

# 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 مهربانی

##### 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

#### Phone

+98 41 3444 0057

#### Fax

#### Email

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138947977

**Phone**

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**Fax**

+98 41 3334 4280

**Email**

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

**Street address**

School of Nursing &amp; Midwifery, South Shariati St., Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138947977

**Phone**

+98 41 3479 6770

**Email**

sabamnj@gmail.com

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Esmat Mehrabi

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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**Email**

b.mehrabi62@gmail.com

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Esmat Mehrabi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

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**City**

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**Province**

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**Postal code**

5138947977

**Phone**

+98 41 3479 0364

**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 Mehrabi: 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**