

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparison the effectiveness and non-effectiveness of cognitive-behavioral counseling on lifestyle and weight gain in pregnant women

#### Protocol summary

##### Summary

This study will be done with aim to survey the effectiveness and non-effectiveness of cognitive-behavioral counseling on lifestyle and weight gain in pregnant women. This is a non-blinded clinical trial. The study population will included 20-24 weeks pregnant women who referred to health centers of Sanandaj city. A total of 70 eligible pregnant women will be selected in available method and randomly will be assigned in to two experimental and control groups. Baseline, health promoting lifestyle questionnaire will be provided to both groups, height and weight is measured and body mass index will be calculated. The intervention group will receive cognitive behavioral group counseling eight sessions (if necessary up to 10 sessions) of 60-90 minutes for a session in week. The control group only will receive the usual centers care. The end of the study and one month after the end of the study lifestyle questionnaire will be provided to both groups, the body mass index will be measured and both groups will be compared. Inclusion criteria: Age between 19 and 50 years; 20-24 weeks gestational age; Literacy, Wanted pregnancy; Singleton pregnancy; No mental illness; No known fetal illness; No history of drug addiction; Lack of sleep medication use and Neurological drugs; Having a BMI underweight, normal, overweight and obese. Exclusion criteria: Abortion; Childbirth or hospitalization during the study; No participation in the two or more sessions of meetings.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017041014333N72**

Registration date: **2017-04-24, 1396/02/04**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-04-24, 1396/02/04

##### Registrant information

###### Name

Feizollah Foroughi

###### Name of organization / entity

kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1821 4653

###### Email address

fforoughi@kums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

##### Expected recruitment start date

2017-04-30, 1396/02/10

##### Expected recruitment end date

2017-07-01, 1396/04/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effectiveness and non-effectiveness of cognitive-behavioral counseling on lifestyle and weight gain in pregnant women

##### Public title

The effectiveness and non-effectiveness of cognitive-behavioral counseling on lifestyle and weight gain in

pregnant women.

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Age more than 19 years; 20-24 weeks gestational age; Literacy, Wanted pregnancy; No underlying disease or complications labeled in pregnancy (pre-eclampsia, gestational diabetes, a history of giving birth to infants and IUGR,...); Singleton pregnancy; No mental illness; No known fetal illness; No history of drug addiction; Lack of sleep medication use and Neurological drugs; Having a BMI underweight, normal, overweight and obese. Exclusion criteria: Abortion; Childbirth or hospitalization during the study; No participation in the two or more sessions of meetings.

### **Age**

From **19 years** old to **50 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **70**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

Simple randomly sampling, using encoded on the card

## **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**

2017-03-08, 1395/12/18

#### **Ethics committee reference number**

kums.rec.1395.763

## **Health conditions studied**

### 1

#### **Description of health condition studied**

pregnancy

#### **ICD-10 code**

Z34.8

#### **ICD-10 code description**

Supervision of other normal pregnancy

## **Primary outcomes**

### 1

#### **Description**

Life style

#### **Timepoint**

The beginning of the study, after study and one month after the end of the study

#### **Method of measurement**

Based on lifestyle questionnaire Walker (HPLP)

### 2

#### **Description**

Weight gain

#### **Timepoint**

The beginning of the study, after study and one month after the end of the study

#### **Method of measurement**

Weighbridge branded Seca

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

The intervention group will receive cognitive behavioral group counseling eight sessions (if necessary up to 10 sessions) of 60-90 minutes for a session in week.

#### **Category**

Lifestyle

### 2

#### **Description**

The control group only will receive the usual centers care.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

**Name of recruitment center**

Health centers  
**Full name of responsible person**  
Mahnaz Farhoodi  
**Street address**  
Abidar Street  
**City**  
Sanandaj

**Fax**  
**Email**  
iclddoctor12@Gmail.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Dr. Sosan Heydarpour  
**Position**  
PhD Reproductive Health  
**Other areas of specialty/work**  
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+98 83 3827 9394  
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**Email**  
s.heydarpour1394@yahoo.com  
**Web page address**

## 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

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Mahnaz Farhoodi Moghadam  
**Position**  
MA Student of consultation in midwifery  
**Other areas of specialty/work**  
**Street address**  
School of Nursing & Midwifery, First of Dolatabad  
Boulevard,Eisar Square  
**City**  
Kermanshah  
**Postal code**  
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+98 83 3827 9394

## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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iclddoctor12@Gmail.com  
**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*