

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Aug 2026

Design, validation and testing of the application "Promoting health during pregnancy" under the smartphone based on the experiences of mothers: a clinical trial study

Protocol summary

Study aim

Design, validation and testing of "Pregnancy Health Promotion" application under smartphones based on mothers' experiences

Design

The study is a clinical trial on 60 pregnant women in two experimental and control groups with randomized specialization by quadruple blocking method.

Settings and conduct

Clinical trial on 60 pregnant women referred to comprehensive urban health centers in two groups of experimental and control. The first day of the study is completed by the UTAUT questionnaire and the modified health-promoting lifestyle questionnaire in pregnancy. Then install the duplication intervention group and use it daily for free for a month. For the control group, only the usual prenatal care of health centers is performed. After the test, both groups will be pre-tested in the same way after the end of the fourth week.

Participants/Inclusion and exclusion criteria

Willingness to participate in the study, at least a diploma, low-risk pregnancy Having a smartphone with Internet access, obtaining a score higher than 50 out of 100 points of the Electronic Health Literacy Questionnaire

Intervention groups

The intervention group is asked to install the application and use the application features daily for one month and completely free of charge. For both groups, routine and routine programs will be implemented in health centers.

Main outcome variables

Score of Modified Health Promoting Lifestyle Questionnaire in Pregnancy, Technology Acceptance Score in UTAUT Questionnaire, Tendency to Continue Using Technology in UTAUT Questionnaire,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180412039276N2**

Registration date: **2022-05-23, 1401/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-23, 1401/03/02**

Update count: **0**

Registration date

2022-05-23, 1401/03/02

Registrant information

Name

Fateme Asadollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3822 6371

Email address

fasadollahi8@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-21, 1400/08/30

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, validation and testing of the application "Promoting health during pregnancy" under the smartphone based on the experiences of mothers: a clinical trial study

Public title

Design and testing of "Pregnancy Health Promotion" application under smartphones based on mothers' experiences

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate in the study, at least a diploma, low-risk pregnancy, gestational age at the time of enrollment at least 8 weeks and a maximum of 36 weeks, no medical and underlying diseases, having a smartphone with Internet access and Having the skill of using a smartphone, earning a score equal to 50 out of 100 points of the Electronic Health Literacy Questionnaire

Exclusion criteria:

Reluctance to use the application within the specified period, delivery before the end of the research period, disconnection of communication channels of the research unit with the researcher, lack of access to smartphones and Internet during the study period, occurrence of any pregnancy-related complications during the study period, Do not use the application in the intervention group for more than seven consecutive days

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of allocating samples in groups is defined as four-way Permuted block randomization in a ratio of 1: 1. In this method, different modes of the two groups (a total of 4 conditions: 1-control-intervention, 2-intervention-control, 3-intervention-intervention, 4-control-control) are written on four cards and placed in a container. May be. It should be noted that the sequence of these cases will be determined by a statistician. The researcher will first acquaint the pregnant mothers with a full explanation of the research and its objectives, and then informed written consent will be obtained from the volunteers. In order to assign randomly, a person outside the research team and uninformed from the study is asked to take a card from the container and specify which group each of the patients who enter the study should be in. This process continues until all the cards are taken out of the box and the cards are returned to the box, and this random selection will be repeated to

provide the desired sample size.

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**

Research Ethics Committees of Mashhad University of Medical Sciences

Street address

Mashhad, Sarafrazan Boulevard, Sarafrazan 11, No. 4

City

mashhad

Province

Razavi Khorasan

Postal code

9177116763

Approval date

2021-09-25, 1400/07/03

Ethics committee reference number

۴۰۰۲۰۱

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

pregnancy care

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

Score of Modified Health Promoting Lifestyle Questionnaire in Pregnancy, Technology Acceptance Score in UTAUT Questionnaire, Tendency to Continue Using Technology in UTAUT Questionnaire,

Timepoint

The measurement periods are the first day of the study and the second period is 40 days later.

Method of measurement

Modified Health Promoting Lifestyle Assessment in Pregnancy - UTAUT Questionnaire,

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Get routine pregnancy care

Category

Lifestyle

2

Description

Intervention group: Install the application and use the application features daily for one month and completely free of charge

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad No. 1 Health Center

Full name of responsible person

Dr. Nasser Amini

Street address

Health Center No. 1 of Mashhad , next to Shahrbanii Township, Vakil Abad Blvd , Mashhad

City

Mashhad

Province

Razavi Khorasan

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Fax

Email

AminiN1@mums.ac.ir

Web page address

<http://ch-mashhad1.mums.ac.ir/index.php>

2

Recruitment center

Name of recruitment center

Mashhad No. 2 Health Center

Full name of responsible person

Dr. Ali Asghar Mahmoudi

Street address

Mashhad Health Center No. 2, Panjrah Paeen Kheyaban Ave , Mashhad

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Mashhad

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Email

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Web page address

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3

Recruitment center

Name of recruitment center

Mashhad No. 3 Health Center

Full name of responsible person

Dr. Brat Ali Arabnejad

Street address

Mashhad No. 3 Health Center, Payam Street ,Ershad 8 blvd,Khayyam blvd, Mashhsad ,Iran

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arabnejadba1@mums.ac.ir

Web page address

<http://behdasht3.mums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Qureishi building ,Daneshgah Ave ,Mashhad, Razavi Khorasan Province

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Postal code

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Email

tafaghodim@mums.ac.ir

Web page address

<http://v-research.mums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

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**

Mashhad University of Medical Sciences

Full name of responsible person

fateme asadollahi

Position

phd student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Fateme Asadollahi

Position

Master of Science student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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

Mashhad University of Medical Sciences

Full name of responsible person

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Position

phd student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street addressNo. 4, sarafrazan 11 Ave., sarafrazan Blvd., mashhad
Town**City**

mashhad

Province**Sharing plan****Deidentified Individual Participant Data Set (IPD)**Undecided - It is not yet known if there will be a plan to
make this available**Study Protocol**Undecided - It is not yet known if there will be a plan to
make this available**Statistical Analysis Plan**Undecided - It is not yet known if there will be a plan to
make this available**Informed Consent Form**Undecided - It is not yet known if there will be a plan to
make this available**Clinical Study Report**Undecided - It is not yet known if there will be a plan to
make this available**Analytic Code**Undecided - It is not yet known if there will be a plan to
make this available**Data Dictionary**Undecided - It is not yet known if there will be a plan to
make this available