

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Comparison of effect of group counseling (Cognitive Therapy) and Interaction lecture on Anxiety During Pregnancy in Primiparas

#### Protocol summary

##### Summary

This study aimed to compare the effect of group counseling, cognitive therapy, speech interactive approach anxiety nulliparous women during pregnancy has been implemented. The population studied in this research project, nulliparous pregnant women with backgrounds in health care centers since the late 1393's and early 1394's periodic pregnancy have . The sample size in this study 91 patients, who were randomly assigned to three groups: group counseling, interactive lecture and control group . In group counseling, participants in 4 sessions of cognitive therapy group . The interactive lectures were also participants in the 4 sessions. The control group in this study received only usual care. Inclusion criteria for this study were: nulliparous pregnant women ; gestational age between 13 and 28 weeks ; non-smoking ; hookah and drugs ; the lack of medical and mental illness ; the mother would like to participate in this plan. Exclusion criteria in the study were: the mother's unwillingness to continue the work ; creating the danger signs in pregnancy such as: bleeding, discharge, abortion. In this study ,The state anxiety, trait entire Spielberger anxiety questionnaire at baseline prior to intervention, and 4 weeks after treatment was measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015071022609N1**

Registration date: **2015-07-10, 1394/04/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-07-10, 1394/04/19

#### Registrant information

##### Name

Zohre Shahhosseini

##### Name of organization / entity

Mazandaran University of Medical Science, Nasibe  
School Of Nursing and Midwifery

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3336 7342

##### Email address

z.shahhosseini@mazums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Mazandaran University Of Medical Science

#### Expected recruitment start date

2015-03-11, 1393/12/20

#### Expected recruitment end date

2015-05-10, 1394/02/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of effect of group counseling (Cognitive Therapy) and Interaction lecture on Anxiety During Pregnancy in Primiparas

#### Public title

Comparison of Effect of group counseling (Cognitive Therapy) and Interaction lecture on Anxiety During Pregnancy in Primiparas

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

. Inclusion criteria for this study were: nulliparous

pregnant women ; gestational age between 13 and 28 weeks ; non-smoking ; hookah and drugs ; the lack of medical and mental illness ; the mother would like to participate in this plan. Exclusion criteria in the study were: the mother's unwillingness to continue the work ; creating the danger signs in pregnancy such as: bleeding, discharge, abortion

#### Age

From **16 years** old to **39 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **91**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mazandaran Univercity Of Medical Science

##### Street address

Serah Joybar , Emam khomeini square , Sari , Mazandaran

##### City

Sari

##### Postal code

#### Approval date

2015-06-06, 1394/03/16

#### Ethics committee reference number

IR.MAZUMS.REC.94.1411

## Health conditions studied

### 1

#### Description of health condition studied

Anxiety

#### ICD-10 code

F41.1

#### ICD-10 code description

GENERALIZED ANXIETY DISORDERS

## Primary outcomes

### 1

#### Description

State of Anxiety

#### Timepoint

4 weeks after The finishing of intervantion

#### Method of measurement

questionnare of espielberger

### 2

#### Description

Trait Anxiety

#### Timepoint

4 weeks after The finishing of intervantion

#### Method of measurement

Questionnare of espielberger

### 3

#### Description

Total Anxiety

#### Timepoint

4 weeks after The finishing of intervantion

#### Method of measurement

Questionnare of espielberger

## Secondary outcomes

### 1

#### Description

Corellation of Study Variables with Anxiety

#### Timepoint

4 weeks after interventin

#### Method of measurement

Questionnare

## Intervention groups

### 1

#### Description

group counseling Consultations in 4 sessions of cognitive therapy sessions based on the identification cycle, thoughts, feelings and behavior in relation to the participants' anxiety.:

#### Category

Treatment - Other

### 2

#### Description

Interaction lecture Speeches by the way, fully interactive with participants , defined the position of the cycle amplifications anxiety,situation , thoughts,feelings , behavior, respectively.:

#### Category

Treatment - Other

### 3

#### Description

Control Group: The group as a control group received only usual care during pregnancy:

#### Category

Other

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Health Center Of Number 7

###### Full name of responsible person

Mrs. Hafezian

###### Street address

Rahband , Center of Health 7 ,Sari ,Mazandaran

###### City

Sari

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Mazandaran , Uavercity of Medical Science

###### Full name of responsible person

Dr ,Ravanbakhsh Esmaeili

###### Street address

Serah Joybar ,Square of Emam khomeini , Sari , Mazandaran

###### City

Sari

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Mazandaran , Uavercity of Medical Science

##### Proportion provided by this source

100

##### Public or private sector

empty

##### Domestic or foreign origin

empty

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

empty

### Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Mazandara University of Medical Science

##### Full name of responsible person

Zohre Shahhosseini

#### Position

phd

#### Other areas of specialty/work

#### Street address

Vesal Nasibe School of Nursing and Midwifery ,Vesal Street , Amir Mazandarani Street , Sari , Mazandaran

#### City

Sari

#### Postal code

#### Phone

0089113329123

#### Fax

#### Email

Z.shahhosseini@mazums.ac.ir

#### Web page address

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mazandaran University of Medical Science

##### Full name of responsible person

Fariba Salehi

##### Position

Masters

##### Other areas of specialty/work

##### Street address

Nasibe School of Nursing and Midwifery , Vesal Street , Amir Mazandarani Street , Sari , Mazandaran

##### City

Sari

##### Postal code

IRAN

##### Phone

+98 911 155 8302

##### Fax

##### Email

salehy.fariba@yahoo.com

##### Web page address

### Person responsible for updating data

#### Contact

##### Name of organization / entity

Mazandaran University of Medical Science

##### Full name of responsible person

Fariba Salehi

##### Position

Masters

##### Other areas of specialty/work

##### Street address

Nasibe School Of Nursing and Midwifery ,Vesal Street , Amir Mazandarani Street , Sari , Mazandaran

##### City

Sari

##### Postal code

##### Phone

+98 113392123

##### Fax

##### Email

salehy.fariba@yahoo.com

**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*