Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of maternal role education on distress tolerance and maternal-infant attachment in primiparous mothers with hospitalized premature neonates in Neonatal Intensive Care Units

Protocol summary

Study aim
The effect of maternal role education on distress tolerance and maternal-infant attachment in primiparous mothers with hospitalized premature neonates in NICU.

Design
A non-random stratified convenience sample of 95 primiparous mothers with preterm infants will be selected. After obtaining written informed consent, the demographic questionnaire and mother's distress tolerance and attachment scales will be completed. Then training will be provided for mothers, Immediately and one month after training, evaluation will be done.

Settings and conduct
This study is a quasi-experimental intervention. Among the premature mothers hospitalized in the neonatal intensive care unit, 95 mothers who have the characteristics of entering the study were randomly selected and they will be selected and at the first, the informed consent form is completed by the mothers, and then the demographic, distress tolerance and mother's attachment to the baby questionnaires are provided to them. After completing the questionnaires, in the next step, training will be provided for all mothers.

Participants/Inclusion and exclusion criteria
The participants would be primiparous mothers who have preterm infants admitted to the NICU. The inclusion criteria are: having a preterm infant born between 26 and 32 weeks and 6 days of gestation, having no history of infertility or abortion, having no chronic medical or psychological illnesses, being able to read and write, and willingness to participate in the study.

Intervention groups
At first, the mother's distress tolerance and attachment questionnaire are completed by the intervention group, then mother's role training based on the concepts of Mercer theory in 2 sessions with an interval of one week and each session for 2 hours, in the form of face-to-face and group workshops (up to 20 persons) will be given.

Main outcome variables
Distress Tolerance; Maternal attachment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240117060712N1**
Registration date: **2024-03-19, 1402/12/29**
Registration timing: **registered_while_recruiting**

Last update: **2024-03-19, 1402/12/29**
Update count: **0**

Registration date
2024-03-19, 1402/12/29

Registrant information

Name
SeyedehZeinab hossini

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 938 482 8454

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zeinabhosseini@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01

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
The effect of maternal role education on distress tolerance and maternal-infant attachment in primiparous mothers with hospitalized premature neonates in Neonatal Intensive Care Units

Public title
The effect of maternal role education on distress tolerance and maternal-infant attachment in primiparous mothers with hospitalized premature neonates in Neonatal Intensive Care Units
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Primiparous mothers Absence of infertility and abortion history in participants Mothers who have preterm infants between 32 to 36 weeks and 6 days. Neonates admitted to intensive care ward more than 48 hours. Absence of any congenital anomaly in neonates Hospitalization of newborn at the third level of care in the Neonatal Intensive Care Unit Absence of any chronic physical and psychological illnesses in mothers Citizenship of Iran Ability to read and write Willingness to participate in the study.
Exclusion criteria:
Having the history pf participation in the same previous educational sessions.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **95**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Zand Blvd
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2024-01-16, 1402/10/26
Ethics committee reference number
IR.SUMS.NUMIMG.REC.1402.120

Health conditions studied

1

Description of health condition studied
Distress tolerance and maternal-infant attachment to premature neonates
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Distress Tolerance
Timepoint
At the beginning of the study (beforethe intervention), immediately after the end of the intervention, one month after the end of the intervention
Method of measurement
Simons and Gaher Distress Tolerance Scale

Secondary outcomes

1

Description
Maternal- Infant Attachment
Timepoint
At the beginning of the study (before the intervention), immediately after the end of the intervention, one month after the end of the intervention
Method of measurement
Condon & Corkindale Infant Attachment Scale

Intervention groups

1

Description
Maternal role training will be provided in 2 sessions, one week apart and each session will last for 2 hours, in the

form of face-to-face and group workshops (up to 20 people). In these sessions, the researcher created the maternal role in the form of a booklet, the content of which is derived from Mercer's theory of the maternal role and includes strengthening the mother's identity and resolving role conflicts, increasing self-confidence, strengthening self-belief, improving parenting attitudes, teaching anxiety control, creating feelings Self-satisfaction, maternal attachment behaviors to the baby and familiarity with the appearance and temperament of the premature infant will be taught. Also, this booklet will be available to mothers at the end of the workshop.

Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
Ahmad Hosseinzadeh
Street address
Namazi Square, Zand St
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2

Recruitment center
Name of recruitment center
Hazrat-e-Zeinab hospital
Full name of responsible person
Fatemehsadat Najib
Street address
Defa-e-moghadas crossroads
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Email
zeinabhp@sums.ac.ir

3

Recruitment center
Name of recruitment center
Hafez hospital
Full name of responsible person
Fariba Hemati
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At the beginning of Abiverdi, Chamran St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Street address
The central building of Shiraz University of Medical Sciences, in front of Palestine St, Zand St
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Postal code
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Fax
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Email
info@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Seyedezeinab Hosseini

Position
MS student in Neonatal Intensive Care Nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Assistant Professor

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Ph.D.

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Nursery

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Person responsible for updating data

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

Analytic Code
Not applicable

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