# 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

**Public title**
Effect of a mobile application on weight gain control of pregnant women
**Purpose**
Supportive
**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.
**Age**
From **18 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **100**
**Randomization (investigator's opinion)**
Randomized
**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.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**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 smartphone-based application.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee in Research Faculty of Nursing and Midwifery, Health and Paramedicine - Kashan Univ
**Street address**
Qutb Rawandi Blvd
**City**
kashan
**Province**
Isfehan
**Postal code**
8715973474
**Approval date**
2022-10-04, 1401/07/12
**Ethics committee reference number**
IR.KAUMS.NUHEPM.REC.1401.053

## Health conditions studied

### 1

**Description of health condition studied**
pregnancy
**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**
Isfehan
**Postal code**
8713743444
**Phone**
+98 31 5545 1515
**Email**
zahravahedpoor@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Kashan University of Medical Sciences
**Full name of responsible person**
Gholam Ali Hamidi
**Street address**
Qutb Rawandi Blvd
**City**
Kashan
**Province**
Isfehan
**Postal code**
8715988141
**Phone**
+98 31 5558 9399
**Email**
hamidi_gh@kaums.ac.ir
**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

**Street address**
Qutb Rawandi Blvd

**City**
Kashan

**Province**
Isfehan

**Postal code**
8715973449

**Phone**
0098 31 55540021-25

**Email**
farzandipour_m@kaums.ac.ir

## 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**
Gynecology and Obstetrics

**Street address**
Qutb Rawandi Blvd

**City**
Kashan

**Province**
Isfehan

**Postal code**
8715973474

**Phone**
+98 31 5554 0026

**Email**
zahravehedpoor@gmail.com

## 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**
Health Information Technology

**Street address**
Qutb Rawandi Blvd

**City**
Kashan

**Province**
Isfehan

**Postal code**
8157993411

**Phone**
+98 31 3529 0404

**Email**
safoora.ramezani@yahoo.com

## 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**