

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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