

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.

City

Tehran

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Postal code

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Phone

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Email

fatemehabbasi3560@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

Fatemeh abbasi

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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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
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Province
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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