Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of the continued implementation of developmental supportive care program by mothers with premature infants on the level of resilience and mental health of mothers

Protocol summary

Study aim
Determining the impact of continuing the implementation of supportive/developmental care program by mothers with premature infant on the resilience and mental health of mothers

Design
Randomized clinical trial, with parallel groups, without blinding, 60 premature infants (30 infants in the control group and 30 infants in the intervention group) will be included in the study. Random Allocation Software will be used for randomization.

Settings and conduct
The present study will be conducted on mothers with premature infant hospitalized in the neonatal intensive care unit of Rouhani Hospital. The supportive/developmental intervention program will be taught to mothers during 5 sessions starting one week before the possible date of the infant's discharge and for 5 consecutive days.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The mother with infant hospitalized in the neonatal intensive care unit with a fetal age of 28 to 34 weeks and a birth weight of less than 2500 grams. Exclusion criteria: absence of more than 2 sessions of mothers during 5 days of educational intervention.

Intervention groups
The level of resilience and mental health will be completed by mothers using the resilience and mental health questionnaire at the first meeting with the infant, during discharge and one month after discharge. The supportive/developmental care program based on the educational model will be taught to mothers in the intervention group in 5 sessions.

Main outcome variables
Resilience and mental health of mothers

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240327061370N2**
Registration date: **2024-10-18, 1403/07/27**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-18, 1403/07/27**
Update count: **0**

Registration date
2024-10-18, 1403/07/27

Registrant information
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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
2024-10-05, 1403/07/14
Expected recruitment end date
2025-03-04, 1403/12/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of the continued implementation of developmental supportive care program by mothers with premature infants on the level of resilience and mental health of mothers

Public title
The effect of the implementation developmental supportive care program on the resilience and mental health of mothers

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
The mother with premature infants hospitalized in the neonatal intensive care unit with a fetal age of 28 to 34 weeks Minimum hospitalization for 7 days Literate mother Being of Iranian origin No history of hospitalization of previous children in the neonatal intensive care unit No history of taking neuropsychiatric drugs or drug use by the mother

Exclusion criteria:
Death of neonate Sending the neonate to other centers for further treatment Mother's unwillingness to continue participating in the study Absence of more than 2 sessions of mothers during 5 days of educational intervention Mothers who are absent for more than one measurement time other than the initial time in the study process

Age
From **198 days** old to **238 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization method will be used. In order to hide the random allocation, the codes created by the software will be placed in opaque envelopes so that it is not clear which group the next person will be assigned to. In this study, eligible male participants, after receiving informed consent, according to the block randomization protocol (produced by Random Allocation Software) were assigned to one of the two control and intervention groups with a ratio of 1:1 and in blocks of 6. will be given, in such a way that the researcher cannot predict in which intervention group the next person will be placed. The codes will be placed in the opaque envelopes, and with the entry of each new person, the envelope will be opened and the person's belonging to the relevant group will be determined.

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
Research ethics committee of health research institute - Babol University of Medical Sciences

Street address
Ganj Afrouz Avn., Babol, Mazandaran

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babol

Province
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Approval date
2024-10-02, 1403/07/11

Ethics committee reference number
IR.MUBABOL.REC.1403.106

Health conditions studied

1

Description of health condition studied
Developmental Supportive Care. Resilience of mothers. Mental health of mothers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Resilience of mothers

Timepoint
first meeting with the infant During discharge and one month after discharge

Method of measurement
Connor and Davidson Resilience Questionnaire

2

Description
Mental health of mothers

Timepoint
first meeting with the infant During discharge and one month after discharge

Method of measurement
Goldberg General Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After receiving the code of ethics, the protocol will be registered in the IRCT system and then sampling will begin. Informed consent will be obtained from the mother before the intervention. A pre-test will be taken to determine the state of resilience and mental health of mothers before the intervention during the first meeting of the mother with the infant in the unit. Then, the intervention group, during 5 sessions on 5 consecutive days, the supportive/developmental care program, one week before the possible date of discharge of their infant, every day and between the time period of 8 am to 8 pm and in one of the rooms of the neonatal special care department of Rouhani hospital. They will receive an individual form. Although the content of the day the mother was absent will be taught on the next day. During the intervention, the post-test for the intervention group will be completed by mothers at discharge and one month after discharge. It should be noted that the educational content of developmental supportive care will be presented face-to-face in 5 sessions for 30-45 minutes in the form of educational slides individually in one of the rooms of the neonatal intensive care unit of Rouhani Hospital. An educational video that includes (kangaroo mother care-how to breastfeed-changing diapers-bathing-moving and positioning) with a short duration (maximum 15 minutes) when mothers are in the ward (at least one week before the possible date of discharge) individually will be displayed. The pamphlet and educational content will be placed in the form of a text, audio and video file on the Iranian virtual messaging channel (ITA) so that mothers can use it in case of absence and lack of proper understanding of the concepts. In the current study, the researcher will give this opportunity to the mothers by forming virtual groups, so that the mothers can communicate with each other and with the researcher in a group and individually, and continuous follow-up in the form of a phone call every other day and if needed daily and It will even be done face-to-face with the mothers, and the necessary follow-ups and care will be pointed out to the mothers, so that the mother can fully participate in the care and participation of her infant. The intervention includes: Partnering with Families, Optimizing Nutrition management, Safeguarding Sleep, Protecting Skin care, Positioning & Handling will be provided to mothers. Therefore, the mothers of the intervention group will be able to communicate with their peers (peer group) as well as with the researcher, in addition to phone calls, by sending text messages and on the messaging channel(ITA) with easy access and regardless of age, race and place of residence. Communicate with each other to emphasize and remind and review the contents

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Rouhani hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Babol 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
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Afsane Arzani
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
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