

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effect of Education through the Mobile Program on blood sugar and Health Promoting lifestyle of women with pregnancy diabet

Protocol summary

Study aim

Determining the Effect of Education through the Mobile Program on blood sugar and Health Promoting lifestyle of women with pregnancy diabet

Design

Clinical trial with control and intervention group, with groups of parallel groups, without blinding, randomized, on 76 patients. For randomization, a randomization list is used by a statistician.

Settings and conduct

The place is the health center and hospital of Baghmalek city. Before the intervention, intervention and control groups, in addition to informed consent, fasting blood sugar tests and oral glucose tolerance test are performed. Health and demographic health-promoting lifestyle questionnaire is completed. Lifestyle software is installed on the intervention group mobile phone. And the control group receive only routine care. The tests are taken again 4 weeks after the intervention and the lifestyle questionnaire is completed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Literacy for reading and writing - Pregnant women with prediabetes -Gestational age between 24 to 28 weeks-Having a smart phone-Willingness to participate in the study Exclusion criteria: over diabetes - Use of lifestyle software - preeclampsia - hypertension - Reluctance to participate in the study

Intervention groups

Before the intervention, fasting blood sugar tests and oral glucose tolerance test are performed from the two intervention and control groups. The health-promoting lifestyle questionnaire is completed. The lifestyle software is installed on the intervention group's mobile phone and the control group only takes care of Receive routine. 4 weeks after the intervention, the tests are taken again and the questionnaire is completed.

Main outcome variables

Improving the right lifestyle; Improve blood sugar; Reduction of maternal and neonatal complications

General information

Reason for update

The expected start and end dates are before the registration date of the clinical trial, and the journals have objections to publish the article.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200817048434N1**

Registration date: **2020-11-04, 1399/08/14**

Registration timing: **prospective**

Last update: **2023-07-24, 1402/05/02**

Update count: **1**

Registration date

2020-11-04, 1399/08/14

Registrant information

Name

Maryam Maleki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3323 9519

Email address

maleki.ma@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2022-04-20, 1401/01/31

Actual recruitment start date

2020-12-21, 1399/10/01

Actual recruitment end date

2022-04-20, 1401/01/31

Trial completion date

Scientific title

Effect of Education through the Mobile Program on blood sugar and Health Promoting lifestyle of women with pregnancy diabet

Public title

Effect of Education through the Mobile Program on blood sugar and Health Promoting lifestyle of women with pregnancy diabet

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Literacy pregnant women with pre-diabetes gestational age between 24 and 28 weeks having a smart phone willingness to participate in the study

Exclusion criteria:

overt diabetes use of lifestyle software preeclampsia hypertension unwillingness to participate in the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Actual sample size reached: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of assigning the type of intervention of the participants is random and random permutation blocks with block size 6 (using the table related to random permutations). A random list is prepared by a statistician. According to the randomized list, it is assigned by someone outside the study and according to the corresponding codes, to each person who enters the study.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Mobile application designed by Dr. Rokh Afrooz. Includes educational materials on six dimensions of a health-promoting lifestyle (diet and nutrition, physical activity and exercise, responsibility, interpersonal relationships, spiritual growth, stress management).

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ahvaz University of Medical Sciences

Street address

University Square, Golestan Highway, Ahvaz
Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

1579461357

Approval date

2020-04-18, 1399/01/30

Ethics committee reference number

IR.AJUMS.REC.1399.076

Health conditions studied**1****Description of health condition studied**

Gestational Diabetes

ICD-10 code

O24.41

ICD-10 code description

Gestational diabetes mellitus in pregnancy

Primary outcomes**1****Description**

Gestational Diabetes

Timepoint

Before intervention, after intervention

Method of measurement

Blood sugar test, health-promoting lifestyle questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: After randomization and informed consent, fasting blood sugar tests and oral glucose tolerance test are performed and a health-promoting lifestyle questionnaire is completed. Then, in addition to routine and routine care, Lifestyle software, which includes six dimensions of a health-promoting lifestyle, is installed on the intervention group's mobile phone and how to use it. It (including the use of educational materials, observance and attention to the correct principles of nutrition, exercise) is taught to pregnant

mothers. 4 weeks after the test is taken again and the questionnaire is completed.

Category

Lifestyle

2

Description

Control group: After randomization and informed consent, fasting blood glucose and oral glucose tolerance tests are evaluated for the control group and a demographic questionnaire and a health-promoting lifestyle are completed. For people in the control group, only routine and normal care is considered. 4 weeks later, the tests are checked again and the health-promoting lifestyle questionnaire is completed. Finally, the results of the two groups are compared.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

City Clinic Number One

Full name of responsible person

Dr. Ali Davarpanah

Street address

Ayatollah Khamenei Street, next to Sepah Bank, Clinic No. 1 in the city

City

Baghmalek

Province

Khouzestan

Postal code

6135715794

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+98 61 4372 2497

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info@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badvi

Street address

Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Province

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6315733653

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badvi-m@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Maryam Maleki

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Gendarmerie plaza, Street next to Haj Heshmat Shahbazi University, The alley in front of the culture store

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Nahavand

Province

Hamadan

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Email

Maleki.ma@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Parvaneh Mousavi

Position

teacher

Latest degree

Master

Other areas of specialty/work

Midwifery
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Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Maryam Maleki
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Gendarmerie plaza, Street next to Haj Heshmat
Shahbazi University, The alley in front of the culture
store
City

Nahvand
Province
Hamadan
Postal code
6591717851
Phone
0098 81 39519
Email
Maleki.ma@ajums.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