

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 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

#### City

Sabzevar

#### Province

Razavi Khorasan

#### Postal code

9613985641

#### Phone

+98 51 4464 5200

#### Email

Vc.Health@medsab.ac.ir

#### 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, Shahruod,Haft Tir Square,Shahruod,Semnan, Iran

#### City

Shahroud

#### Province

Semnan

#### Postal code

36147-73947

#### Phone

+98 23 3239 5054

#### Email

emamian@shmu.ac.ir

#### Web page address

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

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#### Province

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#### Postal code

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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

**Name of organization / entity**  
Shahroud University of Medical Sciences  
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Razieh Karrabi  
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Msc Student of consultation in Midwifery  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Midwifery  
**Street address**

NO.9,Besat alley,Best street,Sabzevar.Khorasan  
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9613985641  
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+98 51 4464 7170  
**Email**  
karabi@shmu.ac.ir

## 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