

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The effect of massage infant on state anxiety and mood state in mothers with preterm infants, discharged from the Neonatal Intensive Care Unit

#### Protocol summary

##### Summary

**Objectives:** The Effect of massage on preterm newborns has been shown in many studies, but has not been adequately studied in their mothers. This study will be undertaken to determine if infant massage will be decreased state anxiety or improved mood state in mothers of preterm newborns. **Design:** In a semi experimental study, 70 Iranian mothers who will be discharged their preterm newborns from the Neonatal Intensive Care Unit (NICU) will be participated in this study. To avoid data transfer, sampling will be done for the control or intervention group within a week. **Participants:** 70 Iranian mothers 18- 40 years old and singleton pregnancy with their preterm infants who are born at 32-37 weeks gestational age. **Exclusion criteria** including the mother's unwillingness to continue participation in the trial and Re-hospitalization of neonate. **Intervention:** Intervention will be done for mother-infant dyads in case group as 8 min massage session consisted of two identical standardized 4-min. The first 4 min will be involved the researcher demonstrating the massage and for the second 4 min, the mother will be performed the massage. Then interventions will be repeated in the day of discharge. No intervention will be done in control group. **Intervention:** Using the palms of her hands, and with the infant in a prone position, she firmly stroked with moderate pressure for four 1-min periods (12 strokes at approximately 5 s per stroking motion) the infant's head and the back in the following sequence: (1) from the top of the head to the neck and back to the top of the head; and (2) from the upper back to the waist and back to the upper back. The mother then repeated the same moderate pressure stroking procedure modeled by the researcher. **Main outcome:** State anxiety and mood state. The day before discharge, maternal state anxiety (MSA) will be measured using the State-Trait Anxiety Inventory (STAI) Scale (Spielberger) and will be measured mood state using The profile of mood states

(POMS). After intervention, the MSA will be re-measured using Spielberg's and mood state scale for all mothers.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201305262324N10**

Registration date: **2014-03-25, 1393/01/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-03-25, 1393/01/05

##### Registrant information

##### Name

Maryam Keshavarz

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4365 1813

##### Email address

keshavarz@iums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

vice chancellor for research of Tehran University of Medical Sciences

##### Expected recruitment start date

2013-06-24, 1392/04/03

##### Expected recruitment end date

2013-10-12, 1392/07/20

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of massage infant on state anxiety and mood state in mothers with preterm infants, discharged from the Neonatal Intensive Care Unit

**Public title**

The effect of massage infant on state anxiety and mood state in mothers with preterm infants

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: Iranian singleton preterm infants with gestational age 32-37 weeks; no congenital anomalies; the newborn's discharge until next 24 hours; no history of mental health in mother; no history of addiction in mother Exclusion criteria: The mother's unwillingness to continue participation in the trial; Re-hospitalization of neonate

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids****1****Registry name**

no

**Secondary trial Id**

no

**Registration date**

empty

**Ethics committees****1****Ethics committee**

Name of ethics committee

Ethical commitment of Tehran University of Medical Sciences

**Street address**

Sixth floor ,Central office, Ghods St, Keshavarz Blvd- Tehran, Iran

**City**

Tehran

**Postal code****Approval date**

2013-05-21, 1392/02/31

**Ethics committee reference number**

326/130/92/3

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

State anxiety and mood state

**ICD-10 code**

F53.0

**ICD-10 code description**

mild mental and behaviorl disorders associated with the puerperium , not elsewhere classified

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

The State anxiety in mothers of preterm infants

**Timepoint**

The day before discharge and the day of newborn's discharge

**Method of measurement**

The State-Trait Anxiety Inventory (STAI) Scale (Spielberger)

**2****Description**

Effect on mother's mood state

**Timepoint**

The day before discharge and the day of discharge infant

**Method of measurement**

The Profile of Mood States (POMS)(McNair)

**Secondary outcomes****1****Description**

no

**Timepoint**

no

**Method of measurement**

no

**Intervention groups**

## 1

### Description

The intervention is provided the 8-min massage session consisted of two identical standardized 4-min segments. The first 4 min will be done by researcher and then the second 4 min, will be done by the mother. Using the palms of her hands, and with the infant in a prone position, she firmly stroked with moderate pressure for four 1-min periods (12 strokes at approximately 5 s per stroking motion) the infant's head and the back in the following sequence: (1) from the top of the head to the neck and back to the top of the head; and (2) from the upper back to the waist and back to the upper back. The mother then repeated this massage for 4min

### Category

Prevention

## 2

### Description

Intervention Will not be done in the control group

### Category

Prevention

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Shahid Akbarabadi treatment & education center

#### Full name of responsible person

Maryam Keshavarz

#### Street address

Molavi street

#### 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 Fotohi

#### Street address

Sixth floor ,Central office, Ghods St, Keshavarz Blvd- 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

Nursing and Midwifery, Iran University of Medical Sciences

#### Full name of responsible person

Maryam Keshavarz

#### Position

Assistant Professor in Midwifery education

#### Other areas of specialty/work

#### Street address

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#### City

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

School of Nursing Midwifery, Iran University of Medical Sciences

#### Full name of responsible person

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Assistant Professor in Midwifery education

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**Person responsible for updating data**

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**Other areas of specialty/work**

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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*