

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jul 2026

### The effect of preterm infant massage by mothers on mothers' anxiety and self-esteem

#### Protocol summary

##### Study aim

Determining the effect of maternal preterm infant massage on mothers' anxiety and self esteem

##### Design

This study was conducted with 60 samples (intervention group = 30 and control group = 30). The random sampling method is performed by quadruple blocking method.

##### Settings and conduct

Self-esteem and anxiety questionnaires are filled up at the time of entering the department by the mothers of the control and intervention group. In the intervention group, massage is performed after they are taught to mothers. At the end of 5 days, the anxiety and self-esteem questionnaires are filled by the mothers of the intervention and control group. The mothers were not aware of being in the control or intervention group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Mother does not have any addiction  
Mother's does not have any disease like high blood pressure - Gestational diabetes and any maternal physical and mental illness  
Preterm Infant with Physiological stability and birth weight between 1500 to 2500 grams  
Non-entry criteria: The mother's inability to stay in hospital for any reason

##### Intervention groups

Rosenberg's self-esteem and Beck's anxiety questionnaires are filled up at the time of entering the department by the mothers of the control and intervention group. Subsequently, in the intervention group, massage is performed after they are taught to mothers. Massage is performed three hours after an infant's lactation under physiological stability of the infant by controlling heart rate, respiration and skin color for 15 minutes in three times for 5 consecutive days. At the end of 5 days, the Beck anxiety and Rosenberg questionnaires self-esteem are filled by the mothers of the intervention and control group and at the end of the analysis, the data will be analyzed and compared in the

control and intervention groups.

##### Main outcome variables

Mothers' anxiety and self esteem score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181004041229N1**

Registration date: **2018-10-12, 1397/07/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-10-12, 1397/07/20**

Update count: **0**

##### Registration date

2018-10-12, 1397/07/20

##### Registrant information

##### Name

Fatemeh Abbasi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3377 9923

##### Email address

fatemehabbasi3560@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-17, 1397/06/26

##### Expected recruitment end date

2018-12-17, 1397/09/26

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effect of preterm infant massage by mothers on mothers' anxiety and self-esteem

**Public title**  
Effect of infant massage on mothers' anxiety and self-esteem

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Mother does not have any addiction Mother's does not have any disease like high blood pressure - Gestational diabetes and any maternal physical and mental illness  
 Preterm Infant with Physiological stability and birth weight between 1500 to 2500 grams  
**Exclusion criteria:**  
 The mother's inability to stay in hospital for any reason

**Age**  
No age limit

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: 60

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
A random assignment with quadrilateral blocking will be designed by the Professor of Statistics. The sampler person will be asked the type of group after the assurance of the Sample entry with the Professor of Statistics. In each section, only one type of intervention will be done. Each sample that goes out of the research will be replaced with the next one.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The present study is one-blind clinical trial (so that the mothers were not aware of being in the control or intervention group).

**Placebo**  
Not used

**Assignment**  
Other

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**  
**Name of ethics committee**  
 Ethics Committee of Nursing and Midwifery Faculty and Faculty of Rehabilitation, Tehran University o  
**Street address**  
 Nosrat street, Tohid square.  
**City**  
 Tehran  
**Province**  
 Tehran  
**Postal code**  
 1419733177  
**Approval date**  
 2018-08-31, 1397/06/09  
**Ethics committee reference number**  
 IR.TUMS.FNM.REC.1397.094

## Health conditions studied

1

**Description of health condition studied**  
Anxiety and Self-esteem of mothers

**ICD-10 code**  
F06.4

**ICD-10 code description**  
Anxiety disorder due to known physiological condition

## Primary outcomes

1

**Description**  
Anxiety

**Timepoint**  
Before the intervention and at the end of the fifth day

**Method of measurement**  
Beck Anxiety questionnaire

## Secondary outcomes

1

**Description**  
Self-esteem

**Timepoint**  
Before the intervention and at the end of the fifth day

**Method of measurement**  
Rosenberg self-esteem questionnaire

## Intervention groups

1

**Description**  
Intervention group: Self-esteem and anxiety questionnaire is completed first. Massage is done after they are taught to mothers. Massage is performed three times a day after lactation in infants with physiological stability of the baby by controlling heart rate, respiration

and skin color for 15 minutes in three times for 5 consecutive days. At the end of 5 days, the anxiety and self-reported questionnaire is again completed.

**Category**

Rehabilitation

**2**

**Description**

Control group: The self-esteem and anxiety questionnaire is completed at first. At the end of 5 days, the anxiety and self-reported questionnaire will be completed again.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Mosavi hospital

**Full name of responsible person**

Fatemeh abbasi

**Street address**

Gavazange road, Mosavi hospital

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4515648446

**Phone**

+98 24 3313 1292

**Email**

Fatemehabbasi3560@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Vida kardan

**Street address**

Nosrat street, Tohid square.

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**Province**

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**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**

Fatemeh abbasi

**Position**

Nurse

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Etemadieh street

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Batool pour aboli

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Fatemeh abbasi  
**Position**  
Nurse  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Etemadieh street  
**City**  
Zanjan  
**Province**  
Zanjan  
**Postal code**  
4515648446

## 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

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

### Informed Consent Form

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

### Clinical Study Report

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

### Analytic Code

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

### Data Dictionary

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