Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of game-based education about preterm infant care to mothers on their self-efficacy and happiness

Protocol summary

Study aim
Determining the effect of game-based premature baby care training to mothers on mothers' self-efficacy and happiness

Design
A non-randomized clinical trial with two control and intervention groups on 80 samples (mothers of premature babies)

Settings and conduct
The present study is a non-randomized controlled trial study with two control and intervention groups, which will be conducted in Kausar Hospital, Qazvin province. The target population in this study will include mothers with premature babies hospitalized in the neonatal intensive care unit of Kausar Qazvin Hospital. Sampling will be done by the accessible method and will be placed in two control and intervention groups in a non-random way. In the control group, the mothers receive the routine training of the department, which is provided by the nurses of the department in the form of lectures. In the intervention group, mothers receive game-based training during training sessions using playing cards and on a daily basis.

Participants/Inclusion and exclusion criteria
Entry requirements Mothers of premature babies Four days have passed since hospitalization No history of psychiatric disorders Non-entry conditions Unwillingness The baby has a specific disease Mother's non-attendance in training sessions for more than one session Early discharge of the baby

Intervention groups
In the control group, the mothers receive the routine training of the department, which is provided by the nurses of the department in the form of lectures. In the intervention group, mothers receive game-based training during training sessions using playing cards.

Main outcome variables
Self-efficacy of mothers of premature babies Happiness of mothers of premature babies

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231111060019N1**
Registration date: **2023-11-26, 1402/09/05**
Registration timing: **prospective**

Last update: **2023-11-26, 1402/09/05**
Update count: **0**

Registration date
2023-11-26, 1402/09/05

Registrant information
Name
Mona Habibi
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-12-23, 1402/10/02
Expected recruitment end date
2024-04-18, 1403/01/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Investigating the effect of game-based education about preterm infant care to mothers on their self-efficacy and happiness

Public title
Investigating the effect of game-based education about preterm infant care to mothers on their self-efficacy and happiness
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Mothers of babies whose babies were born prematurely (34-37 weeks). At least 4 days have passed since the baby was admitted Absence of history of known psychiatric disorders under treatment in the mother, based on individual statements and documents in the file
Exclusion criteria:
In case of unwillingness to participate in the study at any stage of the research A newborn suffering from a specific disease, including heart disorders or various syndromes Mother's non-attendance for more than one session in training sessions using playing cards Early discharge of the baby (earlier than 3 sessions of training using playing cards) from the neonatal intensive care unit
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
In order to prevent data contamination, first the data will be collected in the control group and after the discharge of the last baby in the control group, the intervention will begin.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of school of Nursing and Midwifery and Rehabilitation - Tehran Univers
Street address
Tawheed Square, Dr. Mirkhani St. (East Nusrat)
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Province
Tehran
Postal code
1419733171
Approval date
2023-10-07, 1402/07/15
Ethics committee reference number
IR.TUMS.FNM.REC.1402.136

Health conditions studied

1

Description of health condition studied
Self-efficacy and happiness of mothers of premature babies
ICD-10 code
P07.3
ICD-10 code description
Other preterm infants

Primary outcomes

1

Description
In this research, happiness means the score that the mother gets from the Oxford Happiness Questionnaire. This questionnaire has 29 items. The questions of the questionnaire are scored based on a four-point spectrum and measure the level of individual happiness. The theoretical basis of this questionnaire is Argyll and Crosland's definition of happiness; It is graded based on a four-point scale from 0 to 3. Thus, the highest score that the respondent can get in this scale is 87, which represents the highest level of happiness, and the lowest score of this scale is 0.
Timepoint
The Oxford happiness questionnaire will be completed by the mothers of both control and intervention groups before the start of the first game session, and the same questionnaires will be completed in the control and intervention groups after the intervention (at discharge).
Method of measurement
Oxford Happiness Questionnaire

2

Description
In this research, self-efficacy means the score that the mother gets from the questionnaire of mothers' self-efficacy in motherhood. This questionnaire has 20 items and each item is based on a Likert scale from completely agree to completely disagree. This questionnaire has four areas including: caring processes, stimulating behaviors, understanding behaviors and situational beliefs. The range of points is between 20 and 80.The

score is scored between 1 and 25 for low self-efficacy, 26 to 65 for medium self-efficacy, and 66 to 80 for high self-efficacy.

