

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Design, implementation, and evaluation of a theory-based educational intervention based on the mobile app to promote cervical cancer prevention behaviors

Protocol summary

Study aim

educational intervention program using mobile application to promote cervical cancer prevention behaviors

Design

This study is a clinical trial (RCT) with two intervention groups and a control group. Blocked randomization will be used to assign participants to three groups. Envelopes are used to allocate concealment.

Settings and conduct

According to the inclusion criteria, the target group is women aged 18 to 48 years which will be announced through an internet call on several common social networks for participation in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with sexual experience, 18-49 years, Resident in Ramsar, Having a smartphone and the ability to use it, no mental disorders, drug dependence and addiction, having a minimum Literacy and the ability to answer questions and discuss in classrooms, lack of midwifery base and related fields of study, having consent to participate in the study. Exclusion criteria: Mental disorders, drug dependence and addiction, failure to complete the questionnaire, lack of access to the participant for any unpredictable reason.

Intervention groups

Intervention group 1: The intervention is designed based on the content of the training obtained from the qualitative and review stage of the study using online group discussion teaching methods, photos, videos and etc. will be provided in the mobile application platform. Intervention group 2: The intervention designed based on the educational content obtained from the qualitative and review stage of the study using the educational content will be received digitally.

Main outcome variables

Preventive behaviors of cervical cancer prevention

behaviors including The intention for doing a screening test (pap-test, genital examination).

General information

Reason for update

The protocol article is under review in BMC-TRIAL.
Correct spelling mistakes

Acronym

IRCT registration information

IRCT registration number: **IRCT20181205041861N3**
Registration date: **2021-10-26, 1400/08/04**
Registration timing: **prospective**

Last update: **2022-07-03, 1401/04/12**

Update count: **1**

Registration date

2021-10-26, 1400/08/04

Registrant information

Name

Sara Kazemi

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8882 4546

Email address

sara.kazemi@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, implementation, and evaluation of a theory-based educational intervention based on the mobile app to promote cervical cancer prevention behaviors

Public title

The effect of mobile application-based educational intervention on promoting cervical cancer prevention behaviors

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Married women of childbearing age 18-49 (having married at least once regardless of their current marital status) Resident of Ramsar Having a smartphone and knowing how to use it Has not received training before the intervention literate

Exclusion criteria:

Opt out of study Patients with learning disabilities

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method was used to randomize the samples. Envelopes will be ready, printed, and embedded in the envelope by a member of the research team and random numbers on the Randomaize.com site. The envelopes will be closed and their contents will not be visible. Then the researcher explains the purpose of the study by phone for people who were eligible to enter the study. If the person is willing to participate in the study, she will be required to submit the informed consent form by email or the contact number registered on one of the social networks, such as Telegram and WhatsApp. Then the applicant is allowed to the researcher to open an envelope on his behalf. The researcher then unpacks the envelope and, based on the contents of the envelope, the applicant will be categorized for the intervention or control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Educational intervention in the field of promoting cervical cancer prevention behaviors through smart mobile application software.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Trabiat Modares University

Street address

Jalal Al-Ahmad St., Nasr Bridge, Tarbiat Modares University, School of Medicine

City

Tehran

Province

Tehran

Postal code

111-14115

Approval date

2021-05-24, 1400/03/03

Ethics committee reference number

IR.MODARES.REC.1400.049

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

Cervical cancer

ICD-10 code

C53.9

ICD-10 code description

Malignant neoplasm of cervix uteri, unspecified

Primary outcomes**1****Description**

Preventive measures for cervical cancer

Timepoint

Measurement of behavior before intervention, Immediately after intervention, and 3 months after intervention

Method of measurement

Use of preventive behaviors questionnaire to promote cervical cancer

2**Description**

Knowledge about the preventive behaviors of cervical cancer

Timepoint

Measurement of awareness before intervention,
Immediately after intervention, and 3 months after the
intervention

Method of measurement

Use of preventive behaviors questionnaire to promote
cervical cancer

3

Description

Motivation for preventive behaviors of cervical cancer

Timepoint

Measurement of motivation before the intervention,
Immediately after the intervention, and 3 months after
the intervention.

Method of measurement

Use of preventive behaviors questionnaire to promote
cervical cancer

4

Description

Behavioral intention to prevent cervical cancer

Timepoint

Measurement of action to preventive behavior before the
intervention, Immediately after the intervention, and 3
months after the intervention.

Method of measurement

Use of preventive behaviors questionnaire to promote
cervical cancer

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Description

Information Factors Related to Cervical Cancer
Preventive Behaviors

Timepoint

Measurement of Information factors to preventive
behavior before the intervention, Immediately after the
intervention, and 3 months after the intervention.

Method of measurement

Use of preventive behaviors questionnaire to promote
cervical cancer

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Description

Predisposing factors cervical cancer preventive
behaviors

Timepoint

Measurement of predisposing factors to preventive
behavior before the intervention, Immediately after the
intervention, and 3 months after the intervention.

Method of measurement

Use of preventive behaviors questionnaire to promote
cervical cancer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Educational content on preventive
behaviours on cervical cancer is prepared based on the
effective structures of I-Change theory, which will be
obtained from the qualitative and review phase. The
educational content designed in the form of an
educational application is installed in the smartphones of
the intervention group (women 18-49 years old).
Educational content through online group teaching
methods, Q&A and collaborative learning, problem-
solving, talking about positive experiences, posters,
brochures, photos, videos and educational slides,
retelling memories, etc. in the context of the mobile
application will be provided.

Category

Behavior

2

Description

Intervention group 2: This group will receive the
educational intervention in accordance with the
conceptual framework resulting from the influential
structures of I-Change theory in digital form.

Category

Behavior

3

Description

Control group: After evaluating and comparing the two
educational interventions, based on ethical principles,
this group will also receive the desired interventions.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol University of Medical Sciences

Full name of responsible person

Sara Kazemi

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Fatemeh Zahra School of Nursing Ramsar, Imam
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of Medical Sciences, Tarbiat Modares University

Full name of responsible person

Dr Yaghoub Fathollahi

Street address

Faculty of Medical Sciences, Tarbiat Modares University, Jalal Ale Ahmad Highway.Tehran

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141173116

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f.zarei@modares.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Faculty of Medical Sciences, Tarbiat Modares University

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**

Faculty of Medical Sciences, Tarbiat Modares University

Full name of responsible person

Sara Kazemi

Position

Ph.d student

Latest degree

Master

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Fateme Zarei

Position

Assistant professor

Latest degree

Ph.D.

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Person responsible for updating data

Contact**Name of organization / entity**

Tarbiat Modares University

Full name of responsible person

Sara Kazemi

Position

ph.d student

Latest degree

Master

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Part of the data on the main consequences can be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Repeated measurement analysis to evaluate the duration of training 6 months after the last intervention

From where data/document is obtainable

By sending an email to the email address of Dr. Fatemeh Zarei f.zarei@modares.ac.ir

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

One week after sending the email by the applicant to the email address of Dr. Fatemeh Zarei f.zarei@modares.ac.ir will be answered.

Comments