

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of expressive writing on posttraumatic stress disorder and hopelessness in mothers with premature neonate hospitalized in Neonatal Intensive Care Unit

Protocol summary

Study aim

The effect of expressive writing on PTSD and hopelessness in mothers with premature neonate

Design

A non-randomized clinical trial with control and intervention groups on 70 mothers with premature babies

Settings and conduct

Location: the NICU of Esfahan Shahid Beheshti Hospital. The demographic information questionnaire of the mother and the baby will be completed during the first week after delivery. Then during the fourth week using the PPQ and Beck hopelessness questionnaire; Mothers with a score higher than six from the PPQ and any score from the Beck Questionnaire (because it does not have a cutoff point) will be included in the study. The expressive writing and how to write it for the intervention group is explained and they are asked to write in a private and quiet place, regardless of grammar about their deepest feelings and thoughts regarding the birth and hospitalization of their baby in the NICU . Writing three times a week (every other day) and each time will be for at least 15 minutes. The control group will only receive routine care. Then, after two to four weeks , PPQ and Beck's questionnaire will be completed again by the mothers of the two groups and they will be compared with before the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria:18-year-old,literate,with premature babies, a score higher than six in the PPQ Exclusion criteria: history of suffering from PTSD, addiction and hospitalization of the baby for less than ten days

Intervention groups

In order to prevent the exchange of information, first all mothers who meet the entry criteria will be selected as the control group. After the discharge of the control group, sampling of the intervention group will begin. The

control group does not receive any intervention and the intervention group will write expressive writing.

Main outcome variables

Posttraumatic stress disorder, Hopelessness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230305057623N1**

Registration date: **2023-04-15, 1402/01/26**

Registration timing: **prospective**

Last update: **2023-04-15, 1402/01/26**

Update count: **0**

Registration date

2023-04-15, 1402/01/26

Registrant information

Name

Behnaz Soltanpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3651 8095

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-04, 1402/02/14

Expected recruitment end date

2023-09-05, 1402/06/14

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of expressive writing on posttraumatic stress disorder and hopelessness in mothers with premature neonate hospitalized in Neonatal Intensive Care Unit

Public title
The effect of expressive writing on stress and hopelessness in mothers with premature neonate

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Mothers 18 years and older if they want to participate in the research Being literate (having at least a high school education) Iranian and fluent in Persian language Mothers with premature neonate less than 37 weeks Obtaining a score higher than six from the PPQ questionnaire Not having a hearing problem
Exclusion criteria:
 History of post-traumatic stress disorder Drug addiction, use of anti-anxiety and depression or psychotropic drugs up to one month before sampling Existence of acute stressful situations during the last six months A history of being in the NICU and having a premature baby Mothers' use of other stress reduction methods Taking care of the baby by other family members other than the mother Genetic disease in the baby Hospitalization of the baby less than ten days

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Not randomized

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 Yazd University of Medical Sciences

Street address

Professor Hesabi Boulevard, Safaeiye

City

Yazd

Province

Yazd

Postal code

8915813135

Approval date

2023-02-28, 1401/12/09

Ethics committee reference number

IR.SSU.REC.1401.103

Health conditions studied

1

Description of health condition studied

posttraumatic stress disorder

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD)

2

Description of health condition studied

Hopelessness

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Post-traumatic stress disorder

Timepoint

During the fourth week after birth (first stage) and after two to four weeks of the first stage

Method of measurement

Perinatal Posttraumatic Stress Disorder Questionnaire

2

Description

hopelessness

Timepoint

During the fourth week after birth (first stage) and after two to four weeks of the first stage

Method of measurement

Beck Hopelessness Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the mothers in the intervention group are asked to write in a private and quiet place, regardless of grammar about their deepest feelings and thoughts regarding the birth and hospitalization of their baby in the intensive care unit.

Category

Other

2

Description

Control group: There is no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Behnaz Soltanpour

Street address

Shahid Motahari Ave

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi Abarghuei

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Behnaz Soltanpour

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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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

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