

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

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2

Recruitment center

Name of recruitment center

Behdasht And Darman

Full name of responsible person

Miss shojaaddini ardakani

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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

Tayyebeh Shojaaddini Ardakani

Position

Msc student

Other areas of specialty/work

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Person responsible for scientific inquiries

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

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Full name of responsible person

Tayyebeh Shojaaddini Ardakani

Position

MSc student,Counseling In Midwifery

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

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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