# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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)

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**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 psychothrapy 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

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## Person responsible for scientific inquiries

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Faculty Member, phD

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**

Sara Esmaelzadeh Saeieh

**Position**

Faculty Member - phD

**Other areas of specialty/work**

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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*