

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The Effect of Educational-Behavioral Program on neurotic disorders (Depression, Anxiety and Stress) in Pregnant Diabetic Women

Protocol summary

Study aim

Determining the Effect of Educational Program on Neuropsychiatric Disorders (Depression, Anxiety and Stress) in Pregnant Women with Diabetics

Design

This study will be in the semi-experimental format with a pre-test,post-test design with the control group. The research community consists of diabetic pregnant women who visited health centers in Khoy, 2016.

Settings and conduct

The location of research will be health centers in Khoy. 40 samples will be selected through available sampling based on the inclusion criteria. Then, by means of coding the questionnaires are random choice, the odd numbers will be the intervention group and the even numbers will be the control group.Later, the samples will be put in both intervention and control group by means of random allocation. The participants will be unaware of the allocation of groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: reading and writing literacy: gestational age more than 20 weeks: age 18-35: history of 5_1 years of diabetes: score less than 23 in the questionnaire general health Non inclusion criteria: history of admission during the past 6 months: history of chronic and psychological illnesses

Intervention groups

The intervention group will receive both the regular pregnancy cares and five sessions for learning behavioral program(1 session per week for 90 minutes) in the classroom of teaching health centers. The control group will receive the regular pregnancy cares conducted in the center.

Main outcome variables

Depression score; anxiety score; stress score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151004024340N12**
Registration date: **2018-05-21, 1397/02/31**
Registration timing: **retrospective**

Last update: **2018-05-21, 1397/02/31**

Update count: **0**

Registration date

2018-05-21, 1397/02/31

Registrant information

Name

Hamideh Mohaddesi

Name of organization / entity

Urmia University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-06-04, 1395/03/15

Expected recruitment end date

2017-08-06, 1396/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Educational-Behavioral Program on neurotic disorders (Depression, Anxiety and Stress) in Pregnant

Diabetic Women

Public title

The impact of educational program on neurotic disorders (depression, anxiety, stress) in diabetic women with pregnancy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Literacy reading and writing Pregnant women are married Age 35_18 years Gestational age 20 weeks up Having 1_5 years of diabetes history Earn less than 23 points in the General Health Questionnaire

Exclusion criteria:

Having a hospital stay in the last two weeks Having a history of infertility History of chronic diseases History mental illness History of stressful life events in the last 6 months Having a history of abortion and stillbirth

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, 40 samples will be selected according to entry criteria. Then, by coding questionnaires and drawings (the numbers of the intervention group, the pair numbers of the control group) by random allocation method in two groups of intervention and control were given

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants will be unaware of the allocation of groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

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Orghance Street, Resalat blvd, Urmia University of Medical Sciences

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Approval date

2017-01-20, 1395/11/01

Ethics committee reference number

IR.UMSU.REC.13950367

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.9

ICD-10 code description

Depressive episode, unspecified

2

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

3

Description of health condition studied

Stress

ICD-10 code

Z73.3

ICD-10 code description

Stress, not elsewhere classified

Primary outcomes

1

Description

Depression

Timepoint

Before intervention; two months after intervention

Method of measurement

Depression Anxiety Stress Questionnaire_42

2

Description

Anxiety

Timepoint

Before intervention; two months after intervention

Method of measurement

Depression Anxiety Stress Questionnaire_42

3

Description

Stress

Timepoint

Before intervention; two months after intervention

Method of measurement

Depression Anxiety Stress Questionnaire_42

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group after completing the anxiety, stress and depression questionnaire, will be divided into two groups of ten, and separately for each group in 5 sessions (weekly one session for 90 minutes, by lecture, group discussion and Questions and answers) Educational-behavioral interventions such as diabetes and pregnancy and its complications on mother and fetus, self-care and family support in controlling diabetes, stress management training, relaxation, meditation and training in respiratory techniques in pregnancy, in addition to care they will usually get pregnant.

Category

Prevention

2

Description

Control group: The control group after completing the anxiety, stress and depression questionnaire, received only routine health care from their care providers.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Gabari Mogadam Health Center

Full name of responsible person

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Sponsors / Funding sources

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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

Oroumia 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Publishing research results in the form of article publishing

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

public

Under which criteria data/document could be used

Prevention in health centers

From where data/document is obtainable

Hamideh mohaddesi Contact number: 09143413242 E-mail: mohaddesi.ham@gmail.com

What processes are involved for a request to access data/document

Login to Urmia University of Medical Sciences and search for thesis title

Comments