Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of group counseling on pregnancy anxiety

Protocol summary

Summary

This research was a clinical trial study that was designed to examine the effect of group counseling on pregnant women' anxiety in Sheibani Health service. Inclusion criteria : 18-35 years age; first pregnancy; 8-18 weeks gestational age based on last menstrual Period; lack of mental diseases or anxiety induced diseases such as hyperthyroidism; lack of sever and pathologic anxiety based on Speigel Berger anxiety questionnaire. Exclusion criteria : gaining 10 or more score in Beck depression scale; presence in pregnancy period preparation classes out of designed program and absence in consultation classes more than 1 session. The study population consisted of all pregnant women were referred to Sheibani Health Centeri. Study population were 90 pregnant women. They were allocated into two experimental and control groups. Experimental group received group consultation and routine pregnancy period cares but control group received only routine cares. Group consultation sessions were designed for 5 sessions during 5 weeks that each session lasted 60 to 90 minutes. Evaluation at the end of the fifth week intervention was conducted by Spielberger Anxiety Questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111214529N2**
Registration date: **2012-02-27, 1390/12/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-02-27, 1390/12/08

Registrant information

Name

Nourossadat Kariman

Name of organization / entity

Shaheed Beheshti University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 3133

Email address

n_kariman@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Nursing and Midwifery College of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2010-12-30, 1389/10/09

Expected recruitment end date

2011-07-03, 1390/04/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of group counseling on pregnancy anxiety

Public title

Effectiveness of group counseling on pregnancy anxiety

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria : 18-35 years age; first pregnancy; 8-18 weeks gestational age based on last menstrual Period; lack of mental diseases or anxiety induced diseases such as hyperthyroidism; lack of sever and pathologic anxiety based on Speigel Berger anxiety questionnaire. Exclusion criteria : gaining 10 or more score in Beck depression scale; presence in pregnancy period preparation classes out of designed program and absence in consultation

classes more than 1 session.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Shahid Beheshti Medical University, Den of research

Street address
Shahid Beheshti Medical University, Evin, Tehran

City
Tehran

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
116/3043

Health conditions studied

1

Description of health condition studied
Anxiety in Pregnancy

ICD-10 code
F40-F48

ICD-10 code description
Neurotic, stress-related and somutoform disorders

Primary outcomes

1

Description
Anxiety

Timepoint
5 Weeks

Method of measurement
Speigel Berger Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: Group counseling / Control: Routine pregnancy care

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Sheibani Health Center

Full name of responsible person
Marjaneh Dayhimi

Street address
Sheibani Health Center, Hafez Alley, Between Qanat and Dibaj, Kolahdooz street, Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti Medical University

Full name of responsible person
DR. Ghanati K

Street address
International Branch Shahid Beheshti University of Medical Sciences, Tavanir street, Tehran, Iran

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti Medical University

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

Nursing and Midwifery College of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Marjaneh Dayhimi

Position

MSc in Midwifery

Other areas of specialty/work

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Position

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty