Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Two Educational Intervention Methods With Mobile Application vs. Face-to-Face Instruction on Knowledge, Attitude, Practice, Perceived Self-Efficacy, and Adherence with Pap Smear Testing among Women Aged 30-59

Protocol summary

Study aim

Investigation and comparison of two methods of educational intervention by mobile phone application and face-to-face training in knowledge, attitude, performance, perceived self-efficacy and compliance to repeat pap smear test among women aged 30-59

Design

This study is a clinical trial (RCT) with two intervention groups and one control group. Randomized block method will be used to assign the participants to three groups. The envelope is used to hide the allocation

Settings and conduct

Entering, the target population is women (30-59) years old. The participants will announce their readiness to participate in the study through an internet call on several popular social networks.

Participants/Inclusion and exclusion criteria

1. A resident of Saveh city 2. Covered by the centers and has an active electronic file of the Sib system 3. Age between 30 and 59 years 4. Having marriage experience 5. More than 3 years have passed since the first sex 6. Obtaining a weak and average knowledge score in the first stage of study 7. Using a smart mobile phone to use virtual networks (ITA program) 8. Desire to participate in research

Intervention groups

The first intervention group: the intervention designed based on the training content obtained from the qualitative and review phase of the study will be presented using the face-to-face and in-person training method. The second intervention group: the intervention designed based on the training content obtained from the qualitative and review phase of the study with They will receive the use of the mobile phone application. Control group: they will not receive it during the educational study, after the study the educational content will be provided to them.

Main outcome variables

The average score of knowledge, attitude, performance, perceived self-efficacy and adherence to re-doing the pap smear test of women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231130060228N1**
Registration date: **2024-02-19, 1402/11/30**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-19, 1402/11/30**
Update count: **0**

Registration date

2024-02-19, 1402/11/30

Registrant information

Name

Leila Ahadi

Name of organization / entity

The University of Tarbiat Modares

Country

Iran (Islamic Republic of)

Phone

+98 86 4224 7093

Email address

leila.ahadi@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-19, 1402/11/30

Expected recruitment end date

2024-08-19, 1403/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Two Educational Intervention Methods With Mobile Application vs. Face-to-Face Instruction on Knowledge, Attitude, Practice, Perceived Self-Efficacy, and Adherence with Pap Smear Testing among Women Aged 30-59

Public title

Comparison of Two Educational Intervention Methods With Mobile Application vs. Face-to-Face Instruction on Knowledge, Attitude, Practice, Perceived Self-Efficacy, and Adherence with Pap Smear Testing among Women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

1. A resident of Saveh city Covered by the centers and has an active electronic file of the Sib system Age between 30 and 59 years Having marriage experience More than 3 years have passed since the first sex Obtaining a weak and average knowledge score in the first stage of study Using a smart mobile phone to use virtual networks (ITA) Desire to participate in research

Exclusion criteria:

1. Participation in another educational program at the same time or parallel to the intervention Being pregnant now Perform hysterectomy Genital warts or cervical cancer known and under treatment Conducting a pap smear test in the last 2 years Conducting HPV screening tests in the last 10 years

Age

From **30 years** old to **59 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

A list of individuals who have achieved poor and average knowledge scores will be compiled. These individuals will be numbered consecutively for random assignment to one of three groups: A, B, or C. This study will involve 120 participants. The method of permutation blocks will be employed for this purpose. We will utilize Random Allocation Software, which will be used to create 20 blocks of six. This software aids in balancing the number of samples allocated to each group under study. This feature is particularly beneficial when intermediate analyses are required during the sampling process, as it ensures an equal number of samples in each group. In this study, the blocking type is consistent across all blocks. Out of the total 120 participants, groups A (control group), B (intervention group receiving face-to-face training), and C (intervention group receiving training via a mobile phone application) will each be assigned 40 participants. Upon selection of the samples, they will be contacted. A brief overview of the study, its objectives, the teaching method, and the criteria for inclusion and exclusion from the study will be provided. If they are willing to participate, they will be included in the study. If they decline, the next individual will be contacted. Written consent will be obtained from all participants agreeing to participate in the study.

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 Tarbiat Modares University

Street address

Jalal Al Ahmad Street, Nasr Bridge, Tarbiat Modares University, Faculty of Medicine

City

Tehran

Province

Tehran

Postal code

111-14115

Approval date

2023-11-18, 1402/08/27

Ethics committee reference number

IR.MODARES.REC.1402.171

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
Knowledge score in the Farsi version of cervical cancer screening self-efficacy questionnaire
Timepoint
Before the intervention, immediately, one month later and three months after the intervention
Method of measurement
Persian version of cervical cancer screening self-efficacy questionnaire

2

Description
Attitude score in the Persian version of cervical cancer screening self-efficacy questionnaire
Timepoint
Before the intervention, immediately, one month later and three months after the intervention
Method of measurement
Persian version of cervical cancer screening self-efficacy questionnaire

3

Description
Self-efficacy score in the Farsi version of cervical cancer screening self-efficacy scale
Timepoint
Before the intervention, immediately, one month later and three months after the intervention
Method of measurement
Persian version of cervical cancer screening self-efficacy questionnaire

4

Description
Practice score in the Farsi version of cervical cancer screening self-efficacy questionnaire
Timepoint
Before the intervention, immediately, one month later and three months after the intervention
Method of measurement
Persian version of cervical cancer screening self-efficacy questionnaire

5

Description
Adhereance to action score in Persian version of the Adhereance to action pap smear
Timepoint
Before the intervention, immediately, one month later and three months after the intervention
Method of measurement
Persian version of the Adhereance to action pap smear

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group of the intervention will be in such a way that at first the participants will be members of the ITA group. After welcoming and introducing himself, the researcher will again remind the objectives of the research, the research team, the duration of training in this group and the timing of completing the questionnaire; Then the time and place of the first training session was announced in the groupThe schedule of training sessions will be in person one day a week. These sessions include 2 training sessions to increase members' knowledge in the field of knowledge, 2 training sessions to improve women's attitudes and beliefs regarding Pap smear testing, 2 training sessions aimed at improving women's self-efficacy regarding Pap smear testing, and 1 A training session will be held with the aim of improving the performance of women regarding the Pap smear test and 1 training session will be held regarding the improvement of compliance to the Pap smear test. After 4 weeks have passed since the beginning of the training. The post-examination process will be immediate, one month and three months later.
Category
Behavior

2

Description
Intervention group: In the second group, the intervention will be in the form that at first the participants will be members of the ITA group. After welcoming and introducing himself, the researcher will again remind the objectives of the research, the research team in this group and the schedule for completing the questionnaire, then the link to the mobile application. will be sent to them for installation. After 4 weeks from the beginning of the training. The post-test process was immediate, one month and three months later. The measurement and evaluation tools will be the same in all stages before and after the intervention
Category
Behavior

3

Description
Control group: After evaluating and comparing two educational interventions, the control group will also receive the desired intervention based on ethical principles.
Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Saveh Faculty Of Medical Sciences

Full name of responsible person
Leila Ahadi

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Saveh University Of Medical Sciences, Jomhouri St., Saveh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tarbiat Modares University

Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
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
Tarbiat Modares University

Full name of responsible person
Fatemeh Zarei

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Health Promotion

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is a plan to make this available
Title and more details about the data/document
Part of the data related to the main outcomes can be shared
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
The data will be made available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
Repeated measures analysis to investigate the effect of training persistence 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 from the requester to the email address of Dr. Fatemeh Zarei f.zarei@modares.ac.ir, a reply will be given.
Comments