

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 2026

### Effect of cognitive-behavioral counseling based on mind-fullness on weight gain and quality of life of pregnant woman with overweight and obese

#### Protocol summary

##### Study aim

determine the effect of cognitive-behavioral counseling based on mind-fullness on weight gain and quality of life of pregnant woman with overweight and obese referring to health care centers of Shahid Sadoughi University of Medical Sciences in Yazd .

##### Design

This is a parallel clinical trial. Among the patients referring to three health care centers, 60 people were selected based on the criteria for entering and Exit the study and divided into two intervention and control groups according to the random numbers table.

##### Settings and conduct

This is a parallel clinical trial. Among the patients referring to three health care centers, 60 people were selected based on the criteria for entering and Exit the study and divided into two intervention and control groups according to the random numbers table.

##### Participants/Inclusion and exclusion criteria

The criteria for entering the study include: aged over 19, BM I (Body mass Index) between 25, 39.9, gestational age 16 to 26 weeks, single pregnancy and low risk, at least the first prenatal care until the 16th week of gestation. Exit criteria include: Experience of stressful events in the last six months , using psychiatric medications last year , , metabolic disorders related to obesity and substance abuse.

##### Intervention groups

For the intervention group, in addition to receiving routine pregnancy care, 8 sessions of 90 minutes of group counseling will be held on a weekly basis. The control group will receive only routine pregnancy care.

##### Main outcome variables

In the case of effective cognitive-behavioral counseling based on the mindfulness of changes in weight and quality of life of pregnant women with overweight and obesity, this method of counseling is used to prevent

overweight in pregnant women, and to improve their quality of life in the context of the care provided for these groups.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190316043071N1**

Registration date: **2019-06-24, 1398/04/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-06-24, 1398/04/03**

Update count: **0**

##### Registration date

2019-06-24, 1398/04/03

##### Registrant information

##### Name

Mozhgan Dehghani mohammad abadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3836 3789

##### Email address

mo.dehghani@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-22, 1398/03/01

##### Expected recruitment end date

2020-02-20, 1398/12/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of cognitive-behavioral counseling based on mindfulness on weight gain and quality of life of pregnant woman with overweight and obese

**Public title**

Effect of cognitive-behavioral counseling based on mindfulness on weight gain and quality of life of pregnant woman with overweight and obese referring to health care centers of Shahid Sadoughi University of Medical Sciences in the Yazd.

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

The inclusion criteria : ages older than 19 years, BMI(Body Mass Index) between 25 and 39.9, gestational age 16 to 26 weeks, singleton pregnancy, low risk pregnancy (no significant medical or obstetric problem before or during pregnancy such as: the history of thyroid disease, gestational diabetes, hypertension, ...), wanted pregnancy and performing the first prenatal care until the 16th week of pregnancy at a health care center

**Exclusion criteria:**

Exclusion criteria: Experience of stressful events in the past six months, such as the loss of a husband or other relative, the history of psychotherapy over the past year, the development of metabolic disorders associated with obesity, such as diabetes, etc and substance abuse

**Age**From **19 years** old**Gender**

Female

**Phase**

0

**Groups that have been masked***No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

**Randomization description**

The sample size is equivalent to 60 pregnant women who are referred to health care centers. They are randomly assigned to two groups using random numbers. For the intervention group, in addition to receiving routine pregnancy care, 8 sessions of 90 minutes of mind - fullness group counseling will be held on a weekly basis. The control group will receive only routine pregnancy care. At the end of the study, if the counselor wishes to be effective and they desired, mindfulness sessions will be held for the control group. Samples were weighted in each group at the time before intervention, immediately after the end of 8 sessions, one month later. They will also complete the quality of life questionnaire at all three times.

