Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of expressive writing on postpartum depression and stress of mothers with preterm infants hospitalized in the neonatal intensive care unite

Protocol summary

Study aim

Determination and comparison of average score of postpartum depression of mothers with preterm infants hospitalized in NICU between two intervention and control group before and after doing intervention Determination and comparison of average score of postpartum stress of mothers with preterm infants hospitalized in NICU between two intervention and control group before and after doing intervention

Design

In this study, 96 mothers with the preterm infants less than 37 weeks which have the conditions of the study and hospitalized for more than three days in the neonatal intensive care unit (NICU) of Uromieh Motahary Educational Center, are chosen. Mothers randomly assigned into two intervention and control groups and one code is allocated to each participant.

Settings and conduct

In this study, the effect of the expressive writing on postpartum depression and stress of mothers with preterm infants hospitalized in the neonatal intensive care unit (NICU) of Uromieh Motahary Educational Center will be evaluated. Postpartum depression in the control and intervention group will be measured by using Edinburghs'questionnaire on the third and 10th day, one and three months after the admission of the infant to the NICU and mothers' stress in both groups will be measured by using Parents' stress in the NICU questionnaire On the third and 10th day after the admission and Cohen' perceived stress- 14 items questionnaire in one and three months after the admission of the infant in the NICU.

Participants/Inclusion and exclusion criteria

Inclusion criteria: attending the NICU at least three days a week.

Intervention groups

Mothers in the intervention group will be asked to write their deepest emotions and thoughts about their infants' birth and hospitalized in a private place, regardless of grammar and sentence structure, three times for 15 minutes each time. The duration of the intervention will be once a day from third to 10th day of hospitalized to the NICU. Mothers in the control group will receive the routine care.

Main outcome variables

postpartum depression؛ postpartum stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170726035328N2**
Registration date: **2018-02-20, 1396/12/01**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-20, 1396/12/01**
Update count: **0**

Registration date

2018-02-20, 1396/12/01

Registrant information

Name
Naemeh VatankhahAlamdary
Name of organization / entity
Uromieh University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date
2017-07-25, 1396/05/03
Expected recruitment end date
2018-03-21, 1397/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of expressive writing on postpartum depression and stress of mothers with preterm infants hospitalized in the neonatal intensive care unite

Public title
Postpartum depression and stress of mothers with preterm infants
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Having at least a low secondary education Attendance at the NICU for at least three days a week
Exclusion criteria:
previous record of newborns admitted to the neonatal intensive care unite (NICU) acute stressful conditions, such as death of loved ones within the past six months history of depression and hospitalization and antidepressant use within the past six month history of psychoactive use and lack of drug addiction during the past six months genetic disease in the newborn
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
A total number of 96 envelopes containing number one or two was designed for mothers to choose from. mothers who received number one were assigned to intervention group (48 mothers) and the others were assigned to control group (48 mothers).
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Uromieh University of Medical Sciences
Street address
Jahad Street، Urmia University of Medical Sciences, Uromieh
City
Urmia
Province
West Azarbaijan
Postal code
57147-83734
Approval date
2017-06-07, 1396/03/17
Ethics committee reference number
IR.UMSU.rec.1396.103

Health conditions studied

1

Description of health condition studied
postpartum depression and stress
ICD-10 code
F53- F43.1
ICD-10 code description
Mental and behavioural disorders associated with the puerperium, not elsewhere classified - Post-traumatic stress disorder

Primary outcomes

1

Description
postpartum depression
Timepoint
The third day, 10th day, one and three months after the admission of the baby to the neonatal intensive care unite
Method of measurement
Edinburgh questionnaire

2

Description
Stress of mothers' with preterm infants
Timepoint
The third day, 10th day, one and three months after the admission of the baby to the neonatal intensive care unite
Method of measurement
Parenatal stressor scale for neonatal intensive care units

and Cohen' perceived Stress - 14 items questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: Mothers will be asked to write in their own private place without attention to grammar about their deepest emotions and their work on the inconvenient event.Writes three times a week and each time for 15 minutes. The period from the third day until the tenth day will be admitted to NICU.
Category
N/A

2

Description
Control group: The control group will receive the routine care.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Motahary Educational Center
Full name of responsible person
Naemeh VatankhahAlamdary
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Ayatollah Kashani Ave: Motahari Educational Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Iraj Mohebbi
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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
Oroumia 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
Assistance for Research and Technology of Uromieh University of Medical Sciences
Full name of responsible person
Dr. Iraj Mohebbi
Position
Assistant for Research and Technology
Latest degree
Specialist
Other areas of specialty/work
Occupational Medicine
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Urmia University of Medical Sciences

Full name of responsible person
Soheila Rabeepoor

Position
Faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Masters student

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Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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

Title and more details about the data/document
Because the paper out from the thesis will probably be published until July 2018

When the data will become available and for how long
I have not decided yet - its release plan is still unclear

To whom data/document is available
I have not decided yet - its release plan is still unclear

Under which criteria data/document could be used
I have not decided yet - its release plan is still unclear

From where data/document is obtainable
I have not decided yet - its release plan is still unclear

What processes are involved for a request to access data/document
I have not decided yet - its release plan is still unclear

Comments