Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Oct 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
۴۰۰۰۲۰۱

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 Shahrbani Township, Vakil Abad Blvd , Mashhad
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Email
AminiN1@mums.ac.ir
Web page address
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2

Recruitment center
Name of recruitment center
Mashhad No. 2 Health Center
Full name of responsible person
Dr. Ali Asghar Mahmoudi
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Mashhad Health Center No. 2, Panjrah Paeen Kheyaban Ave , Mashhad
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Email
MahmoudiAA1@mums.ac.ir
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
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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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Province
Razavi Khorasan
Postal code
91735-951
Phone
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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
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Person responsible for updating data

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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