Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Letter-Writing on Resilience and Post-Traumatic Growth Among Mothers of Preterm Infants Hospitalized in the Neonatal Intensive Care Unit

Protocol summary

Study aim

To determine and compare level of resilience and post-traumatic growth before, immediately after, and four weeks after the letter writing in intervention and control groups

Design

Randomised trial with using a block randomization method with a block size of 4. Based on previous studies, 30 participants will be recruited in each group.

Settings and conduct

Vali-e-asr Hospital, Neonatal Intensive Care Unit .The intervention group receives the letter-writing intervention from the third to the tenth day of hospitalization, while the control group receives routine care. The questionnaires are completed again on the tenth day. Blinding: The analyst is unaware of the participants' group allocation

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mothers who are literate in Persian being able to read and write or to communicate in Persian, Willingness to participate in the study and provision of written informed consent, The infant's first hospitalization Mothers of preterm infants with a gestational age of 34 weeks or less Exclusion criteria: Maternal diagnosis of pathological depression or a self-reported history of psychiatric disorders, Concurrent participation in other intervention programs or research studies

Intervention groups

Intervention Group: On the second day of hospitalization, and the researcher will instruct them on the letter-writing process. From the third to the tenth day of hospitalization, the mothers will write a letter to their infant every day for eight days in a quiet environment. Then the questionnaires will be completed again. Control Group: The mothers in the control group will receive routine care.

Main outcome variables

Maternal resilience, using the 10-item Connor–Davidson Resilience Scale ؛ Maternal post-traumatic growth, using the Post-Traumatic Growth Inventory developed by Tedeschi and Calhoun

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241225064162N4**
Registration date: **2026-07-31, 1405/05/09**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-31, 1405/05/09**
Update count: **0**

Registration date

2026-07-31, 1405/05/09

Registrant information

Name

Saleheh Tajalli

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2027-02-19, 1405/11/30

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

Scientific title
The Effect of Letter-Writing on Resilience and Post-Traumatic Growth Among Mothers of Preterm Infants Hospitalized in the Neonatal Intensive Care Unit

Public title
The Effect of Letter-Writing on Resilience and Post-Traumatic Growth Among Mothers of Preterm Infants Hospitalized in the Neonatal Intensive Care Unit
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Mothers who are literate in Persian (able to read and write) or able to communicate in Persian Willingness to participate in the study and provision of written informed consent This is the infant’s first hospitalization Mothers of preterm infants with a gestational age of 34 weeks or less, born by either cesarean section or vaginal delivery, who are admitted to the Neonatal Intensive Care Unit
Exclusion criteria:
Maternal diagnosis of pathological depression or a self-reported history of psychiatric disorders Concurrent participation in other intervention programs or research studies
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, block randomization will be used to allocate participants to the intervention and control groups. Participants will be conveniently selected from the study site, and then block randomization will be performed to minimize bias and ensure balance in the number of individuals in each group. Blocks with a fixed size (e.g., 4 participants) will be created, and the allocation order within each block will be randomly determined using a random number table. In the first phase, participants will be allocated to the control group, and after completing this group, randomization for the intervention group will be conducted.
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
Joint Institutional Ethics Committee of the School of Nursing and Midwifery and the School of Rehabi
Street address
Mirkhani Ave.,Nosrat St.,Tehran,Iran
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2026-07-10, 1405/04/19
Ethics committee reference number
IR.TUMS.FNM.REC.1405.066

Health conditions studied

1

Description of health condition studied
The Effect of Letter-Writing on Resilience and Post-Traumatic Growth Among Mothers of Preterm Infants Hospitalized in the Neonatal Intensive Care Unit
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
To determine and compare level of resilience and post-traumatic growth before, immediately after, and four weeks after the letter writing in intervention and control groups
Timepoint
To determine and compare level of resilience and post-traumatic growth before, immediately after, and four weeks after the letter writing in intervention and control groups
Method of measurement
Maternal resilience, using the 10-item Connor–Davidson Resilience Scale ؛ Maternal post-traumatic growth, using the Post-Traumatic Growth Inventory developed by Tedeschi and Calhoun

Secondary outcomes

1

Description
To determine and compare level of resilience and post-traumatic growth before, immediately after, and four weeks after the letter writing in intervention group compared to control group
Timepoint
To determine and compare level of resilience and post-traumatic growth before, immediately after, and four weeks after the letter writing in intervention group compared to control group
Method of measurement
Maternal resilience, using the 10-item Connor–Davidson Resilience Scale ؛ Maternal post-traumatic growth, using the Post-Traumatic Growth Inventory developed by Tedeschi and Calhoun

Intervention groups

1

Description
Intervention group :To implement the intervention, on the second day of hospitalization, a personalized notebook will be provided to each mother in the intervention group, and the researcher will teach the mothers how to write the letters. The mothers will then be asked to write a letter to their child every day for eight days, from the third to the tenth day of hospitalization, in a quiet environment of their choice (which may be the mothers' room, at the infant's bedside, or at home). The letters may be written at any time of the day or night, according to the mother's preference; however, mothers will be encouraged to write when they are feeling better. The content of the letters may include an expression of feelings, a description of events, or hopes and wishes. After completion of the intervention, with the mothers' consent, a copy of the letters will be made, and the notebook will be given to the mothers as a keepsake. The mothers will then be asked to complete the questionnaires again.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali-e-Asr hospital ,Neonatal Intensive Care Unit
Full name of responsible person
دکتر صالحه تجلی
Street address
Mirkhani Ave.,Nosrat St.,Tehran,Iran
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P95J+WMC
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Email
saleheh_tajalli@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
Street address
Tehran University of Medical Sciences, at the corner of Qods street, Keshavarz Blvd.
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Postal code
1417653761
Phone
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Email
vcr@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
Saleheh Tajalli
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery

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Person responsible for updating data

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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