Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
City
Mashhad
Province
Razavi Khorasan
Postal code
9139963185
Phone
+98 51 3828 4448
Fax
+98 51 3727 7470
Email
peiravit1@mums.ac.ir

2

Recruitment center
Name of recruitment center
Akbar Children's Hospital
Full name of responsible person
Peiravi Dehsorkhi, Tahere
Street address
Namaz Boulevard
City
mashhad
Province
Razavi Khorasan
Postal code
9177897157
Phone
+98 51 3871 3005
Email
ak.pr@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Behnam Vashani Hamid Reza
Street address
School of Nursing and Midwifery - University Street
City
mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
behnamhr@mums.ac.ir
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
Street address
Faculty of Nursing - University Street
City
mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
behnamhr@mums.ac.ir

Person responsible for scientific 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
Street address
School of Nursing and Midwifery-Daneshgah .ST
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
behnamhr@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Peiravi Dehsorkhi Tahere
Position
Head Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Dr. Sheikh Hospital - Qarani 6- Boulevard Qarani
City
Mashhad
Province
Razavi Khorasan
Postal code
9173501385
Phone
+98 51 3728 4448
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