

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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)

##### Phone

+98 21 6600 2986

##### Email address

hamidehsabetrohani@gmail.com

##### 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 Shahrood University of Medical Sciences.

**Street address**

Research and Technology Vice-Chancellor, Faculty of Medicine, Shahrood University of Medical Sciences, Haftom Tir Square.

**City**

Shahrood

**Province**

Semnan

**Postal code**

۳۶۱۴۷۷۳۹۴۳

**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

### **City**

Tehran

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## **Sponsors / Funding sources**

### **1**

### **Sponsor**

#### **Name of organization / entity**

Shahrood University of Medical Sciences

#### **Full name of responsible person**

Dr. Hossein Sheibani

#### **Street address**

Management Office, Shahrood University of Medical Sciences and Health Services, Hafte Tir Square, Shahrood, Iran.

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info@shmu.ac.ir

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Shahrood 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**

Shahrood University of Medical Sciences

#### **Full name of responsible person**

Hamideh Sabetrohani

**Position**

PhD Student

**Latest degree**

Master

**Other areas of specialty/work**

Reproductive Health

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Afsaneh Keramat

**Position**

Faculty member - full professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

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Hamideh Sabetrohani

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Reproductive Health

**Street address**

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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**