Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Examining the impact of mental health education through guided visits on the stress levels of fathers with preterm infants hospitalized in the neonatal intensive care unit.

Protocol summary

Study aim
Determining the effect of mental health education through guided visits on the stress of fathers of premature infants hospitalized in the neonatal intensive care unit

Design
Randomization: Participants randomly assigned using numbered envelopes based on a random number table (odd = intervention, even = control). Sampling: Convenience sampling of eligible fathers of premature infants in NICU, Shahid Sadoughi Hospital, Yazd. Sample size: 38 per group (total 76). Trial phase: Phase 2.

Settings and conduct
This clinical psychology study at Shahid Sadoughi Hospital’s NICU involves fathers of premature infants divided into intervention and control groups. The intervention group receives stress-reduction training, while the control group receives standard care. Data are collected via questionnaires over a 14-day intervention with one-month follow-up.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Father's consent to participate in the study, current hospitalization of the premature infant (28 to 36 weeks) in the NICU, no history of previous hospitalization of the infant, father's proficiency in Persian, Iranian nationality, father's mental and physical health in the past 6 months, no significant abnormality in the infant, and no separation or divorce of the parents. Exclusion criteria: Use of psychotropic or sedative medications, and father's history of participation in stress management courses.

Intervention groups
Control group:Routine NICU visits (3 times/week, 45 minutes); stress measured before and after.Intervention group:Routine plus daily guided visits (45-60 minutes for 14 days) with education; stress measured before, immediately after, and one month later.

Main outcome variables
Perceived stress levels of fathers of premature infants

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250609066134N1**
Registration date: **2025-09-29, 1404/07/07**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-29, 1404/07/07**
Update count: **0**

Registration date
2025-09-29, 1404/07/07

Registrant information
Name
Sanaz Nikbakhtasl
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 38 3326 4821
Email address
s.nikbakhtasl@stu.ssu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-07-11, 1404/04/20
Expected recruitment end date
2026-03-11, 1404/12/20
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Examining the impact of mental health education through guided visits on the stress levels of fathers with preterm infants hospitalized in the neonatal intensive care unit.

Public title

Examining the impact of mental health education through guided visits on the stress levels of fathers with preterm infants hospitalized in the neonatal intensive care unit.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study No previous history of the baby being admitted to the NICU Being able to read and write in Persian Premature baby between 28 and 36 weeks of age The father must have Iranian citizenship Absence of any mental illness in the past 6 months No significant abnormalities in the baby No separation or divorce between parents Current NICU admission of the newborn

Exclusion criteria:

Use of sedatives and psychotropic drugs Participating in care and stress management courses in the past

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

More than 1 sample in each individual

Number of samples in each individual: **38**

Fathers of preterm infant

Randomization (investigator's opinion)

Randomized

Randomization description

To select the samples, a simple random sampling method was used using a random number table. First, the starting point of the table was randomly selected. Then, to assign the samples to the test and control groups, the table was moved horizontally. The numbers in the table were extracted in four digits and assigned to the samples. If the extracted number was greater than the total number of samples, that number was eliminated and we moved on to the next number. The samples that were assigned odd numbers were assigned to the test group and the samples that were assigned even numbers were assigned to the control group. This process was carried out using sealed envelopes to completely preserve the random assignment process.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Our study has no unique design features.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Shahrekord, Saadi Street, Alley 71

City

yazd

Province

Yazd

Postal code

8817714684

Approval date

2025-05-13, 1404/02/23

Ethics committee reference number

IR.SSU.REC.1404.011

Health conditions studied

1

Description of health condition studied

stress

ICD-10 code

F43.0

ICD-10 code description

Acute stress reaction

Primary outcomes

1

Description

Stress scores of fathers of premature infants in the Cohen Stress Questionnaire

Timepoint

Before the intervention, immediately after the intervention, and one month after the intervention.

Method of measurement

Cohen Stress Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, in addition to regular NICU visits, a guided visit is held daily for 45 to 60 minutes for 14 days. In these sessions, training is provided on understanding the NICU environment, prematurity, infection control, mental health, life skills, stress management, and relaxation techniques (such as deep breathing and mindfulness). The sessions also include questions and answers and a summary.

Category
Other

2

Description
Control group: In this group, fathers simply had routine NICU visits and did not receive any educational or guided interventions.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi Hospital, Yazd

Full name of responsible person
Zahra Pourmovahed

Street address
Shahrekord, Saadi Street, Alley 71

City
YAZD

Province
Yazd

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8817714684

Phone
+98 38 3326 4821

Email
sanaznikbakht1379@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr amirhooshang mehrparvar

Street address
Shahrekord, Saadi Street, Alley 71

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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
zahra pourmovahed

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Full name of responsible person
zahra pourmovahed

Position
Professor

Latest degree

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Individual participant data will be shared as an SPSS file after all identifiable information has been removed. This file contains all variables used in the study and allows researchers to use and re-analyze. Data sharing will occur after the study is fully completed.

When the data will become available and for how long
Access to de-identified data will be available six months after the publication of the final study results and will continue for three years thereafter.

To whom data/document is available
Data and documentation are provided only to researchers and faculty members active in universities and medical science research centers. Requests for access by other individuals or organizations are subject to review and approval by the ethics committee and research team.

Under which criteria data/document could be used
In addition to the above requirements, applicants must provide their research objectives in writing and commit that the data will be used solely for research purposes. Any commercial use, publication, or sharing without written permission is prohibited. Applicants must also commit to maintaining the confidentiality of the data and adhering to research ethics. The use of the data will be limited to analyses related to the study topic, and any use beyond this will require re-approval from the research team.

From where data/document is obtainable
First respondent: Ms. Zahra Pourmovahed, faculty member of the Faculty of Nursing and Midwifery, Shahid Sadoughi University of Medical Sciences, Yazd. Email: movahed446@yahoo.com Mobile: +989133511600. Second respondent: Ms. Sanaz Nikbakht Asl, master's student in neonatal intensive care nursing. Email: sanaznikbakht1379@yahoo.com Mobile: +989380771335. Postal address: Shahrekord, Saadi Gharbi Street, Alley 71.

What processes are involved for a request to access data/document
After submitting the request to one of the above-mentioned responders, the request will be reviewed and approved. If approved, the preparation and submission of data or documentation will begin. This process usually takes between 2 and 4 weeks and depends on the volume of the request and the amount of data preparation. If more information or final approval is needed, the responder will contact the applicant.

Comments