

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### The effect of maternal empowerment program on the colostomy complications in infants and tolerance of mother's distress

#### Protocol summary

##### Study aim

Determining the effect of maternal empowerment program on infant colostomy complications and tolerance of maternal distress

##### Design

A clinical trial with two groups of intervention and control, parallel, randomized with 4 blocking method

##### Settings and conduct

Neonates admitted to Neonatal Surgery and Neonatal Intensive Care Unit at Akbar and Dr. Sheikh Hospitals receive maternal consent. The empowerment program for mothers in the intervention group is performed. Mothers in the control group receive routine care. Infants are examined one, two and three months later at the colostomy clinic and complications are assessed. The distress tolerance questionnaire is completed by the mother before and after the intervention.

##### Participants/Inclusion and exclusion criteria

infant 0 to 90 days age infants, both term and pre-term  
Infant's stable clinical condition (including heart rate and respiration)  
Need for colostomy in the treatment process  
Lack of other abnormalities (such as metabolic diseases, immune deficiencies, and chemotherapy that affect colostomy symptoms).

##### Intervention groups

A 30- to 45-minute individualized empowerment program will be held to familiarize the gastrointestinal tract with problems and possible complications, cholestomy care and post-feeding and dressing. In addition, this intervention booklet is available to mothers in the intervention group.

##### Main outcome variables

Complications of skin cholestomy and complications leading to hospitalization  
Tolerance of mother distress

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20191207045633N1**

Registration date: **2019-12-28, 1398/10/07**

Registration timing: **retrospective**

Last update: **2019-12-28, 1398/10/07**

Update count: **0**

#### Registration date

2019-12-28, 1398/10/07

#### Registrant information

##### Name

tahere peiravi dehsorkhi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3728 4448

##### Email address

peiravit1@mums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-03-21, 1398/01/01

#### Expected recruitment end date

2019-09-21, 1398/06/30

#### Actual recruitment start date

2019-03-21, 1398/01/01

#### Actual recruitment end date

2019-08-21, 1398/05/30

#### Trial completion date

2019-11-21, 1398/08/30

#### Scientific title

The effect of maternal empowerment program on the colostomy complications in infants and tolerance of mother's distress

**Public title**

The effect of maternal empowerment program on the colostomy complications in infants and tolerance of mother's distress

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

for Infant: Infant Age 0 to 90 Days - Infant's Clinical Stability (Including Heart Rate and Breathing) - Need for Colostomy in Treatment - No Other Abnormalities (like Metabolic Disorders, Immune Deficiency and Chemotherapy Neonates PerTerm and Term - Infant's Clinical Stability (Including Heart Rate and Breathing Need for Colostomy in Treatment No Other Abnormalities (like Metabolic Disorders, Immune Deficiency and Chemotherapy For the mother: consent to participate in the study No psychiatric disorders ( depression and hoarseness based on physical symptoms and confession of the spouse or accompanying health and illness status) based on self-reported and physical disability or disabling illnesses affecting infant care) Is not addicted to self-expression. Has reading and writing skills.

**Exclusion criteria:**

Physical and mental disorders affecting the care of the baby During the study, according to the physician, a Diagnosis of one of the metabolic diseases, Immune deficiency or chemotherapeutic defects, etc. unwillingness to continue working, not attending one of the three training sessions, not attending to assess the complications of the exclusion criteri for the infant: neonatal death a Diagnosis of one of the metabolic diseases, Immune deficiency or chemotherapeutic defects, etc.

**Age**

From **1 day** old to **90 days** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Balanced Block Randomization: Randomized allocation was used to allocate children to the intervention and control groups using the 4-way blocking method (AAAA) and (BBBB); they were selected by lottery for the first intervention or control group and the rest were randomized. In order to prevent information leakage, the next block was started after the last unit block was cleared.

**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 Mashhad University of Medical Sciences

**Street address**

School of Nursing and Midwifery -Daneshgah St

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Approval date**

2019-03-05, 1397/12/14

**Ethics committee reference number**

IR.MUMS.NURSE.REC.1398.003

**Health conditions studied****1****Description of health condition studied**

Complications of the colostomy

**ICD-10 code**

Z93.3

**ICD-10 code description**

Colostomy status

**Primary outcomes****1****Description**

Complications Ostomy -

**Timepoint**

For complications of ostomy, one, two, three months after ostomy, empowerment

**Method of measurement**

Dermatologic distress tolerance questionnaire

**2****Description**

Tolerance of mother distress

**Timepoint**

Before intervention - Immediately after intervention - One and two months after intervention

**Method of measurement**

DTS distress tolerance questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group:: Three 45 minute sessions of mother empowerment for neonatal colostomy including: first session of maternal information, gastrointestinal complications and complications - second session of correct prenatal care and colostomy - third session including evaluation of maternal performance in neonatal care Practical control group: Only receive the first session of maternal information assessment training, familiarity with the gastrointestinal tract and the causes of colostomy and routine care.

#### Category

Prevention

### 2

#### Description

Control group: The control group will receive the first training session on familiarity with gastrointestinal tract, colostomy and complications of colostomy and will receive routine care.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dr. Sheikh Children's Hospital

##### Full name of responsible person

Peiravi Dehsorkhi, Tahere

##### Street address

6th Street, Boulevard Qarani

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### 2

#### Recruitment center

##### Name of recruitment center

Akbar Children's Hospital

##### Full name of responsible person

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Behnam Vashani Hamid Reza

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School of Nursing and Midwifery - University Street

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#### Grant name

Vice chancellor for research, Mashhad University of Medical Sciences

#### 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

Behnam Vashani Hamid Reza

**Position**

Assistant Professor of Pediatrics, School of Nursing and Midwifery, Mashhad University of Medical Sc

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Mashhad University of Medical Sciences

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**Position**

Head Nurse

**Latest degree**

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**Email**

peiravit1@mums.ac.ir

## 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**

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

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be 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