

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Comparison of the effect of massage compared to regular bedtime routines on the sleep status of 15-20 day old infants and the quality of sleep of their mothers

#### Protocol summary

##### Study aim

Determining infant massage on the infant and mother's night sleep status

##### Design

The present study is a clinical trial with a control group , single blind randomized on 140 neonates. The randomization process will be a lottery with a card.

##### Settings and conduct

An information form will be filled out for all eligible people selected from the postpartum ward of Imam Ali Hospital in Amol. For the experimental group, the infant massage method will be explained and an instructional video on how to massage and instructions related to filling out the questionnaire will be given, and the control group will be given explanations and videos related to how and when to fill out the questionnaire. Individuals in both control and intervention groups completed the infant and mother sleep status questionnaire for 1 week without any intervention. Breastfeeding will be done. The control group will perform only the usual measures before going to bed and after starting the intervention at the end of the first and second week, both groups will fill in the questionnaire again. Assessment of maternal and infant sleep status is done with the help of a separate researcher who does not know the allocation of groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Term singleton infants , birth weight 2500-4000 g exclusive breastfeeding, Exclusion criteria: no history of hospitalization of the infant due to illness, lack of obvious diseases or abnormalities of infant mother does not suffer from postpartum depression

##### Intervention groups

For the intervention group, a two-week period of massage 15 minutes before bedtime is performed, in addition to the usual pre-sleep procedures such as changing diapers, breastfeeding. For the control group, only the usual pre-sleep procedures are performed as

above .

##### Main outcome variables

the sleep status of infants and mothers at night

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140924019277N3**

Registration date: **2022-01-17, 1400/10/27**

Registration timing: **retrospective**

Last update: **2022-01-17, 1400/10/27**

Update count: **0**

##### Registration date

2022-01-17, 1400/10/27

##### Registrant information

##### Name

Sussan Saatsaz

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 4422 1919

##### Email address

s.saatsaz@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-22, 1399/07/01

##### Expected recruitment end date

2021-05-31, 1400/03/10

##### Actual recruitment start date

2020-11-22, 1399/09/02

**Actual recruitment end date**

2021-07-01, 1400/04/10

**Trial completion date**

2021-07-01, 1400/04/10

**Scientific title**

Comparison of the effect of massage compared to regular bedtime routines on the sleep status of 15-20 day old infants and the quality of sleep of their mothers

**Public title**

The effect of massage on the sleep status of infants and mothers

**Purpose**

Other

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

all healthy newborn breastfeed exclusively singleton The first child weight 2500-4000 gr healthy mothers No postpartum depression Taking antidepressants

**Exclusion criteria:**

Sick babies need treatment formula feeding anomaly

**Age**

From **15 days** old to **20 days** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **140**

More than 1 sample in each individual

Number of samples in each individual: **2**

Mother and her newborn

Actual sample size reached: **140**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The card drawing technique was used to randomize the assignment of subjects to the groups. A total of 140 identical cards were first prepared and 70s were labeled A (routine night time ), 70 B( newborn massage ). A card was randomly drawn for each participant who entered the study by an independent assistant researcher (engaged only in the randomization process) and the type of intervention written on the card was announced by another researcher.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Randomization process and assessment of the form of maternal and infant sleep status is performed by the researcher without the knowledge of the allocation of groups

**Placebo**

Not used

**Assignment**

Other

**Other design features****Secondary Ids**

empty

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

Mazandran university of medical sciences

**Street address**

Sari-serah joibar

**City**

Sari

**Province**

Mazandaran

**Postal code**

4615861467

**Approval date**

2019-06-12, 1398/03/22

**Ethics committee reference number**

IR.MAZUMS.REC.1398.545

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

infant sleep condition and mother sleep quality

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

Maternal sleep quality score

**Timepoint**

From 7 days before the intervention, the end of the first week and the end of the second week of the intervention

**Method of measurement**

The Pittsburgh sleep quality index

**2****Description**

Infant sleep status markers

**Timepoint**

From 7 days before the intervention, the end of the first week and the end of the second week of the intervention

**Method of measurement**

The Brief Infant Sleep Questionnaire

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group :Massage the baby before going to bed every night for 2 weeks, 15 minutes each time, plus the usual bedtime interventions such as changing diapers and breastfeeding.Massaging the infant would be done in three 5-minute cycles. At first and to prevent skin friction, the mother would moisturize her hands with baby lotion and begin massaging according to the following procedures:1. In the first 5 minutes, the mother would lay the baby on the stomach, and the massage would begin by applying, in a pat-like manner, moderate pressure on the head, shoulders, back, arms, and legs (each part would be massaged for 6-10 seconds).2. In the second cycle, the baby would be laid on the back for 5 minutes, and the arms and legs would be first given ten extensions and flexions on their own, then both hands and feet.3. In the third 5 minutes, a massage would be given in similar conditions to the first 5 minutes.

### Category

Other

## 2

### Description

Control group: Common bedtime interventions such as diaper changes and breastfeeding

### Category

Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Ali Hospital in Amol

#### Full name of responsible person

Sussan Saatsz

#### Street address

Serah Joibar

#### City

Srie

#### Province

Mazandaran

#### Postal code

4615861467

#### Phone

+98 11 4422 1919

#### Email

s.saatsaz@mazums.c.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Mazandaran University of Medical Sciences

#### Full name of responsible person

majid saeedi

#### Street address

Serah Joibr

#### City

Sri

#### Province

Mazandaran

#### Postal code

4815733971

#### Phone

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#### Email

publicrel@mazums.ac.ir

#### Web page address

<https://www.mazums.ac.ir/>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

#### Full name of responsible person

sussan saatsaz

#### Position

Midwifery phd student

#### Latest degree

Master

#### Other areas of specialty/work

Midwifery

#### Street address

Faculty of Nursing and Midwifery of Amol, Mazandaran University of Medical Sciences, Sari, Iran

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

sussan saatsaz

**Position**

, Faculty of Nursing and Midwifery of Amol,  
Mazandaran University of Medical Sciences, Sari, Iran

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Sussan Saatsaz

**Position**

Faculty member

**Latest degree**

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**Other areas of specialty/work**

Midwifery

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## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available