

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Effect of midwifery led psycho-education in distress, postnatal depression, parental eligibility of women with high risk pregnancy that referred to Kamali hospital 1396-1397

Protocol summary

Study aim

Determining the Effect of midwifery led psycho-education in distress, postnatal depression, parental eligibility of women with high risk pregnancy

Design

Clinical trials with a control group, community based and pragmatic, with parallel, Not blind, randomized groups

Settings and conduct

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

Participants/Inclusion and exclusion criteria

Nulliparous with diagnosed of high risk pregnancy gestational age 34 weeks or more access on phone out go scale: having psychologic disorder or on treatment with psychologist expert and history of hospitalization on psychiatry or treatment by sedative having child with mental or physical malformation reject phone call for pursuit training not participate on one training class

Intervention groups

The intervention group will receive midwifery led psycho-education about increasing parental eligibility, reducing parental distress and preventing postnatal depression. The control group will receive routine care.

Main outcome variables

distress, postnatal depression, parental eligibility of women with high risk pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150119020719N10**

Registration date: **2018-09-01, 1397/06/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-01, 1397/06/10**

Update count: **0**

Registration date

2018-09-01, 1397/06/10

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

Expected recruitment start date

2018-05-13, 1397/02/23

Expected recruitment end date

2018-09-14, 1397/06/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of midwifery led psycho-education in distress, postnatal depression, parental eligibility of women with high risk pregnancy that referred to Kamali hospital 1396-1397

Public title

The Effect of led psycho-education in distress, postnatal

depression, parental eligibility of women with high risk pregnancy

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

nulliparous with diagnosed of high risk pregnancy admit at least one week on perinatal section at kamali hospital gestational age 34 weeks or more At least the reading and writing skills Iranian nationality have a satisfaction on research participation access on phone

Exclusion criteria:

having psychologic disorder or on treatment with psychologist expert and history of hospitalization on psychiatry or tretment by sedative having child with mental or physical malformation mothers with child under 34 weeks reject phone call for pursuit training not have a satisfaction on research participation not participate on one training class

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Use the quadruple random block

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 Alborz University of Medical Sciences

Street address

Alborz University of Medical Sciences, Azimieh, Alborz, Iran

City

Alborz

Province

Alborz

Postal code

3186947535

Approval date

2018-03-10, 1396/12/19

Ethics committee reference number

Abzums.Rec.1396.215

Health conditions studied

1

Description of health condition studied

postpartum depression

ICD-10 code

F53.0

ICD-10 code description

Mild mental and behavioral disorders associated with puerperium, not elsewhere classified

2

Description of health condition studied

parenthood stress

ICD-10 code

53.8

ICD-10 code description

Mild mental and behavioral disorders associated with puerperium, not elsewhere classified

Primary outcomes

1

Description

distress

Timepoint

Before intervention, After intervention and one month after delivery

Method of measurement

distress Questionnaire

2

Description

postnatal depression

Timepoint

Before intervention, After intervention and one month after delivery

Method of measurement

edinburgh postnatal depression scale

3

Description

parental eligibility

Timepoint

Before intervention, After intervention and one month after delivery

Method of measurement

parental eligibility Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group consists of nuliparous women with high-risk pregnancy diagnosis and gestational age of 34 week and more, who are hospitalised in prenatal section in kamali hispital. intervention group will receive midwifery led psycho_education about increasing parental eligibility, reducing parental distress and preventing postnatal depression. Midwifery led psycho_education, is a brief counseling education provided by a midwife and 4 sessions. contents of these session is as follows: First session lasts 60-90 minutes and is attended as group and in person during hispitalisation in high-risk pregnant women section. In this session, the goals of the study are explained and some information about infant necessary cares, how child is growing, child's gender and postnatal depression signs is provided. In the end, information about strategies for mothers to face with stress is provided. Second session is also while being hospitalised in high_risk pregnant women section, immediately after first session is done, and lasts for 60-90 minutes. In this session, information about extending and improving social support, identifying and confronting personal conflicts is provided, and problem solving skills and skills to improve relationship with spouse after the birth of the newborn child is educated. In the end, this session includes respiratory techniques postnatal exercises, mind focus and stress reduction trainings. Third session is right after childbirth, and is attended as personal training. In this sessions before is reviewed, and respiratory techniques, postnatal exercises, mind focus and stress reduction approaches are practised, and how to make use of other mothers experiences and problems the patient has had after childbirth is spoken. Forth session is done, as personal training trough phone call, in one month after childbirth. In this session, educations provided are followed, suggestions about problems faced with after childbirth is offered, worries associated with maternal role is spoken and family support is emphasised.

Category

Behavior

2

Description

The Control group will receive routine care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali Hospital

Full name of responsible person

Leila Chaharrahi Fard

Street address

Kamali Hospital, Kamali St, shohada Sq, Shahid Beheshti Ave, Karaj_Iran

City

Alborz

Province

Alborz

Postal code

0098

Phone

+98 26 3449 7989

Email

Leila.chf1992@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mohammad Noorisepehr

Street address

Iran, Azimieh Sq, The Research Choncellor Department of Alborz University of Medical Sciences

City

Alborz

Province

Alborz

Postal code

0098

Phone

+98 26 3255 8920

Email

Leila.chf1992@yahoo.com

Grant name

Alorz University of Medical Sciences-vice President of Research

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Sara Esmaelzadeh Saeieh

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing Midwifery, Golestan_i, Baghestan,
Alborz, Iran

City

Alborz

Province

Alborz

Postal code

0098

Phone

+98 912 623 2569

Email

esmaelzadeh1360@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Sara Esmaelzadeh Saieh

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Sara Esmaelzadeh Saieh

Position

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Latest degree

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Other areas of specialty/work

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Postal code

0098

Phone

+98 912 623 2569

Email

esmaelzadeh1360@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All participants data can be shared after being
unidentified

When the data will become available and for how long

Start the access period after publishing the results

To whom data/document is available

Public

Under which criteria data/document could be used

For use in studies

From where data/document is obtainable

LEILA CHAHARRAHY

FARD.09127681698.Leila.chf@yahoo.com

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

The application will be sent to the project implementer by
email and within 24 hours will receive the necessary
items

Comments