Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Use of an educational application based on smartphone for maternal role adaptation in women with preterm infants admitted to the Neonatal Intensive Care Unit of educational hospitals

Protocol summary

Study aim

Determination of the effect of utilizing a smartphone-based educational application on maternal role adaptation in women with preterm infants hospitalized in the Neonatal Intensive Care Unit of Teaching hospitals in Gorgan city in the year 2024-2025

Design

The present study is interventional. Initially, from each center, 9 individuals will be selected by convenience sampling for the control group so that the total sample from both centers reaches 18 individuals. Then, with a one-week interval after the discharge of the last individual entered into the control group, sampling for the intervention group will commence. Thus, 9 individuals from each hospital will be selected by convenience sampling.

Settings and conduct

The demographic characteristics form, the Maternal Role Adaptation Questionnaire for mothers of preterm infants, and the DASS-21 questionnaire will be completed in both the control and intervention groups at three time points: at entry into the study, at the time of infant discharge, and one month after infant discharge. Participants in both groups will be blinded to the educational content (intervention).

Participants/Inclusion and exclusion criteria

Inclusion criteria: baby born at least 30 to 36 weeks of pregnancy, have a baby with stable conditions, and have been hospitalized for at least three days. Additionally, the mothers should be married or cohabiting, have access to at least one smartphone. Exclusion criteria: Addict to alcohol or drugs by the woman or her husband. The participant who has a Psychiatric disorder under treatment (Self-reported).

Intervention groups

Mothers in the control group will receive routine hospital training, and mothers in the intervention group_ selected through a similar process implemented for the control group_ will receive the Farnam software and be trained to use the software.

Main outcome variables

Promoting Maternal Role Adaptation

General information

Reason for update

Acronym

MRA-FARNAM

IRCT registration information

IRCT registration number: **IRCT20250205064662N1**
Registration date: **2025-10-22, 1404/07/30**
Registration timing: **prospective**

Last update: **2025-10-22, 1404/07/30**
Update count: **0**

Registration date

2025-10-22, 1404/07/30

Registrant information

Name

Maryam Joghataei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 17 3235 7147

Email address

joghataeim394@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2026-01-21, 1404/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Use of an educational application based on smartphone for maternal role adaptation in women with preterm infants admitted to the Neonatal Intensive Care Unit of educational hospitals

Public title

Use of an educational application based on smartphone for maternal role adaptation in women with preterm infants admitted to the Neonatal Intensive Care Unit of educational hospitals

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The mother should be literate in Persian Have a preterm baby born at least 30 to 36 weeks of pregnancy Have a baby with stable conditions and have been hospitalized for at least three days The mothers should be married or cohabiting Have access to at least one smartphone Be capable of using a smartphone

Exclusion criteria:

Addict to alcohol or drugs by the woman or her husband The mother who has a history of preterm labor and being hospitalized in the neonatal intensive care units The mother who has a premature baby with a congenital anomaly or a disease that limits survival The mother who has a premature baby with grade 3 or 4 intraventricular hemorrhage The participant who has a Psychiatric disorder under treatment (Self-reported)

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Both the intervention and control groups will receive educational content related to preterm infants. The control group will receive routine hospital education, and the intervention group will receive smartphone-based educational content. Additionally, the control group will be sampled before the intervention group to prevent information leakage (i.e., use of the application).

Placebo

Not used

Assignment

Other

Other design features

The present study is an interventional study with two groups: control and intervention. Mothers who meet the inclusion criteria at educational hospitals in Gorgan, including Shahid Sayyad Shirazi and Taleghani hospitals, will be invited to participate in the study after the research objectives have been explained. Due to the importance of preventing information leakage between mothers in the intervention and control groups and accurately examining the effect of the intervention (i.e., using the educational application), participants will be conveniently sampled from the two hospitals in Gorgan with neonatal intensive care units. First, nine participants will be conveniently selected from each center for the control group, bringing the total number of participants from both centers to 18. Then, after a one-week interval from the discharge of the last individual enrolled in the control group, sampling for the intervention group will commence. Accordingly, nine participants will be conveniently selected from each hospital. Mothers in the control group will receive routine hospital education. Mothers in the intervention group will be selected through a similar process to the control group, provided with the Farname application, and individually instructed on how to use it. A demographic questionnaire will be provided in print by the researcher to all participants at the time of enrollment in the study and will be completed by them. The Maternal Role Attainment Questionnaire for mothers of premature infants and the DASS-21 questionnaire will be completed by both the control and intervention groups three times: at the time of enrollment in the study, at the time of infant discharge, and one month after infant discharge. The printed questionnaires will be provided by the researcher to the mothers at the time of enrollment and discharge and will be completed by them. One month after discharge, the questionnaires will be completed online by the participants.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Golestan University of medical Sciences

Street address

Gorgan, beginning of Shast Kola Road, Falsafi Higher Education Complex, Faculty of Nursing and Midwifery Building.

City

Gorgan

Province

Golestan

Postal code
4934174515
Approval date
2025-02-05, 1403/11/17
Ethics committee reference number
IR.GOUMS.REC.1403.421

Health conditions studied

1

Description of health condition studied
Maternal Role Adaptation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Maternal Role Adaptation Scale
Timepoint
Before the intervention, at discharge, and one month after the infant is discharged from the intensive care unit.
Method of measurement
Maternal Role Adaptation Scale in Neonatal Intensive Care Units (MRAS: NICU) (32 details)

Secondary outcomes

1

Description
Depression, Anxiety and Stress Scale
Timepoint
Before the intervention, at discharge, and one month after the infant is discharged from the intensive care unit.
Method of measurement
Short form 21-question questionnaire, Depression Anxiety and Stress Scale (DASS21)

Intervention groups

1

Description
Intervention group: Mothers of the intervention group will also be selected through a similar process that will be implemented for the control group, and the Farnam software will be provided to them, and the method of using the software will be individually instructed to them.
Category
Prevention

2

Description
Control group: Mothers in the control group will receive routine hospital training
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Taliqani Children's Educational-Therapeutic Center
Full name of responsible person
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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Name of organization / entity
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Roshandel@goums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan 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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Full name of responsible person
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Position
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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
Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some data, such as variables in demographic characteristics, can be shared.

When the data will become available and for how long

Access begins 6 months after results are published.

To whom data/document is available

every body

Under which criteria data/document could be used

Access is possible by sending an email.

From where data/document is obtainable

General Manager of the study

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

Access is possible by sending an email.

Comments