

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

comparison of group counseling in a solution-centered way with routine education on the concerns of primigravida

Protocol summary

Study aim

Determination of the comparison of group counseling in a solution-centered way with routine education on the concerns of primigravida

Design

Clinical trials with control group, parallel groups, blind, randomized, quadruple block method, in the first stage, 120 subjects, in the next stage, 54 (control and intervention)

Settings and conduct

The statistical population of this study is the pregnant women referring to Sabzevar health centers to receive prenatal care in the first and second trimesters of pregnancy. Blind : outcomes participant and a statistical analyst will not be aware of the placement of mothers from intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women at the gestational age of 15-45 years old, primitive gravity, having at least reading and writing skills, having no mental disorder, Participate classes, people with scores higher than 55 points of concern for pregnancy Exit criteria: A history of mental disease and any psychiatric medication usage, Women with abortion history Women with infertility history, Women with chronic diseases

Intervention groups

Intervention group: In addition to receiving routine prenatal care, consultation classes will be conducted in five 90- minute sessions for 54 women. After the fifth session, post-test will be taken. Control group: A group of 54 people who receive only routine prenatal care and will take a post-test after 5 weeks. Tracking will be done in both groups months after the end of the consultation sessions.

Main outcome variables

worries pregnant women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180123038485N1**

Registration date: **2018-03-14, 1396/12/23**

Registration timing: **prospective**

Last update: **2018-03-14, 1396/12/23**

Update count: **0**

Registration date

2018-03-14, 1396/12/23

Registrant information

Name

RAZIEH KARRABI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4464 7170

Email address

Karabi@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-05, 1397/01/16

Expected recruitment end date

2018-09-06, 1397/06/15

Actual recruitment start date

empty

Actual recruitment end date

2018-06-22, 1397/04/01

Trial completion date

empty

Scientific title

comparison of group counseling in a solution-centered way with routine education on the concerns of primigravida

Public title

comparison of group counseling in a solution-centered way with routine education on the concerns of primigravida

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Women with gestational capacity and 15-45 years old
Pregnancy first Have at least reading and writing skills
Not having mental disorder Possibility to participate in classes
People with higher score than 55 in concern for pregnancy

Exclusion criteria:

A history of mental disease and any psychiatric medication useage
Women with abortion history
Women with infertility history
Women with chronic diseases

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **120**

More than 1 sample in each individual

Number of samples in each individual: **54**

54 in the intervention group and 54 in the control group

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, since the participants are studying during time, and also for the equalization of the number of people assigned to the groups, a randomized our-block method is used.

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind the control group, the intervention group will be invited to participate in the classes in a different health center. in addition, statistician will not be aware of the grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahroud University of Medical Sciences

Street address

Seventh Tir Square, Shahroud University of Medical Sciences

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Approval date

2018-01-02, 1396/10/12

Ethics committee reference number

ir.shmu.rec.1396.137

Health conditions studied

1

Description of health condition studied

Concerned pregnant women

ICD-10 code

46.6

ICD-10 code description

Undue concern and preoccupation with stressful events

Primary outcomes

1

Description

The score obtained from the Cambridge Worry Questionnaire in pregnant women at the end of the counseling period was two months (two months after intervention).

Timepoint

The questionnaire is completed by pregnant women in the first and second trimesters of pregnancy in three stages. In the first stage, at the beginning of the study (before the intervention) and the second stage, five group counseling sessions were held in both groups and the third stage 2 months after the end of the counseling sessions A group is in both groups (admission and control)

Method of measurement

Cambridge Worry Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 5 Solution-centered counseling sessions (each session has a specific structure) with receiving routine care

Category

Prevention

2

Description

Control group: receive routine pregnancy care(All care provided by pregnant women in accordance with the Ministry of Health)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center of Sabzevar University of Medical Sciences

Full name of responsible person

Razieh karrabi

Street address

Sabzevar Health Center, Taleghani St., Sabzevar, Khorasan Razavi, Iran

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emami

Street address

Central Building of Shahroud University of Medical Sciences, Shahrud,Haft Tir Square,Shahrud,Semnan, Iran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Razieh Karrabi

Position

Mst Student of consultation in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Maryam Farjamfar

Position

Academic staff of Shahrud University of Medical

Sciences
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Person responsible for updating data

Contact

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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

Not applicable

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