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)

Phone

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Email address

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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
City
Tehran
Province
Tehran
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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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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3

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Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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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info@insf.org
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
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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