

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### English Title: Effects of the father empowerment program on the father's stress score and perceived social support of the mothers with premature neonates in neonatal intensive care unit

#### Protocol summary

##### Study aim

Investigating the impact of the father empowerment program on the father's anxiety and care burden of mothers

##### Design

A non-randomized, controlled, parallel-group, single-blind, phase 3 clinical trial on 60 patients.

##### Settings and conduct

The environment of the study is Mehr Madar Torbat Jam Hospital. The population of this study is fathers and mothers with premature babies hospitalized in the NICU who meet the inclusion criteria. Sampling will be done by convenience methods. The study tools include the demographic information form, the parental stress scale: NICU and the multidimensional perceived social support scale. After the approval of the ethics committee, the father empowerment package will be designed first. Sampling of the control group is done at the same time. After completing the control group, sampling of the intervention group will begin. Data collection will be done on the first and seventh day. The data will be compared between the control and intervention groups in the two stages before and after.

##### Participants/Inclusion and exclusion criteria

Admission: fathers and mothers who have a premature baby hospitalized in the NICU.

##### Intervention groups

Intervention group: fathers who will receive empowerment program. In this group according to coordination with the ward, in the afternoons father stays at the baby's bedside for 2 to 4h. During this interval, the mother can choose to rest in the mother's room, go home and rest, or stay with her husband. After this time, father delivers the baby to the mother. The rest of the care of the baby will be left to the mother until the evening of the next day under the supervision of the nurse. The intervention will continue for 7 days. the

control group: The control group will be administered according to the ward routine.

##### Main outcome variables

Fathers' anxiety score and mothers' perceived social support score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221129056663N1**

Registration date: **2023-02-08, 1401/11/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-02-08, 1401/11/19**

Update count: **0**

##### Registration date

2023-02-08, 1401/11/19

##### Registrant information

##### Name

Hossein Nourmohammadih

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3514 7351

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-16, 1401/10/26

##### Expected recruitment end date

2023-05-31, 1402/03/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

English Title: Effects of the father empowerment program on the father's stress score and perceived social support of the mothers with premature neonates in neonatal intensive care unit

**Public title**

non randomized Clinical trial

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Fathers and mothers with premature babies admitted to the Neonatal Intensive Care Unit.

**Exclusion criteria:****Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **2**

Fathers and mothers of premature babies

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The only person who will be blind in this study is the statistical analyst of the study who will be unaware of the allocation of people to control and intervention groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical

Sciences

**Street address**

Deputy of technology and research of Mashhad University of Medical Sciences Qurashi building Next to Hoveize cinema University street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Approval date**

2022-10-31, 1401/08/09

**Ethics committee reference number**

IR.mums.nurse.rec.1401.072

**Health conditions studied****1****Description of health condition studied**

prematurity

**ICD-10 code**

P07.30

**ICD-10 code description**

Preterm newborn, unspecified weeks of gestation

**Primary outcomes****1****Description**

Fathers' stress score

**Timepoint**

It is done in two stages, once before the intervention and then after the intervention on the seventh day or the day of discharge from the hospital, whichever is earlier.

**Method of measurement**

Fathers' stress level questionnaire is completed by fathers

**2****Description**

Mother's perceived social support

**Timepoint**

It is done in two stages, once before the intervention and then after the intervention on the seventh day or the day of discharge from the hospital, whichever is earlier.

**Method of measurement**

Questionnaire of perceived social support will be completed by mothers.

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: the group of fathers who receive the empowerment program. First, the father empowerment package is designed. Then, with the coordination of the department, the fathers come to the baby's bedside for 2 to 4 hours in the afternoon and take care of the baby under the supervision of the nurse and based on the empowerment package. 7 days after the intervention, the results are measured in two groups.

**Category**

Other

**2****Description**

Control group: fathers who did not receive the empowerment program. In this group, care is provided according to the department's routine. This means that all care is provided by the mother under the supervision of a nurse. Fathers can only visit the mother or the baby at the bedside and do not take care of the baby

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Mehrmother Women's Specialized Hospital

**Full name of responsible person**

Dr. Yekta Javadani

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Imam Khomeini street

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr.Majid Ghayur

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University Street, next to Hoizeh Cinema, Qurashi Building, Research and Technology Vice\_Chancellor

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GhayourM@mums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mrs.Aramesh Rezaeian

**Position**

Professor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Torbate-Jam University of Medical Sciences

**Full name of responsible person**

Hossein Nurmohammadi

**Position**

Management of nurses

**Latest degree**

Bachelor  
**Other areas of specialty/work**  
Nursery  
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## Person responsible for updating data

**Contact**  
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**Other areas of specialty/work**  
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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