

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 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

###### 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

2018-10-07, 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

IR.MUBABOL.HRI.REC.1397.127

## 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

##### City

Babol

##### Province

Mazandaran

##### Postal code

47176-47745

#### Approval date

2018-08-19, 1397/05/28

#### Ethics committee reference number

## 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 sessions 120 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**

Maria Esfandyari

###### **Street address**

Babol- Ahangarcola village

###### **City**

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###### **Province**

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###### **Postal code**

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###### **Phone**

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###### **Email**

maryeikimm@gmail.com

#### **2**

##### **Recruitment center**

###### **Name of recruitment center**

Comprehensive health service center of Keshvari

###### **Full name of responsible person**

Maria Esfandyari

###### **Street address**

Babol- Golestan street

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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

###### **Street address**

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

###### **City**

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###### **Phone**

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###### **Email**

r.ghadimi@mubabol.ac.ir

##### **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

**Full name of responsible person**

Mahbobeh Faramarzi

**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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## Person responsible for updating data

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**Position**

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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