Timepoint

The self-efficacy questionnaire of mothers in mothering will be completed by the mothers of both control and intervention groups before the start of the first game session, and the same questionnaires will be completed in the control and intervention groups after the intervention (at discharge).

Method of measurement

Self-efficacy questionnaire of mothers in motherhood

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, mothers meeting the entry criteria received game-based training during training sessions using playing cards (each session for 60 minutes), daily and in groups (choosing mothers to be placed in groups based on homogeneity It will be the day of their hospitalization.) According to the researcher's plan, they will receive and the games will continue daily until the baby is discharged. Game-based training (infection control, hand washing, breastfeeding training, newborn care such as how to bathe, change diapers, warning signs) includes training in three ways: playing cards, station review, and baby care information pool. And in order to teach care in the form of a game, a number of colored cards are used. For each care or educational point, 4 colored cards are prepared (first card: name of care, second card: definition of care, third card: benefits and fourth card: warnings). The game is used.During the first session, first, the method and method of playing the game along with the goals will be presented to the mothers by the researcher along with questions and answers. The implementation of the game in the first session will be based on the fact that first the mothers are divided into two groups, then in each group the mothers face each other. are placed and the cards (green card: name of care, red card: definition of care, red card: benefits and red card: warning) are randomly distributed among mothers so that each mother is given 4 cards. (1 green card and 3 red cards). The first mother, who starts the game, keeps the green card among the cards in her hand until the end of the game, and among the red cards, she keeps those related to the desired care and the unrelated card. Gives to the next mother. The next mothers do the same thing. This game and the rotation of cards between the mothers continues until one of the mothers announces that she has succeeded in completing her care puzzle.Then this mother is obliged to fully explain the care to other mothers, and if the researcher confirms the accuracy of the information, the mother will receive a gold card. Then this mother is out of the game and must be present with other mothers until the end of the game. And the other mothers continue to play until one of them declares that he has completed the care puzzle and the process of checking the accuracy of the contents and receiving the golden card is repeated. The second session is when mothers participate in the station review session. A number of pink cards (which contain descriptive questions about care) are provided to mothers, and the mother chooses a card from among her cards and answers the question, if she answers correctly, she receives a golden card, and if Not knowing the correct answer, other mothers answer the question.In the third meeting, mothers participate in the information pool meeting. Mothers are randomly divided into two groups. In this program, all the cards that were taught on the first day are scattered on the table and the mothers of each group are asked to put the cards related to each care side by side within a period of 15 minutes. In order to increase competition and motivation, each group receives a golden card for the number of cares completed, and finally, in the next sessions, the games of the first to third sessions are repeated by the mothers. At the end of the games, the number of golden cards of the mothers is counted, and the first to third placers are awarded prizes of their choice (diapers, baby shampoo, baby creams and lotions, and other hygiene items needed by the baby, manual breast pump).

Category

Behavior

2

Description

Control group: In the control group, the mothers receive ward routine training (ward rules, infection control, hand washing, breastfeeding training, newborn care) which is provided individually by the ward nurses in the form of lectures and presentation of educational pamphlets.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar hospital

Full name of responsible person

Mona Habibi

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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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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mona Habibi
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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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

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

The access period starts 1 month after the results are published

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The data will be available to researchers working in academic and scientific institutions.

From where data/document is obtainable

To the researcher by email Principal investigator: Dr. Betul Pouraboli b.pouraboli@gmail.com Masters student: Mona Habibi mona.habibi1375@gmail.com

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

The applicant can access the information by submitting valid application documents through the relevant scientific institution.

Comments