

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

Roghaye 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

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

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