consonants

Timepoint

Pre-intervention, post-intervention, after follow-up

Method of measurement

Speech sample

7

Description

Intelligibility

Timepoint

Pre-intervention, post-intervention, after follow-up

Method of measurement

ICS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: speech and language assessment outcomes of each child will be analyzed in experimental intervention group and intervention plans will be set for each child individually according to child speech and language assessment outcomes. The parents who will participate in experimental intervention of EMT+PE, will be educated through supportive speech and language strategies by educated therapists . This education will be based on educational protocol of TMCR. Each therapist is responsible for educating at least 5 parents will participate in the intervention group. Supportive Speech and language strategies separately saves on the USB drive and they are given to the parents. Strategies are selected from primary to advanced according to the level of child speech and language. During the intervention course, the interaction between parent-child will be repeated at home 2 times per week for 3 months (24 sessions) at least 20 minutes each time. In the first month, in each week maximum 2 Supportive speech and language strategies of EMT+PE are educated to the experimental intervention group by educational videos, online and offline sessions in WhatsApp (Teach and model). Then, parents will provide a video from interaction of themselves with child and the application of educated strategies and will send it to the relevant therapist. The therapist will watch the videos and the strengths and weaknesses are identified and appropriate feedback is given to the parent. (Coach and review). Parents must provide a video from interaction sessions between themselves and child 2 times per week for at least 20 minutes and send it to the therapist. In these videos, educated strategies must be clearly implemented. At the end of third week education of Supportive speech and language strategies will be accomplished. In the Last week, educated strategies will be integrated and parents' total skill in simultaneously performing of all strategies will be assessed. Also, the last week of month fidelity measurement scale of parents is completed by the therapist. If parents are not qualified enough in different sections, parent education will be repeated. At the beginning of the second month, each week parent must provide 2 videos to show how to use Supportive speech and language strategies in order to interact with child. These videos will be sent to educated therapists and they will be examined according to TMCR. The assessment of intervention outcomes will be accomplished at the end of third month. 2 months is considered for maintenance of intervention outcomes that in this stage parents will not be coached and follow-up will start after 2 weeks since the assessments of end of intervention complete. speech and language assessment will be repeated after 2 months. in each stage of assessment, inter-rater reliability will be accomplished for at least %20 of all transcripted language and articulation samples. If the raters would not reach an acceptable agreement, two other raters will repeat the assessments. Fidelity of implementation will

be accomplished in sessions 6,12 and 18 in intervention phase and 5,10, and 15 in follow-up phase. Fidelity of implementation will be accomplished in order to ensure therapists and parents perform the intervention strategies correctly that if the therapists and parents would not get appropriate scores in pre-intervention and intervention respectively, education must be repeated.

Category

Rehabilitation

2

Description

Control group: Participants who are randomly assigned in control group, they would not receive experimental intervention of EMT+PE, but they will be underwent conventional interventions in cleft lip and palate teams and private clinics. conventional interventions define as any intervention offers to these children in cleft lip and palate teams and private clinics, except ongoing experimental intervention. Considering that conventional interventions for these children usually offer in the form of speech and language consultations to parents. Assessment steps of pre-intervention and after 3 months intervention will be implemented completely for the control group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

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Recruitment center

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

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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

University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences

Full name of responsible person
University of Social Welfare and Rehabilitation Sciences

Position
Phd student

Latest degree
Master

Other areas of specialty/work
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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
Yes - There is 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
There is no more information

When the data will become available and for how long
There is no more information

To whom data/document is available
There is no more information

Under which criteria data/document could be used
There is no more information

From where data/document is obtainable
There is no more information

What processes are involved for a request to access

data/document

There is no more information

Comments