

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Study of the effect of supportive counseling on anxiety, stress, and perceived control of pregnant women with preterm labor

Protocol summary

Study aim

Determination of the effect of supportive counseling on anxiety, stress, and perceived control of pregnant women with preterm labor

Design

In this study, 60 inpatient pregnant women with gestational age between 24 to 36 weeks entered the study at the Ayatollah Rohani Hospital of the Babol city. An independent statistician to research team allocates participants based on simple random method using computer, with random allocation sequence and equal probability (1:1), into two groups A and B (Intervention and control).

Settings and conduct

Participants with preterm labor, who have conditions for entry the study, will be divided randomly into two groups. The participants of group A (30 persons) receive combination of standard medical care of preterm birth and individual supportive counseling for six consecutive days. The participants of group B (30 persons) receive only standard medical care of preterm birth. All participants fill three questionnaires including: State-Trait Anxiety Inventory of Spielberger (STAI), Revised Prenatal Distress Questionnaire, and Perceived control over pregnancy, at the beginning of the study and the end of the study (six days later).

Participants/Inclusion and exclusion criteria

Inclusion criteria: inpatient pregnant women with preterm labor and gestational age between 24 and 36 weeks, level of education higher than primary school, informed consent. Exclusion criteria: Bleeding, Infection, Hypertension, Pregnancy Induced Hypertension, Gestational Diabetes, Delivery

Intervention groups

Intervention group: Combination of standard medical care of preterm birth with supportive counseling
Control group: standard medical care

Main outcome variables

Anxiety, Stress, Perceived control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110228005931N6**

Registration date: **2018-09-18, 1397/06/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-18, 1397/06/27**

Update count: **0**

Registration date

2018-09-18, 1397/06/27

Registrant information

Name

Mahbobeh Faramarzi

Name of organization / entity

Babol University of medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1329 4456

Email address

m.faramarzi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of supportive counseling on anxiety, stress, and perceived control of pregnant women with preterm labor

Public title

The effect of supportive counseling on anxiety of pregnant women with preterm labor

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

inpatient pregnant women with preterm labor and gestational age of between 24 and 36 weeks, level of education higher than primary school, informed consent

Exclusion criteria:

Bleeding, Infection, Hypertension, Pregnancy Induced Hypertension, Gestational Diabetes, Delivery

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

An independent statistician to research team will be allocates the participants based on simple random method using website www.random.org and an allocation ratio of 1: 1 to two groups of intervention and control.

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 Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafroz Avenue, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

47176-47745

Approval date

2018-07-07, 1397/04/16

Ethics committee reference number

IR.MUBABOL.REC.1397.031

Health conditions studied

1

Description of health condition studied

Preterm labor

ICD-10 code

060

ICD-10 code description

Preterm labour and delivery

Primary outcomes

1

Description

Anxiety score in Strait-Trait Anxiety Spielberger

Timepoint

At binging the study and end of the study (six day after beginning)

Method of measurement

Strait-Trait Anxiety Inventory

2

Description

Stress score in Revised Prenatal Distress Questionnaire

Timepoint

At binging the study and end of the study (six day after beginning)

Method of measurement

Revised Prenatal Distress Questionnaire (NUPDQ)

3

Description

scores of Perceived Control over pregnancy

Timepoint

At binging the study and end of the study (six day after beginning)

Method of measurement

Perceived Control over pregnancy

Secondary outcomes

1

Description

Neonatal and pregnancy outcomes

Timepoint

Postpartum

Method of measurement

Questionnaire and complete the checklist using file

Intervention groups

1

Description

Intervention group: The participants of this group receive combination of standard medical care for preterm birth with individual supportive counseling by a trained psychologist. The aim of the counseling is reduction of the fears and concerns of the patient with supportive counseling techniques. Also, the participants practice relaxation techniques such as deep breathing and progressive relaxation three times a day. Supportive counseling sessions are consisted of 6 sessions per hour for 6 consecutive days. If the patient discharges during the study, the counseling is provided by a telephone conservation.

Category

Behavior

2

Description

Control group: Participants receive standard medical care for preterm birth.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatolah Rohani Hospital

Full name of responsible person

Mahbobeh Mirtabar

Street address

Ayatolah Rohani Hospital, Ganjafroz Avenue, Babol, Mazandaran, Iran

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dr.dini@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University Of ayatollah Amoli

Full name of responsible person

Arsalan Khan Mohamadi

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Email

khanmohammadi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University Of ayatollah Amoli

Proportion provided by this source

20

Public or private sector

Private

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

Babol University of Medical Sciences

Full name of responsible person

Mahbobeh Faraamrzi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Not applicable