

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effect of mindfulness-based group counseling versus control group on perceived stress in pregnant women with gestational diabetes: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of mindfulness-based group counseling versus control group on perceived stress in pregnant women with gestational diabetes

Design

This is a randomized clinical trial with control group, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct

This study will be performed in the Diabetes Center of Besat Hospital in Hamadan city on 80 eligible pregnant women with gestational diabetes. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 16 to 45 years Gestational age of 28 weeks and more Gestational Diabetes Having stress
Exclusion criteria: History of mental illness Occurrence of fetal complications

Intervention groups

Intervention group: Routine care for diabetic patients, in addition to group counseling based on mindfulness, including 8 sessions of 60 to 90 minutes once a week (including the concept of mindfulness, automatic guidance system, facing obstacles, breathing meditation practice, sitting meditation practice, breathing space practice, body inspection awareness of breathing and body and sounds and thoughts, anxiety and its relationship with stress, awareness of pleasant and unpleasant events, self-care, conscious yoga, sleep hygiene, and preparing a list of enjoyable activities)
Control group: Just routine care for diabetic patients

Main outcome variables

Primary outcome: Perceived stress score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N440**

Registration date: **2022-09-09, 1401/06/18**

Registration timing: **prospective**

Last update: **2022-09-09, 1401/06/18**

Update count: **0**

Registration date

2022-09-09, 1401/06/18

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of mindfulness-based group counseling versus control group on perceived stress in pregnant women with gestational diabetes: a double-blind randomized clinical trial

Public title

Effect of mindfulness-based group counseling versus control group on perceived stress in pregnant women with gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 16 to 45 years Gestational age of 28 weeks and more Gestational Diabetes Having stress

Exclusion criteria:

History of mental illness Occurrence of fetal complications

Age

From **16 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2022-08-20, 1401/05/29

Ethics committee reference number

IR.UMSHA.REC.1401.459

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

Gestational diabetes mellitus

ICD-10 code

O24.4

ICD-10 code description

Gestational diabetes mellitus

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

Perceived stress score

Timepoint

Before the intervention and 8 weeks later

Method of measurement

Using Cohen's Perceived Stress Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Routine care for diabetic patients, in addition to group counseling based on mindfulness, including 8 sessions of 60 to 90 minutes once a week (including the concept of mindfulness, automatic guidance system, facing obstacles, breathing meditation practice, sitting meditation practice, breathing space practice, body inspection awareness of breathing and body and sounds and thoughts, anxiety and its relationship with stress, awareness of pleasant and unpleasant events, self-care, conscious yoga, sleep

hygiene, and preparing a list of enjoyable activities)

Category

Other

2

Description

Control group: Just routine care for diabetic patients

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Center of Besat Hospital in Hamadan city

Full name of responsible person

Niloofar Anajafi Marzijani

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Diabetes Center of Besat Hospital, Shahed Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Niloofar Anajafi Marzijani

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Zahra Masoomi

Position

Reproductive Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Phone**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