

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Empowerment program on stress, anxiety and depression in mothers of infants with colostomy

Protocol summary

Summary

Study objective: To determine the impact of the empowerment program on stress, anxiety and depression in mothers of infants with Colostomy - Design study: a double-blind study, selected hospitals were randomly assigned to intervention and control groups - the main criteria to enter the study: the willingness of women to participate in training sessions; ranging in age from newborn to age is 28-0 days; any disease of the digestive system that needs to be treated as a temporary colostomy may be - the main criteria to Exclusion the study: The baby died; refused to continue working mother of; Failure to attend at least two training sessions for the intervention group Sample size: 21 single mothers in the intervention group and control group Intervention Study: Empowering intervention the day after surgical by the researcher and the teaching of verbal and face to face with the mother in the NICU is done. The intervention included training sessions for 30 to 45 minutes depending on the number of sessions required will be determined by participants. Session One: Introduction to the gastrointestinal tract and fecal excretion route and need colostomy surgery and its potential problems (inflammation, infection, necrosis and decay and peeled the skin around the colostomy prolapse, retraction, dehydration and possible bleeding), the second session of practical care Practical care of the baby and about how colostomy bag or diaper refill and use, eliminating the smell of feces and skin care practices, infant bath, stool consistency according to the method of feeding and dressing and infection control and monitoring three session: the role of maternal and infant care by the mother. -Intervention from the day after surgery until discharge -primary outcome variable: stress, anxiety and depression in mothers

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014060417972N1**

Registration date: **2014-07-19, 1393/04/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-07-19, 1393/04/28

Registrant information

Name

Zahra Godarzi

Name of organization / entity

School of Nursing and Midwifery, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

godarziz@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Deputy of Tehran University of Medical Sciences

Expected recruitment start date

2014-04-09, 1393/01/20

Expected recruitment end date

2014-09-20, 1393/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Empowerment program on stress, anxiety and depression in mothers of infants with colostomy

Public title
Effect of Empowerment program on stress, anxiety and depression in mothers of infants with colostomy

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: the willingness of women to participate in training sessions; ranging in age from newborn to age is 28-0 days; any disease of the digestive system that needs to be treated as a temporary colostomy may be.
Exclusion criteria: The baby died; refused to continue working mother of; Failure to attend at least two training sessions for the intervention group

Age
To **28 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Qods St., Keshavarz Blvd Tehran Research Office, 7th Floor

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

93121781633633

Health conditions studied

1

Description of health condition studied

Colostomy

ICD-10 code

k91.4

ICD-10 code description

Abcess, malfuntoin, prolaps, complication

Primary outcomes

1

Description

Stress

Timepoint

Before the intervention and one month after intervention

Method of measurement

Questionnaire dass 21

2

Description

Anxiety

Timepoint

Before the intervention and one month after intervention

Method of measurement

Did you mean: پرسشنامه dass 21

3

Description

Depresion

Timepoint

Before the intervention and one month after intervention

Method of measurement

Did you mean: پرسشنامه dass 21

Secondary outcomes

empty

Intervention groups

1

Description

The intervention training is include review digestion system and defecation route and need colostomy surgery and possible problems it (Inflammation, infection, necrosis and decay and peeled the skin around the colostomy, colostomy prolapse, retraction colostomy, dehydration and possible bleeding) and training on how to refill and use baby care and colostomy bags, diapers, eliminate the odor of feces and skin care, to infant bath, attention stool consistency, the method of feeding and dressing(colostomy how to keep children from accessing it), and infection control and monitoring development and family travel and mother's role. At the end a booklet based on a review of literature, infants have a colostomy

is given.

Category

Other

2

Description

The group control will take routing care include changing diaper and care of skin around colostomy only oral education by a nurse at the time of discharge from NICU without practical education and booklet.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Neonatal intensive care unit of Children's Hospital
Medical Center

Full name of responsible person

Ms.goldost, headnurse

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Ali Asghar Hospital neonatal intensive care unit

Full name of responsible person

Ms.shojaee, Master of Nursing, haed nurse

Street address

City

Tehran

3

Recruitment center

Name of recruitment center

Bahrani Children's Hospital neonatal intensive care
unit

Full name of responsible person

Ms.nori, head nurse

Street address

City

tehran

4

Recruitment center

Name of recruitment center

mofid hospital neonatal intensive care unit of
beneficial

Full name of responsible person

Ms.ghafari, head nurse

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University Research Office

Full name of responsible person

Tehran University Research Office

Street address

Keshavarz Blvd, over six floors, ghods street

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University Research Office

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery, Tehran University of
Medical Sciences

Full name of responsible person

Zahra godarzi

Position

Master of nursing

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty