

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### The effect of peer support through social networks on the stress and caring ability of mothers' premature infants after discharge

#### Protocol summary

##### Study aim

Determining the effectiveness of peer support through social networks on the stress and caregiving ability of mothers of premature after discharge

##### Design

The clinical trial study has a control group with a blinded and randomized parallel group on 60 mothers. For randomization, lottery is done using closed pocket.

##### Settings and conduct

Place of operation and peer groups include 5 groups from 5 Qhaem and Imam Reza and Hasheminezhad and Umm OmolBanin and Shariati hospitals at Mashhad in NICU ward.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Mother of premature babies with a gestational age of less than 30 weeks The mother of a baby with a birth weight of less than 1500 grams Willingness to participate in the study Mother's physical health Having a smartphone The ability to use a smartphone and social networks; Exclusion criteria: Having any health-threatening congenital abnormalities Mother's addiction

##### Intervention groups

Mothers who meet the criteria for entering the research will be included in the study after obtaining informed consent. The working method is that mothers are identified and enter the social network ETA up to 2 days before the discharge of the baby. Qualified peers also enter the group. The research team will hold 2 sessions to teach care tips and prepare a peer support group for them. Peer groups will start communicating with the mother before discharge and will be in contact with the mothers of premature babies in the group during one month through the Ita social network. Peers provide psychological and emotional support to newly discharged mothers and provide them with their experiences according to the questions raised in the group. Peers are asked to give intellectual and advisory help to mothers in taking care of the baby in the first month.

#### Main outcome variables

Care capacity Stress

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230719058841N1**

Registration date: **2023-09-13, 1402/06/22**

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

Last update: **2023-09-13, 1402/06/22**

Update count: **0**

##### Registration date

2023-09-13, 1402/06/22

##### Registrant information

##### Name

mahnaz ebrahimnezhad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3382 4100

##### Email address

ebrahimnezhadm4001@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-23, 1402/06/01

##### Expected recruitment end date

2024-03-19, 1402/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of peer support through social networks on the stress and caring ability of mothers' premature infants after discharge

**Public title**

The effect of peer support through social networks on the stress and caring ability of mothers' premature infants after discharge

**Purpose**

Supportive

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

Premature babies with a gestational age of less than 30 weeks  
Premature babies with a birth weight of less than 1500 grams  
Willingness to participate in the study  
Mother's physical health  
Having a smartphone  
The ability to use a smartphone and virtual space (social networks)

**Exclusion criteria:**

Having any health-threatening congenital abnormalities  
Mother's addiction

**Age**

From **14 days** old to **2 months** old

**Gender**

Both

**Phase**

0

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Sampling is available and allocation of mothers of premature babies to two groups of control and intervention is random and by lottery with closed pocket. The samples will be randomly divided into intervention and control groups. In order to randomly assign the participants to two groups, first 35 cards A (intervention group) and 35 cards B (control group) will be prepared. After shuffling the cards, the mothers are asked to take one card respectively, then the samples will be placed in one of the intervention or control groups based on the card taken. In this way, all participants will have an equal chance to be placed in two groups

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Data analyzer don't know who is control or intervention group

**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**

Central building of Mashhad University of Medical Sciences

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91778-99191

**Approval date**

2023-05-30, 1402/03/09

**Ethics committee reference number**

IR.MUMS.NURSE.REC.1402.033

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

Premature infant

**ICD-10 code**

060.1

**ICD-10 code description**

Preterm spontaneous labour with preterm delivery

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

The care ability of mothers of premature babies will be evaluated in the intervention and control groups

**Timepoint**

They will be evaluated before entering the group and one month after the intervention

**Method of measurement**

They are evaluated using the care capacity questionnaire

**2****Description**

The stress of mothers of premature infant

**Timepoint**

It is checked before entering the group and( after intervention) one month after the training

**Method of measurement**

They are evaluated using Cohen's questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Peer groups will start communicating with the mother before discharge and will be in contact with the mothers of premature babies in the group during one month through the Ita social network. Peers provide psychological and emotional support to newly discharged mothers and provide them with their experiences according to the questions raised in the group. Peers are asked to give intellectual and advisory help to mothers in taking care of the baby in the first month. Facilitating group discussion and providing correct scientific information and paying attention to the process of group dynamics and preventing the exchange of wrong information will be other duties of the researcher. Control group: mothers with premature babies receive routine care and can contact the department if they have any questions or problems. They complete the questionnaires before the baby's discharge and at the end of the first month after the discharge. The samples will be randomly divided into intervention and control groups. In order to randomly assign the participants to two groups, first 35 cards A (intervention group) and 35 cards B (control group) will be prepared. After shuffling the cards, the mothers are asked to take one card respectively, then the samples will be placed in one of the intervention or control groups based on the card taken. In this way, all participants will have an equal chance to be placed in two groups

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital

##### Full name of responsible person

Mahnaz Ebrahimnezhad

##### Street address

Ebne sina Avenu

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91379113316

##### Phone

+98 51 3854 3031

##### Email

razaghin@mums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Ghaem Hospital

##### Full name of responsible person

Mahnaz Ebrahimnezhad

##### Street address

Ahmedabad Blvd

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9176699199

##### Phone

+98 51 3840 0000

##### Email

ghaem@mums.ac.ir

### 3

#### Recruitment center

##### Name of recruitment center

Umm al-Binin Hospital

##### Full name of responsible person

Mahnaz Ebrahimnezhad

##### Street address

Behjat. BLV

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91144734747

##### Phone

+98 51 3223 1061

##### Fax

+98 51 3223 1444

##### Email

oah@mums.ac.it

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Majid Ghayoor

##### Street address

Central Building of Mashhad University of Medical Sciences

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3841 1538

##### Email

vcresraech@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**

Mahnaz Ebrahimnezhad

**Position**

MSc student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

+98 51 3859 1511

**Email**

Ebrahimnezhadm4001@mums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Naghme Razaghi

**Position**

Assistant professor of nursing

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Ebnecina street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

051338591511

**Email**

RazaghiN@mums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mahnaz Ebrahimnezhad

**Position**

Msc Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Ebnecina street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

+98 51 3859 1511

**Email**

Ebrahimnezhadm4001@mums.ac.ir

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

**Title and more details about the data/document**

At the end of the work and after printing the article, with permission from the Mashhad Nursing and Midwifery

Faculty and the relevant professors, the information will be accessible in the central library of the Mashhad Nursing and Midwifery Faculty in the student thesis.

**When the data will become available and for how long**

Access starts 3 months after results are published

**To whom data/document is available**

Researchers working in academic institutions

**Under which criteria data/document could be used**

Researchers with related fields can use the data and

results by mentioning the reference.

**From where data/document is obtainable**

Correspondence with project manager, Dr. Naghme Razaghi RazaghiN@mums.ac.ir Postal code: 91778-99191

**What processes are involved for a request to access data/document**

Apply by email razaghiN@mums.ac.ir

**Comments**