Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Virtual Education Based on the Fogg Model on Health Literacy and Stages of Behavior Change in Cervical Cancer Screening in Women: A Randomized Controlled Clinical Trial

Protocol summary

Study aim
To determine the effect of theory-based virtual education on health literacy and stages of behavioral change for cervical cancer screening

Design
Two arm parallel group randomised trial with blinded outcome assessor and data analyst

Settings and conduct
One-fifth of the health centers in Tabriz with various socioeconomic levels will be selected. Lists of eligible women will be extracted and the women will be invited by phone to visit the relevant center on a specified day if willing. After a complete assessment of inclusion criteria and obtaining written informed consent, relevant questionnaires will be completed through interviews. Participants will then be randomly assigned to either the intervention or control group using block randomization. In this study, the outcome assessor and data analyst will be blinded to group allocation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: married women aged 21 to 65 years; no history of Pap smear in the past three years; no history of cervical cancer; scoring less than 99 on the Cervical Cancer Health Literacy Questionnaire. Exclusion criteria: pregnancy, history of irregular uterine bleeding, genital warts, history of atypical squamous cells of undetermined significance, low-grade or high-grade squamous intraepithelial lesion, history of hysterectomy.

Intervention groups
The intervention group will receive virtual education based on the Fogg Behavior Model. The educational content will be uploaded twice a week for four weeks in the Eitaa messenger channel. In each upload, various multimedia formats (videos and recorded audios maximum two minutes, quizzes, infographics, and text messages) will be used. The control group will receive no intervention.

Main outcome variables
cervical cancer health literacy; stages of behavioral change for cervical cancer screening

General information

Reason for update
The expected date for sampling was incorrectly recorded and has been corrected with the new date.

Acronym

IRCT registration information
IRCT registration number: **IRCT20171007036615N14**
Registration date: **2025-10-21, 1404/07/29**
Registration timing: **prospective**

Last update: **2025-10-23, 1404/08/01**
Update count: **1**

Registration date
2025-10-21, 1404/07/29

Registrant information

Name
عصمت مهرابی

Name of organization / entity
دانشگاه علوم پزشکی تبریز

Country
Iran (Islamic Republic of)

Phone
+98 41 3477 0649

Email address
mehrabie@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-06, 1404/08/15

Expected recruitment end date

2026-02-19, 1404/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Virtual Education Based on the Fogg Model on Health Literacy and Stages of Behavior Change in Cervical Cancer Screening in Women: A Randomized Controlled Clinical Trial

Public title

The Effect of Theory-Based Virtual Education on Health Literacy and Cervical Cancer Screening Behavior

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria:

Married women aged 21 to 65 years No history of Pap smear in the past three years or no intention to undergo it in the next six months No personal history of cervical cancer or history of cervical cancer in first-degree relatives Possession of a smartphone Minimum education level of middle school Verbal and auditory abilities, and the ability to use mobile applications Scoring less than 99 on the Cervical Cancer Health Literacy Questionnaire

Exclusion criteria:

Pregnant women History of post-coital bleeding or irregular uterine bleeding Self-reported history of genital warts Current participation in related educational programs History of atypical squamous cells of undetermined significance, low-grade squamous intraepithelial lesion, or high-grade squamous intraepithelial lesion History of hysterectomy

Age

From **21 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The study will include 80 participants, who will be allocated to either the intervention or control group by a person not involved in sampling, using random block allocation with the Random Allocation Software (RAS), employing blocks of 4 and 6 with a 1:1 ratio. The allocation will be written on paper and placed in sequentially numbered opaque envelopes (Allocation Concealment). The envelopes will be opened in the order of participants' entry into the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome assessor and data analyst in this study will be blinded to the allocation of participants to the groups. The initial outcome assessment before randomization will be conducted by the principal investigator (who administers the intervention). However, the outcome evaluation and data analysis will be performed by other individuals not involved in participant allocation, sampling, or intervention administration.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Central Building, Tabriz University of Medical Sciences, Golgasht St., Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947-977

Approval date

2025-09-08, 1404/06/17

Ethics committee reference number

IR.TBZMED.REC.1404.427

Health conditions studied

1

Description of health condition studied

Cervical cancer

ICD-10 code

C53

ICD-10 code description

Malignant neoplasm of cervix uteri

Primary outcomes

1

Description

Cervical cancer health literacy score

Timepoint

before the intervention and 4 weeks after the completion of the intervention

Method of measurement
Cervical Cancer Health Literacy Questionnaire by Bazaz et al. (2019)

2

Description
Frequency of stages of behavioral change for cervical cancer screening
Timepoint
before the intervention and 8 weeks after the completion of the intervention
Method of measurement
Behavioral Change Stages Checklist (Prochaska)

Secondary outcomes

1

Description
Decision-making self-efficacy score
Timepoint
before the intervention and 4 weeks after the completion of the intervention
Method of measurement
Decision Self-Efficacy scale

2

Description
Anxiety score
Timepoint
before the intervention and 4 weeks after the completion of the intervention
Method of measurement
Spielberger State Anxiety Inventory (Form 1)

Intervention groups

1

Description
Intervention Group: The intervention group will receive virtual education regarding cervical cancer and its screening. The content of the virtual intervention will be based on scientific evidence and aligned with the components of the Fogg Behavior Model, which includes videos (each video maximum two minutes), recorded audio (each recorded audio maximum two minutes), written messages, quizzes (simple written messages but in the form of questions and answers), and images containing educational messages (infographics). The main content titles are: the prevalence of cervical cancer in Iran and the world, the progression of the disease towards cancer, danger signs, ways to prevent cervical cancer and introduction of Pap smear, HPV test and available vaccines, guidelines of the Iranian Ministry of Health and the American College of Obstetricians and Gynecologists for screening. Following preparation, the content will be uploaded to a dedicated channel in the Eitaa messaging application. The intervention will be provided for 4 weeks; 2 times a week (every week on Mondays and Thursdays at 5 pm) along with reminders 2-3 times a week. In each content upload, a combination of the aforementioned formats will be used. Reminders will be delivered via SMS and phone calls. Immediately after uploading the materials, an initial SMS will be sent to participants, informing them of the upload and encouraging them to study the content. Participants will be requested to provide feedback by sending a private message with a 'like' symbol to the researcher once they have reviewed the materials. Additionally, if participants have any questions about the materials posted in the channel, they will receive the necessary guidance. In case of no feedback from the participant until 24 hours after uploading the materials, a second reminder SMS will be sent. In case of no feedback again until 48 hours, a phone call will be made to the participant.
Category
Behavior

2

Description
Control group: The control group will not receive any intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Health Center
Full name of responsible person
Saba Mousavi-Nejad
Street address
Nisfeh Rah St., Jihad Square, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5165990001
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+98 41 3444 0057
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Tabrizphc@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Khosro Adibkia
Street address
Central Building, Tabriz University of Medical Sciences, Golgasht St., Tabriz

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5138947977
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+98 41 3334 4280
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research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Saba Mousavi-Nejad
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Dr. Esmat Mehrabi
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Associate professor
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Email
b.mehrabi62@gmail.com

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

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Part of the data related to the study outcomes will be available for sharing.

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

De-identified data available for meta-analysis or replication studies, with approval from the principal investigator.

From where data/document is obtainable

By sending an email to the email address of Dr. Esmat Mehrabie: b.mehrabi62@gmail.com

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

Emails sent by applicants to Dr. Esmat Mehrabi's email address (b.mehrabi62@gmail.com) will be responded to within one week.

Comments