Clinical Trial Protocol
Iranian Registry of Clinical Trials
15 Aug 2022

Exploring the Effects of Reflection on Cognitive Emotion Regulation and Resilience in Mothers of Premature Infants in NICUs

Protocol summary

Study aim
Determining the effect of reflection on cognitive emotion regulation and resilience of mothers of premature infants in neonatal intensive care unit

Design
The present study is a non-random clinical trial of two groups of intervention and control

Settings and conduct
In this study, mothers with preterm infants who were admitted to the neonatal intensive care unit of Bahonar and Kamali hospitals of Alborz University of Medical Sciences

Participants/Inclusion and exclusion criteria
Having a premature baby aged 28 to 35 weeks without anomalies admitted to the neonatal intensive care unit for at least 15 days • Desire and Satisfaction to participate in the study Being literate to read and write or use cyberspace to send voices about rethinking Lack of mental illness detected Do not misuse drugs or drugs Lack of hospitalization of a newborn or other child No baby death experience

Intervention groups
Measures of two variables: cognitive regulation of excitement and resilience of mothers, using Garmfsky Cognitive Custody Regulation (2001) and the Conner and Davidson (2003) Relief Scale At first: - Sampling control group and after 48 hours measuring two variables - After 15, the two variables are measured in the control group - In the intervention group, two variables were measured after 48 hours - Day 4-6 Training and rehearsal exercises - 7 to 15 days, mothers are asked to write a rehearsal or record each day. - Day 15 Measure two variables

Main outcome variables
Empower mothers with premature infants in the care of the newborn Improve your thinking and thinking skills, which increases your excitement and resilience skills The purpose of this study is to find effective ways of empowerment, in the context of existing economic and social culture, a way to achieve the best goals for the care of infants and children.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20180925041132N1
Registration date: 2019-01-23, 1397/11/03
Registration timing: retrospective

Last update: 2019-01-23, 1397/11/03
Update count: 0
Registration date
2019-01-23, 1397/11/03
Registrant information
Name
Fatemeh Khoshnavay Fomani
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-09-23, 1397/07/01
Expected recruitment end date
2018-11-22, 1397/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
Scientific title
Exploring the Effects of Reflection on Cognitive Emotion Regulation and Resilience in Mothers of Premature Infants in NICUs

Public title
Refresher training for mothers of premature infants in the neonatal intensive care unit and then examining the resilience and cognitive adjustment of their emotions.

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having a premature baby aged 28 to 35 weeks without anomalies admitted to the neonatal intensive care unit for at least 15 days Willingness and consent to participate in the study Having reading and writing skills or using cyberspace to send voices about rethinking The lack of mental illness is recognized to be treated at the time of the study No substance abuse or drug abuse Not having a baby or other child who is admitted to hospital at the time of the study or has a history of admission to infants’ care units. Lack of death of a baby or one of the children Participate in all reflection exercises and training sessions (every half to one flexible hour: first and second sessions, training sessions, and third sessions of practice and feedback to mothers.)

Exclusion criteria:
Baby death Failure to attend training and training sessions (taking into account that the company is required in all three training sessions and other training sessions, samples will be excluded from the study, even if they do not attend a meeting). Mother’s unwillingness to continue attending sessions or rehearsing exercises Transfer to a new department or clearance before the fifteenth day of hospitalization

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator’s opinion)
Randomized

Randomization description
The present study is a non-random clinical trial of two groups of intervention and control.

Blinding (investigator’s opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Faculty of Nursing, Tehran University of Medical Sciences, Tohid Crossroads

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2018-07-04, 1397/04/13

Ethics committee reference number
R.TUMS.FNM.REC.1397.043

Health conditions studied

1

Description of health condition studied
Cognitive emotion regulation and resilience of mothers in preterm infants

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The primary outcome of cognitive emotion regulation for premature mothers in the neonatal intensive care unit is the score of each strategy by adding scores given to each of the phrases forming the strategy and can range from 4 to 20 (because each The component consists of 4 items) and the total score is in the range of 36 to 180. The secondary consequence of maternal resilience is a score above 50 indicating individuals with resiliency, and the higher the score is greater than 50, the same will be the same as the intensity of the person’s resonance, and vice versa.

Timepoint
At first, control group sampling is performed, then after two weeks the sampling interval of the intervention group is performed and after 48 hours after acceptance, two variables of cognitive regulation of excitement and resilience are taken and from day 4 to 6 Reflection exercises are conducted on the intervention group, and from day 7 to 15, mothers are asked to perform a reflaction every day in writing or recording, and the researcher will make the necessary recommendations.
Method of measurement
Measuring two variables, cognitive emotion regulation and resilience of mothers, by using the questionnaire "cognitive emotion regulation Garnfsky 2001" and "Connor and Davidson Resilience Scale (2003)" will be performed.

Secondary outcomes
empty

Intervention groups

1
Description
Intervention group: Nursing mothers are in the intensive care unit of infants. On the third day of admission, the questionnaires are answered by the mothers, and then the reflection training is given to them within three days of the day, then from day one 7 to 14 mothers have recited written or recorded audio or internet and the researcher gave them the necessary feedback, and on the 15th day, the questionnaires were returned to the mothers of the intervention group.

Category
Behavior

2
Description
Control group: In the control group, the third day of the questionnaires are answered by the mothers of the control group and then on the 15th day the questionnaires will be replenished by the control group.

Category
Behavior

Recruitment centers

1
Recruitment center
Name of recruitment center
Kamali and Bahonar Hospital , Alborz Province
Full name of responsible person
Fateme khoshnava fomany
Street address
Tehran University of Medical Sciences,Tohid Crossroads
City
Tehran
Province
Tehran
Postal code
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Email
f-khoshnava@sina.tums.ac.ir

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
dr.Mohammad Ali Sahraeian
Street address
School of Nursing Midwifery, Tehran University of Medical Sciences Nosrat st. Tohid sq. Tehran I.IRAN
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+98 21 6692 7171
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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
Fateme khoshnava fomany
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Faculty of Nursing, Tehran University of Medical Sciences,Tohid Crossroads
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Province
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Postal code
Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
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Assistant Professor
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Person responsible for updating data

Contact
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Tehran University of Medical Sciences
Full name of responsible person
Farzaneh khoshakhlagh
Position
student
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Bachelor
Other areas of specialty/work
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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Study protocols and intervention results will be published as articles.

When the data will become available and for how long
6 months after completion of the study

To whom data/document is available
Officials of Tehran University of Medical Sciences

Under which criteria data/document could be used
The study protocol and the intervention results will be applicable to future studies. In this case, it is required to obtain a permit from the owner of the research project and the authorities of the Tehran University of Medical Sciences.

From where data/document is obtainable
Dr. Fatemeh Khoshnavay Fomani f-khoshnav@tums.ac.ir

What processes are involved for a request to access data/document
Sending a request will be made by email to the project manager. The project's executive officer will publish information upon obtaining a university license and study styles.

Comments