Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the Effect of Teaching Ethical Principles Using the Flipped Classroom Method on Distress and Moral Sensitivity in Neonatal Intensive Care Unit Nurses

Protocol summary

Study aim

Assessing the impact of flipped classroom ethical principles training on ethical distress and ethical sensitivity among nurses in neonatal and pediatric intensive care units.

Design

This two-group clinical trial includes 80 participants selected by total enumeration and randomly assigned to intervention and control groups. Blinding of researchers and participants is not feasible, but the statistician remains unaware of group allocation.

Settings and conduct

Eighty nurses from Children’s Medical Center in Tehran were selected via total enumeration and randomly assigned to intervention and control groups. The control group receives standard hospital training, while the intervention group also receives flipped-classroom nursing ethics education

Participants/Inclusion and exclusion criteria

Nurses with at least a bachelor's degree in nursing and a minimum of six months of experience in neonatal and pediatric intensive care units. (due to having the minimum required training)

Intervention groups

After validation by nursing ethics experts, intervention group members were contacted to complete "ethical sensitivity" and "ethical distress" questionnaires. They received electronic educational content on ethical distress, resilience, and ethics knowledge, which they studied before attending three two-hour in-person sessions involving review, exercises, and discussions. Participants were continuously evaluated and given feedback. The control group received only standard hospital training.

Main outcome variables

moral distress; moral sensitivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220203053920N4**
Registration date: **2025-05-29, 1404/03/08**
Registration timing: **prospective**

Last update: **2025-05-29, 1404/03/08**
Update count: **0**

Registration date

2025-05-29, 1404/03/08

Registrant information

Name

Reihane Moghimian Shahrbabaki

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8895 9438

Email address

moghimianreihane1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the Effect of Teaching Ethical Principles Using the Flipped Classroom Method on Distress and Moral Sensitivity in Neonatal Intensive Care Unit Nurses

Public title
Investigating the Effect of Teaching Ethical Principles Using the Flipped Classroom Method on Distress and Moral Sensitivity in Neonatal Intensive Care Unit Nurses in Tehran Infant Medical Center

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Nurses who hold at least a Bachelor's degree in Nursing. Nurses who have worked in the Neonatal and Pediatric Intensive Care Unit for at least six months. (So that they have received at least basic initial training.)

Exclusion criteria:
failure to meet the eligibility criteria for participation in the study failure to attend two sessions of the training courses

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple Random Sampling and Randomization

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants are unaware.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethical committee of Kerman University of Medical Sciences

Street address
No. 2, floor, on the right., Alley 21 North 1., Bastani Paryizi Blvd., Kerman Town

City
Kerman

Province
Kerman

Postal code
7615864899

Approval date
2024-12-10, 1403/09/20

Ethics committee reference number
IR.KMU.REC.1403.471

Health conditions studied

1

Description of health condition studied
distress and moral sensitivity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Moral distress, moral sensitivity

Timepoint
Before the start of the intervention (holding the training sessions) and after completing the education via flipped classroom methods, with a total duration equivalent to four weeks.

Method of measurement
The Corley Ethical Stress Questionnaire, The Lutzen Ethical Sensitivity Questionnaire, Demographic Information Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Nurses working in Neonatal and Pediatric Intensive Care Units.

Category
Behavior

2

Description
Control group: Nurses working in Neonatal and Pediatric Intensive Care Units.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Children's Medical Center Hospital, Tehran City.

Full name of responsible person
Roghaye Badakhshan

Street address
No. 62, Dr. Mohammad Gharib Street, End of Keshavarz Boulevard, Next to Imam Khomeini Hospital, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Hamid Sharifi PHD

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Kerman University of Medical Sciences, Medical univesity Beginning of Haft Bagh-e-Alavi , Kerman, Iran

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Web page address
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Monirsadat Nematollahi

Position
Associate Professor and Head of the Pediatric Nursing and Neonatal Care Department

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Latest degree
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Other areas of specialty/work
Nursery

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Position

Master’s student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable