Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Oct 2026

The effectiveness of health literacy consultation on lifestyle in women with high risk pregnancy in selected centers of Alborz province in 1396

Protocol summary

Summary

(1)Objectives:This study conducted as effectiveness of health literacy counseling on life style of high risk pregnant women affected by gestational diabetes.(2) Design:This is a randomized clinical trial without blinding.(3)Setting and conduct:2 selected centers in Alborz province(Alborz and Kamali hospitals)(4)Participants:The sample size will be 84 pregnant women in 2 selected centers.inclusion criteria: Iranian women between 18-35 years old,affected by gestational diabetes that they diagnosed at the first time in pregnancy by FBS or OGTT test and they have tendency and conscious consent to inter the study and they do not affect by other physical or psychological disorder and exclusion criteria: Unwillingness to continue participation in the study and if they do not present at least 2 sessions of total counseling sessions and affection to other disorder than diabetes.(5) Intervention: lifestyle counselling (6) main outcome measures: The primary outcome measure is lifestyle and secondary is gestational diabetes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021427728N3**
Registration date: **2017-04-05, 1396/01/16**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-04-05, 1396/01/16

Registrant information

Name

Zohreh Mahmoodi

Name of organization / entity

Nursing&Midwifery faculty

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Alborz University of Medical Sciences

Expected recruitment start date

2017-05-01, 1396/02/11

Expected recruitment end date

2017-09-01, 1396/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of health literacy consultation on lifestyle in women with high risk pregnancy in selected centers of Alborz province in 1396

Public title

The effectiveness of health literacy consultation on lifestyle in women with high risk pregnancy in selected centers of Alborz province in 1396

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Iranian women between 18-35 years old; affected by gestational diabetes that they diagnosed at the first time in pregnancy by FBS or OGTT test; have tendency and conscious consent to inter the study; do not affect by other physical or psychological disorder.

Exclusion criteria: Unwillingness to continue participation in the study; if they do not present at least 2 sessions of total counseling sessions; affection to other disorder than diabetes.

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

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Block sampling with random numeral

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Alborz University of Medical Sciences

Street address
ninth floor, Dara building, north Yasmin, east Pune street, 45 Yards of Golshahr, karaj, Iran

City
karaj

Postal code

Approval date
2017-01-28, 1395/11/09

Ethics committee reference number
Abzums.Rec.1395.146

Health conditions studied

1

Description of health condition studied
Gestational diabetes mellitus

ICD-10 code
O24.9

ICD-10 code description
Diabetes mellitus in pregnancy, unspecified

Primary outcomes

1

Description
life style

Timepoint
Before intervention _ Immediately after the intervention -3 weeks after intervention

Method of measurement
use of questionaire

Secondary outcomes

1

Description
health literacy

Timepoint
Before intervention; Immediately after the interventio; 3 weeks after intervention

Method of measurement
use of questionaire

Intervention groups

1

Description
1-Intervention group : In this group hold 6 health literacy consultation sessions weekly .The time of each session is 90 minute. In the control group: hold 6 routine consultation sessions weekly and The time of each session is 90 minute

Category
Lifestyle

2

Description
2-control group :They receive routine consultation

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Kamali hospitall

Full name of responsible person
DrZohreh Mahmoodi

Street address
Kamali Hospital,Kamali Allay,Tallegani street,Karaj.Iran Karaj

City
Karaj

2

Recruitment center
Name of recruitment center
Alborz hospitall
Full name of responsible person
Dr Zohreh Mahmoodi
Street address
Parastar boulevard ; Baghestane Gharb; Karaj
City
Karaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz University of Medical Sciences
Full name of responsible person
Dr Mohammad Noori sepehr
Street address
Department of Nursing., Alborz University of Medical Scienc.,Golestan 1, Eshteraki Street, Baghestan, Karaj,Iran.
City
Karaj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Alborz 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
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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