Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Country
Iran (Islamic Republic of)

Phone
+98 44 3275 4963

Email address
mohaddesi.h@umsu.ac.ir

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
Street address
Orghance Street,Resalat blvd, Urmia University of Medical Sciences
City
Urmia
Province
West Azarbaijan
Postal code
571478334
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
Strees
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
Hamideh Mohaddesi
Street address
Shahid Kochari Street
City
Khoy
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3633 3680
Email
hmohaddesi.han@gmail.com

2

Recruitment center
Name of recruitment center
Shahid Samadzadeh Health Center
Full name of responsible person
Hamideh Mohaddesi
Street address
Darvaze Mako Street, Khoy
City
Khoy
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3623 4840
Email
hmohaddesi.han@gmail.com

3

Recruitment center
Name of recruitment center
Khorablo Health Center
Full name of responsible person
Hamideh Mohaddesi
Street address
Resalat Street, Khoy
City
Khoy
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3633 3810
Email
hmohaddesi.han@gmail.com

4

Recruitment center
Name of recruitment center
Golsanamlo Health Center
Full name of responsible person
Hamideh Mohaddesi
Street address
Engelab Street, Khoy
City
Khoy
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3644 0335
Email
hmohaddesi.han@gmail.com

5

Recruitment center

Name of recruitment center
Shahid Safarzadeh Health Center
Full name of responsible person
Hamideh Mohaddesi
Street address
Shahid Fahmideh Street, Khoy
City
Khoy
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3645 3929
Email
hmohaddesi.han@gmail.com

6

Recruitment center
Name of recruitment center
Jamshid Abad Health Center
Full name of responsible person
Hamideh Mohaddesi
Street address
Not reaching the gas station Kalavani, Khoy
City
Khoy
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3646 8780
Email
hmohaddesi.han@gmail.com

7

Recruitment center
Name of recruitment center
Yadilar Health Center
Full name of responsible person
Hamideh Mohaddesi
Street address
Emam Hossein Street
City
Khoy
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3636 1578
Email
hmohaddesi.han@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Iraj Mohebbi
Street address
Urmia University of Medical Sciences ,Orjhans Street ,Resalat Boulevard
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3625 0035
Email
Mohebi.i@gmail.com
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
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Hamideh Mohaddesi
Position
Assistance professor, Nursing and Midwifery department
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Nursing and Midwifery Faculty Urmia, Urmia University Of Medical Science
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3275 4963
Fax

Email
mohaddesi.ham@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Hamideh Mohaddesi
Position
Assistant Professor, Nursing and Midwifery Department
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Nursing & Midwifery Faculty Urmia
City
Urmia
Province
West Azarbaijan
Postal code
511473734
Phone
+98 44 3275 4963
Fax
Email
mohaddesi.ham@gmai.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Leila khoshkalam
Position
Master Student of Midwifery Counseling
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Valiasr Bolvar, Khoy
City
Khoy
Province
West Azarbaijan
Postal code
1476656763
Phone
+98 44 3625 0035
Fax
Email
Leilakhoshkalam29@gmail.com
Web page address

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