

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Investigating the effect of educational intervention based on the theory of planned behavior on the intention and behavior of Kangaroo mother care in the mothers who have premature infants hospitalized in the intensive care units of premature infants

#### Protocol summary

##### Study aim

Determining the effect of education based on the theory of planned behavior on the intention and behavior of kangaroo mother care in mothers with premature infants

##### Design

Quasi experimental design with pre-test, post-test in control and intervention group, based on training, with 60 people

##### Settings and conduct

Pre-test will be done through a questionnaire from both intervention and control groups. The face-to-face training intervention will take place in three sessions with once every two days. Training classes will be held at the hospital. Pictures and videos of kangaroo mother care will be used. Before discharging the infant, the post-test questions will be completed by the mothers participating in the study in both groups.

##### Participants/Inclusion and exclusion criteria

Having a premature baby (under 37 weeks), the mother's willingness to cooperate in the study, having a minimum of basic education, no problem with congenital anomalies, the mother has no history of infertility and the pregnancy is not the result of IVF. Having an Apgar score above 5 at birth, the baby weights more than 1200 grams, stable position of infant on the mechanical ventilation

##### Intervention groups

After obtaining informed consent from both groups, for the intervention group, face-to-face educational intervention based on the structures of the theory of planned behavior will be performed in three sessions on every two days. Training classes will be held with 3-4 people in each group at the hospital. The control group will receive routine training.

##### Main outcome variables

intention of kangaroo mother care, performing kangaroo

mother care

#### General information

##### Reason for update

##### Acronym

KMC

##### IRCT registration information

IRCT registration number: **IRCT20220407054443N1**

Registration date: **2022-05-24, 1401/03/03**

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

Last update: **2022-05-24, 1401/03/03**

Update count: **0**

##### Registration date

2022-05-24, 1401/03/03

##### Registrant information

##### Name

Saeedeh Nemati

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3368 7875

##### Email address

elnaznemati14@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-21, 1401/02/01

##### Expected recruitment end date

2022-06-10, 1401/03/20

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of educational intervention based on the theory of planned behavior on the intention and behavior of Kangaroo mother care in the mothers who have premature infants hospitalized in the intensive care units of premature infants

**Public title**  
The effect of educational intervention based on the theory of planned behavior on Kangaroo mother care in mothers who have premature infants

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Having informed consent to participate in the study  
Having a infant under 37 weeks hospitalized in the neonatal ward or NICU neonatal intensive care unit  
Having a minimum of basic literacy The baby should be in a stable condition on the mechanical ventilation The baby may receive oxygen through a breathing tube, mask, or nose while caring for the baby, but the amount of oxygen needed should be approximately constant The baby shall be kept in an incubator or cutter

**Exclusion criteria:**

having a fifth minute Apgar score less than 5 having less than 1200 grams weight. having less than 30 weeks Intrauterine age of infant During the last 12 hours, there is no need to change the device setting by doctor and nurse. having no congenital malformations such as cleft palate, myelomeningocele, hydrocephalus and any other problems that lead to surgery and prevent the mother from being able to perform the usual care of a premature baby. Maternal infertility history Pregnancy resulting from IVF

**Age**  
No age limit

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: 60

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

A pre-test will be performed through a questionnaire from both intervention and control groups. In the intervention group; an educational intervention will be conducted. Post-test will be done before discharging from hospital.

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Urmia University of Medical Sciences

**Street address**

Urzhans Ave , Resalat Blvd

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5719819762

**Approval date**

2022-03-09, 1400/12/18

**Ethics committee reference number**

IR.UMSU.REC.1400.469

**Health conditions studied**

1

**Description of health condition studied**

Kangaroo mother care

**ICD-10 code**

**ICD-10 code description**

2

**Description of health condition studied**

kangaroo mother care in mothers with premature infant

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

Intention of Kangaroo mother care in mothers who have premature infant

**Timepoint**

Before the intervention and when the baby is going to discharge

**Method of measurement**

Researcher-made questionnaire

## Secondary outcomes

### 1

#### Description

Kangaroo mother care performing in mothers who have premature infant

#### Timepoint

Before the intervention and when the baby is going to discharge

#### Method of measurement

Researcher-made questionnaire

## Intervention groups

### 1

#### Description

Intervention group: The face-to-face educational intervention will be done based on the structures of the theory of planned behavior in three sessions at every two days. Training classes in groups of 3-4 people will be held at the hospital. The educational content will be adjusted based on the needs assessment of the analysis of pre -test results. The educational content will be based on the structures of the theory of planned behavior. The duration of face-to-face training will be 45-60 minutes. content of the first session including: introduce and establish communication with the participants in the research, expression of purpose of the study, introduce kangaroo mother care, and readiness to do it. In the second session, prognosis related to premature infants, the consequences of kangaroo mother care, maternal and neonatal benefits of kangaroo mother care will be explained. In the third session, the father of the infant or one of relatives will be participate in secession, and barriers and facilitators of kangaroo mother care will be expressed. Lecture, question and answer strategy, and group discussion will be used in these sessions. Educational booklets, pamphlets, mobile phones, Whats App text messages, videos and pictures are used as teaching aid methods.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mahzad Women's Comprehensive Educational and Medical Center

##### Full name of responsible person

Saeedeh Nemati

##### Street address

Hasani St.

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5715859497

##### Phone

+98 44 3346 5079

##### Email

mahzad@umsu.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Shahid Motahari Educational and Medical Center

##### Full name of responsible person

Saeedeh Nemati

##### Street address

Kashani Street

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5714615463

##### Phone

+98 44 3222 7002

##### Email

nursing\_college@umsu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Dr.Saber Golizadeh

##### Street address

Urmia University of Medical Sciences , Resalat Blvd

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5714783734

##### Phone

+98 44 3223 1930

##### Fax

+98 44 3224 0642

##### Email

Irajmohebbi@umsu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Oroumia 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**

Oroumia University of Medical Sciences

**Full name of responsible person**

Saeedeh Nemati

**Position**

Master student in midwifery counseling

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Unit 7,Elin Apartment, First 16 Meters St.,Sadi St.

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5719819762

**Phone**

+98 44 3368 7875

**Email**

elnaznemati14@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Roghayeh Bayrami

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

**Street address**

School of Nursing and Midwifery ,Nazlu Campus ,  
Urmia University of Medical Sciences

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5756115111

**Phone**

0098 44 327549614

**Email**

rozabayrami@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Saeedeh Nemati

**Position**

Master student in midwifery counseling

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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elnaznemati14@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Yes - There is a plan to make this available

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

Publication of research results in the form of publishing a scientific article

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

The access period starts 6 months after the publication of the article.

**To whom data/document is available**

All people

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

To inform researchers and mothers with premature babies

**From where data/document is obtainable**

Dr. Roghieh Bayrami, Assistant Professor, School of Nursing and Midwifery, Urmia Email :rozabayrami@yahoo.com

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

Enter the site of Urmia University of Medical Sciences and search for thesis title

## Comments