Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

عنوان طرح(انگلیسی) Investigating the effect of regular breathing on anxiety of mothers with premature infant hospitalized in the Neonatal Intensive Care Unit

Protocol summary

Study aim
Determining the effect of regular breathing on the anxiety of mothers with premature babies admitted to the nicu

Design
A clinical trial with a control group, with parallel groups, randomized, phase 2 on 66 patients, Random Allocation software was used for randomization

Settings and conduct
This research will be conducted in the neonatal intensive care unit of Shahid Sadoughi Hospital, Yazd, on 66 mothers with premature infant.

Participants/Inclusion and exclusion criteria
The gestational age is 26 to 36 weeks and the mother does not have experience in hospitalization of premature babies and does not work in a medical environment.

Intervention groups
The control group, after completing the demographic information questionnaire and checking the entry criteria, if they are eligible, entered the study and completed the Spielberger Anxiety Questionnaire, and the intervention was carried out in the aforementioned manner, and the Spielberger Questionnaire was completed again. The control group received usual ward care. After the end of the study, the Spielberger anxiety questionnaire is completed again by the mothers.

Main outcome variables
anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240216061027N1**
Registration date: **2024-03-28, 1403/01/09**
Registration timing: **registered_while_recruiting**
Last update: **2024-03-28, 1403/01/09**
Update count: **0**

Registration date
2024-03-28, 1403/01/09

Registrant information

Name
Alireza Ghobad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-05, 1402/12/15

Expected recruitment end date
2024-06-21, 1403/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
عنوان طرح(انگلیسی) Investigating the effect of regular breathing on anxiety of mothers with premature infant hospitalized in the Neonatal Intensive Care Unit

Public title
Investigating the effect of regular breathing on anxiety

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1) Gestational age 26 to 36 weeks 2) They do not have the experience of admitting a newborn or premature baby in the neonatal intensive care unit, regardless of the birth order of the baby 3) Don't have any significant crises in the last six months (loss of parents, divorce) 4) Babies should be hospitalized in the intensive care unit for at least three days 5) People who want to participate in the study 6) Parents should not participate in any other intervention program on anxiety during the study

Exclusion criteria:

The baby has a recognizable abnormality that increases the mother's anxiety Taking anti-anxiety and anti-depressant drugs Working mothers in healthcare and medical science environments

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to prevent the exchange of information between the intervention and control groups, a time block is used. First, sampling is done from the control group and then the intervention, and then the questionnaires are completed by the control group, and after the number of samples in the control group is completed, sampling is stopped for 3 weeks so that the parents of the participants in the control group are discharged. become After that, the sampling of the intervention group will be started in the mentioned way. In each group, from the first day of sampling, the statistical consultant has provided us with a number of random numbers based on the people who are accepted from the first day, using the Random Allocation software. Sampling is done from people who meet the entry criteria.

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 Yazd University of Medical Sciences

Street address

Shahid Sadoughi Blvd., Ba Honar Square, Yazd

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2024-01-03, 1402/10/13

Ethics committee reference number

IR.SSU.REC.1402.100

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

Primary outcomes

1

Description

The anxiety score in the Spielberger questionnaire ranges from none or the least to the most severe.

Timepoint

Spielberger anxiety questionnaire before the start of the intervention and after the end of the intervention (seven days)

Method of measurement

Spielberger anxiety questionnaire

Secondary outcomes

1

Description

Anxiety score of mothers with hospitalized premature infant

Timepoint

before the start of the intervention and after the start of the intervention (seven days)

Method of measurement

Spielberger questionnaire with 40 questions

Intervention groups

1

Description

Intervention group: The intervention group is included in the study after completing the demographic information

questionnaire and checking the entry criteria if eligible, and the Spielberger anxiety questionnaire is completed before the intervention. In this research, from the second or third day after the admission of the babies (fixation of the mother's physical condition), mothers are taught regular breathing until complete learning by the researcher. In this type of regular breathing, hey-hu technique is used. In this method, mothers first take a deep breath and while exhaling, they whisper hei, and they take a deep breath again and exhale by whispering ho. This work is practiced and repeated for a precise performance. The breathing rate is 16-20 times per minute for mothers. Breathing exercises by mothers every day at two specific times, once in the morning after the doctor's visit and once in the evening, each time for 20 minutes and every five minutes and each time for one minute (one minute of regular breathing and four minutes of rest) for It is done for seven days according to the method taught. After the intervention, the Spielberger anxiety level questionnaire is completed again by the mothers.

Category

Behavior

2

Description

Control group: After completing the demographic information questionnaire and checking the entry criteria, the control group entered the study and completed the Spielberger anxiety questionnaire. The control group received usual ward care. After the end of the study, the Spielberger anxiety questionnaire is completed again by the mothers.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital, Yazd

Full name of responsible person

Zahra pour Movahed

Street address

Shahid Sadouqi Hospital, Ibn Sina Boulevard, Shahid Kandi Boulevard, Yazd city, Yazd province

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Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi Abargoui

Street address

Central building of Yazd University of Medical Sciences, Bahnar Square, Yazd

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Alireza Ghobad

Position

Master's student in neonatal nursing

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact
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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
Yes - There is a plan to make this available
Title and more details about the data/document
The main results of this study are sharing and it is not possible to identify people due to the confidentiality of their personal information before sharing
When the data will become available and for how long
Time period of 3 months after printing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Do not make unauthorized and personal use of the data They are only allowed to publish scientific results
From where data/document is obtainable
To the email address Ali25ghobad@gmail.com Contact number 09338903314 or refer to Mrs. Doktorpour Mohed's office at the address of the Faculty of Nursing in Yazd.
What processes are involved for a request to access data/document
Request by email or in person Duration of one week
Comments