Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

effect of emotion regulation training based on the Grass method on mothers' rumination and bonding with preterm infants hospitalized in the neonatal intensive care unit in

Protocol summary

Study aim
Determining the effect of emotion regulation training based on the Gross model on mothers' rumination and bonding with premature babies admitted to the neonatal intensive care unit in the gorgan teaching hospitals in 1403

Design
Among the mothers of premature babies hospitalized in the neonatal intensive care unit who had the conditions to participate in the study, 60 people were selected by non-probability sampling in a simple random manner. Random allocation was also done using the table of random numbers, in such a way that odd numbers were placed in the control group (30 people) and even numbers were placed in the test group (30 people).

Settings and conduct
classic experimental research. the demographic information form that includes information about the mother and information about the baby complete after the baby will be admitted After that, the rumination questionnaire of Nolen and Maru (1989) and the questionnaire for assessing mother-infant bond after delivery by Brockington et al. (2006) are distributed by both test and control groups under the same conditions in the pre, then the educational program will be implemented in the test group by the researcher during 8 sessions of 90 minutes per day face to face and individually.

Participants/Inclusion and exclusion criteria
literacy age at least18 for mother Gestational age less than 37 weeks neonate must not be twins Hospitalization of the baby according to the doctor's order for at least 8 days Willingness to participate in the study No history of abnormal or premature birth in the mother Non-use of drugs by the mother The absence of the baby from certain congenital diseases, including heart disease and severe syndromes

Intervention groups
All mothers of premature babies hospitalized in the intensive care unit

Main outcome variables
Rumination of the mother of a premature baby bonding the mother with a premature baby

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240617062154N1**
Registration date: **2024-06-26, 1403/04/06**
Registration timing: **registered_while_recruiting**

Last update: **2024-06-26, 1403/04/06**
Update count: **0**

Registration date
2024-06-26, 1403/04/06

Registrant information

Name
negar shafiei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 17 3233 2734

Email address
ngrshafieii@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-06-21, 1403/04/01

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effect of emotion regulation training based on the Grass method on mothers' rumination and bonding with preterm infants hospitalized in the neonatal intensive care unit in

Public title

effect of emotion regulation training based on the Grass method on mothers' rumination and bonding with preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

having the premature infant who hospitalized in neonatal intensive care unit Hospitalization of the baby according to the doctor's order for at least 8 days literacy the neonate must not be twins Gestational age less than 37 weeks Willingness to participate in the study

Exclusion criteria:

Not having a history of abnormal or premature birth in the mother mother has not to be drug users The absence of the baby from a specific congenital disease, including heart disease and severe syndromes

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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 Golestan University of Medical Sciences

Street address

aryana building/shahrivar street/edalat 28 av

City

Gorgan

Province

Golestan

Postal code

4916616469

Approval date

2024-04-30, 1403/02/11

Ethics committee reference number

IR.GOUMS.REC.1403.083

Health conditions studied

1

Description of health condition studied

effect of emotion regulation training based on the Grass method on mothers' rumination and bonding with preterm infants hospitalized in the neonatal intensive care unit

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Rumination of mothers of premature babies-the bonding of mothers and infant

Timepoint

Before the start of the intervention - after the completion of the intervention

Method of measurement

Rumination Questionnaire of Nolen and Maru (1989) - Maternal and Infant Bonding Questionnaire of Brockington et al. (2006)

Secondary outcomes

1

Description

Rumination score

Timepoint

Before starting the intervention_ after ending the intervention

Method of measurement

Nolen Hoeksma and Maro's 22-item questionnaire

2

Description

Mother and baby bond

Timepoint
Before starting the intervention_ after ending the intervention
Method of measurement
Brockington's 25-question mother-infant bonding questionnaire

Intervention groups

1

Description
Intervention group: Mothers of hospitalized premature babies
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
neonatal intensive care unit in taleghani hospital
Full name of responsible person
Negar shafiei
Street address
taleghani hospital.janbazan blv
City
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Province
Golestan
Postal code
4916668198
Phone
+98 17 3222 7720
Fax
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Email
taleghanilib@goums.ac.ir

2

Recruitment center
Name of recruitment center
neonatal intensive care unit in sayad shirazi hospital
Full name of responsible person
negar shafiei
Street address
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Email
Sayyadlib@goums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
negar shafiei
Street address
azad university of aliabad katul . university blv
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aliabad katool
Province
Golestan
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9345149417
Phone
+98 17 3422 2300
Fax
+98 17 3422 5673
Email
info@aliabadiau.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
private
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
nafiseh hekmatipur
Position
assistant professor
Latest degree
Ph.D.
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Person responsible for updating data

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Master student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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City
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4916616469

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Email
Ngrshafieii@gmail.com

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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable