

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigation of effectiveness of Articulation therapy for 4-12 years old children with cleft palate via Telepractice and in person sessions.

Protocol summary

Study aim

The purpose is to compare the effectiveness of Telepractice and in person sessions in children with cleft palate.

Design

Two arm parallel group randomised trial, Double-Blinded Trial, Simple randomized, Phase 1 on 50 patients. Randomization is done in a simple Randomization through lottery.

Settings and conduct

50 children aged 4-12 with cleft palate are divided into two groups. The intervention group received Articulation therapy via Telepractice in ZOOM platform for 10 45minutes sessions. The control group received Articulation therapy in 10 in person sessions. Articulation therapy includes routine Articulation approaches. Before and after treatment, 20minutes of spontaneous speech samples are recorded from each child. The (intelligibility) and (Production of consonants) in the CAPS form are scored. The level of mothers' satisfaction is measured using a 5-level Likert survey form. Numbers are measured and compared by Spss tool. Participants, analysts are blinded to the information of this research.

Participants/Inclusion and exclusion criteria

Unilateral, complete primary and secondary cleft palate
2. Absence of fistula after surgery
3. Absence of genetic or neurological syndromes
4. Calendar age of 4 to 12 years
5. Failure to identify severe language disorders
6. Presence of VPI after palate surgery
7. Presence of compensatory articulation errors with VPI through articulation evaluation tests
8. Normal hearing, recently evaluated by pure tone audiometry

Intervention groups

The main intervention group: Articulation therapy to correct compensatory Articulation errors is done via Telepractice. Control group: for this group, Articulation therapy is done in the form of in person sessions to correct compensatory Articulation errors.

Main outcome variables

speech intelligibility The percentage of correct consonants produced
The level of mother's satisfaction with Articulation therapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221031056353N1**

Registration date: **2022-11-15, 1401/08/24**

Registration timing: **prospective**

Last update: **2022-11-15, 1401/08/24**

Update count: **0**

Registration date

2022-11-15, 1401/08/24

Registrant information

Name

ayda abdi dezfuli

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3338 6881

Email address

abdi.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-01, 1401/09/10

Expected recruitment end date

2023-03-01, 1401/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation of effectiveness of Articulation therapy for 4-12 years old children with cleft palate via Telepractice and in person sessions.

Public title
Investigation of effectiveness of Articulation therapy for 4-12 years old children with cleft palate via Telepractice and in person sessions.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Unilateral, complete primary and secondary cleft palate
Absence of fistula after surgery
Normal hearing, recently evaluated by pure tone audiometry
Calendar age of 4 to 12 years
Absence of middle ear infection
Presence of VPI after palate surgery
Presence of compensatory Articulation errors with VPI through Articulation evaluation tests
Exclusion criteria:
genetic or neurological syndromes identify severe language disorders

Age
From **4 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization is done in the form of a lottery, so that the name of each participant is written on the same size and similar papers. The names are placed in a container. After that, the names are placed in two groups in order of coming out. One person enters the intervention group and one person enters the control group (odds receive Telepractice and evens receive face-to-face treatment) respectively. Randomization is done by a person who is not involved in the research process.

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants will not know whether the received technique is the main intervention or the routine intervention. The data analyzer analyzes the Spss file and does not meet the participants.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

No. 27, 23th Ave, Kian Abad Blvd

City

Ahvaz

Province

Khuzestan

Postal code

6155764137

Approval date

2022-10-22, 1401/07/30

Ethics committee reference number

IR.AJUMS.REC.1401.329

Health conditions studied

1

Description of health condition studied

cleft palate

ICD-10 code

Q35

ICD-10 code description

Cleft palate

Primary outcomes

1

Description

intelligibility of speech

Timepoint

Before treatment - After treatment

Method of measurement

5-level grading of speech intelligibility based on the CAPS form (0 = normal clarity and 4 = completely unnatural and unclear)

2

Description

The percentage of correct consonants produced

Timepoint

Before treatment - After treatment

Method of measurement

Dividing the correct produced consonants by the total produced consonants based on the speech sample

3

Description

The level of mother's satisfaction with Articulation therapy

Timepoint

Before treatment - After treatment

Method of measurement

Based on a 5-point Likert scale by asking the question: Were you satisfied with the treatment of your child?

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Articulation therapy for 25 children with cleft palate is carried out via Telepractice in 10 45-minutes sessions.

Category

Behavior

2

Description

Control group: Articulation therapy for 25 children with cleft palate is carried out in 10 in person 45-minutes sessions.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

cleft lip and cleft palate center of Ahvaz

Full name of responsible person

Ayda Abdi dezfuli

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PArastar St., Pasdaran Blvd., Zeitoun Karmandi Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Negin moradi

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Ayda Abdi Dezfuli

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Speech therapy

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Person responsible for scientific inquiries

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Latest degree

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available