

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Aug 2026

### The effect of massage on compliance with maternal role in mothers with premature infants admitted to the intensive care unit

#### Protocol summary

##### Study aim

The effect of massage on compliance to parental role of mothers of premature infants hospitalized in NICU

##### Design

This is a quasi-experimental study with a control group with parallel groups. the sequential method will be used with non-random Allocation to groups. The sample size is 90 mothers who will be divided equally into two groups.

##### Settings and conduct

This study will be done in the neonatal intensive care unit of Amol city. The researcher will teach infant massage to the mothers of intervention group in two sessions . Mothers will done massage their child daily for 15 minutes for 5 consecutive days. The mothers of both groups will be completed questionnaire before, in the fifth and 14 days after completing the intervention for massage group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria for mothers of preterm infants (32-37 weeks gestation): no history of physical and mental illness and history of infertility. Inclusion criteria for preterm infants: clinical condition stability of baby's and no respiratory distress or congenital abnormalities.

##### Intervention groups

The infants in the intervention group will be massaged by the mother from the third day of hospitalization for 5 consecutive days. Compliance with Mather's role before the intervention will be re-measured on the fifth and 14th days. At the same time, mothers in the control group also responded to Compliance with Mather's role questionnaire, but only routine care would be provided for them.

##### Main outcome variables

Compliance with motherhood role

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20160119026104N11**

Registration date: **2020-02-27, 1398/12/08**

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

Last update: **2020-02-27, 1398/12/08**

Update count: **0**

##### Registration date

2020-02-27, 1398/12/08

#### Registrant information

##### Name

Mahnaz Shoghi

##### Name of organization / entity

Iran university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4687 1192

##### Email address

shoghi.m@iums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

##### Expected recruitment start date

2019-12-22, 1398/10/01

##### Expected recruitment end date

2020-08-22, 1399/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

The effect of massage on compliance with maternal role in mothers with premature infants admitted to the intensive care unit

**Public title**

The effect of massage on compliance with maternal role in mothers with premature infants

**Purpose**

Supportive

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

Gestational age 32 to 37 weeks Stability of the baby's clinical condition and lack of respiratory distress or congenital abnormalities Having no history of infertility

**Exclusion criteria:**

Mother's addiction Maternal history of physical and mental illness

**Age**

From **1 day** old to **14 days** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**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**

empty

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

Ethics Committee of Iran University of Medical Sciences

**Street address**

School of Nursing and Midwifery, Rashid Yasimi St., Vali-e-Asr Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

1996713883

**Approval date**

2019-03-11, 1397/12/20

**Ethics committee reference number**

IR.IUMS.REC.1397.700

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

compliance with maternal role

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

compliance with maternal roles

**Timepoint**

The day before the intervention, the fifth day of the intervention and the 14th day after the intervention

**Method of measurement**

Compliance to maternal role

**Secondary outcomes**

empty

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

Intervention group: Massage will be performed by the mother from the third day of hospitalization, if the baby is stable, once a daily for 15 minutes for 5 consecutive days. questionnaire will be completed by the mothers before the beginning of the intervention and on the 5th and 14th day after the intervention. .

**Category**

Behavior

**2****Description**

Control group: Neonates in this group will receive routine care in the ward and questionnaire will be completed by this mothers in first day, fifth day and 14 days after .

**Category**

Behavior

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

Emam Ali hospital

**Full name of responsible person**

Mahnaz Shoghi

**Street address**

Noor Road to Chamestan

**City**

Amol

**Province**

Mazandaran  
**Postal code**  
47646-76893  
**Phone**  
+98 11 4426 4978  
**Email**  
shoghi.m@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Doctor Masoud Naseri  
**Street address**  
University of Nursing and Midwifery, Shahid yasemi,  
Kordestan highway  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1449614535  
**Phone**  
+98 21 86701  
**Email**  
pr@iums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Iran 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**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Mahnaz Shoghi  
**Position**  
Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nursery

**Street address**  
School of Nursing and Midwifery, Shahid yasemi.  
Kodestan highway  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1996713883  
**Phone**  
+98 21 6543 1000  
**Email**  
shoghi.m@iums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Mahnaz Shoghi  
**Position**  
Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nursery  
**Street address**  
School of Nursing and Midwifery, Shahid yasemi.  
Kodestan highway  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1996713883  
**Phone**  
+98 21 6543 1000  
**Email**  
shoghi.m@iums.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Mahnaz Shoghi  
**Position**  
Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nursery  
**Street address**  
School of Nursing and Midwifery, Vali-e-Asr St,  
Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran

**Postal code**  
199673883  
**Phone**  
+98 21 6543 1000  
**Email**  
shoghi.m@iums.ac.ir

## Sharing plan

### **Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

### **Study Protocol**

Yes - There is a plan to make this available

### **Statistical Analysis Plan**

Yes - There is a plan to make this available

### **Informed Consent Form**

Yes - There is a plan to make this available

### **Clinical Study Report**

Yes - There is a plan to make this available

### **Analytic Code**

Yes - There is a plan to make this available

### **Data Dictionary**

Not applicable

### **Title and more details about the data/document**

Data is encoded to make the profile of individuals unrecognizable and confidential

### **When the data will become available and for how long**

From the end of sampling 1398 to 6 months after the article was published

### **To whom data/document is available**

University Ethics Committee, Project Review Committee, Paper Review Committee, other researchers

### **Under which criteria data/document could be used**

Perform systematic or meta-analysis tasks with a document

### **From where data/document is obtainable**

Mahnaz shoghi shoghi@iums.ac.ir

### **What processes are involved for a request to access data/document**

The request will be sent by academic email, and information files will be made available to people no later than one week.

### **Comments**