

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The Impact of Empowering Mothers of Infants hospitalized in Neonatal Intensive Care Unit on Their Participation Rate in the Infant Care.

Protocol summary

Summary

Objective main: The impact of empowering mothers of infants hospitalized in neonatal intensive care unit on their participation rate in the infant care. **Design:** The study is single group, Semi- experimental method, with a comparison before and after event. **Setting and conduct:** Training needs of mothers are determined by questionnaire of training needs. The training plan is conducted based on measuring the training needs of mothers. **Checklist of mother participation before and after the intervention is completed, then after checklist completion, educational intervention is implemented at time interval of 2 to 4 days. The participation rate of mothers is determined before and after the educational program. Participants including major eligibility criteria:** Inclusion criterion for this study is to have the age above of 15 and the ability to read and write. **Exclusion criteria** according to information obtained from medical files and mother is the mother with a mental and physical disease, and then the infants with an illness incompatible with life. 59 mothers having hospitalized infant in modif medical center are participated in this study. **Interventions:** The intervention of the study is educational plan including giving mothers the booklets and holding training sessions for them. **The main outcome variables:** Determining the educational needs of mothers regarding to newborn care in neonatal intensive care unit to implement empowerment programs. Determining mother participation rate regarding to newborn care before and after implementing the empowerment program. Comparing mother participation rate regarding to newborn care unit before and after implementing the empowerment program.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112631099N1**

Registration date: **2017-01-20, 1395/11/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-20, 1395/11/01

Registrant information

Name

Manijeh Shakibifard

Name of organization / entity

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manijehshakibi49@gmail.com

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences and Health Care Services, Nursing and Midwifery Collage of Vice chancellor of Reaserch

Expected recruitment start date

2016-12-20, 1395/09/30

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Impact of Empowering Mothers of Infants

hospitalized in Neonatal Intensive Care Unit on Their Participation Rate in the Infant Care.

Public title

The Impacts of Mothers Empowerment on Thier Participation in Newborn Care

Purpose

Supportive

Inclusion/Exclusion criteria

Major inclusion criterion for this study is to have the age above 15 and the ability to read and write for mother. Major exclusion criteria is the mother with a mental and physical disease, and then the infants with an illness incompatible with life.

Age

From **15 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **59**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahid Beheshti University of Medical Sciences and Health Care Services, Nersing and Midwifery Colla

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Nersing and Midwifery Collage Opposite of Shahid Rajaei Hospital, Niayesh Cross Road, Vaiye Asr Ave, Tehran

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Tehran

Postal code

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Approval date

2016-05-16, 1395/02/27

Ethics committee reference number

IR.SBMU.PHNM.1395.387

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

Empowerment

ICD-10 code

F60.7

ICD-10 code description

Dependent personality disorder

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

Determining mother participation rate regarding to newborn care before and after implementing the empowerment program.

Timepoint

Participation rate of mothers is determined before the educational intervention and 2 to 4 days after the intervention.

Method of measurement

Chek list of Mothers Participation

Secondary outcomes

empty

Intervention groups**1****Description**

In this study implementing the training program is an intervention. First the educational needs of mothers were obtained by questionnaire, and accordingly educational programs are implemented. Booklet and face to face training were instruction methods. The participation of mothers is determined and compared before and after implementing the training program lasting 2 to 4 days.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kodakan Mofid Hospital

Full name of responsible person

Maryam Momeni Oremi, BS., Nursing Maneger

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences and Health Care Services, Nursing and Midwifery Colla

Full name of responsible person

Dr.Mahrokh Dolatian

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Nursing and Midwifery Collage, Opposite of Shahid Rajaei Hospital, Niayesh Cross Road, Valiye Asr Ave,Tehran

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Thran

Grant name**Grant code / Reference number**

7536

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences and Health Care Services, Nursing and Midwifery Colla

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**Name of organization / entity**

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Full name of responsible person

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Person responsible for scientific inquiries

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Full name of responsible person

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Master Degree Student of Neonatal Intensive Care Unit, Nurse

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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