Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of group counseling versus no counseling on self-care behaviors and quality of life in pregnant prediabetic women: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of group counseling versus no counseling on self-care behaviors and quality of life in pregnant prediabetic women

Design
This a randomized clinical trial, phase II, in which 70 eligible pregnant prediabetic women will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible pregnant prediabetic women who will refer to Comprehensive Health Centers during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 35 years Gestational age of 6 to 10 weeks Gestational prediabetes Residence of Karaj City or its suburbs Having a medical record in Comprehensive Health Centers Exclusion criteria: Chronic diseases Acute or chronic mental diseases A history of previous gestational diabetes

Intervention groups
Intervention group: Routine pregnancy cares and prediabetes cares plus 4 group-sessions for 45 to 60 minutes Control group: Just routine pregnancy cares and prediabetes cares

Main outcome variables
(a) assessing self-care behaviors before intervention and at 24 to 28 weeks of pregnancy with taking history; (b) Assessing quality of life before intervention and at 24 to 28 weeks of pregnancy with a standard questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N209**
Registration date: **2018-03-09, 1396/12/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-09, 1396/12/18**
Update count: **0**

Registration date
2018-03-09, 1396/12/18

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 81 1838 0090

Email address
poorolajal@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-26, 1396/10/05

Expected recruitment end date
2020-07-31, 1399/05/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of group counseling versus no counseling on self-care behaviors and quality of life in pregnant prediabetic women: a randomized clinical trial

Public title
Effect of group counseling versus no counseling on self-care behaviors and quality of life in pregnant prediabetic women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 35 years Gestational age of 6 to 10 weeks Gestational prediabetes Residence of Karaj City or its suburbs Having a medical record in Comprehensive Health Centers
Exclusion criteria:
Chronic diseases Acute or chronic mental diseases A history of previous gestational diabetes
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment of the patients to the intervention and control groups through drawing of lots
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
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2017-09-27, 1396/07/05
Ethics committee reference number
IR.UMSHA.REC.1396.369

Health conditions studied

1

Description of health condition studied
pregnant prediabetic
ICD-10 code
O24.41
ICD-10 code description
Gestational diabetes mellitus in pregnancy

Primary outcomes

1

Description
Assessing self-care behaviors
Timepoint
Before intervention and at 24 to 28 weeks of pregnancy
Method of measurement
With taking history

2

Description
Assessing quality of life
Timepoint
Before intervention and at 24 to 28 weeks of pregnancy
Method of measurement
With a standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine pregnancy cares and prediabetes cares plus 4 group-sessions for 45 to 60 minutes
Category
Treatment - Other

2

Description
Control group: Just routine pregnancy cares and prediabetes cares
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive Health Centers
Full name of responsible person
Soraya Dargahi
Street address
School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
soraya.dargahi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
info.research@umsha.ac.ir
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
Soraya Dargahi
Position
Midwifery Student
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
soraya.dargahi@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Parsa Parsa
Position
Community Health Specialist
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
pparsa2003@yahoo.com

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
Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Email
poorolajal@umsha.ac.ir

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