Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Implementing a Positive Group Thinking Program on the Anxiety and Attachment of Mothers of Premature Infants Hospitalized in Neonatal Intensive Care Unit

Protocol summary

Study aim

Determining and comparing the anxiety and attachment of mothers of premature infants admitted to the neonatal intensive care unit before and after the intervention in the control and intervention groups

Design

A quasi-experimental clinical trial with two control and intervention groups will be performed on 72 mothers of premature infants in two separate hospitals by available sampling.

Settings and conduct

Mothers with premature infants with a gestational age of less than 37 weeks will be hospitalized in the neonatal intensive care unit of Imam Reza (AS) and Mohammad Kermanshahi hospitals in Kermanshah, which will meet the inclusion criteria in this study. Spielberger anxiety and postpartum attachment will be used between mother and baby. Then, a course of group positive thinking exercises will be prepared for the intervention group in ten one-hour sessions for ten days. In the control group, there will be routine hospital care. Upon completion of the training, post-test will be performed for both groups.

Participants/Inclusion and exclusion criteria

Mothers with premature infants less than 37 weeks gestational age admitted to neonatal intensive care unit with inclusion criteria (maternal consent to participate in the study;mothers with preterm infants less than 37weeks; neonatal hospitalization for at least10 days in the ward;not passing the same course;no chronic illness of the mother such as depression and anxiety;no history of taking sedatives and psychotropic drugs before pregnancy; no history of maternal hospitalization; not previous attending in studies in the field of positive thinking.

Intervention groups

Group positive thinking exercises will be prepared for the intervention group in ten one-hour sessions for ten days. The control group receives routine care without any intervention.

Main outcome variables

Anxiety and attachment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210108049965N1**
Registration date: **2021-01-28, 1399/11/09**
Registration timing: **prospective**

Last update: **2021-01-28, 1399/11/09**
Update count: **0**

Registration date

2021-01-28, 1399/11/09

Registrant information

Name

Venus Boochani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 4372 3293

Email address

vboochani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Implementing a Positive Group Thinking Program on the Anxiety and Attachment of Mothers of Premature Infants Hospitalized in Neonatal Intensive Care Unit

Public title
The Effect of Implementing a Positive Group Thinking Program on the Anxiety and Attachment
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Maternal consent to participate in the study Mothers with premature babies less than 37 weeks Infant hospitalization for at least 10 days in the ward Do not pass the same course No chronic illness of the mother such as depression and anxiety (disturbing) No history of taking sedatives and psychotropic drugs before pregnancy (confounder) No history of hospitalization of the mother in a mental hospital No chronic underlying neonatal disease and abnormalities Not previous study in the field of positive thinking (distorter)
Exclusion criteria:
Dissatisfaction with enrollment
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee Of Tehran University Of Medical Science
Street address
Qods Ave, Keshavarz Blv, Tehran town
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2020-02-18, 1398/11/29
Ethics committee reference number
IR.TUMS.FNM.REC.1398.200

Health conditions studied

1

Description of health condition studied
Anxiety of mothers of premature infants in neonatal intensive care unit
ICD-10 code
P00.9
ICD-10 code description
Encounter for newborn, infant and child health examinations

2

Description of health condition studied
attachment of mothers of premature infants in neonatal intensive care unit
ICD-10 code
P00.9
ICD-10 code description
Newborn (suspected to be) affected by unspecified maternal condition

Primary outcomes

1

Description
Anxiety
Timepoint
Before the intervention and immediately after the end of the intervention
Method of measurement
Spielberger Anxiety Questionnaire

Secondary outcomes

1

Description
Attachment
Timepoint

Before the intervention and immediately after the end of the intervention

Method of measurement

Maternal Postnatal Attachment Scale(MPAS)

Intervention groups

1

Description

Intervention group: Includes 36 peopleOne of the mothers of premature infants is hospitalized who, after obtaining informed consent, enter an intervention to receive positive thinking training by a facilitator and a psychologist.The training will be based on Seligman's book on positive thinking and will be given to mothers in ten one-hour sessions for ten days.

Category

Behavior

2

Description

Control group: Includes 36 mothers of premature infants hospitalized who enter the study in an available manner and after obtaining informed consent. This group receives routine care without any intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Venus boochani

Street address

Parastar Blvd., Kermanshah Town

City

Kermanshah

Province

Kermanshah

Postal code

6715936465

Phone

+98 83 3427 6301

Email

Vboochani@gmail.com

2

Recruitment center

Name of recruitment center

Mohamad Kermanshahi Hospital

Full name of responsible person

Venus boochani

Street address

Helal Ahmar Intersection, Kermanshah Town

City

Kermanshah

Province

Kermanshah

Postal code

6715934465

Phone

+98 83 3721 8202

Email

vboochani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mehrnaz Geranmaye

Street address

Tohid Square, East Nusrat Street

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4000

Email

fnm@tums.ac.ir

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

Venus Boochani

Position

Master Of Neonatal Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery
Street address
Tehran School of Nursing, Midwifery, Dr. Mirkhani Street, Tohid Square
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4000
Fax
Email
vboochani@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Venus Boochani
Position
Master Of Neonatal Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Tehran School of Nursing, Midwifery, Dr. Mirkhani Street, Tohid Square
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4000
Fax
Email
vboochani@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Venus Boochani
Position
Master Of Neonatal Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Tehran School of Nursing, Midwifery, Dr. Mirkhani Street, Tohid Square
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4000
Fax
Email
vboochani@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the request of intervention groups
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available