Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study the effect of group counseling based on motivational interviewing approach on self-efficacy, anxiety, and fear of childbirth, in pregnant women

Protocol summary

Study aim
Determination of the effect of group counseling based on motivational interviewing approach on self-efficacy, anxiety, and fear of childbirth, in pregnant women

Design
Randomized controlled clinical trial with two parallel arms

Settings and conduct
This study will be conducted on pregnant women referring to obstetric clinic of Yahyanejad Hospital of Babol city. The researchers will invite the pregnant women with gestational age of 26 to 33 weeks to participate in the study. Participants with who have conditions for entry the study, allocate randomly into two groups. The participants of group A (35 persons) will be receive combination of standard medical care of prenatal care and group motivational interviewing for 5 weeks. The participants of group B (35 persons) receive only standard medical care of prenatal care. All participants will be filled four questionnaires including; Childbirth Self-efficacy Inventory (CBSI), Revised Prenatal Distress Questionnaire (NUPDQ), State-Anxiety of Spielberge (STAI) Expectancy /Experiece Questionnaire(W-DEQ), at the beginning of the study and the end of the study (5 weeks after beginning the study). The researchers dose not aware about randomized allocation because of closed packets. At the end of the study, the questionnaires will complete by another person except researcher. Also, the analyzer dose not aware about the people in the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: gestational age between 26 to 33 weeks, level of education higher than primary school, informed consent. Exclusion criteria: previous cesarean delivery, complete bed rest during pregnancy

Intervention groups
Intervention group: Combination of standard medical care of prenatal care with motivational interviewing.
Control group: standard medical care

Main outcome variables
Self-efficacy, stress, anxiety, fear of childbirth

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110228005931N5**
Registration date: **2018-09-04, 1397/06/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-04, 1397/06/13**
Update count: **0**

Registration date
2018-09-04, 1397/06/13

Registrant information

Name
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
2018-08-28, 1397/06/06

Expected recruitment end date
2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of group counseling based on motivational interviewing approach on self-efficacy, anxiety, and fear of childbirth, in pregnant women

Public title

The effect of motivational counseling on fear of childbirth

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age between 26 to 33 weeks level of education higher than primary school informed consent Age between 18 to 50 years

Exclusion criteria:

Previous cesarean delivery Complete bed rest during pregnancy

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: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

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).

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

Ethic Committe of Babol University of Medical Sciences

Street address

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

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Babol

Province

Mazandaran

Postal code

47176-47745

Approval date

2018-08-19, 1397/05/28

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.116

Health conditions studied

1

Description of health condition studied

Fear of childbirth

ICD-10 code

F40.9

ICD-10 code description

Phobic anxiety disorder, unspecified

Primary outcomes

1

Description

Self-efficay of childbirth

Timepoint

At beginning of the study and end of the study (5 weeks after beginning)

Method of measurement

Childbirth Self-efficacy Inventory (CBSEI)

2

Description

Anxiety

Timepoint

At beginning of the study and end of the study (5 weeks after beginning)

Method of measurement

State-Anxiety of Spillberger

3

Description

Stress

Timepoint

At beginning of the study and end of the study (5 weeks after beginning)

Method of measurement

Revised Prenatal Distress Questionnaire (NUPDQ)

4

Description

Fear of childbirth

Timepoint

At beginning of the study and end of the study (5 weeks after beginning)

Method of measurement

Expectancy /Experience Questionnaire(W-DEQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants of this group will be receive combination of standard prenatal care with group counseling based on motivational interviewing for five sessions120 minutes, once a week.

Category

Behavior

2

Description

Control group: The participants of this group will be receive only standard prenatal care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahyanejad Hospital

Full name of responsible person

Somayeh Abdollahi

Street address

Yahyanejad Hospital, Modares street, Babol, Mazandaran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

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Grant name

Master of thesis

Grant code / Reference number

4853

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Mahbobeh Faramarzi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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
Undecided - It is not yet known if there will be a plan to make this available