

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effectiveness of the educational program on knowledge and caring performance of parents of children with colostomy

Protocol summary

Caring performance of colostomy

Study aim

Determining the effectiveness of the educational program on knowledge and caring performance of parents of children with colostomy

Design

Sampling will be done with a sequential non-probability method. With a control group, with parallel groups, the samples will be randomly divided into two test groups (N=39) and control (N=39) using the randomized permutation method

Settings and conduct

The research sample includes 78 infants aged 1 month to 2 years with colostomy. The research environment is teaching hospitals affiliated to Ahvaz University of Medical Sciences. In the test group (39 people), the educational intervention will be implemented in a combined form (face-to-face and showing an educational film approved by the doctor and presenting a pamphlet) by the researcher during 10, 45-minute sessions (one session per week). For the control group, no educational intervention will be done.

Participants/Inclusion and exclusion criteria

1. Having a child with colostomy 2. Child age between 1 month and 2 years 3. Not having a history of uncontrolled underlying disease 4. Parents have the ability to receive education (at least elementary literacy level) 5. Lack of parents participating in the previous class non criteria Non-entry conditions: 1. Children below 1 month and above 2 years 2. Lack of proficiency in Persian language

Intervention groups

For the test group, the educational intervention will be conducted in a combined form (face-to-face and showing an educational film approved by the doctor and presentation of a pamphlet) by the researcher during 10, 45-minute sessions (one session per week). No educational intervention will be done for the control group

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230507058110N1**

Registration date: **2023-05-13, 1402/02/23**

Registration timing: **prospective**

Last update: **2023-05-13, 1402/02/23**

Update count: **0**

Registration date

2023-05-13, 1402/02/23

Registrant information

Name

Ashrafalsadat Hakim

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8268

Email address

sara.kz1989@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-14, 1402/02/24

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of the educational program on knowledge and caring performance of parents of children with colostomy

Public title

Investigating the effectiveness of the educational program on the knowledge and caring performance of parents of children with colostomy

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having a child with colostomy Child age between 1 month and 2 years Not having a history of uncontrolled underlying disease Parents have the ability to receive education (at least elementary literacy level) lack of parents participating in the previous class

Exclusion criteria:

Children below 1 month and above 2 years Lack of proficiency in Persian language

Age

From **1 month** old to **2 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples were first selected from among the research community based on the inclusion criteria. The random assignment of the research sample to two intervention and control groups will be done based on quadruple permutation blocks (using the table related to random permutation blocks, of Twenty groups of four). In this method, the number of people assigned to each group is almost equal. Blocks are formed based on the variables in question, and half of the intervention people and half of the control people are included in each block. The main goal is to balance the number of participants in each group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Sampling will be done with a sequential non-probability method. With a control group, with parallel groups, the samples will be randomly divided into two test groups (N=39) and control (N=39) using the randomized permutation method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Jundishapur University of Medical Sciences, Ahvaz

Street address

Esfand St, Golestan Blvd, University of Medical Sciences

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Approval date

2023-05-06, 1402/02/16

Ethics committee reference number

IR.AJUMS.REC.1402.084

Health conditions studied

1

Description of health condition studied

Colostomy

ICD-10 code

k94.00

ICD-10 code description

Colostomy complication, unspecified

Primary outcomes

1

Description

Colostomy

Timepoint

Before the start of the intervention and two months after the intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Colostomy

Timepoint

Before the start of the intervention and two months after the intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: In intervention group, in order to educate the parents, educational sessions will be held in the form of group discussions, during which the parents will be divided into groups of 6 people. About colostomy, treatment, general care and nursing care will be carried out by the researcher during 10 sessions of 45 minutes (one session per week), and at the end of the training sessions, an educational pamphlet will be provided to them.

Category

Behavior

2

Description

Control group: In the control group, no educational intervention will be done. However, in order to comply with ethical considerations, after analyzing the results, the educational pamphlet will be delivered to the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Aboozar hospital

Full name of responsible person

Ashrafalsadat Hakim

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Parastar Ave, Pasdaran Blvd, Zeitun karmandi, Ahvaz

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Deputy of research and technology- Dr. Mehrnoosh Zakerkish

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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

Ashrafalsadat Hakim

Position

Assistant professor, faculty member

Latest degree

Master

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Ashrafalsadat Hakim

Position

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Latest degree

Master

Other areas of specialty/work

Pediatrics

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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)**

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

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