Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of a palliative care-based educational program on self-efficacy and resilience of mothers with premature neonate: A randomized controlled trial

Protocol summary

Study aim

This study examines the effect of palliative care-based education on the self-efficacy and resilience of mothers with premature infants

Design

A clinical trial with a control group, parallel groups, without blinding and without randomization, conducted on 70 mothers with premature infants.

Settings and conduct

By referring to Al-Zahra Educational and Medical Center (PBUH) in Rasht and from the neonatal and neonatal intensive care units, sampling will be conducted without randomization, considering the inclusion criteria. First, the control group will be selected and assessed, followed by the intervention group, where the educational program will be implemented.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers with premature infants (gestational age 28-37 weeks), having at least basic literacy (ability to read and write), no history of giving birth to a premature infant in previous pregnancies, and no history of infant death in previous pregnancies. Exclusion criteria: Having psychological problems and taking psychiatric medications based on the mother's self-report, inability to communicate with others due to hearing, visual, or speech impairments, unwillingness of the mother to continue participation in the study, or infant death before completing the educational sessions.

Intervention groups

The intervention group will receive the palliative care-based educational program in four half-hour sessions, while the control group will receive the routine education provided by the respective ward

Main outcome variables

Measurable outcomes in this study include: the level of self-efficacy (before and one month after the intervention) and resilience (before and one month after the last educational session)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171008036651N5**
Registration date: **2025-08-12, 1404/05/21**
Registration timing: **prospective**

Last update: **2025-08-12, 1404/05/21**
Update count: **0**

Registration date

2025-08-12, 1404/05/21

Registrant information

Name

Yasaman Yaghobi

Name of organization / entity

Guilan University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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yasamanyaghobi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2025-12-22, 1404/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of a palliative care-based educational program on self-efficacy and resilience of mothers with premature neonate: A randomized controlled trial

Public title

Investigating the effect of a palliative care-based educational program on self-efficacy and resilience of mothers with premature neonate

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Mothers who have hospitalized premature infants Mothers who are willing to participate in the study Mothers who have at least basic literacy skills Mothers who have no history of giving birth to a premature infant Mothers who have no history of infant death

Exclusion criteria:

Mothers with psychological and emotional problems Mothers who have difficulty communicating with others

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

N/A

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

Ethics committee of Guilan University of Medical Sciences

Street address

Opposite 17 Shahrivar Hospital، Siadati Street، Namjoo Street

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2025-07-09, 1404/04/18

Ethics committee reference number

IR.GUMS.REC.1404.176

Health conditions studied

1

Description of health condition studied

Preterm newborn

ICD-10 code

P07.3

ICD-10 code description

Preterm newborn

Primary outcomes

1

Description

Self-efficacy

Timepoint

Before the start of the intervention and one month after the intervention

Method of measurement

Self-efficacy measurement questionnaire

2

Description

Resilience

Timepoint

Before the start of the intervention and one month after the intervention

Method of measurement

Resilience measurement questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 35 mothers with premature infants hospitalized will participate in four in-person training sessions over the course of one week

Category

Behavior

2

Description
Control group: 35 mothers with hospitalized premature infants who will receive routine training from the relevant department
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Fatemeh Hosseinzadeh
Street address
Namjoo Street
City
Rasht
Province
Guilan
Postal code
4144654839
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Fax
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azzahra@gums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Ramyar Farzan
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Parastar Street
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4193713111
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riasat@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
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Yasaman Yaghobi
Position
Associate Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available