

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of kangaroo care by mother and surrogate on nutritional behavior of preterm neonates : A randomised controlled clinical trial

#### Protocol summary

##### Study aim

Comparison of neonate nutritional behavior score between two groups on days 1,2,3,4,5 after intervention with baseline score control

##### Design

Randomized clinical trial with control group, parallel, sample size of 80

##### Settings and conduct

This study is a randomized controlled clinical trial. After obtaining permission from the Ethics Committee and registration at Iran Clinical Trials Center, the researcher will begin the daily sampling of 80 premature neonates in Alzahra and Taleghani Hospitals through convenience sampling. After evaluating inclusion and exclusion criteria, the goals and methods will be explained to mothers. Samples will be randomly divided and stratified based on neonate's age (31-32,6 and 33-35 weeks old) with blocks size 4 , 6 with 1:1 ratio in two groups: intervention group, 3 times of daily care once by mother and twice by surrogate in the last two times of care and the control group 3 times of daily care by mother (up to 5 days each time 60 minutes).Allocation sequences will be determined using RAS. Allocation concealment will be done using opaque-sealed envelopes numbered in sequence and opened by someone other than the researcher. Nutritional behavior will be measured using the Preterm Infant Breastfeeding Behavior Scale and physiological outcomes; temperature will be measured with a thermometer; heart-rate and arterial oxygen saturation will be checked with Pulse-oximeter; respiratory rate will be tested by chest touch and observation once before intervention and once again afterwards for up to 5 days.

##### Participants/Inclusion and exclusion criteria

31-35 weeks neonates, weighing more than 1500 g and no connection to ventilator Gravida 1,2

##### Intervention groups

Intervention: Three times a day of care, once by mother - two times surrogate Control:Three times a day of

mother's care

##### Main outcome variables

Nutritional behavior score of preterm infant

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150424021917N10**

Registration date: **2020-04-22, 1399/02/03**

Registration timing: **prospective**

Last update: **2021-01-21, 1399/11/02**

Update count: **1**

##### Registration date

2020-04-22, 1399/02/03

##### Registrant information

##### Name

Sevil Hakimi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3479 6770

##### Email address

hakimis@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-04, 1399/02/15

##### Expected recruitment end date

2020-10-06, 1399/07/15

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of kangaroo care by mother and surrogate on nutritional behavior of preterm neonates : A randomised controlled clinical trial

**Public title**

The effect of kangaroo care by mother and surrogate on nutritional behavior of preterm neonates : A randomised controlled clinical trial

**Purpose**

Supportive

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

Gravida 1,2 31-35 weeks neonates Neonate weight more than 1500 g unfixed female surrogate

**Exclusion criteria:**

Neonatal sepsis Neonate connection to ventilator CPAP use Catheter in umbilical vein Prescribing any medication to the neonate that may affect it's sleep Neonate intra ventricular hemorrhage Cleft lips and cleft palate Mother's epilepsy or surrogate Mother's or surrogate's addiction to any drug New scare in part of mother's/surrogate's body that is in direct contact with baby's Skin rash Use of perfume and perfume soap

**Age**

From **217 days** old to **245 days** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples will be randomly divided and stratified based on neonate`s age (31-32,6 and 33-35 weeks old) with 4 and 6 blocks with 1:1 ratio in two groups: intervention and control groups. Allocation sequences will be determined using RAS. Allocation concealment will be done using opaque-sealed envelopes numbered in sequence and opened by someone other than the researcher.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Research department, Third floor, Central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138665793

**Approval date**

2020-02-03, 1398/11/14

**Ethics committee reference number**

IR.TBZMED.REC.1398.1213

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

Preterm neonates

**ICD-10 code**

P07.33

**ICD-10 code description**

Preterm newborn, gestational age 30 completed weeks

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

Nutritional behavior of preterm neonate

**Timepoint**

Once before the intervention and once again after the intervention for up to 5 days

**Method of measurement**

Using the questionnaire Preterm Infant Breastfeeding Behavior Score (PIBBS)

**Secondary outcomes****1****Description**

Nutritional effect

**Timepoint**

once before the intervention and once again after the intervention for up to 5 days

**Method of measurement**

With using of standard questionnaire

## 2

### **Description**

Physiological function of preterm neonate (heart rate, temperature, respiratory rate and arterial oxygen saturation)

### **Timepoint**

once before the intervention and once again after the intervention for up to 5 days

### **Method of measurement**

temperature will be measured with a thermometer; heart-rate and arterial oxygen saturation will be checked with Pulse-oximeter; respiratory rate will be tested by chest touch and observation.

## **Intervention groups**

### 1

### **Description**

Intervention group: Mother/surrogate kangaroo care, 3 times of daily care once by mother and twice by surrogate in the last two time of care up to 5 days each time 60 minutes

### **Category**

Behavior

### 2

### **Description**

Control group: 3 times of daily care by mother up to 5 days each time 60 minute

### **Category**

Behavior

## **Recruitment centers**

### 1

### **Recruitment center**

#### **Name of recruitment center**

Khalij e Fars Hospital, Bandar Abbas

#### **Full name of responsible person**

Sevil Hakimi

#### **Street address**

Azad University st

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#### **Postal code**

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#### **Email**

mahboubeh.jamehdar@yahoo.com

### 2

### **Recruitment center**

#### **Name of recruitment center**

Children's Educational and Medical Center, Bandar

Abbas

#### **Full name of responsible person**

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#### **Street address**

Golshar Shomali, Emam Khomeini blvd, Bandar Abbas

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## **Sponsors / Funding sources**

### 1

### **Sponsor**

#### **Name of organization / entity**

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#### **Full name of responsible person**

Dr.Mohammad Samiei

#### **Street address**

Research department, Third floor, Central construction, Number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz

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#### **Email**

hakimis@tbzmed.ac.ir

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences  
**Full name of responsible person**  
Mahboubeh Jamehdar  
**Position**  
MSc student of Midwifery  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

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

Only part of the information, such as information on the main outcome or the like, can be shared. The results of clinical study will be published as article.

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

Start publishing period 6 months after printing results. Immediately after publishing the results.

### To whom data/document is available

All researchers

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

Scientific using with citation to article

### From where data/document is obtainable

Sevil Hakimi hakimis@tbzmed.ac.ir

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

The applicant sends an application via e-mail. After receiving the email, the results will be sent.

### Comments