

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Effectiveness of foot reflexology on fatigue and anxiety after cesarean section in mothers with hospitalized preterm neonate in Neonatal Intensive Care Unit(NICU)

#### Protocol summary

##### Summary

The purpose of this study is to evaluate the foot reflexology effect (Reflex Zone Therapy) on the fatigue severity and anxiety in mothers with cesarean section and hospitalized preterm neonate in the neonatal intensive care unit (NICU) of Valieasr and Jame e Zanan Hospitals . In this single blind randomized clinical trial, 99 of mothers who hospitalized at least 3 days in the maternity hospitals will be recruited. The participants with gestational age of 30 to 37 weeks, will be randomly assigned to three groups of reflexology, placebo and control. Data will be collected by questionnaire and entered to SPSS Software version 17. Data analysis will be done by descriptive and inferential statistics pre-intervention and post-intervention to evaluate the effectiveness of reflexology on reducing fatigue and anxiety of the participants.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201203229322N1**

Registration date: **2012-06-30, 1391/04/10**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-06-30, 1391/04/10

##### Registrant information

###### Name

Elaheh Ruhi rahim begloo

###### Name of organization / entity

Faculty of Nursing and Midwifery - tehran university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6693 3600

##### Email address

e-ruhi@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2012-09-22, 1391/07/01

##### Expected recruitment end date

2012-12-20, 1391/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of foot reflexology on fatigue and anxiety after cesarean section in mothers with hospitalized preterm neonate in Neonatal Intensive Care Unit(NICU)

##### Public title

the effect of foot reflexology massage on fatigue and anxiety

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Nulliparous mothers with cesarean section and hospitalized for three full days ; mothers with the age of 20-35 years old; mothers should be literate; mothers with no serious physical and psychological disorders; mothers with no tissue damage on their feet; mothers with gestational age of 30-37 weeks; mothers

with preterm neonate hospitalized in NICU; the newborns have to be breastfed. Exclusion criteria: -mothers with no willingness to participate in the trial anymore; mothers with less than three full days hospitalization; mothers who will develop serious health conditions during the trial; mothers who will develop a tissue damage on their feet, during the intervention; mothers who give birth with gestational age of less than 30 weeks; initiating formula feeding in the neonates, for any reasons.

#### Age

From **20 years** old to **35 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **99**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Faculty of Nursing and Midwifery- Tehran University of Medical Sciences

###### Street address

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat St., Tohid Sq. ,1419733171, Tehran, Iran

###### City

Tehran

###### Postal code

1419733171

##### Approval date

2012-05-24, 1391/03/04

##### Ethics committee reference number

171/130/91/3

### Health conditions studied

#### 1

##### Description of health condition studied

fatigue

##### ICD-10 code

F48.8

##### ICD-10 code description

Other specified neurotic disorders

#### 2

##### Description of health condition studied

anxiety

##### ICD-10 code

F41.1

##### ICD-10 code description

Generalized anxiety disorder

### Primary outcomes

#### 1

##### Description

anxiety intensity

##### Timepoint

pre and post intervention (before the initiation of first intervention and after the 3rd day of intervention)

##### Method of measurement

Spielberger State Anxiety Inventory

#### 2

##### Description

fatigue intensity

##### Timepoint

pre and post intervention (before the initiation of first intervention and after the 3rd day of intervention)

##### Method of measurement

visual analogue scale for fatigue

### Secondary outcomes

#### 1

##### Description

pulse

##### Timepoint

Once before and once after the third day of intervention and within 10 minutes after intervention

##### Method of measurement

According to minutes using the standard digital clock

#### 2

##### Description

blood pressure

##### Timepoint

Once before and once after the third day of intervention and within 10 minutes after intervention

##### Method of measurement

Mercury blood pressure devices (Richter)

#### 3

##### Description

Breathing

### Timepoint

Once before and once after the third day of intervention and within 10 minutes after intervention

### Method of measurement

According to minutes using the standard digital clock

## Intervention groups

### 1

#### Description

"Foot reflexology massage" or "reflexology" will be done for the intervention group which include three stages: preparation, heating with a 15-step techniques and massage techniques on reflex points of the pituitary, spinal cord and solar plexus. reflection of the pituitary is in inner edge of middle portion in the first Knucklebone of the big in plantar plantar, solar plexus is in end of the first metatarsal bone in foot and reflection of the spinal cord is in the inner edge of the foot, starting from the end of the first Knucklebone of the thumb and leads to heel. The total intervention time will be 40 minutes for both legs (20 minutes per foot), within three consecutive days.

#### Category

Other

### 2

#### Description

The intervention in the placebo group includes the preparation and heating with a towel and massage the legs and it is done within three consecutive days and takes 40 minutes for both legs (20 minutes per foot)

#### Category

Placebo

### 3

#### Description

In the control group, no intervention will be applied. This group will only receive routine care.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mirza Koochak Khan Hospital

##### Full name of responsible person

Elaheh Ruhi Rahim Begloo- MS Student in Nursing

##### Street address

Bimarestane Jame e Zanan. Karimkhane Zand St- Nejatollahi St, Tehran, Iran.

##### City

Tehran

### 2

#### Recruitment center

##### Name of recruitment center

Valiasr Hospital, Imam Khomeini Hospital

##### Full name of responsible person

Elaheh Ruhi Rahim Begloo- MS Student in Nursing

##### Street address

Imam Khomeini Hospital, Blvd. Keshavarz, Square Valiasr, Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research Tehran University of Medical Sciences

##### Full name of responsible person

Dr Akbar Fotoohi - Research Vice Chancellor Tehran University of Medical Sciences

##### Street address

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat St., Tohid Sq., 1419733171, Tehran, Iran

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice Chancellor for Research Tehran University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Faculty of Nursing and Midwifery - Tehran University of Medical Sciences

##### Full name of responsible person

Elaleh Ruhi Rahim Begloo

##### Position

MS Student in Nursing

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Dr Farideh Bastani

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Faculty member - Assistant professor

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## Person responsible for updating data

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**Web page address**

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## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*