Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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