Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of relaxation training on breastfeeding self-efficacy and quality of sleep in mothers with premature infants

Protocol summary

Summary

This research will be random clinical trial in two groups on 60 mothers having premature neonate (gestational age between 32–36 week) bed ridden in the NICU Mashhad University of Medical Sciences Research and Training centers. Sampling will be done based inclusion criteria. Sampling will be based on inclusion criteria using two-month time block method. The control group receives the ward's regular treatment. The experimental group includes mothers with premature infants admitted in NICU that are selected during the first 24-72 hours after delivery and undergo relaxation training. Progressive muscular relaxation training for mothers is done by the researcher using Jacobson's method in the form of sixteen fold contractions and stretching of body, practically and individually, for thirty to forty five minutes. Mothers are required to do the method at least once a day. Self-efficacy variable of breastfeeding and quality of sleep is measured with breastfeeding self-efficacy questionnaire (Denis 2003) and Petersburg's Sleep Quality Index (PSQI). The questionnaire is initially evaluated during the first 24-72 hours of delivery and then four weeks after delivery and eventually during the eighth week after delivery. Mother inclusion criteria: The mother should be willing to take part in the research, Should be over 18 and under 35 years old, drug abuse is not. Mother exclusion criteria: When the mother hasn't done the relaxation exercise more than three times in a row.

General information

Acronym

Relaxation training

IRCT registration information

IRCT registration number: **IRCT2013082914516N1**
Registration date: **2013-12-28, 1392/10/07**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-12-28, 1392/10/07

Registrant information

Name

Sayedeh Maryam Hoseini

Name of organization / entity

Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Council of Mashhad University of Medical Sciences

Expected recruitment start date

2013-10-24, 1392/08/02

Expected recruitment end date

2014-01-30, 1392/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of relaxation training on breastfeeding self-efficacy and quality of sleep in mothers with premature infants

Public title

Effects of relaxation training on breastfeeding self-efficacy and quality of sleep in mothers with premature

infants

Purpose

Supportive

Inclusion/Exclusion criteria

Mother inclusion criteria: the mother should be willing to take part in the research; should be over 18 and under 35 years old; should have finished at least fifth grade of elementary school; shouldn't have skeletal and muscular problems; should have poor quality sleep (Petersburg's Sleep Quality Index score being 5 or above); should be physically fit; should not have temperamental and emotional disorders that hinder effective communication; should have access to audiovisual equipments at home; there may be a phone call; drug abuse is not. Neonate inclusion criteria: age between 32 - 36 weeks; no IUGR; the infant shouldn't be congenitally abnormal; enteral feeding for the infant should have been started in the form of po or pg. Neonate exclusion criteria: the infant should be put on a ventilator; the infant's digestive system should undergo surgery; after feeding has been started, the infant should undergo NPO for more than two days; neonate dies.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

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

Mashhad University of Medical Sciences

Street address

School of Nursing and Midwifery Mashhad, Four ways PhD

City

Mashhad

Postal code

Approval date

2013-10-23, 1392/08/01

Ethics committee reference number

research/920827/1/296

Health conditions studied

1

Description of health condition studied

Breastfeeding self-efficacy and quality of sleep

ICD-10 code

O94-O99

ICD-10 code description

Other obstetric conditions, not elsewhere classified

Primary outcomes

1

Description

Breast feeding self-efficacy

Timepoint

Two months after the start of the intervention

Method of measurement

Dennis questionnaire

Secondary outcomes

1

Description

Quality of sleep

Timepoint

Two months after the start of the intervention

Method of measurement

Pittsburgh sleep quality index (PSQI)

Intervention groups

1

Description

The experimental group includes mothers with premature infants admitted in NICU that are selected during the first 24-72 hours after delivery and undergo relaxation training. Progressive muscular relaxation training for mothers is done by the researcher using Jacobson's method in the form of sixteen fold contractions and stretching of body, practically and individually, for thirty to forty five minutes. Mothers are required to do the method at least once a day.

Category

Other

2

Description

The control group receives the ward's regular treatment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
NICU, Educational and Research Center Mashhad University of Medical Sciences

Full name of responsible person
Soheyla Karnadi

Street address
Mashhad School of Nursing and Midwifery

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Council of Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mohsen Tafaghodi

Street address
Building Qureshi

City
Mashhad

Grant name

Grant code / Reference number

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

Title of funding source
Research Council of Mashhad 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
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Position
MSc in Nursing,neonatal intensive care

Other areas of specialty/work

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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