Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effectiveness and non-effectiveness of group discussion on anxiety and stress of primipara pregnant women in Khorramabad in2015

Protocol summary

Summary

This study would be done with aime to assess the effect of group discussions on anxiety and stress of primipara pregnant women in Khorramabad . This is not blind clinical trial. The study population included primipara pregnant women (with gestational age of 20 weeks and more) referring to Poshte number 1 health center in the city of Khorramabad that 46 peoplein available sampling selected as sample and randomly would divided in two control and study groups. Both groups would be homogenous for intervention variables. Before the intervention, to assess the level of anxiety and stress Spillberger and Cohen questionnaire will be provided to both groups . Then the experimental group participantsfor 6 Session 1-1.5 hours (each week a meeting) will participate in group discussions. But in the control group the routine care of health center will be executed. After four weeks of the last session of discussion, anxiety and stress by mentioned tools in both groups Is measured. Inclusion criteria: primipara pregnant women with gestational age 20 to 25 weeks; no known cardiovascular disease, diabetes, mental illness; lack of participation on training program on the topic over the past 20 week, no history of pregnancy and abortion; participants husband alive.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092814333N40**
Registration date: **2015-10-12, 1394/07/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-10-12, 1394/07/20

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2015-08-07, 1394/05/16

Expected recruitment end date

2015-11-07, 1394/08/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness and non-effectiveness of group discussion on anxiety and stress of primipara pregnant women in Khorramabad in2015

Public title

the effect of group discussions on anxiety and stress of primipara pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: primipara pregnant women with gestational age 20 to 25 weeks; no known cardiovascular

disease, diabetes, mental illness; lack of participation on training program on the topic over the past 20 week, no history of pregnancy and abortion; participants husband alive Exclusion criteria: not wanting to continue the cooperation; the creation of any physical or mental health problem; more than twice absence in training

Age
No age limit

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomly by throwing coin

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City
Kermanshah

Postal code

Approval date
2015-06-23, 1394/04/02

Ethics committee reference number
kums.rec.1394.43

Health conditions studied

1

Description of health condition studied
Anxiety and stress in pregnancy

ICD-10 code
F41.3

ICD-10 code description
Other mixed anxiety disorder

Primary outcomes

1

Description
Anxiety

Timepoint
Beginning of the study and 4 weeks after the study

Method of measurement
According to Spielberger Questionnaire

2

Description
Stress

Timepoint
Beginning of the study and 4 weeks after the study

Method of measurement
According to Cohen Stress Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In experimental group participantsfor 6 Session 1-1.5 hours (each week a meeting) will participate in group discussions.

Category
Treatment - Other

2

Description
In the control group the routine care of health center will be executed.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Poshte number 1 health center

Full name of responsible person
Elham Sheykh Azadi

Street address

City
Khoramabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Azam Bakhteh

Position

MSc of maternal and child health

Other areas of specialty/work

Street address

School of Nursing & Midwifery, First of Dolatabad Boulvard,Eisar Square

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+98 83 3828 0642

Fax

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Bakhteh_a@yahoo.com

Web page address

Person responsible for updating data

Contact

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