

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effect of stress management consulting on stress and quality of life of pregnant women with gestational diabetes attending to health care centers

Protocol summary

Summary

The purpose of this study will be to determine the effect of stress management counseling on stress management and quality of life in women with gestational diabetes. The research environment will include all health centers in Hamadan city. The study population will be included all pregnant women with gestational diabetes referred to Hamadan Health Center. In this study, 59 people in each of the test and control groups will be selected among people with inclusion criteria. The Hamadan Health Centers will be divided into 4 geographical areas, and 3 centers will randomly be selected from each areas. From a total of 12 Health Centers, 6 will be assigned to the experimental group and 6 to the control group randomly. The intervention group has 4 group counseling sessions on stress management. Counseling will take place in the form of GATHER counseling stages in 45-60 minutes (one weekly). The level of stress management and quality of life in the research samples will be measured before and one month after the consultation. Finally, the data will be evaluated using descriptive and analytical tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017062010635N3**
Registration date: **2017-09-02, 1396/06/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-02, 1396/06/11

Registrant information

Name

Soodabeh Aghababaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0150

Email address

aghababaii@yahoo.com

Recruitment status

Recruitment complete

Funding source

Hamadan Medical University

Expected recruitment start date

2017-07-06, 1396/04/15

Expected recruitment end date

2017-10-07, 1396/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of stress management consulting on stress and quality of life of pregnant women with gestational diabetes attending to health care centers

Public title

Effect of stress management consulting on stress and quality of life of pregnant women with gestational diabetes attending to health care centers

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of Gestational Diabetes; Not having other underlying illnesses; Single pregnancy; Gestational age 28- 32 weeks; Getting score 150 from

stress test; Having primary and higher education; Not having a history of gestational diabetes; Only treated with insulin; Do not use the medicine to reduce stress. Exclusion criteria: Not attending more than one class of training sessions; Major stressful events during research (serious illness of spouse and child, death of one of loved ones; accident, severe family disorder, divorce, migration) during study; Unwillingness to continue to study; Occurrence of pregnancy-related complications.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 78

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Random sampling method

Secondary Ids

empty

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

Hamadan University of Medical Sciences

Street address

Shahid Fahmideh Ave, Hamadan medical university,
Hamadan, Iran.

City

Hamadan

Postal code**Approval date**

2017-07-06, 1396/04/15

Ethics committee reference number

IR.UMSHA.REC.1396.254

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

Gestational Diabet

ICD-10 code

O24.9

ICD-10 code description

Diabetes mellitus in pregnancy, unspecified

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

Stress management

Timepoint

Before and after intervention

Method of measurement

Harry's Stress Questionnaire

Secondary outcomes**1****Description**

Quality of Life

Timepoint

Before and after intervention

Method of measurement

Quality of Life Questionnaire

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

The intervention group will have 4 group counseling sessions on stress management.

Category

Lifestyle

2**Description**

There is no intervention in the control group.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hamadan Medical University

Full name of responsible person

Aghababaei Soodabeh

Street address

Sahid Fahmideh Ave, Hamadan Medical University,
Hamadan, Iran.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Aghababaei Soodabeh

Street address

Hamadan

City

Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamadan University of Medical Sciences

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

Hamadan Medical University

Full name of responsible person

Aghababaei Soodabeh

Position

PhD/ Academic member

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Aghababaei Soodabeh

Position

Academic member/ PhD

Other areas of specialty/work

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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