

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Aug 2026

### The effects of Kangaroo Mother Care education intervention on the Premature Infants based on expanded health belief model : Shahid Sadoughi hospital 'Yazd

#### Protocol summary

##### Study aim

The aim of this study was to investigate the effects of Kangaroo Mother Care education intervention on the Premature Infants based on expanded health belief model in Shahid Sadoughi hospital 'Yazd.

##### Design

This research is a randomized controlled trial. The convenience or accidental sampling method, which will be done on 124 premature infants admitted to Shahid Sadoughi Hospital in Yazd, Iran, in two intervention and control groups.

##### Settings and conduct

At first, the control group after receiving routine training provided at the NICU of the hospital in relation to kangaroo care by the education officer for the mothers, the questionnaire of the variables considered including the characteristics of the newborn and the parents and the EHBM construct questionnaire for the mothers of this group is completed. After discharge, the EHBM constructs questionnaire and the outcome of the infant will be completed again. In the intervention group, the sampling was done in the same way as the control group based on the inclusion criteria of the study. After receiving the routine training, the questionnaires of the variables including newborn and parent characteristics and the EHBM construct questionnaire They will be completed. Then, all mothers in the intervention group receive a kangaroo care education based on the EHBM model and at the time of discharge, the EHBM construct questionnaire and the outcome of the newborn are completed.

##### Participants/Inclusion and exclusion criteria

Neonatal conditions for the study of gestational age less than 32 weeks, birth weight less than 1800 grams, sustained cardiovascular status at the start of kangaroo care and parents' consent to participate and cooperate with the study.

##### Intervention groups

Interventions will include individual training sessions and small groups.

##### Main outcome variables

Baby weighing - Oxygen therapy time

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181024041451N1**

Registration date: **2019-02-17, 1397/11/28**

Registration timing: **retrospective**

Last update: **2019-02-17, 1397/11/28**

Update count: **0**

##### Registration date

2019-02-17, 1397/11/28

##### Registrant information

##### Name

Sedigheh Safari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3820 9100

##### Email address

se.safari71@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-16, 1397/07/24

##### Expected recruitment end date

2019-02-13, 1397/11/24

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effects of Kangaroo Mother Care education intervention on the Premature Infants based on expanded health belief model : Shahid Sadoughi hospital 'Yazd

**Public title**

The effects of Kangaroo Mother Care education intervention on the Premature Infants

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

The gestational age is less than and equal to 32 weeks  
the birth weight is less than and equal to 1800 grams the  
cardiovascular condition is stable

**Exclusion criteria:****Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **124****Randomization (investigator's opinion)**

Not randomized

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

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

**Other design features**

One of the strengths of this study was its exploratory approach to the design of the research instrument. By measuring CVI and CVRs, an attempt was made to develop an adapted valid and reliable instrument to the conditions of the study population to objectively reflect mothers' perceptions;

**Secondary Ids**

empty

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

Ethics committee of shahid Sadoughi University of  
Medical Sciences in Yazd

**Street address**

School of Public Health, shahid Sadoughi University of  
Medical Sciences, Gomnam Shahid Blvd,Alem Square

**City**

Yazd

**Province**

Yazd

**Postal code**

891517316

**Approval date**

2017-07-03, 1396/04/12

**Ethics committee reference number**

IR.SSU.SPH.REC.1396.62

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

premature infants

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Mother's perceived sensitivity score

**Timepoint**

Before starting kangaroo care and time to discharge the  
baby

**Method of measurement**

Researcher-made questionnaire based on expanded  
health belief model

**2****Description**

Mother's perceived intensity score

**Timepoint**

Before starting kangaroo care and time to discharge the  
baby

**Method of measurement**

Researcher-made questionnaire based on expanded  
health belief model

**3****Description**

Mother's perceived benefit score

**Timepoint**

Before starting kangaroo care and time to discharge the  
baby

**Method of measurement**

Researcher-made questionnaire based on expanded  
health belief model

## 4

### **Description**

The score of the perceived barriers of the mother

### **Timepoint**

Before starting kangaroo care and time to discharge the baby

### **Method of measurement**

Researcher-made questionnaire based on expanded health belief model

## 5

### **Description**

The score of the Cues to action of the mother

### **Timepoint**

Before starting kangaroo care and time to discharge the baby

### **Method of measurement**

Researcher-made questionnaire based on expanded health belief model

## 6

### **Description**

Mother's self-efficacy score

### **Timepoint**

Before starting kangaroo care and time to discharge the baby

### **Method of measurement**

Researcher-made questionnaire based on expanded health belief model

## 7

### **Description**

Mother's perceived social support score

### **Timepoint**

Before starting kangaroo care and time to discharge the baby

### **Method of measurement**

Researcher-made questionnaire based on expanded health belief model

## 8

### **Description**

Mother's Locus of control score

### **Timepoint**

Before starting kangaroo care and time to discharge the baby

### **Method of measurement**

Researcher-made questionnaire based on expanded health belief model

## **Secondary outcomes**

## 1

### **Description**

Weight of baby discharge time

### **Timepoint**

At the time of discharge the baby

## **Method of measurement**

Using Digital Scales

## 2

### **Description**

The duration of oxygen therapy

### **Timepoint**

At the time of discharge the baby

### **Method of measurement**

Use of a baby's treatment file - The number of days the baby has received supplemental oxygen in any form.

## 3

### **Description**

Duration of hospitalization

### **Timepoint**

At the time of discharge the baby

### **Method of measurement**

The sum of the days when the baby was admitted to the NICU due to complications of prematurity.

## 4

### **Description**

retinopathy

### **Timepoint**

At the time of discharge the baby

### **Method of measurement**

Use of a baby's treatment file

## 5

### **Description**

The death of babies

### **Timepoint**

At the time of discharge the baby

### **Method of measurement**

Whether or not a baby is alive

## 6

### **Description**

Average baby's weight gain per day

### **Timepoint**

Daily

### **Method of measurement**

Using Digital Scales

## **Intervention groups**

## 1

### **Description**

Intervention group: In addition to routine hospital training, mothers with preterm infants also receive Kangaroo Care Education based on the Expanded Health Belief Model.

### **Category**

N/A

2

**Description**

Control group: Only receive routine hospital training.

**Category**

N/A

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Shahid Sadoughi Hospital in Yazd

**Full name of responsible person**

Sedighe Safari

**Street address**

Shahid Sadoughi Hospital, Ebnesina Blvd, Shahid Ghani Blvd

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**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

مسعود میرزایی

**Street address**

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**Grant name**

Research Deputy of Shahid Sadoughi University of Medical Sciences, Yazd

**Grant code / Reference number**

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

Yes

**Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Sedighe Safari

**Position**

MSC student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Health Promotion

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## 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**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

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

Given the preparation of the article for the publication of scientific journals, individual data of unidentified samples will be available to reputable journals.

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

3 months after the publication of the article, information will be provided to individuals upon request.

**To whom data/document is available**

Only those who are busy at university centers will have access.

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

There are no other conditions to correspond with the author.

**From where data/document is obtainable**

Author responsible by email

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

After submitting the application on average after one to two weeks

**Comments**