

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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 University Of Medical Science

Street address

Seraj 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 intervention

Method of measurement

questionnaire of espielberger

2

Description

Trait Anxiety

Timepoint

4 weeks after The finishing of intervention

Method of measurement

Questionnaire of espielberger

3

Description

Total Anxiety

Timepoint

4 weeks after The finishing of intervention

Method of measurement

Questionnaire of espielberger

Secondary outcomes

1

Description

Correlation of Study Variables with Anxiety

Timepoint

4 weeks after intervention

Method of measurement

Questionnaire

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

Seraj 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	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>