

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Controlled trial of effectiveness of Mindfulness integrated Cognitive Behavior Therapy on depression, anxiety and quality of life in pregnant women

Protocol summary

Summary

(1) Objectives: This study aims at investigating the effectiveness of mindfulness-integrated cognitive behavior therapy on pregnant women's depression, anxiety, and quality of life at Kashan. (2) Design: This is a pretest-post test experimental study. The intervention also includes a one-month follow-up course. (3) Methods: A sample of 70 eligible pregnant women will be recruited. Women will be randomly allocated to either the experimental or the control groups. The women in the experimental group will receive mindfulness-integrated cognitive behavior therapy while the women in the control group will receive no intervention. Study instruments include the Edinburgh Postnatal Depression Scale, the Beck Anxiety Inventory, and the Quality of Life Questionnaire. These instruments will be completed before, immediately after, and one month after the intervention. (4) Inclusion criteria: Having an age of 18-50 years and a gestational age of 2-6 months. (5) Exclusion criteria: Obtaining a score of less than 13 on the Edinburgh Postnatal Depression Scale, obtaining a score of less than 16 on the Beck Anxiety Inventory, receiving psychotherapy or drug therapy during the six months prior to the study, and having a previous history of suicide. (6) Intervention: The intervention of this study is a mindfulness-integrated cognitive behavior therapy which includes eight 90-minute sessions. (7) Primary outcomes: The primary outcomes are depression, anxiety, and quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012920869N1**
Registration date: **2015-06-02, 1394/03/12**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-02, 1394/03/12

Registrant information

Name

Reza Yazdanimehr

Name of organization / entity

Kashan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

yazdanimehr-re@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Kashan University of Medical Sciences and Health Services

Expected recruitment start date

2015-02-24, 1393/12/05

Expected recruitment end date

2015-03-01, 1393/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Controlled trial of effectiveness of Mindfulness integrated Cognitive Behavior Therapy on depression, anxiety and quality of life in pregnant women

Public title

Effectiveness of Mindfulness integrated Cognitive Behavior Therapy in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria 1. Being in the second to sixth months of pregnancy; 2. Having an age of 18–50 years; and 3. Having a degree in secondary education or higher. Exclusion criteria: 1. Obtaining a score of less than 13 on the Edinburgh Postnatal Depression Scale; 2. Obtaining a score of less than 16 on the Beck Anxiety Inventory; 3. Having a known-cause depression or anxiety following problems such as loss, marital conflicts, unwanted pregnancy, and divorce; 4. Having a history of psychotic disorders; 5. Receiving psychotherapy or drug therapy during past six months; 6. Opting for withdrawing from the study; 7. Failing to participate in more than two sessions of the study intervention; 8. Having a preterm delivery; 9. Having a previous history of suicide; and 10. Having a history of addiction.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Seventy eligible pregnant women will be recruited by using the convenience sampling method and allocated to either the control or the experimental groups by drawing.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences and Health Services

Street address

Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd

City

Kashan

Postal code**Approval date**

2014-12-17, 1393/09/26

Ethics committee reference number

29/5/1/4770/پ

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

Depression

ICD-10 code

F32.0

ICD-10 code description

Two or three of the above symptoms are usually present. The patient is usually distressed by these but will probably be able to continue with most activities.

2**Description of health condition studied**

Anxiety

ICD-10 code

F49.1

ICD-10 code description

Anxiety NOS

Primary outcomes**1****Description**

Depression

Timepoint

Before intervention, After intervention, One month after intervention

Method of measurement

Edinburgh Postpartum Depression Scale

2**Description**

Anxiety

Timepoint

Before intervention, After intervention, One month after intervention

Method of measurement

Beck Anxiety Inventory

3**Description**

Quality of life

Timepoint

Before intervention, After intervention, One month after intervention

Method of measurement

Quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group; Mindfulness-integrated cognitive behavior therapy; A systematic therapeutic approach which integrates mindfulness with cognitive behavior therapy. The aim of this approach is to help clients internalize their attention and hence, regulate their emotions and attention and use these skills for managing their problems in their immediate environments.

Category

Behavior

2

Description

Control group; Will receive no intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akramiyan health services center

Full name of responsible person

Zahra Aqazadeh

Street address

Akramiyan health services center, 22 Bahman St

City

Kashan

2

Recruitment center

Name of recruitment center

Ketabchi health services center

Full name of responsible person

Zahra Sabzikariyan

Street address

Ketabchi health services center, Bahonar Blvd,
Moalem Sq

City

Kashan

3

Recruitment center

Name of recruitment center

Taleqani health services center

Full name of responsible person

Zohreh Rabbani

Street address

Taleqani health services center, Taleqani St

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Kashan University of
Medical Sciences and Health Services

Full name of responsible person

Dr Qolam Ali Hamidi

Street address

Vice chancellor for research of Kashan University of
Medical Sciences and Health Services, Pezeshk Blvd,
5th of Qotbe Ravandi Blvd

City

Kashan

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 Kashan University of
Medical Sciences and Health Services

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

Kashan University of Medical Sciences and Health
Services

Full name of responsible person

Reza Yazdanimehr

Position

M.Sc candidate in clinical psychology

Other areas of specialty/work

Street address

Department of Clinical Psychology, School of
Medicine, Kashan University of Medical Sciences and
Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi
Blvd

City

Kashan

Postal code

Phone

+98 31 5554 0021

Fax

Email

rym1368@yahoo.com; yazdanimehr-re@kaums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences and Health services

Full name of responsible person

Reza yazdanimehr

Position

M.Sc candidate in clinical psychology

Other areas of specialty/work

Street address

Department of Clinical Psychology, School of Medicine, Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd

City

Kashan

Postal code

Phone

+98 31 5554 0021

Fax

Email

rym1368@yahoo.com; yazdanimehr-re@kaums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences and Health Services

Full name of responsible person

Reza Yazdanimehr

Position

M.Sc candidate in clinical psychology

Other areas of specialty/work

Street address

Department of Clinical Psychology, School of Medicine, Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd

City

Kashan

Postal code

Phone

00

Fax

Email

rym1368@yahoo.com

Web page address

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