

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### The Effect of Educational Support based on Parenting Self-Efficacy on Attachment and Self-Efficacy of Mothers of Newborns

#### Protocol summary

##### Study aim

Determining of The Effect of Educational Support based on Parenting Self-Efficacy on Attachment and Self-Efficacy of Mothers of Newborns Admitted in the NICU

##### Design

• Two arm parallel group trial with outcome assessment and simple randomization • The total sample is 84 people.

##### Settings and conduct

This research was carried out in the neonatal intensive care unit of Kashani Hospital. The mothers of the intervention group hold on Supportive education based on self-efficacy during three sessions. The mothers of the control group are routinely trained.

##### Participants/Inclusion and exclusion criteria

Interior Criteria: A newborn with gestational age above 36 weeks admitted in NICU. Exterior Criteria: 1) Serious illness of newborn during the study 2) Depression or postpartum psychosis during the study 3) Admission to the baby for more than 4 weeks 4) Discharge of the baby earlier than a week

##### Intervention groups

Mothers who have a baby admitted in the NICU are divided into two groups by coin throwing (according to the inclusion and exclusion criteria). The first group of mothers are received by the researcher during the 3-4 sessions of the neonatal developmental care program. The second group, which is the control group, includes mothers who receive routine training.

##### Main outcome variables

The main consequence of this study is increased self-efficacy and attachment in mothers with hospitalized infant.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150928024239N3**

Registration date: **2018-02-06, 1396/11/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-02-06, 1396/11/17**

Update count: **0**

##### Registration date

2018-02-06, 1396/11/17

##### Registrant information

###### Name

**Name of organization / entity**

###### Country

Iran (Islamic Republic of)

###### Phone

+98 66927171

###### Email address

zareikh@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-11-16, 1396/08/25

##### Expected recruitment end date

2018-04-20, 1397/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Educational Support based on Parenting Self-Efficacy on Attachment and Self-Efficacy of Mothers of Newborns

##### Public title

The Effect of Educational Support based on Parenting

Self-Efficacy on Attachment and Self-Efficacy of Mothers of Newborns in NICU

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

newborn with a gestational age older than 36 weeks are admitted to the NICU Ability for reading and writing in Persian language

### Exclusion criteria:

Serious illness of newborn during the study Depression or postpartum psychosis during the study Admission to the baby for more than 4 weeks Discharge of the baby earlier than a week

## Age

No age limit

## Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 84

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization by throwing coins

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

### 1

#### Registry name

ثبت نشده است

#### Secondary trial Id

-

#### Registration date

2018-01-21, 1396/11/01

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tehran University of Medical sciences

##### Street address

Faculty of Nursing and Midwifery Tehran, West Nusrat Street , Tohid Square , Tehran

##### City

Tehran

## Province

Tehran

## Postal code

۱۴۱۹۷۳۳۱۷۱

## Approval date

2017-11-12, 1396/08/21

## Ethics committee reference number

IR.TUMS.FNM.REC.1396.3880

## Health conditions studied

### 1

#### Description of health condition studied

Self-Efficacy - Attachment

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Avent checklist for measuring maternal and infant attachment behaviors.

#### Timepoint

Attachment questionnaire gets complete in the intervention and control groups in the 2nd week of admission by the researcher.

#### Method of measurement

Avent checklist.

### 2

#### Description

Self\_efficacy by The Perceived Maternal Parenting Self\_efficacy Questionnaire ) Barnes ---- and

#### Timepoint

The self- efficacy questionnaire will be done in 4th weeks after admission by the mothers of both groups.

#### Method of measurement

The Perceived Maternal Parenting Self\_efficacy Questionnaire (Barnes)

## Secondary outcomes

### 1

#### Description

Increased attachment

#### Timepoint

A week to ten days after being admitted.

#### Method of measurement

Avant mother attachment check list.

## Intervention groups

### 1

#### Description

Intervention group: Mothers who have a baby admitted

in the NICU can receive education during three sessions. The first session, they will introduce with the setting and the characteristics of the premature baby and its needs. During the second session, they discuss the developmental care philosophy and how to care for the baby based on the principles of developmental care on the model. The context includes care positions, correct movement, baby feeding, nursing care, bathing, and diaper change. The third session is conducted practically done by the mothers on their newborn in the presence of the researcher.

#### Category

Behavior

### 2

#### Description

Control group: Mothers who have a baby admitted in the NICU are received educational routine.

#### Category

Behavior

### Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatollah Kashani Hospital, Tehran

##### Full name of responsible person

Fatemeh Tahmasebi

##### Street address

Second Square, Bukhara-ey Khzaneh Street, Besat Road, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1834893113

##### Phone

+98 21 5103 6230

##### Fax

+98 21 5506 1137

##### Email

Fatemeh.tahmasebi140@gmail.com

##### Web page address

### Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Research Deputy of Tehran University of Medical Sciences

##### Street address

Tohid Square, Faculty Of Nursing and Midwifery  
Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733171

##### Phone

+98 21 6692 7171

##### Fax

+98 21 6690 4252

##### Email

resdeputy@tums.ac.ir

##### Web page address

http://fnm.tums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tehran 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

### 2

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Maryam Modares

##### Street address

Sixth Floor, Central Organization of the University, Corner of Quds Street, Keshavarz Blvd, Tehran University of Medical Sciences.

##### City

Tehran

##### Province

Tehran

##### Postal code

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##### Phone

+98 21 8898 7381

##### Fax

+98 21 8898 9664

##### Email

resdeputy@tums.ac.ir

##### Web page address

http://fnm.tums.ac.ir

#### Grant name

Medical University Tehran

#### Grant code / Reference number

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

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Fatemeh Tahmasbi

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

1st Floor, No 5, Bozorgi Alley, Hoday Street, Southern Majidiye Neighborhood.

**City**

Tehran

**Province**

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**Position**

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**Email**

fatemeh.tahmasebi140@gmail.com

**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**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Only a portion of the data which is the main outcome information could be shared.

**When the data will become available and for how long**

A clinical study will report six months after the publication of the results

**To whom data/document is available**

Professors, and students who have permission from me and my professors.

**Under which criteria data/document could be used**

Not applicable to the public.

**From where data/document is obtainable**

baharzar42@gmail.com

fatemeh.tahmasebi140@gmail.com And the Library of the Faculty of Medicine, which is the basis of the thesis.

**What processes are involved for a request to access****data/document**

No documented documents except the thesis recorded in the University Library of the Faculty of Medical Sciences are currently available.

**Comments**

Only those written in the thesis are available, in which the thesis is also available at the Faculty Library.