

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Evaluating the effect of using the most appropriate existing mobile health application and an innovative mobile health application to conduct a nutritional intervention study in pregnancy

Protocol summary

Study aim

Determining the impact of using the most appropriate existing mobile health App, and an innovative mobile health App in a nutritional intervention study in pregnancy

Design

A phase 2 clinical trial study without blinding and with parallel design will be performed on 60 pregnant mothers with a gestational age of less than 20 weeks. Participants will be randomly assigned to study groups using the table of random numbers.

Settings and conduct

Study site: Health care centers of 3 medical universities in Tehran province Method: The intervention will start from the 20th week of pregnancy. In addition to routine pregnancy care, intervention groups will receive the most appropriate available or an innovative mobile health app in the field of nutritional intervention, along with training on how to use the app. Routine prenatal care will be provided until delivery, and data including blood pressure, weight, and pregnancy complications will be recorded. The use of the application will also be assessed.

Participants/Inclusion and exclusion criteria

Pregnant mothers with: singleton pregnancy, over 18 years of age, gestational age under 20 weeks, having a smart phone; and without: chronic systemic diseases, eating disorders, any medication use, and movement disorders

Intervention groups

- The 1st intervention group: Using the most appropriate mobile health application available in the field of nutritional intervention - The 2nd intervention group: Using an innovative mobile health application produced in the field of nutritional intervention by researchers - Control group: Only routine pregnancy care

Main outcome variables

Weight gain during pregnancy, weight, height, and head circumference of the newborn at birth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211229053562N1**

Registration date: **2022-04-18, 1401/01/29**

Registration timing: **prospective**

Last update: **2022-04-18, 1401/01/29**

Update count: **0**

Registration date

2022-04-18, 1401/01/29

Registrant information

Name

sabereh ahmadi

Name of organization / entity

The University of Tarbiat Modares

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of using the most appropriate existing mobile health application and an innovative mobile health application to conduct a nutritional intervention study in pregnancy

Public title

A nutritional intervention study in pregnancy based on mobile health application

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian citizenship Resident of Tehran province 18 -45 years old Singleton pregnancy Having a smartphone Ability to read and speak Persian to understand the content of the application Gestational age less than 20 weeks

Exclusion criteria:

Chronic systemic diseases such as diabetes, hypertension, respiratory diseases, kidney diseases, and polycystic ovary syndrome, ... Eating disorders Use of any medication except for routine pregnancy supplements Any movement disorders

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the generation of random allocation sequence is done using a table of random numbers, and the two study groups are concealed as group A and group B, and then the participants will be assigned to one of the two groups according to the generated sequence.

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 Tarbiat Modares University

Street address

Ai-e-Ahmad Highway, Tarbiat Modares University

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Postal code

1411716911

Approval date

2021-12-25, 1400/10/04

Ethics committee reference number

IR.MODARES.REC.1400.258

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

pregnancy

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

nutrition

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

pregnancy weight gain

Timepoint

Beginning of the study (before the intervention), 31 to 34 weeks of gestation, time of delivery

Method of measurement

Will be extracted from the mother's prenatal care record

2**Description**

Anthropometric indices of the newborn including weight, height, and head circumference

Timepoint

At birth

Method of measurement

Based on the measurements recorded on the newborn's birth card

Secondary outcomes

1

Description

Gestational age at birth

Timepoint

Time of delivery

Method of measurement

Will be extracted from the mother's prenatal care and delivery records

Intervention groups

1

Description

The first Intervention group: The most suitable mobile health application available will be determined based on "the Mobile App Rating Scale" (MARS) in a preliminary study on nutritional applications available in the field of pregnancy. Mothers in the first intervention group will then receive a nutritional intervention based on the application of choice along with the necessary training on how to use the application, in addition to routine care during the Covid 19 pandemic, which has been reduced from 8 sessions to 4-5 sessions. The intervention will start from the 20th week of pregnancy. They will receive information about how to use the application, and the intervention will start from the 20th week of pregnancy. Routine follow-up and prenatal care will be provided until delivery, and maternal information including blood pressure, weight, and pregnancy complications will be recorded. In the follow-up process, the use of the nutritional intervention application will also be assessed.

Category

Lifestyle

2

Description

The second intervention group: Mothers in the second intervention group, in addition to routine prenatal care during the Covid 19 period, which has been reduced from 8 sessions to 4-5 face-to-face sessions, will receive an innovative mobile health application developed in the field of nutritional intervention by researchers in this same study. They will receive information about how to use the application and the intervention will start from the 20th week of pregnancy. Routine follow-up and prenatal care will be provided until delivery, and maternal information including blood pressure, weight, and pregnancy complications will be recorded. In the follow-up process, the use of the nutritional intervention application will also be assessed.

Category

Lifestyle

3

Description

Control group: Mothers in the control group will receive only routine pregnancy care, which according to the clinical guideline of Covid 19 disease in pregnancy, in low-risk pregnancies, the number of face-to-face care is

4-5 times according to the conditions of the residence area and absentee care is 4 times. Routine prenatal care and follow-up will be performed until delivery, and prenatal care information including blood pressure, weight, and pregnancy complications will be recorded.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Deputy of Health, Tehran University of Medical Sciences

Full name of responsible person

Dr. Alireza Oliaei Manesh

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No. 252, first floor, Intersection of Hafez and Jomhory Avenues

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Email

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Web page address

<https://health.tums.ac.ir>

2

Recruitment center

Name of recruitment center

Deputy of Health, Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Recruitment center

Name of recruitment center

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Web page address<https://iums.ac.ir>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tarbiat Modares University

Proportion provided by this source

20

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

2**Sponsor****Name of organization / entity**

Iran National Science Foundation

Full name of responsible person

Dr. Iman Eftekhari

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No. 33, 5th Street, above Jalal Al-Ahmad intersection, North Kargar Street

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Web page address<https://insf.org>**Grant name****Grant code / Reference number**

4002586

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

Yes

Title of funding source

Iran National Science Foundation

Proportion provided by this source

80

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**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

Tarbiat Modares University

Full name of responsible person

Lida Moghaddam-Banaem

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Maternal and Child Health

Street address

Department of Reproductive Health and Midwifery,

Faculty of Medical Sciences, Tarbiat Modares
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Maternal and Child Health

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Person responsible for updating data

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Sabereh Ahmadi

Position

MSc Student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

At the end of the study, the final report will be provided in 2 forms: - A theses for obtaining an MSc degree in Tarbiat Modares University - The final report of the approved research by the Iran National Scientific Foundation In both reports, details of the study protocol, statistical analysis map, and informed consent form will be mentioned. In addition, after the publication of the final report and also the articles extracted from the data of this project, at the request of researchers and scientific centers related to the research topic, data file, study protocol, statistical analysis map, informed consent form, and codes used in the analysis will be provided for them.

When the data will become available and for how long

After the end of the study, and publication of the mentioned reports

To whom data/document is available

Researchers and scientific centers related to the research topic

Under which criteria data/document could be used

In case of sending a written request via e-mail, and in order to use the results of the study in executive and research fields in order to promote pregnancy health

From where data/document is obtainable

Person in charge of the scientific research, Lida Moghaddam-Banaem

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

- Sending an email to the person in charge of the scientific research - Sending the mentioned request to the members of the research team - Assessment of the request by the research team - Sending the requested items to the applicant person or center, if approved by the research team, by the person in charge of the scientific research

Comments

