Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of the Effectiveness of Mindfulness-based Counseling on Anxiety in Pregnant Women with Gestational Diabetes

Protocol summary

Study aim
determination of the effectiveness of mindfulness-based counseling on anxiety in pregnant women with gestational diabetes

Design
This research is a clinical trial with pretest-post test design with control group and with parallel groups without blindness. The sample size is 88 people and will be divided into two groups of control and test according to the random numbers table

Settings and conduct
This study will be carried out on pregnant women with gestational diabetes referred to health centers in Kerman.To select samples from the available sampling method, they will be invited by telephone call. After obtaining the consent and justification of the participants about the goals of the study and its implementation, as well as ensuring the confidentiality of the results, the demographic and midwifery profile questionnaire and Spielberg Situational and Attribute Anxiety are completed.

Participants/Inclusion and exclusion criteria
The inclusion criteria consisted of Age of 18-45 years; Reading and writing literacy; Having score of Situational anxiety 20-53 and Attribute anxiety 20-56; Gestational age 24-28 weeks; Gestational diabetes mellitus. The exclusion criteria consisted of History of mindfulness training; Having diabetes before pregnancy; Exposure to major stress caused by unforeseen incidents (grief, divorce)

Intervention groups
The intervention group will receive 8 sessions of group counseling based on mindfulness. sessions are 120 minutes and once a week by researcher. The control group does not receive intervention. At the end of the session, all participants in the study will be given a book on the subject of mindfulness.

Main outcome variables
Mean score of anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180627040261N1**
Registration date: **2018-09-04, 1397/06/13**
Registration timing: **retrospective**

Last update: **2018-09-04, 1397/06/13**
Update count: **0**

Registration date
2018-09-04, 1397/06/13

Registrant information

Name
Fatemeh Hamidi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2018-08-23, 1397/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Study of the Effectiveness of Mindfulness-based Counseling on Anxiety in Pregnant Women with Gestational Diabetes

Public title
The Effect of Counseling on Anxiety in Pregnant Women with Gestational Diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18-45 years Reading and writing literacy Having score of Situational anxiety 20-53 and Attribute anxiety 20-56 Gestational age 24-28 weeks Gestational diabetes mellitus
Exclusion criteria:
History of mindfulness training Having diabetes before pregnancy Exposure to major stress caused by unforeseen incidents (grief, divorce)
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals will be placed in one of the two intervention and control groups using simple randomization sequences based on random numbers
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
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Deputy of Research and Technology Development, Jundishapur University of Medical Sciences, Ahwaz, Ground floor
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2018-03-06, 1396/12/15
Ethics committee reference number
IR.AJUMS.REC.1396.1088

Health conditions studied

1

Description of health condition studied
Gestational Diabetes
ICD-10 code
O24.4
ICD-10 code description
Gestational diabetes mellitus

Primary outcomes

1

Description
Anxiety
Timepoint
Before the intervention, immediately after the intervention and one month after the intervention
Method of measurement
Spielberger Situational and Attribute Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group is divided into 4 groups of 11 people and each group will receive 8 sessions of group counseling based on mindfulness.The duration of each session is 120 minutes and once a week.
Category
Behavior

2

Description
Control group: No intervention
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Health centers in Kerman

Full name of responsible person
Fatemeh Hamidi

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Health centers in Kerman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

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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
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
Fatemeh Hamidi

Position
Master's student in midwifery counseling

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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Other areas of specialty/work

Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available