Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 wiil 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
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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