

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jul 2026

### The effect of foot reflexology on fatigue and anxiety during post partum in primiparous.

#### Protocol summary

##### Study aim

The effect of foot reflexology on fatigue and anxiety postpartum in primiparous

##### Design

Available sampling method in similar health centers also be randomly selected will be done. A sample size of 35 cases was calculated for each group.

##### Settings and conduct

This study is a quasi-experimental trial that will be conducted in two groups of intervention and contro. Sampling in each center simultaneously until completion of samples it will continue every day except for Fridays. To avoid interference between research samples, health centers in intervention and control groups will be selected separately.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Be primiparous. Natural vaginal delivery without tool must be done. The infant to be term and healthy, singleton. Exclusive Breastfeeding. No chronic and acute disease. The absence of unexpected incidents in the last 3 months for a first-degree relative according to the referring. Earn 40 or higher scores from the Fatigue Questionnaire and having mild and moderate levels of anxiety. Visit between day 10 and maximum 15 days after childbirth. Whith out varicose veins leg, Infection, pain or injury in the lower legs, ankles or feet. Exclusion criteria: Unwillingness women to continuation of presence at research. Take special medication such as Anti-anxiety drugs and sedatives and sleeping. Unfollow the massage by mothers in the program for one session. Occurrence of any side effects during the intervention including tenderness of sensitive oil and touch sensitive mothers

##### Intervention groups

Foot reflexology for the intervention group will take time since the beginning of massage for both feet 30 minutes( every foot 15 minutes) per day for each person it will take 3 consecutive days. Control group will receive postpartum routine care , educational pamphlets will be

given.

##### Main outcome variables

State anxiety :Trait anxiety' Fatigue

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110425006284N13**

Registration date: **2018-12-31, 1397/10/10**

Registration timing: **retrospective**

Last update: **2018-12-31, 1397/10/10**

Update count: **0**

##### Registration date

2018-12-31, 1397/10/10

##### Registrant information

##### Name

Maryam Modarres

##### Name of organization / entity

Tehran university of Medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6656 8142

##### Email address

modarres@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-06, 1396/12/15

##### Expected recruitment end date

2018-08-21, 1397/05/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of foot reflexology on fatigue and anxiety during post partum in primiparous.

**Public title**

The effect of foot reflexology on fatigue and anxiety.

**Purpose**

Supportive

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

Be primiparous Natural vaginal delivery without tool must be done The infant to be term and healthy, singleton Exclusive breastfeeding No chronic and acute disease (diabetes,blood pressure,depression) The absence of unexpected incidents in the last 3 months for a first-degree relative according to the said referrer Earn 40 or higher scores from the Fatigue Questionnaire and having mild and moderate levels of anxiety Visit between day 10 and maximum 15 days after childbirth With out varicose veins leg,Infection,pain or injury in the lower legs, ankles or feet

**Exclusion criteria:**

Unwillingness women to continuation of presence at research Take special medication such as anti-anxiety drugs and sedatives and Sleeping Unfollow the massage by mothers in the program for one session Occurrence of any side effects during the intervention including tenderness of sensitive oil and touch sensitive mothers

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 70

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization, lottery

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Factorial

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

empty

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

Ethics committee of Tehran University of Medical Sciences Faculty of Nursing and Midwifery and Rehab

**Street address**

Nursing And Midwifery School , Nosrat St., District 6., Tehran., Tehran Province

**City**

Tehran

**Province**

Tehran

**Postal code**

کد پستی : 1419733171

**Approval date**

2017-12-25, 1396/10/04

**Ethics committee reference number**

IR.TUMS.FNM.REC.1396.4070 کد اخلاق

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

State anxiety

**ICD-10 code**

F53

**ICD-10 code description**

Puerperal psychosis

**2****Description of health condition studied**

Trait anxiety

**ICD-10 code**

F53

**ICD-10 code description**

Puerperal psychosis

**3****Description of health condition studied**

Fatigue

**ICD-10 code**

F53

**ICD-10 code description**

Puerperal psychosis

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

State anxiety

**Timepoint**

At the beginning of the study (before intervention).After 3 consecutive sessions (ten minutes after the intervention) and one week after the end of the intervention

**Method of measurement**

Spielberger State-Trait Anxiety questionnaire

**2****Description**

Trait anxiety

**Timepoint**

At the beginning of the study (before intervention).After 3 consecutive sessions (ten minutes after the intervention) and one week after the end of the intervention

**Method of measurement**

Spielberger State-Trait Anxiety questionnaire

**3****Description**

Fatigue

**Timepoint**

At the beginning of the study (before intervention).After 3 consecutive sessions (ten minutes after the intervention) and one week after the end of the intervention

**Method of measurement**

Visual Fatigue Assessment Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: After placing the patient in a proper position, firstly do heating techniques from the dominant person's feet. Then will be done massage from the dominant foot and at three points of the pituitary gland, the solar plexus and the spine. The Tonify technique use to stimulate the pituitary point and to stimulate the solar plexus point and the spine will be used with the Basic grip technique. Duration of the intervention since the beginning of massage for both feet 30 minutes( every foot 15 minutes) per day for each person it will take 3 consecutive days. Before intervention, after 3 consecutive sessions(ten minutes after the end of the intervention) and one week after the end of the intervention again the Spielberger test questionnaire and visual assessment of fatigue will be completed by the participants and educational pamphlets will be given.

**Category**

Behavior

**2****Description**

Control group: control group will receive postpartum routine care. fatigue and anxiety with Spielberger test questionnaire and visual assessment of fatigue will be measured. in the end, educational pamphlets will be given.

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

South Tehran Health Center

**Full name of responsible person**

Shekoufeh.Maleki

**Street address**

No.2, Abbas Shafei Aleey, Taleghani Ave, Vesale Shirazi Ave, Enghelab Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

1417863181

**Phone**

+98 21 0069 6695

**Email**

malekisherkoufeh@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Esmat Karimi

**Street address**

No23, Valiasr Avenue, Dameshgh Street, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1417863181

**Phone**

+98 21 3685 8163

**Fax****Email**

malekisherkoufeh@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Sekoufeh.Maleki

**Position**

MS Student in reproductive health

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Nursing And Midwifery School , Nosrat St., District 6.,  
Tehran., Tehran Province

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Phone**

+98 217171669221

**Email**

malekiskoufeh@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr.Modares Maryam

**Position**

Phd Medical education

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Education

**Street address**

Nursing And Midwifery School , Nosrat St., District 6.,  
Tehran., Tehran Province

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Phone**

+98 21 6105 4312

**Email**

modarres@sina.tums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Shekoufeh.Maleki

**Position**

MS Student in reproductive health

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Nursing And Midwifery School , Nosrat St., District 6.,  
Tehran., Tehran Province

**City**

Tehran

**Province**

Tehran

**Postal code**

1345764418

**Phone**

+98 21 7171 6692

**Email**

malekiskoufeh@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

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

### Study Protocol

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

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available