

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The Effectiveness of Parent-to-Parent Support Program on the Grief of Mothers Following a Premature Birth

Protocol summary

Improvement of mother and newborn interactions,
Secure attachment in neonate

Study aim

To determine the effectiveness of parent to parent support on the grief of mothers following premature birth

Design

Quasi-experimental clinical trial with control and intervention group, Convenient sampling with pretest and post test will be done. Sample size with counting of 10% failure will be 90 person that divided in two groups, 45 person in control group and 45 in intervention group. To avoid date contamination, at first control group will be given and after the exit of all control members from setting, intervention group and peer support program will be done.

Settings and conduct

Study will be in NICU of selected hospital of Tehran University of Medical Science. At first, control group will be sampled and after the discharge of all control members, intervention sampling will be started. Designing blindness in sampling isn't possible and mothers who are eligible will enter to project by convenient sampling.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18; Having premature neonate between 24 to 37 weeks, admitted in NICU; Having mental health; No history of divorce or separation from husband; Mothers of neonates with no life threatening or congenital anomalies; Being familiar to cell phones and communicating apps; Exclusion criteria: Mothers of dying neonates; Having no consent for participation.

Intervention groups

support program and empathizing with mothers having neonates admitted in NICU will present during 3 periods of time within 2 weeks. Questionnaire will fill before and after intervention. In control group, only questionnaires will be filled two times, after first visit and after two weeks.

Main outcome variables

Motherhood role and breast feeding improvement,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180429039464N2**

Registration date: **2018-11-22, 1397/09/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-22, 1397/09/01**

Update count: **0**

Registration date

2018-11-22, 1397/09/01

Registrant information

Name

Marzieh Hasanpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4413

Email address

m-hasanpour@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Parent-to-Parent Support Program on the Grief of Mothers Following a Premature Birth

Public title

The Effectiveness of Parent-to-Parent Support Program on the Grief of Mothers Following a Premature Birth

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

-Age over 18 -having premature neonate between 24 to 37weeks, admitted in NICU -Having mental health - No history of divorce or separation from husband -Neonates of these mothers haven't had life threatening condition or congenital anomalies -Being familiar to cell phones and communicating apps

Exclusion criteria:

- Mothers of dying neonates - Having no consent for participation

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)

Not randomized

Randomization description**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**

Research Ethics Committee of School of Nursing and Midwifery & Rehabilitation - Tehran University of

Street address

School of Nursing and Midwifery of Tehran, Tohied Sq. Dr Mirkhani St(East Nosrat)

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2018-07-03, 1397/04/12

Ethics committee reference number

IR.TUMS.FNM.REC.1397.035

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

Grief of premature birth

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Grief of premature birth

Timepoint

First measurement will be from the first visit of mother with her newborn until 3 days. Second measurement will be after two weeks.

Method of measurement

Researcher made questionnaire

Secondary outcomes

empty

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

Intervention group: Mothers of neonate who are admitted in NICU will filled questionnaire before and after intervention. At first, peer group will be selected and trained. Then intervention applied in three times. After first visit of mother with her newborn till 3 days, 7 to 10 day after support will be followed by peer and third support plan will be between 10 to 14 days.

Category

Behavior

2**Description**

Control group: Mothers in control group will be given routine care and will fill grief questionnaire after the first visit and after 2 weeks.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Valieasr Hospital, Imam Khomeini Hospital Complex

Full name of responsible person

Dr. Khosro Sadeqniai

Street address

Imam Khomeini Hospital Complex., Dr. Qarib Ave.,
End of Keshavarz Blvd

City

Tehran

Province

Tehran

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1419733141

Phone

+98 21 6119 2358

Email

Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vida Kardan Moghadam

Street address

School of Nursing and Midwifery of Tehran, Tohied Sq.
Dr Mirkhani St(East Nosrat)

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Email

m-hasanpour@sina.tums.ac.ir

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Marzieh Hasanpour

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is 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

All of data will be reported except the name of participants

When the data will become available and for how long

6 months after printing of results

To whom data/document is available

researchers working in university setting

Under which criteria data/document could be used

researchers working in university setting

From where data/document is obtainable

Dr. Marzieh Hasanpour m-hasanpour@sina.tums.ac.ir

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

No plan yet

Comments