

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 least 18 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

ngrshafiei@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

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Fax

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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

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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.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Nafiseh hekmatipur

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Professeur assistant

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Person responsible for updating data

Contact

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Full name of responsible person

Negar shafiei

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Master student

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Email

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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

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