

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Determining the effect of group cognitive-behavioral counseling on pregnancy depression in pregnant women 12 - 22 weeks

Protocol summary

Summary

Introduction: The aim of this study is to investigate the effect of group cognitive-behavioral therapy on antepartum depression. Research method: The study population of this clinical trial included 12-22 weeks pregnant women who went to Qazvin health centers and were diagnosed with mild to moderate depression (based on the Beck Depression Inventory), for the first time. 60 individuals were selected using convenience sampling method and were randomly divided into two groups of 30 subjects, including the test and the control groups. Randomization was done through block randomization using blocks of random sizes. Subjects in the test group underwent 6 sessions of group cognitive-behavioral therapy on a weekly basis, based on the brief guide to depression intervention provided by Iranian Ministry of Health and Medical Education; and the control group received no training. Immediately after the end of the course and two months later, the Beck test was performed on all subjects, as a post-test. Criteria for entering the study: 12 - 22 week pregnant women who were diagnosed with mild to moderate depression for the first time; middle school or higher education; Not being diagnosed with chronic and infectious diseases (diabetes, high blood pressure, etc.); Not having symptoms of pregnancy (bleeding, placenta previa, ...) Conditions because of which one would have to leave the study: Use of psychiatric drugs; lack of interest in continuous participation in counseling sessions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042533518N3**

Registration date: **2017-10-17, 1396/07/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-17, 1396/07/25

Registrant information

Name

Zinat Jourabchi

Name of organization / entity

Qazvin University of Medical Sciences

Country

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Phone

+98 28 3323 7268

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Qazvin University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effect of group cognitive-behavioral counseling on pregnancy depression in pregnant women 12 - 22 weeks

Public title

Determining the effect of group cognitive-behavioral counseling on pregnancy depression in pregnant women

12 - 22 weeks

Purpose

Treatment

Inclusion/Exclusion criteria

Criteria for entering the study: 12 - 22 week pregnant women who were diagnosed with mild to moderate depression for the first time; middle school or higher education; Not being diagnosed with chronic and infectious diseases (diabetes, high blood pressure, etc.); Not having symptoms of pregnancy (bleeding, placenta previa, ...) Conditions because of which one would have to leave the study: Use of psychiatric drugs; lack of interest in continuous participation in counselor sessions.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization was done through block randomization using blocks of random sizes.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin

City

Qazvin

Postal code

34197-59811

Approval date

2017-05-27, 1396/03/06

Ethics committee reference number

IR.QUMS.REC.1395.196

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.9

ICD-10 code description

Depressive episode - unspecified

Primary outcomes

1

Description

Depression during pregnancy

Timepoint

Immediately after the intervention and two months later

Method of measurement

Beck Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The program of cognitive group therapy lasted 6 weeks. Each session lasted about an hour and in cases of delay in holding the discussion or the discussion taking too long, the duration of the meeting would increase. The interval between sessions was decided to be one day a week. The sessions plan included five areas: changing beliefs and sketchy processes, discovering a negative belief system, testing beliefs, changing beliefs and changing ineffective behavior.

Category

Behavior

2

Description

Control group: Did not receive any treatment. For the control group, no particular plan was considered, but were controlled only by other intervention factors.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bolandian Health Center

Full name of responsible person

Atefe Safaralinezhad

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Web page address

-

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research of Qazvin University of
Medical Sciences

Full name of responsible person

Dr.Zihinat jourabchi

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Qazvin University of Medical Sciences, bahonar blv,
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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 of Qazvin 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**

Qazvin University of Medical Sciences

Full name of responsible person

Zinat Jourabchi

Position

PhD in Community Health, Assistant Professor

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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