

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of supportive counselling on the anxiety of women who are at risk of preterm birth

Protocol summary

Summary

The aim of the present study was to investigate the effectiveness of supportive counseling in reducing anxiety of pregnant women at risk of preterm labor. Population of this study was pregnant women at risk of preterm labor and conducted with the participation of 42 each group (intervention and control). They were randomly assigned in two groups. This study has two-phase survey, in the first phase anxiety questionnaire was completed by participants and in the second phase intervention was done and then the questionnaire was completed again. For preventing contamination the data were gathered every other week. Each group (control, intervention) were selected randomly for placing in which week. The inclusion criteria were, gestational age between 26-34 week, positive Nitrazine test (based on laboratory documents), doesn't have preterm delivery and delivery abnormal infant, history of infertility, history of using psychotic drugs and no history of hospitalized because of mental problems, and exclusion criterion was mothers who delivered baby before completing questionnaire. Intervention was supportive counseling (two session, each session 60 minutes in morning shift) that was conducted by clinical psychologist. The secondary outcome of this study was level of anxiety.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072823382N1**

Registration date: **2016-01-30, 1394/11/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-30, 1394/11/10

Registrant information

Name

Zhila Soltanahmadi

Name of organization / entity

Kerman University of Medical Sciences faculty of nursing and midwifery

Country

Iran (Islamic Republic of)

Phone

+98 34131325219

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j_soltanahmadi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of supportive counselling on the anxiety of women who are at risk of preterm birth

Public title

Effect of supportive counselling on the anxiety of women who are at risk of preterm birth

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria were, gestational age between 26-34 week, positive Nitrazine test (based on laboratory documents), doesn't have preterm delivery and delivery

abnormal infant, history of infertility ,history of using psychotic drugs and no history of hospitalized because of mental problems, and exclusion criterion was mothers who delivered baby before completing questionnaire. Intervention was supportive counseling) (two session, each session 60 minutes in morning shift) that was conducted by clinical psychologist. The secondary outcome of this study was level of anxiety.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 84

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

kerman university of Medical Sciences

Street address

Islamic Republic Blve, Kerman,Iran

City

Kerman

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

93/540/k

Health conditions studied

1

Description of health condition studied

preterm birth

ICD-10 code

O60.0

ICD-10 code description

Preterm labour without delivery

2

Description of health condition studied

anxiety

ICD-10 code

f30-f39

ICD-10 code description

Mood [affective] disorders

Primary outcomes

1

Description

Anxiety

Timepoint

Before intervention and after finishing intervention

Method of measurement

standard Spielberger Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Supportive Counselling/ Intervention

Category

Behavior

2

Description

No Intervention/Control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipoor Hospital

Full name of responsible person

Mahdie Moghadasi

Street address

1.3.S Emam Blv, Afzalipoor Hospital, Iran, Kerman

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Abbas Pardakhty

Street address

1.2, S Ebnesina, Jahad Ave, Vice Chancellor of Research

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Kerman Medical University of Medical Sciences

Full name of responsible person

Jila Soltanahmadi

Street address

1, 3, University Pardis, Razi School of Nursing and Midwifery

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman Medical University of Medical Sciences

Proportion provided by this source

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

Razi Faculty of Nursing and Midwifery, Kerman University of Medical Sciences

Full name of responsible person

Zhila Soltanahmadi

Position

Instructor/Master of Midwifery

Other areas of specialty/work

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Other areas of specialty/work

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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