

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Assesment the role effect of consultation on maternal role, parenthood stress and postpartum depression the approach interpersonal psychothrapy in women first-time who have an infant being hospitalized in NICU

Protocol summary

Summary

Present study is a randomized controlled trial, aim of this study is assesment the role effect of consultation on maternal role, parenthood stress and postpartum depression with the approach interpersonal psychothrapy in women first-time who have an infant being hospitalized in NICU in karaj. sampling method will perform according to availability of participants. After obtaining informed consent of participants samples based on quarterly block randomization will be divided into two intervention and control groups. In This study blinding is impossible. Inclusion criteria included: Iranian nationality, fluency in Persian language, singleton, first pregnancy, gestational age of 28-34 weeks, newborns without anomalies, the absence of any known medical or psychological problems as reported by mother herself and Exclusion criteria included: Mother's absence at two consecutive counseling sessions, lack of participation in counseling sessions, and reluctance to continue to participate in the sessions. The study population comprised 92 nulliparous women with newborn in special care in Kamali Hospital of Karaj. Intervention group underwent two consecutive sessions on consecutive days, each session lasting 60 minutes, and a telephone-based follow-up session after two weeks with interpersonal psychotherapy approach. Questionnaires of adaptation to motherhood, parenting stress and postpartum depression will be completed before and after the counseling sessions and two weeks later in both intervention and control groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022520719N5**

Registration date: **2017-05-20, 1396/02/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-20, 1396/02/30

Registrant information

Name

Sara Esmaelzadeh Saeieh

Name of organization / entity

Alborz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 26 3433 6007

Email address

s-esmaelzadeh@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Alborz University of Medical Sciences

Expected recruitment start date

2017-04-19, 1396/01/30

Expected recruitment end date

2017-05-31, 1396/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assesment the role effect of consultation on maternal

role, parenthood stress and postpartum depression the approach interpersonal psychotherapy in women first-time who have an infant being hospitalized in NICU

Public title

The effect of counseling on maternal role, parenthood stress, postpartum depression in women first-time

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria included: Iranian nationality, fluency in Persian language, singleton, first pregnancy, gestational age of 28-34 weeks, newborns without anomalies, the absence of any known medical or psychological problems as reported by mother herself. Exclusion criteria: Mother's absence at two consecutive counseling sessions, lack of participation in counseling sessions, and reluctance to continue to participate in the sessions.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 46

Randomization (investigator's opinion)

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**

Alborz University of Medical Sciences

Street address

Alborz University of Medical Science, Azimieh, Alborz, Iran

City

Alborz

Postal code

0098

Approval date

2017-03-04, 1395/12/14

Ethics committee reference number

Abzums.Rec.1395.152

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

Postpartum depression

ICD-10 code

F53.0

ICD-10 code description

Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

2**Description of health condition studied**

Maternal role

ICD-10 code

F53.9

ICD-10 code description

Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

3**Description of health condition studied**

Parenthood stress

ICD-10 code

F53.8

ICD-10 code description

Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

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

Postpartum depression

Timepoint

Before the intervention, After the intervention, two week after the intervention

Method of measurement

Edinburgh Depression questionnaire (EPDS)

2**Description**

Maternal role

Timepoint

Before the intervention, After the intervention, two week after the intervention

Method of measurement

Maternal role questionnaire

3**Description**

Parenthood stress

Timepoint

Before the intervention, After the intervention, two week after the intervention

Method of measurement

Parenthood stress questionnaire in Neonatal Intensive

Care Unit Miles(PSS:NICU)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group underwent two consecutive sessions on consecutive days, each session lasting 60 minutes, and a telephone-based follow-up session after two weeks with interpersonal psychotherapy approach. The content of the following sessions was reviewed and confirmed by professors from faculties of nursing, midwifery and children psychology as follows: First session: It contained a description of the aims of the study, necessary care for premature infants, process of the development of the baby, talking to mothers about their concerns and problems, assuming role of motherhood, providing information on assuming role of motherhood, factors hindering and facilitating communication with baby, baby gender issues, symptoms of postpartum depression, providing strategies for coping with stresses. Second session: Providing information on the development and improvement of social protection, identifying and dealing with personal conflicts, problem solving skills, education and improving skills of relationship with wife after the birth of a new baby. Third session: Training on an individual basis and after discharge from the hospital through telephone calls, including follow-up of skills instructed, providing counseling on problems encountered after leaving the hospital, concerns encountered in adapting to motherhood and emphasis on familial support. Meetings are held on consecutive days and the training in which educational and counseling skills such as group discussion, role playing, problem solving skills are used. Questionnaires of adaptation to motherhood, parenting stress and postpartum depression will be completed before and after the counseling sessions and two weeks later in both intervention and control groups And analyzed using spss software will be.

Category

Behavior

2

Description

control group: Receive routine care

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali Hospital - Neonatal Intensive Care Unit

Full name of responsible person

Maryam Rasouli

Street address

Martyr Beheshti Avenue, Martyrs Square, Kamali Avenue, kamali Hospital

City

Alborz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences-Vice President of Research

Full name of responsible person

Mohammad Noorisepehr

Street address

The Research Choncellor Department Of Alborz Medical University, Azimieh Square, Alborz, Iran

City

Alborz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Alborz University of Medical Sciences-Vice President of Research

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

Research Assistant Alborz University of Medical Sciences

Full name of responsible person

Katayoon Salehi

Position

Master of Research

Other areas of specialty/work

Street address

Azomyh Square , Research Assistant Alborz University of Medical Sciences

City

Alborz

Postal code

0098

Phone

+98 26 3452 9133

Fax

Email

salehi.katayoun@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Sara Esmaelzadeh Saeieh

Position

Faculty Member, PhD

Other areas of specialty/work

Street address

School Of Nursing And Midwifery, first Golestan,
Baghestan, Alborz

City

Alborz

Postal code

0098

Phone

+98 26 3452 9133

Fax

Email

Esmaelzaded1360@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Sara Esmaelzadeh Saeieh

Position

Faculty Member - PhD

Other areas of specialty/work

Street address

School Of Nursing And Midwifery, first Golestan,
Baghestan, Alborz

City

Alborz

Postal code

0098

Phone

+98 26 3452 9133

Fax

Email

Esmaelzadeh1360@gmail.com

Web page address

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