

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effect of group discussion between mothers and caregivers team about premature neonate on their stress and coping in Neonatal Intensive Care Unit

Protocol summary

Summary

Determining the effect of group discussion between mothers and caregivers team about premature infants on stress and coping in neonatal intensive care unit. Designing the study: this is a quasi-experimental study with two intervention and control groups. Environment: neonatal intensive care units of Arash and Valiasr hospitals, affiliated to Tehran University of Medical Sciences. Population: mothers with gestational age less than 35 weeks with the risk of hospitalization for more than two weeks in the neonatal intensive care unit. Sampling: available sampling between mothers with less than 35 weeks of gestation based on inclusion criteria. Inclusion criteria: mothers under 35 weeks with risk of hospitalization for more than two weeks, no history of mental illness. Exclusion criteria: mothers of infants who have had surgery or died, or did not participate in two of four sessions of group discussion. Sample size: two intervention and control groups, each with 40 individuals. Intervention Studied: group discussion sessions between mothers and premature infants' care team in two intervention and control groups. The intervention was performed in intervention group as meetings between mothers and caregivers teams, in cases of premature infants in groups with 6-10 individuals, twice a week, each session 60 minutes, for two weeks. The control group program will be routine. In each group, parenting stress and The Brief Cope questionnaires were filled at first three days of admission and two weeks later; results of the questionnaires were compared in the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120631262N1**
Registration date: **2017-03-10, 1395/12/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-10, 1395/12/20

Registrant information

Name

Zobeydeh Saada

Name of organization / entity

School of Nursing and Midwifery, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66717695

Email address

saada_z@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-07-21, 1396/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group discussion between mothers and caregivers team about premature neonate on their stress

and coping in Neonatal Intensive Care Unit

Public title

The effect of group discussion between mothers and caregivers team about premature neonate on their stress and coping in Neonatal Intensive Care Unit

Purpose

Supportive

Inclusion/Exclusion criteria

: inclusion criteria consisted of mothers with infants hospitalized in neonatal intensive care unit at gestational age less than 35 weeks. Mothers' willingness to participate in the study, no history of mental illness and use of psychotropic drugs, the ability to understand and read in Persian, no previous premature infants, and risk of hospitalization for more than two weeks. Exclusion criteria included surgical complications for infants, or not participating in two of four meeting or the baby death.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran

City

Tehran

Postal code

1419733171

Approval date

2017-02-04, 1395/11/16

Ethics committee reference number

IR.TUMS.FNM.REC.1395.1639

Health conditions studied

1

Description of health condition studied

stress and coping

ICD-10 code

F43

ICD-10 code description

Neurotic, stress-related and somatoform disorders

Primary outcomes

1

Description

stress

Timepoint

in the first three days of admission and again two weeks later.

Method of measurement

PSS:NICU

2

Description

Coping

Timepoint

in the first three days of admission and again two weeks later.

Method of measurement

The Brief Cope

Secondary outcomes

empty

Intervention groups

1

Description

control group: mothers who have signed a written informed consent and filled demographic data form, Parental Stress Scale and The Brief Cope questionnaire in the first three days of admission and again two weeks later.

Category

Behavior

2

Description

Intervention group: intervention group: after necessary explanations about study aims to mothers, and filling written contest, in first three days of admission, demographic data form, Parental Stress Scale and The Brief Cope questionnaire should be filled with participant and group discussion meetings should be held between mothers, infant specialist, head nurse, charge nurse and researcher with themes about the environment and personnel of neonatal intensive care unit, conditions and

specifications of premature infants, alternative methods of feeding premature infants, common problems in premature infants, routine care of premature infants and mothers concerns regarding the baby, in group with 6-10 individuals, twice a week, 60 minutes per session, for two weeks; after the last session mothers will fill parenting stress and The Brief Cope questionnaire.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash and Hospital, Affiliated to Tehran University of Medical Sciences.

Full name of responsible person

Zobeydeh Saada

Street address

Corner 126 Kalantary, Shahid Baghbaniyan Ave.,
Resalat Highway

City

Tehran

2

Recruitment center

Name of recruitment center

Valiasr Hospitals, Affiliated to Tehran University of Medical Sciences.

Full name of responsible person

Zobeydeh Saada

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research Tehran University of Medical Sciences

Full name of responsible person

Dr. Taghizadeh

Street address

Nosrat Eastern Street, Tohid Squar.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for Research Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Jila Mirlashari

Position

Faculty Member

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty