Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Comparison of the effect of back massage and muscle relaxation on the anxiety factors of mothers with premature newborns in al-Zahra hospital in Isfahan

Protocol summary

Study aim

Determination and Comparison of the Effect of Massage Back and Muscle Relaxation on Anxiety Components of Mothers with Premature Infants in Alzahra Hospital, Isfahan

Design

The randomized clinical trial has three groups of massage, relaxation and control.The sample size was 35 in the intervention group and 70 in the control group.After intervention, the results were evaluated.

Settings and conduct

Samples were divided into three groups according to inclusion criteria: massage, relaxation and control groups.Swedish Massage technique in the intervention group Massage and Benson relaxation technique was performed in the relaxation group and no action was performed in the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria include mothers 18 years of age and older, literate and literate who have never had the experience of hospitalization of a newborn or premature infant in intensive care, with gestational age of 26 to 36 weeks, no epilepsy, disorders and Mental illness, No history of using anti-anxiety and sedative drugs, no history of attending massage and relaxation classes, no life-threatening crises in the past 6 months (loss of parents, divorce), no history of spinal cord injury and surgery, fracture , Wounds and skin problems in massage areas and no other anti-anxiety methods during the study. Exclusion criteria include death, transfer and discharge of the infant or unwilling or unable of mothers to continue working.

Intervention groups

Massage and relaxation

Main outcome variables

hysical, cognitive, behavioral anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190912044750N1**
Registration date: **2019-10-10, 1398/07/18**
Registration timing: **retrospective**

Last update: **2019-10-10, 1398/07/18**
Update count: **0**

Registration date

2019-10-10, 1398/07/18

Registrant information

Name

maryam lali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3227 8224

Email address

lm24756@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-06, 1398/05/15

Expected recruitment end date

2019-09-06, 1398/06/15

Actual recruitment start date

2019-08-06, 1398/05/15

Actual recruitment end date

2019-09-06, 1398/06/15

Trial completion date

2019-09-06, 1398/06/15

Scientific title
Comparison of the effect of back massage and muscle relaxation on the anxiety factors of mothers with premature newborns in al-Zahra hospital in Isfahan

Public title
Comparison of the effect of back massage and muscle relaxation on the anxiety factors of mothers with premature newborns in al-Zahra hospital in Isfahan

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria include mothers 18 years of age and older, literate who have never had the experience of hospitalization of a newborn or premature infant in intensive care, with gestational age of 26 to 36 weeks, no epilepsy, disorders and Mental illness, No history of using anti-anxiety and sedative drugs, no history of attending massage and relaxation classes, no life-threatening crises in the past 6 months (loss of parents, divorce), no history of spinal cord injury and surgery, fracture , Wounds and skin problems in massage areas and no other anti-anxiety methods during the study.
Exclusion criteria:
Exclusion criteria include death, transfer and discharge of the infant or unwilling or unable of mothers to continue working.

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **140**
Actual sample size reached: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked randomization

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
National Ethics Committee on Biomedical Research
Street address
Islamic Azad University of Najafabad, University Boulevar, Najafabad
City
Najafabad
Province
Isfehan
Postal code
8514143131

Approval date
2019-08-05, 1398/05/14

Ethics committee reference number
IR.IAU.NAJAFABAD.REC.1398.054

Health conditions studied

1

Description of health condition studied
Anxiety Components

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Anxiety Components Score in Cognitive and Behavioral Anxiety Questionnaire

Timepoint
Before and after the intervention

Method of measurement
Physical Anxiety, Cognitive and Behavioral Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Back massage Back massage was performed by a qualified researcher using surface massage techniques in 5 minutes each morning for 20 minutes on the intervention group.

Category
Other

2

Description
Intervention group: Muscle relaxation. Muscle relaxation was performed on the intervention group using Benson muscle relaxation technique for 5 minutes each morning for 20 minutes

Category
Other

3

Description
Control group: Routine actions
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
AlZahra Hospital
Full name of responsible person
Mina Jouzi
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Sponsors / Funding sources

1

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Full name of responsible person
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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
Islamic Azad University
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
Islamic Azad University
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Lali Maryam
Position
Masters student
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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
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