

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The Effectiveness of Self-Care-Based Cognitive Behavioral Therapy on Depression During Pregnancy

Protocol summary

Study aim

The purpose of this study was to investigate the effect of cognitive-behavioral group therapy on pregnancy-related depression. 68 eligible pregnant women with mild or moderate depression (based on Edinburgh's postpartum depression questionnaire) were selected through convenience sampling and were randomly assigned to two groups of 34 (control and test groups) The routine midwifery control group and the intervention group receive 7 sessions of one-hour cognitive-behavioral group therapy twice a week. Immediately after 4 and 8 weeks after the consultation sessions, all samples are invited to complete the questionnaire.

Design

This study is a randomized controlled trial. Samples were randomly divided into two groups of 34 controls and intervention.

Settings and conduct

This is a randomized controlled study that after receiving a written Letter of reference from Ahvaz University of Medical Sciences, received the Ethics Code from the Jundishapur University of Medical Sciences Ahwaz Medical Center, Shoushtar city due to the large number of pregnant women Covered by these centers will be referred.

Participants/Inclusion and exclusion criteria

Inclusion criteria: First gravid; Age of 15 to 45 years; Ability to speak Persian; Literacy of reading and writing; Earn Score 10 to 15 from the Edinburgh Postpartum Depression Scale; gestational age between 22 to 26 weeks. Exclusion criteria: Drug abuse; Mental illnesses other than depression; Neurological diseases; Receive any treatment during research for depression; Body Mass Index more than 25

Intervention groups

The control group will receive the routine obstetric cares from a midwife of the health center. The intervention includes: cognitive-behavioral therapy and its role in depression, self-care, learning to solve problems, and

challenging negative thoughts.

Main outcome variables

Reduce depression during pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180823040855N1**

Registration date: **2018-09-12, 1397/06/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-12, 1397/06/21**

Update count: **0**

Registration date

2018-09-12, 1397/06/21

Registrant information

Name

masumeh mehri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3623 3430

Email address

mehri.m@stu.ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-18, 1397/04/27

Expected recruitment end date

2018-09-18, 1397/06/27

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty
Scientific title
The Effectiveness of Self-Care-Based Cognitive Behavioral Therapy on Depression During Pregnancy

Public title
The Effectiveness of Self-Care-Based Cognitive Behavioral Therapy on Depression

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Gravid First Age of 15 to 45 years Ability to speak Persian Literacy reading and writing Earn score 10 to 15 from the Edinburgh Postpartum Depression Inventory Gestational age 22 to 26 weeks

Exclusion criteria:

Drug abuse Cause of other Mental Illnesses other than Major Depressive Disorder Neurological Diseases Receive any Treatment during Research for Major Depressive Disorder BMI More than 25

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples are randomly divided into two groups of intervention and control. The software is random statistical software

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

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan, Esfand Street
City
Ahvaz
Province
Khuzestan
Postal code
15794-61357

Approval date
2018-07-14, 1397/04/23

Ethics committee reference number
IR.AJUMS.REC.۱۳۹۷.۳۱۳

Health conditions studied

1

Description of health condition studied

depression

ICD-10 code

F32.9

ICD-10 code description

Major depressive disorder, single episode, unspecified

Primary outcomes

1

Description

Pregnancy Depression Score in Edinburgh Postpartum Depression Questionnaire

Timepoint

At the beginning of the study, immediately, 4 weeks and 8 weeks after the end of the intervention

Method of measurement

Edinburgh Postpartum Depression Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention according to a protocol called cognitive-behavioral self-care cognitive-behavioral therapy, a guide for women, written by Dr. Michel Herring Cognitive-behavioral counseling counselor in collaboration with the British Columbia mental health program, mental health services in British Columbia. The intervention was presented as 7 sessions of one-hour cognitive-behavioral group therapy once a week. The sessions include: providing information on depression, providing information on treatment options in women with depression during pregnancy and postpartum, including drug therapy and psychological treatments such as cognitive-behavioral therapy, explaining cognitive-behavioral therapy and its role in depression, Explain self-care and its importance, a description of different areas of self-care such as nutrition, exercise and the way to incorporate and nurture each of these

areas in the person's life, how to determine the goal of developing each of the areas of self-care and learning to solve existing problems To make positive changes in life, educate all kinds of wrong thoughts Intensify depression, learn how to identify and challenge these ideas, and provide solutions to prevent the return of symptoms of depression.

Category

Treatment - Other

2**Description**

Control group: The routine midwifery care group will receive a midwife from the health center and will be monitored for interventional factors.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Health Center No. 3

Full name of responsible person

Masumeh Mehri

Street address

Darvazeh, Fakharian Blvd

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Province

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

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Behzad Sharif MakhmalZade

Street address

School of Nursing and Midwifery, Jundishapur University of Medical Sciences, Ahvaz University City, Khuzestan, Ahvaz

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Grant name

Vice-chancellor for Research, Jundishapur University of Medical Sciences

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz University of Medical Sciences

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**

Ahvaz University of Medical Sciences

Full name of responsible person

Masumeh Mehri

Position

Ms in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mina Iravani

Position

Ph.D of Midwifery

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Web page address<http://ajums.ac.ir>**Person responsible for updating data****Contact****Name of organization / entity**

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Other areas of specialty/work

Midwifery

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Web page address<http://ajums.ac.ir>**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 total data of individuals after being unidentifiable is
shared.

When the data will become available and for how long

Two months after the publication of the article

To whom data/document is available

Anyone interested can access the data.

Under which criteria data/document could be used

In the case of citations for other research or comparison
of results with other research

From where data/document is obtainable

Masumeh Mehri mehry.masumeh@ yahoo.com
009163223880

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

A correspondent with the researcher's email and an
explanation of the purpose of reading and using the data

Comments