

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

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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 analyst

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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

majid saeedi

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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

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

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Latest degree

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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