

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Comparing the effect of two Methods of Couple-Oriented Group Counseling and Client-Oriented Counseling Using the Cognitive Behavioral Approach during pregnancy, on Anxiety, Stress, and Depression in postpartum period

#### Protocol summary

##### Summary

This study is Intervention - experimental type (Rct). The aim of study will compared the Effectiveness of Two Methods of Couple-Oriented Group Counseling and Client-Oriented Counseling Using the Cognitive Behavioral Approach during pregnancy, on Anxiety, Stress, and Depression in postpartum period. The study population includes all pregnant woman who refers to Child Birth preparation center; of these, 78 samples with informed consent will be selected. According to inclusion (for women: age between 20-40; gestational age 28-32 week- for men: ninth grade education; drug addiction) and exclusion criteria (mood disorders; a history of infertility; history of use psychiatric drugs) for samples, qualified samples were randomly divided into three groups (control, client oriented, couple oriented). Counseling classes during pregnancy will be conducted for 8 sessions, once a week. In this research depression anxiety stress score and will be used for data gathering. After data gathering, data will be analyzed. It is expected average score (anxiety, stress and depression) is dropped; immediately after the end of sessions and postpartum period.

#### General information

##### Acronym

cbct.cbgt

##### IRCT registration information

IRCT registration number: **IRCT2016081029293N1**

Registration date: **2016-10-30, 1395/08/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-10-30, 1395/08/09

##### Registrant information

###### Name

Tayyebeh Shojaaddini Ardakani

###### Name of organization / entity

Shahid Sadoughi University Of Medical Sciences.  
Nursing And Midwifery College

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3224 4305

###### Email address

maryam\_dafei@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

ShahidSadoughi University Of Medical Science.

##### Expected recruitment start date

2016-07-07, 1395/04/17

##### Expected recruitment end date

2016-08-22, 1395/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of two Methods of Couple-Oriented Group Counseling and Client-Oriented Counseling Using the Cognitive Behavioral Approach during pregnancy, on Anxiety, Stress, and Depression in postpartum period

##### Public title

Effect of Counseling Using the Cognitive Behavioral Approach on Anxiety, Stress, and Depression in postpartum period

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

Woman inclusion criteria: Age between 20-40; Ability to speak and understand the language of Persian; ninth grade education; gestational age between 28-32 week. Man inclusion criteria: ninth grade education. Woman exclusion criteria: Complications during pregnancy; a history of serious psychiatric disorders such as: mood disorders, psychosis and anxiety, major depression and bipolar disorder; a history of infertility; use of assisted reproductive technology; history of use psychiatric drugs; History of participation in cognitive-behavioral counseling sessions relating to the treatment of depression; stress score greater than 33, anxiety score greater than 28 and depression scores more than 20; drug dependence; first-degree relatives died in the last three months (grief) Man exclusion criteria: drug addiction; history or current mental illness; history of participation in counseling sessions of cognitive-behavioral treatment for depression

### **Age**

From **20 years** old to **40 years** old

### **Gender**

Both

### **Phase**

N/A

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

*No information*

### **Sample size**

Target sample size: **78**

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

Randomized

### **Randomization description**

### **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**

Shahid Sadoughi university of medical science.

##### **Street address**

yazd. bahonar square.

##### **City**

yazd

##### **Postal code**

### **Approval date**

2016-07-09, 1395/04/19

### **Ethics committee reference number**

ir.ssu.rec.1395.57

## **Health conditions studied**

### **1**

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

stress, anxiety and depression in postpartum period

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

F43, F41,

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

Reaction to severe stress, and adjustment disorders, Other anxiety disorders, Depressive episode

## **Primary outcomes**

### **1**

#### **Description**

stress

#### **Timepoint**

pretest, post test, 14 day after delivery

#### **Method of measurement**

DEPRESSION, ANXIETY, STRESS SCORE

### **2**

#### **Description**

anxiety

#### **Timepoint**

pretest, post test, 14 day after delivery

#### **Method of measurement**

DEPRESSION, ANXIETY, STRESS SCORE

### **3**

#### **Description**

depression

#### **Timepoint**

pretest, post test, 14 day after delivery

#### **Method of measurement**

DEPRESSION, ANXIETY, STRESS SCORE

## **Secondary outcomes**

### **1**

#### **Description**

postpartum depression

#### **Timepoint**

14 day after delivery

#### **Method of measurement**

Dass21

## **Intervention groups**

### 1

#### Description

couple oriented approach Counseling for once a week for 8 sessions with Cognitive Behavioral Approach

#### Category

Behavior

### 2

#### Description

client oriented approach Counseling for once a week for 8 sessions with Cognitive Behavioral Approach

#### Category

Behavior

### 3

#### Description

control group without intervention

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ziae Hospitah

##### Full name of responsible person

Miss Poorhusseini

##### Street address

Yazd, Ardakan , Sadrabad Street

##### City

Ardakan

### 2

#### Recruitment center

##### Name of recruitment center

Behdasht And Darman

##### Full name of responsible person

Miss shojaaddini ardakani

##### Street address

Yazd, Ardakan , Emam Street

##### City

Ardakan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Sadoughi University Of Medical Science.  
Nursing And Midwifery College

##### Full name of responsible person

Research Accessorial Of Shahid Sadoughi University  
Of Medical Science. Nursing And Midwifery Colleg

##### Street address

Yazd. Bahonar squar

##### City

yazd

#### Grant name

27940000

#### Grant code / Reference number

4699

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

Yes

#### Title of funding source

Shahid Sadoughi University Of Medical Science. Nursing  
And Midwifery College

#### 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

Shahid Sadoughi University Of Medical Science.  
Nursing And Midwifery College

##### Full name of responsible person

Tayyebah Shojaaddini Ardakani

##### Position

Msc student

##### Other areas of specialty/work

##### Street address

Nursing and Midwifery college, Bu Ali Street, Yazd

##### City

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##### Postal code

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##### Fax

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##### Email

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##### Web page address

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Sadoughi UniversityOf Medical Science.  
Nursing And Midwifery College

##### Full name of responsible person

Tayyebah Shojaaldini Ardakani

##### Position

MSc student. Counseling In Midwifery

##### Other areas of specialty/work

**Street address**

Dead ended 88, Alley90, Khatami BLV, Ardakan, Yazd

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Sadoughi University Of Medical Science.  
Nursing And Midwifery College

**Full name of responsible person**

Tayyebeh Shojaaddini Ardakani

**Position**

MSc student, Counseling In Midwifery

**Other areas of specialty/work****Street address**

Dead ended 88, Alley90, Khatami BLV, Ardakan, Yazd

**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*