Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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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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
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Latest degree
Master
Other areas of specialty/work
Nursery
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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