Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Mahbobeh Faramarzi
Name of organization / entity
Babol University of medical Sciences
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Iran (Islamic Republic of)
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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
Ṡtress 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 Haspital

Full name of responsible person
Mahbobeh Mirtabar

Street address
Ayatolah Rohani Haspital, 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

Street address
Islamic Azad University Of ayatollah Amoli, old rode of Amol-Babol

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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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Other areas of specialty/work
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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