

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Study the effect of a mobile-based application on weight gain control of pregnant women during pregnancy

Protocol summary

Study aim

Determining the effect of a mobile phone-based application in controlling the weight gain of pregnant women during pregnancy

Design

In this randomized controlled trial study, all pregnant women (overweight and non-overweight) are divided into two intervention (50 people) and control (50 people) groups. Randomization is done by block method and using a table of random numbers.

Settings and conduct

When pregnant women in the 13th week of pregnancy go to the specialized gynecology office and clinic implementing the project, first, an introduction regarding the goals of the project will be given to the study subjects by the researcher in simple language, and then written informed consent will be obtained from the participants. Then the basic evaluations including weight, height, diet and physical activity are performed according to the criteria used in the application program. After allocating the participants to the intervention and control groups, the application program is installed and described by the researcher on the mobile phones of the people in the intervention group. The doctor will provide them with a full explanation of how to use the program.

Participants/Inclusion and exclusion criteria

Pregnant women who are overweight (body mass index above 25) and not overweight (body mass index below 25) with a gestational age of 13 weeks, with a smart phone with a singleton pregnancy, with at least elementary education, age above 18 years

Intervention groups

The control group includes pregnant women who receive their standard and usual care, and the intervention group includes pregnant women who, in addition to standard and usual care, use a designed smartphone-based application.

Main outcome variables

weight gain, food intake, physical activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221025056295N1**

Registration date: **2022-10-31, 1401/08/09**

Registration timing: **prospective**

Last update: **2022-10-31, 1401/08/09**

Update count: **0**

Registration date

2022-10-31, 1401/08/09

Registrant information

Name

Safoora Ramezani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3529 0494

Email address

ramezani-s@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-21, 1401/09/30

Expected recruitment end date

2023-07-21, 1402/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of a mobile-based application on weight gain control of pregnant women during pregnancy		smartphone-based application.	
Public title	Effect of a mobile application on weight gain control of pregnant women	Secondary Ids	empty
Purpose	Supportive	Ethics committees	
Inclusion/Exclusion criteria	Inclusion criteria: Pregnant women with overweight (body mass index above 25) and without overweight (body mass index below 25) with a gestational age of 13 weeks. Have a smart mobile phone with an Android operating system that has the ability to install an application. Have documents of singleton pregnancy. Have a minimum level of primary education. Age above 18 years. Exclusion criteria: Addiction or use of alcohol and drugs. Change of living place during the study period.	1	
Age	From 18 years old	Ethics committee	
Gender	Female	Name of ethics committee	Ethics Committee in Research Faculty of Nursing and Midwifery, Health and Paramedicine - Kashan Univ
Phase	N/A	Street address	Qutb Rawandi Blvd
Groups that have been masked	No information	City	kashan
Sample size	Target sample size: 100	Province	Isfahan
Randomization (investigator's opinion)	Randomized	Postal code	8715973474
Randomization description	In this randomized controlled trial study, all pregnant women (overweight and non-overweight) are divided into two intervention (50 people) and control (50 people) groups by block randomization method. Randomization is done by the block method in such a way that first all the 4 blocks containing two codes A and B are prepared (6 blocks), then the numbers one to six are selected using the table of random numbers (20 numbers).) and the corresponding block will be written based on the randomly selected number. With this, a sequence of 80 letters A and B will be obtained. Each of the sample will have a number from 1 to 80 (20 people to take into account attrition) and will receive an A or B code based on the list of letters based on the number of each person. Both groups will be almost the same. It should be mentioned that the effect of confounding variables will be controlled by the block randomization method.	Approval date	2022-10-04, 1401/07/12
Blinding (investigator's opinion)	Not blinded	Ethics committee reference number	IR.KAUMS.NUHEPM.REC.1401.053
Blinding description		Health conditions studied	
Placebo	Not used	1	
Assignment	Parallel	Description of health condition studied	pregnancy
Other design features	This study has two groups. The control group includes pregnant women who receive standard and usual care, and the intervention group includes pregnant women who, in addition to standard and usual care, use a	ICD-10 code	
		ICD-10 code description	
		Primary outcomes	
		1	
		Description	Weight gain
		Timepoint	From the 13th week of pregnancy monthly until the last week of pregnancy
		Method of measurement	In order to measure the weight, all subjects of the monthly study are weighed without shoes and with as little clothing as possible. To weigh pregnant women, the scale (seca) available in the specialized obstetrics and gynecology office and clinic of the project executive will be used, and the correct performance of the scale will be evaluated by weighing a 500-gram weight at each weighing session.
		2	
		Description	Food intake
		Timepoint	From the 13th week of pregnancy weekly until the last week of pregnancy

Method of measurement

To measure food intake, the food frequency questionnaire, which is a standard questionnaire, will be used.

3

Description

Physical activity

Timepoint

From the 13th week of pregnancy weekly until the last week of pregnancy

Method of measurement

In order to measure physical activity, the International Physical Activity Questionnaire, which is a standard questionnaire, will be used.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: includes pregnant women who use intervention in addition to standard and usual care. The intervention includes an application that was designed in a previous study by a team of health information management specialists and gynecologists using Adobe Air software under the Android operating system. It is an application with various capabilities, including providing educational information, recording information, calculating gestational age, birth date and body mass index, setting reminders and communicating with the doctor, which helps pregnant women to control weight gain during pregnancy. In this study, the capabilities of providing educational information, recording information and calculating gestational age, birth date and body mass index are used to measure the results of the study.

Category

Behavior

2

Description

Control group: includes pregnant women who are under their standard and usual care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi hospital

Full name of responsible person

Zahra Vahedpoor

Street address

Rajaei street

City

Kashan

Province

Isfahan

Postal code

8713743444

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholam Ali Hamidi

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Qutb Rawandi Blvd

City

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Province

Isfahan

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8715988141

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Email

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Mehrdad Farzandipour

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Information Management

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zahra Vehedpoor

Position

Specialist doctor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Safoora Ramezani

Position

MSc student of health information technology

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data file of participants and statistical analysis in SPSS file format will be available. Clinical study data in article format It will be published.

When the data will become available and for how long

6 months after the publication of the final results of the study.

To whom data/document is available

The final results of the study for the public and the data file and statistical analysis if requested by scientific institutions.

Under which criteria data/document could be used

Only scientific and academic institutions can send data access requests for scientific analysis.

From where data/document is obtainable

Kashan University of Medical Sciences, Department of Health Information Technology and Management, Safoora Ramezani.

What processes are involved for a request to access data/document

The application should be sent by post to the Health Information Technology and Management Department of Kashan University of Medical Sciences or to the following email: Ramezani-s@kaums.ac.ir

Comments