

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of nursing support program on stress disorder tolerance of mothers of premature babies hospitalized in neonatal intensive care unit

Protocol summary

Study aim

Determining the nursing support program on the distress tolerance of mothers of premature babies hospitalized in the neonatal intensive care unit

Design

The current study is an intervention type that is based on 84 samples (42 people in the intervention group and 42 people in the comparison group).

Settings and conduct

Mothers with premature babies admitted to the neonatal intensive care unit in Bent Al-Hoda Hospital in Bojnord.

Participants/Inclusion and exclusion criteria

Entry requirements: they were literate, had a premature baby of 28 to 30 weeks and were hospitalized for at least one week. Not having a definite diagnosis of depression, not taking antidepressants and any narcotic and psychoactive drugs, and not having a history of hospitalization of a premature baby in the neonatal intensive care unit; Conditions for non-entry: death, discharge or illness of the baby and unwillingness of the mother to continue cooperation, physical manifestation of congenital disease in the baby, discharge earlier than 14 days of the baby, twin babies, and the mother's non-participation in at least 5 training sessions

Intervention groups

Mothers referred to the neonatal intensive care unit of Bent Al-Hadi Hospital in Bojnord, who were trained by the researcher during 8-10 sessions in 4 weeks (2 sessions per week on even days in the morning and evening shifts, for a total of 45 minutes per session) They were supported by nursing. Individual profile questionnaire and emotional distress tolerance questionnaire (DTS) are completed once before training in both control and intervention groups.

Main outcome variables

nursing support; Tolerate distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230126057235N2**

Registration date: **2023-11-08, 1402/08/17**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-08, 1402/08/17**

Update count: **0**

Registration date

2023-11-08, 1402/08/17

Registrant information

Name

Narges Sefidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3223 6553

Email address

a.abbaszadeh@nkums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-12, 1402/07/20

Expected recruitment end date

2024-01-10, 1402/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nursing support program on stress disorder tolerance of mothers of premature babies hospitalized in neonatal intensive care unit		Secondary Ids
		empty
Public title	The effect of nursing support program on stress disorder tolerance of mothers of premature babies hospitalized in neonatal intensive care unit	Ethics committees
Purpose	Education/Guidance	<u>1</u>
Inclusion/Exclusion criteria		Ethics committee
Inclusion criteria:	Mothers with babies hospitalized in the neonatal intensive care unit, who were literate, had a premature baby of 28 to 30 weeks, were hospitalized for at least one week, did not have a definite diagnosis of depression, did not take antidepressants, did not take any narcotics and psychotropic drugs, had no history Admitting a premature baby to the neonatal intensive care unit	Name of ethics committee
Exclusion criteria:	Death, discharge or illness of the baby, mother's unwillingness to continue to cooperate in the study of physical manifestations of congenital disease in the baby, discharge earlier than 14 days of the baby, twin babies, mother's non-participation in at least 5 training sessions	Ethics Committee of North Khorasan University of Medical Sciences
Age	No age limit	Street address
Gender	Both	Dolat Blvd, Central Building of North Khorasan University of Medical Sciences, Bojnord
Phase	N/A	City
Groups that have been masked	Participant	bojnurd
Sample size	Target sample size: 84	Province
Randomization (investigator's opinion)	Randomized	North Khorasan
Randomization description	The randomization method is the coin flip method in such a way that one of the study groups is considered to be the lion and the other group is considered to be the line, and based on the desired sample size, the same number of coins are tossed and people are assigned to two groups. They find it by accident	Postal code
Blinding (investigator's opinion)	Single blinded	94137436941
Blinding description	In order to avoid the effect of the intervention on the control group and homogenize the two groups, the first group was selected by lottery and the control group was selected as the first group.	Approval date
Placebo	Not used	2023-10-22, 1402/07/30
Assignment	Parallel	Ethics committee reference number
Other design features		IR.NKUMS.REC.1402.098
		Health conditions studied
		<u>1</u>
		Description of health condition studied
		Premature infants
		ICD-10 code
		P07.3
		ICD-10 code description
		Preterm [premature] newborn [other]
		Primary outcomes
		<u>1</u>
		Description
		Enduring the distress of mothers with premature babies
		Timepoint
		Mothers were given nursing support training by the researcher during 8-10 sessions in 4 weeks (2 sessions per week on even days in the morning and evening shifts, for a total of 45 minutes in each session).
		Method of measurement
		Personal profile questionnaire and emotional distress tolerance questionnaire
		Secondary outcomes
		empty
		Intervention groups
		<u>1</u>
		Description
		Intervention group: Mothers were given nursing support

training by the researcher during 8-10 sessions within 4 weeks (2 sessions per week on even days in the morning and evening shifts, for a total of 45 minutes per session).

Category

Behavior

2**Description**

Control group: They receive routine care, including regular training of the department, and they complete the center's routine training once before and once at the end of the study, the distress tolerance questionnaire.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bent Al-Hadi Bojnord Hospital

Full name of responsible person

Narges sefidi

Street address

Art street

City

Bojnurd

Province

North Khorasan

Postal code

94137436941

Phone

+98 58 3223 6551

Email

Sepidin@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bojnourd University of Medical Sciences

Full name of responsible person

Dr. Bahram Bibak

Street address

Central Building of North Khorasan University of Medical Sciences, Dolat Blvd, Bojnurd

City

Bojnurd

Province

North Khorasan

Postal code

94137436941

Phone

+98 58 3223 6551

Email

Sepidin@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Bojnourd 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**

Bojnourd University of Medical Sciences

Full name of responsible person

Hojat Allah ehtesham Manesh

Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Dolat Blvd, Central Building of North Khorasan University of Medical Sciences, Bojnord

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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

No - There is not 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Nursing support and distress tolerance

When the data will become available and for how long

6 months

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Print the article

From where data/document is obtainable

sepidin@yahoo.com narges sefidi

What processes are involved for a request to access data/document

After analyzing the data and printing the article

Comments

Person responsible for updating data

Contact

Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Hojat Allah ehtesham Manesh
Position
Consultant
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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