Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A Comparison of the effect of expressive writing and music therapy on distress tolerance and maternal role adaptation in mothers of preterm Infants hospitalized in neonatal intensive care units of hospitals affiliated with Shiraz University of Medical Sciences, 2025-2026

Protocol summary

Study aim
Comparison of the effectiveness of expressive writing and music therapy on distress tolerance and maternal role adaptation in mothers of premature infants

Design
Randomized clinical trial with control group, 2 intervention groups and 1 control, unblinded, on 90 patients. G*Power3 software was used for randomization.

Settings and conduct
This randomized controlled clinical trial compares expressive writing and music therapy on distress tolerance and maternal role adaptation in 90 mothers of preterm infants in Namazi and Hafez Hospitals, Shiraz. Participants are assigned to three groups and receive interventions over six 15–20 minute sessions for two weeks. Data are collected using demographic questionnaires, the Simons and Gaher Distress Tolerance Scale, and the Heydarpour et al. Maternal Role Adaptation Instrument at three time points and analyzed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: -Maternal age above 18 years. -Preterm birth (less than 37 weeks of gestation). -Minimum level of maternal literacy sufficient for completing the questionnaires. -Absence of psychiatric disorders or use of related psychotropic medications (self-reported), and absence of chronic physical illnesses. -Singleton pregnancy. -No history of previous preterm delivery. -Hospital stay of at least 14 days. Exclusion criteria: -Mothers other than those in the neonatal ward -Mothers of infants admitted to other hospitals

Intervention groups
Expressive writing group: Mothers in this group write down their thoughts and feelings using paper and pen. Music therapy group: Mothers in this group listen to 6 pieces of music selected by a music specialist using headphones. Control group: They receive routine ward care without any additional intervention.

Main outcome variables
Peace of mind and life of mothers of preterm infants; maternal stress and anxiety; maternal care for their infant in the ward

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260814070641N1**
Registration date: **2026-10-13, 1405/07/21**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-13, 1405/07/21**
Update count: **0**

Registration date
2026-10-13, 1405/07/21

Registrant information

Name
Zohreh Dehghan Harati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3324 4233

Email address
nursezohrehdh2002@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-11, 1405/07/19

Expected recruitment end date
2027-01-09, 1405/10/19
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparison of the effect of expressive writing and music therapy on distress tolerance and maternal role adaptation in mothers of preterm Infants hospitalized in neonatal intensive care units of hospitals affiliated with Shiraz University of Medical Sciences, 2025-2026

Public title
A Comparison of the effect of expressive writing and music therapy on distress tolerance and maternal role adaptation
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Maternal age over 18 years Preterm birth (gestational age < 37 weeks) Minimum literacy level of the mother to complete the questionnaires (ability to read and write) No history of psychiatric disorders or use of related psychiatric medications (based on self-report), and no chronic physical illnesses Singleton pregnancy No prior history of preterm delivery Hospitalization of the infant for at least 14 days
Exclusion criteria:
Mothers other than those in the neonatal ward Mothers of infants admitted to other hospitals
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomly assign samples to the two test and control groups, a random allocation method using permuted blocks with a block size of 4 was used. Accordingly, 19 four-unit blocks were designed to maintain balance in the number of samples in each group and reduce the probability of bias. Randomization procedure in the software: After entering the website https://www.sealedenvelope.com/simple-randomiser, the number of groups was set to 2 (test and control), the allocation ratio to 1:1, the randomization method to "Permuted blocks," and the block size to 4. Then, by defining 19 blocks, the allocation list was automatically generated and downloaded by the software. This software uses a cryptographically secure random number generator, which minimizes the predictability of the allocation sequence. The order of group allocation in each block was determined randomly, and the final allocation list was attached to the proposal as an appendix. This method allows the researcher to maintain relative balance between the groups at all stages throughout the sampling process.
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 Shiraz University of Medical Sciences
Street address
Namazi Square - Hazrat Fatemeh (S) School of Nursing and Midwifery
City
shiraz
Province
Fars
Postal code
7193613119
Approval date
2026-07-04, 1405/04/13
Ethics committee reference number
IR.SUMS.NUMIMG.REC.1405.042

Health conditions studied

1

Description of health condition studied
distress tolerance
ICD-10 code
ICD-10 code description

2

Description of health condition studied
maternal role adaptation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Mean score of distress tolerance based on the Distress Tolerance Scale (DTS) by Simons and Gaher
Timepoint
Measurement of distress tolerance score at baseline, immediately after the intervention, and one week after the intervention
Method of measurement
Simons & Gaher Distress Tolerance Scale

2

Description
Mean score of maternal role adaptation based on the Maternal Role Adaptation Questionnaire in Mothers of Preterm Infants (Heydarpour et al., 2016)
Timepoint
Measurement of maternal role adaptation score at baseline, immediately after the intervention, and one week after the intervention
Method of measurement
Maternal Role Adaptation Questionnaire in Mothers of Preterm Infants (Heydarpour et al., 2016)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group : expressive writing - Participants wrote about their thoughts, mental ruminations, concerns, and related content using paper and pen provided by the researcher to the mothers in this group. This intervention consisted of six 15- to 20-minute sessions conducted over a period of two weeks (every other day). The sessions were held in a quiet, private room to facilitate greater concentration and relaxation for the mothers.
Category
Behavior

2

Description
The intervention group received a music therapy protocol, in which mothers listened to six musical pieces selected by a music specialist using headphones in a quiet, private room. The pieces consisted of three Iranian and three classical Western compositions. This intervention was delivered over six sessions, each lasting 15 to 20 minutes, conducted over a period of two weeks (every other day).
Category
Behavior

3

Description
Control group: In the control group, participants will receive only the routine and standard care of the neonatal intensive care unit, and no supplementary or additional intervention will be provided to them.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
Zohreh Dehghan Harati
Street address
Namazi
City
Shiraz
Province
Fars
Postal code
7193613311
Phone
+98 71 3612 5000
Email
Nemazee_inf@sums.ac.ir
Web page address
https://namazi.sums.ac.ir/

2

Recruitment center
Name of recruitment center
Hafez hospital
Full name of responsible person
Zohreh Dehghan Harati
Street address
Chamran Street
City
Shiraz
Province
Fars
Postal code
کد پستی: ۷۱۹۴۶-۳۴۷۸۶
Phone
+98 71 3612 8000
Email
hafezhospt@sums.ac.ir
Web page address
https://hafez.sums.ac.ir/home

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person
Dr. Hamid Mohammadi

Street address
Zandieh Boulevard

City
Shiraz

Province
Fars

Postal code
7134814336

Phone
+98 71 3212 2430

Email
vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Mitra Soltanian

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Namazi

City
Shiraz

Province
Fars

Postal code
71936131189

Phone
+98 71 3222 0078

Email
Mitsoltan@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Neda Jamali Moghaddam

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Namazi

City
Shiraz

Province
Fars

Postal code
7193613119

Phone
+98 71 3647 4254

Email
nedajamali21@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Zohreh Dehghan Harati

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
namazi?

City
Shiraz

Province
Fars

Postal code
7193613119

Phone
+98 71 3647 4254

Email
nursezohrehdh2002@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
No further information is available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available