

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of combined education on the knowledge and care and supportive performance of parents with children with cleft lip and palate

Protocol summary

Study aim

Determining the effect of combined education on the knowledge and care-supportive practice of parents with a child with cleft lip and palate

Design

Clinical trial with control group, Samples will be randomly divided into two groups of intervention (N = 20) and control (N = 20) by the method of random permutation blocks with block size 4 (using the table related to random permutations).

Settings and conduct

Forty parents of children with cleft lip and palate who meet the inclusion criteria are enrolled in the study. Then the samples are randomly divided into two groups of intervention and control groups. The study site is located in the Imam Khomeini hospital in Ahvaz.

Participants/Inclusion and exclusion criteria

Inclusion criteria for this study included registering and defining diagnosis of cleft lip and palate in child medical records, exclusion criteria was included Parental absenteeism in at least one session of educational classes.

Intervention groups

for the experimental group (20 people), the educational intervention will be performed in combination (face to face and demonstration (educational video approved by the treating physician) by the researcher during 4 sessions of 45 minutes (one session per week). In addition, no educational intervention will be performed for the control group. However, in order to observe ethical considerations, at the end of the training sessions (after the post-test), an educational pamphlet will be given to the control group.

Main outcome variables

Combined education, parental performance, parental knowledge

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190308042967N1**

Registration date: **2021-06-29, 1400/04/08**

Registration timing: **retrospective**

Last update: **2021-06-29, 1400/04/08**

Update count: **0**

Registration date

2021-06-29, 1400/04/08

Registrant information

Name

Zahra Zakizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 5289 2117

Email address

zaki.zari@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-02, 1398/07/10

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combined education on the knowledge and care and supportive performance of parents with children with cleft lip and palate

Public title

The effect of combined education on the knowledge and care and supportive performance of parents with children with cleft lip and palate

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Registration and definitive diagnosis of cleft lip and palate in the child's medical record Parents' mastery of Persian language

Exclusion criteria:

Having psychiatric illness in parents Drug addiction in parents

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the samples were randomly divided into two groups of intervention (N = 20) and control (N = 20) by the method of random permutation blocks with block size 4 (using the table related to random permutations).

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 Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Esfand st, Golestan Blvd, Ahvaz, Khuzestan, Iran

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Approval date

2019-01-29, 1397/11/09

Ethics committee reference number

IR.AJUMS.REC.1397.796

Health conditions studied

1

Description of health condition studied

cleft lip and cleft palate disease

ICD-10 code

XVII

ICD-10 code description

Congenital Malformations, Deformations and Chromosomal Abnormalities

Primary outcomes

1

Description

The level of knowledge and practice of parents with a child with cleft lip and palate

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Researcher-made questionnaire (Assessment of knowledge and performance)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For Intervention group (20 people), the educational intervention will be performed in combination (face to face and demonstration (educational video approved by the treating physician) by the researcher during 4 sessions of 45 minutes (one session per week).

Category

N/A

2

Description

Control group: No educational intervention will be performed for the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital and Abuzar Hospital, Ahvaz

Full name of responsible person

Ashrafalsadat Hakim

Street address

Imam khomeini Hospital Azadegan BLV; Ahvaz, Iran

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hakim3448200@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Ashrafalsadat Hakim

Street address

Ahvaz Jundishapur University of Medical Sciences,
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Web page address**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

50

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

Ashrafalsadat Hakim

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Pediatric Management

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

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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 more 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

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