Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of a maternal care virtual model based on a mobile phone application during pregnancy compared to in-person routine care

Protocol summary

Study aim

Determining the effectiveness of a mobile app-based virtual maternal care model during pregnancy compared to routine in-person care

Design

A quasi-randomized clinical trial, with a parallel control group, without blinding, on 150 pregnant mothers (two groups of 75 people)

Settings and conduct

A group of pregnant mothers covered by comprehensive health service centers of Iran University of Medical Sciences, who receive pregnancy care using a virtual model based on a mobile phone application, are compared with mothers receiving in-person routine.

Participants/Inclusion and exclusion criteria

Mothers with a low-risk pregnancy, age 18 to 40 years, planned pregnancy and singletons, with middle school education and above, ability and skill to use the mobile smartphone.

Intervention groups

Intervention group: pregnant mothers covered by a virtual model of care based on a mobile phone application. Control group: pregnant mothers covered by in-person routine care (usual).

Main outcome variables

-Technical quality (TQ) includes: - The number of overall care received, - The weight gain of the mother and fetus, - The number of • risk assessment, • self-care sessions recorded by the mother, • times the FHR is checked, • training received by mothers, • receiving medicinal supplements, • attended childbirth preparation classes, - How often to perform and record the results of blood and urine tests, - Frequency of performing and recording ultrasound results. -Service quality (SQ) includes: - Choosing a care provider, -Communication and interaction, -Authority - Support group availability, - Continuity of care, - Basic facilities and amenities - Preserving dignity, - Timeliness and immediate attention, - Safety, -Prevention, -Access, -The trust. Satisfaction in the following sections includes: - planning and scheduling, - Technology (for virtual group), - Provider, - Privacy, -General.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231109060006N1**
Registration date: **2024-01-01, 1402/10/11**
Registration timing: **prospective**

Last update: **2024-01-01, 1402/10/11**
Update count: **0**

Registration date

2024-01-01, 1402/10/11

Registrant information

Name

Hamideh Sabetrohani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-13, 1402/10/23

Expected recruitment end date

2024-06-08, 1403/03/19

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of a maternal care virtual model based on a mobile phone application during pregnancy compared to in-person routine care

Public title
Investigating changes in part of the maternal care process compared to routine care
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
The mother has a low-risk pregnancy. She refers to comprehensive health service centers. Her pregnancy should be planned and singleton. The mother should have a guidance school education or higher. The mother has the ability and skill to use a smart mobile phone (it does not mean ownership)
Exclusion criteria:
The mother has a high-risk pregnancy (including: a history of infertility, frequent miscarriage, heart disease, hypertension, diabetes, twin and multiple pregnancy, first trimester bleeding) Illiterate mother The mother's lack of access to a smart phone
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Not randomized
Randomization description
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 Shahroud University of Medical Sciences.
Street address
Research and Technology Vice-Chancellor, Faculty of Medicine, Shahrood University of Medical Sciences, Haftom Tir Square.
City
Shahroud
Province
Semnan
Postal code
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Approval date
2021-02-07, 1399/11/19
Ethics committee reference number
IR.SHMU.REC.1399.168

Health conditions studied

1

Description of health condition studied
Prenatal care
ICD-10 code
O36.7
ICD-10 code description
Maternal care for viable fetus in abdominal pregnancy

Primary outcomes

1

Description
1- Technical quality includes: - the number of general care received, - the amount of mother and fetus weighing, - the number of self-care recorded by the mother, - the number of fetal heart sound checks, - the number of training Received from mothers on various topics (such as symptoms that require attention during pregnancy, nutrition and weight gain, personal hygiene, oral and dental hygiene, mental health, common complaints during pregnancy, breastfeeding), - the number and time of starting to receive medicinal supplements, - the number Attended childbirth preparation classes, - Frequency of performing and recording blood and urine test results, - Frequency of performing and recording ultrasound results.
Timepoint
Once at the end of care number 5 of pregnancy (35-37 weeks).
Method of measurement
Technical quality - using the maternal health care checklist registered in the electronic health record.

2

Description
2- Service quality includes: - choice of care provider, - communication and interaction, - having authority, - availability of support group, - continuity of care, - facilities and basic facilities, - preservation of dignity, -

timeliness and immediate attention, - safety, - Prevention, - Access, and trust.

Timepoint

Once at the end of care number 5 of pregnancy (35-37 weeks).

Method of measurement

Service quality - using the questionnaire providing the CQMH model, which was prepared and approved by Tabrizi et al., the Persian version of this tool.

3

Description

3- Satisfaction in the following areas: - planning and scheduling, - technology (for virtual group), - provider, - privacy, - public.

Timepoint

Once at the end of care number 5 of pregnancy (35-37 weeks).

Method of measurement

Satisfaction - using the standard questionnaires presented in articles including (Pflugeisen 2017), this tool requires psychometrics for Iranian mothers.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: pregnant mothers covered by a virtual model of care based on a mobile phone application. A group of mothers (75 people) will be cared for during pregnancy based on the above-designed model after obtaining written informed consent.

Category

Other

2

Description

Control group: Pregnant mothers covered by in-person routine (usual) care. This group of pregnant mothers (75 people) will receive the same routine care during pregnancy after obtaining written informed consent and will only complete questionnaires.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health service centers under the health vice-chancellor of Iran University of Medical

Full name of responsible person

Dr. Seyyed Mohammad Tabatabai

Street address

3rd floor, Hafez campus building, intersection of Jomohri-e-Islami St. and Hafez St., Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Hossein Sheibani

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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

Shahroud University of Medical Sciences

Proportion provided by this source

1

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

Shahroud University of Medical Sciences

Full name of responsible person

Hamideh Sabetrohani
Position
PhD Student
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The written form of informed consent in two groups of mothers (intervention and control groups). Standard psychometric questionnaire of satisfaction in pregnancy care. The comparative pregnancy outcomes (like technical quality TQ, quality CQ, SQ, and satisfaction) in two groups of mothers (intervention and control groups).
When the data will become available and for how long
After finishing the doctoral course in the winter of 1403 (new year 2025)
To whom data/document is available
Researchers Students
Under which criteria data/document could be used
To complete your thesis and provide another aspect of virtual care. The use of data can be published only with the permission of Shahroud University of Medical Sciences and the first supervisor.
From where data/document is obtainable
Electronic Library of Shahroud University of Medical Sciences
What processes are involved for a request to access data/document
A written request must be given to the library, and after the approval of the first supervisor (Mrs. Dr. Karamet's office), access will be followed.
Comments