

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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)

Phone

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Email address

Hamidi.f@ajums.stu.ac.ir

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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Kerman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Deputy of Research, Ahwaz Jundishapur 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

Contact

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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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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