

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Sep 2026

Evaluation of mobile applications in the field of pregnancy healthcare and investigating the effect of selected application on knowledge and self-care skills of pregnant women

Protocol summary

Study aim

Investigating the effect of mobile phone-based self-care application on pregnancy self-care knowledge and skills

Design

A clinical trial with a control group, with parallel groups, without blinding, randomized, on 108 patients. The randomization function of Excel software will be used for randomization.

Settings and conduct

This study will be conducted in Mako and Poldasht health centers.

Participants/Inclusion and exclusion criteria

Mothers who experience pregnancy for the first time;
Mothers who own smart cell phones; Mothers who have a diploma to a bachelor's degree (no less than a diploma and no more than a bachelor's degree).

Intervention groups

In the current study, the intervention group will use a mobile phone-based application while receiving ongoing care from health centers. The control group will receive only the usual care provided by the health center.

Main outcome variables

Self-care knowledge and skills

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230426057997N1**

Registration date: **2023-05-12, 1402/02/22**

Registration timing: **prospective**

Last update: **2023-05-12, 1402/02/22**

Update count: **0**

Registration date

2023-05-12, 1402/02/22

Registrant information

Name

Aynaz Nourani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 2307

Email address

nourani.a@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

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

Evaluation of mobile applications in the field of pregnancy healthcare and investigating the effect of selected application on knowledge and self-care skills of pregnant women

Public title

investigating the effect of mobile application on knowledge and self-care skills of pregnant women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Mothers who experience pregnancy for the first time.

Mothers who own smart cell phones.
Exclusion criteria:
Mothers with less than a diploma or more than a bachelor's degree.

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **108**

Randomization (investigator's opinion)
Randomized

Randomization description
simple randomization In this method, the table of random numbers will be used. A number is randomly assigned to each participant. If the number is even, the participant will be in the intervention group, and if it is odd, the participant will be in the control group.

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 Urmia University of Medical Sciences

Street address

Pardis Nazlou, 11 km of Nazlou Road,Urmia,Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2023-03-08, 1401/12/17

Ethics committee reference number

IR.UMSU.REC.1401.412

Health conditions studied

1

Description of health condition studied

Pregnancy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

Self-care knowledge and skills

Timepoint

Trimester

Method of measurement

Researcher made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Providing applications to pregnant mothers: In this intervention, a mobile application has been approved by the Scientific Association of Women and Reproductive Health, and will be available to pregnant mothers for three months. In addition to receiving common care from health centers, mothers will use this program to improve their self-care knowledge and skills. In this mobile application, educational content will be provided to pregnant mothers. These contents include common diseases and complications during pregnancy, maternal and fetal health, important times in pregnancy such as screening time, important ultrasounds, basic tests, etc.

Category

Other

2

Description

Control group: Providing routine pregnancy care from the health center

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center of Poldasht city

Full name of responsible person

Nasrin Niknafs

Street address

Poldasht city, Sarbaz St., next to the telecommunications office, Poldasht city health center

City

Poldasht

Province
West Azarbaijan
Postal code
5877136183
Phone
+98 44 3428 2626
Email
nasrin.niknafs@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Saber Golizadeh
Street address
11th km of Saro Road - Urmia University of Medical Sciences Educational Campus - Faculty of Paramedicine
City
Urmia
Province
West Azarbaijan
Postal code
5756115198
Phone
+98 44 3275 2301
Email
saber@umsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia University of Medical Sciences

Proportion provided by this source

50

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
Oroumia University of Medical Sciences
Full name of responsible person
Aynaz Nourani
Position
Assistant Professor
Latest degree
Ph.D.

Other areas of specialty/work

Medical Informatics

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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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

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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The documents and data of this study will be provided to

the audience in the form of a final project report and article while maintaining the confidentiality and privacy of the participants.

When the data will become available and for how long

The starts time at the same time as the results are published

To whom data/document is available

All researchers

Under which criteria data/document could be used

In order to compare the results and data with the results of other applications used as an intervention in another clinical trial

From where data/document is obtainable

Applicants can refer to the Department of Health Information Technology, Urmia University of Medical Sciences, at km 11 of Sarro Road, University of Medical Sciences Campus, Faculty of Paramedicine, Dr. Aynaz Noorani. The mobile number is 09144433526 and the postal code is 5756115198.

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

Given that the data will remain confidential with the responsible person. Applicants can submit an application to the research vice-chancellor of the university and provide documentation related to the use of data to the research ethics committee of Urmia University of Medical Sciences and obtain data permission from the person in charge.

Comments