Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study the effect of group supportive counseling on stress, anxiety, and health behaviors of pregnant women

Protocol summary

Study aim
Determination of group supportive counseling on stress, anxiety, and health behaviors of pregnant women

Design
Randomized controlled clinical trial with two parallel groups

Settings and conduct
80 pregnant women with gestational age of 6 to 32 weeks referring to two comprehensive health center services of Babol city will be allocated randomly into two groups. The participants of group A (40 persons) will be receive combination of standard medical care of prenatal care and group for 6 weeks. The participants of group B (40 persons) receive only standard medical care of prenatal care. All participants will be filled four questionnaires including; Prenatal Distress Questionnaire(NuPDQ), State-Anxiety Inventory , Perceived Stress, and Health Behaviors Questionnaire, at the beginning of the study and the end of the study (6 weeks after beginning the study). Also, all participants will be taken salivary cortisol sample at the beginning of the study and the end of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: gestational age between 6 to 32 weeks, level of education higher than primary school, informed consent. Exclusion criteria:severe intellectual disability, severe mental disorders

Intervention groups
Intervention group: Combination of standard medical care of prenatal care with supportive counselling. Control group: standard medical care

Main outcome variables
Stress of pregnancy, Anxiety, Health behavior

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110228005931N7**
Registration date: **2018-10-09, 1397/07/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-09, 1397/07/17**
Update count: **0**

Registration date
2018-10-09, 1397/07/17

Registrant information

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Name of organization / entity
Babol University of medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-07, 1397/07/15

Expected recruitment end date
2019-01-20, 1397/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study the effect of group supportive counseling on stress, anxiety, and health behaviors of pregnant women

Public title

The effect of supportive counseling on stress of pregnant women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 to 50 years Gestational age between 6 to 32 weeks Level of education higher than primary school Informed consent

Exclusion criteria:

Severe Intellectual disability Severe mental disorders

Age

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

Gender

Female

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method will be done by an independent statistician research team who allocates the participants to either the control or experimental group in equal probability 1:1, according to a computer-generated random numbers.

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

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Approval date

2018-08-19, 1397/05/28

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.127

Health conditions studied

1

Description of health condition studied

Anxiety and stress of pregnancy

ICD-10 code

F41.3

ICD-10 code description

Other mixed anxiety disorder

Primary outcomes

1

Description

Stress of pregnancy

Timepoint

At beginning of the study and end of the study (6 weeks after beginning)

Method of measurement

Prenatal distress questionnaire (NUPDQ)

2

Description

Anxiety of pregnancy

Timepoint

At beginning of the study and end of the study (6 weeks after beginning)

Method of measurement

State Anxiety Inventory

3

Description

Health behaviors of pregnancy

Timepoint

At beginning of the study and end of the study (6 weeks after beginning)

Method of measurement

Prenatal Health behaviors Scale (PHBS)

Secondary outcomes

1

Description

General stress

Timepoint

At beginning of the study and end of the study (6 weeks after beginning)

Method of measurement

Salivary cortisol

2

Description

Perceived stress

Timepoint

At beginning of the study and end of the study (6 weeks after beginning)

Method of measurement

Perceived stress Questionnaire

Intervention groups

1

Description

Intervention group:The participants of this group will be receive combination of standard prenatal care with group counseling based on supportive therapy for six sessions120 minutes, once a week. Each group will be consisted of 8-12 participants. The group supportive therapy sessions will be constructed in a dynamic way to consider the health behaviors domains of pregnancy. Supportive counseling is a non-directive patient approach, except in the therapist's pursuit of the patient's affect. Common elements of supportive counseling are; make an emotional connection, follow affect, encourage catharsis, build the alliance, emphasize patient's strengths (but not to avoid negative affect). A supportive therapist builds the therapeutic alliance with three core techniques including; allows the patient to set the course of treatment, listens carefully, and reflects back affect to the patient with careful clarifications.

Category

Behavior

2

Description

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

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health service center of Ahangercola

Full name of responsible person

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Sponsors / Funding sources

1

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Grant name

Master of thesis

Grant code / Reference number

4900

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
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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