**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**

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

**Street address**

Central Building of Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd

**City**

yazd

**Province**

Yazd

**Postal code**

8916877443

**Approval date**

2019-01-06, 1397/10/16

**Ethics committee reference number**

IR.SSU.MEDICINE.1397.178

**Health conditions studied****1****Description of health condition studied**

Weight gain

**ICD-10 code****ICD-10 code description****2****Description of health condition studied**

quality of life

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Weight gain

**Timepoint**

Before intervention, after intervention and one month After intervention

**Method of measurement**

Based on kilograms and using the weight in health centers

## 2

### **Description**

quality of life

### **Timepoint**

Before Intervention, after intervention and one month after intervention

### **Method of measurement**

Quality of Life questionnaire SF-36

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group:

#### **Category**

Behavior

### 2

#### **Description**

Control group:

#### **Category**

Behavior

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Rahmat Abad Health center

##### **Full name of responsible person**

Mohammadabadi Dehghani mozhgan

##### **Street address**

101Alley, Shahid Dashti Boulevard, Yazd

##### **City**

yazd

##### **Province**

Yazd

##### **Postal code**

8916877443

##### **Phone**

+98 35 3824 1751

##### **Fax**

+98 35 3824 9705

##### **Email**

mo.dehghani@ssu.ac.ir

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Azadshahr Health center

##### **Full name of responsible person**

Mohammadabadi Mozhgan

##### **Street address**

Mokhaberat Alley-, Second Square,Azadshahr yazd

### **City**

yazd

### **Province**

Yazd

### **Postal code**

8916877443

### **Phone**

+98 35 3824 1751

### **Email**

m.dehghani2279@yahoo.com

### 3

#### **Recruitment center**

##### **Name of recruitment center**

Farabi Health center

##### **Full name of responsible person**

Mohammadabadi Mozhgan

##### **Street address**

Shahid Dashti Blvd yazd

##### **City**

yazd

##### **Province**

Yazd

##### **Postal code**

8916877443

##### **Phone**

+98 35 3824 1751

##### **Email**

m.dehghani2279@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice Chancellor for Research of Shahid Sadoughi University of Medical Science

##### **Full name of responsible person**

Dr. Amir Houshang Mehrparvar

##### **Street address**

Headquarters of Yazd University of Medical Sciences, Bahonar Square, Yazd

##### **City**

yazd

##### **Province**

Yazd

##### **Postal code**

8916877443

##### **Phone**

+98 35 3724 0171

##### **Email**

m.dehghani2279@yahoo.com

#### **Grant name**

00

#### **Grant code / Reference number**

00

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

Yes

#### **Title of funding source**

Vice Chancellor for Research of Shahid Sadoughi  
University of Medical Science  
**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**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
DehghaniMohammadabadi Mozghan  
**Position**  
A graduate student in midwifery advice  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Nursing Midwifery Faculty, Bou ali Avenue, Thimsar  
Fallahi Avenue, Safaiyeh, Yazd  
**City**  
yazd  
**Province**  
Yazd  
**Postal code**  
8916877443  
**Phone**  
+98 38241751  
**Email**  
m.dehghani2279@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Azam Khoshbin  
**Position**  
Faculty trainer  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Nursing Midwifery Faculty, Bou ali Avenue, Thimsar  
Fallahi Avenue, Safaiyeh, Yazd.  
**City**  
yazd  
**Province**  
Yazd

**Postal code**  
8916877443  
**Phone**  
+98 35 3824 1751  
**Email**  
a.khoshbin@ssu.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Mohammadabadi Dehghani Mozghan  
**Position**  
A graduate student in midwifery advice  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Yazd Akhbaran Kashani Alley Sepideh  
**City**  
Yazd  
**Province**  
Yazd  
**Postal code**  
8916877443  
**Phone**  
+98 35 3836 3789  
**Email**  
m.dehghani2279@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

The Whole data is Available After identifying individuals.such as weigh again quality of life

### When the data will become available and for how long

6 months after the results were published.

### To whom data/document is available

Researchers working in academic institutions

### Under which criteria data/document could be used

The data are available only to rely on the future papers of individuals.

### From where data/document is obtainable

E-mail:m.dehghani2279@yahoo.com TEL;09135269522

mozghan dehghani  
**What processes are involved for a request to access data/document**

A maximum of a week after your email is sent or the phone call is called.  
**Comments**