

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Designing and evaluating a theory-based educational intervention using mobile app for promoting preventive behaviors of sexually transmitted infections in women.

Protocol summary

Study aim

The effect of mobile-based educational intervention on the improvement of preventive behaviors of sexually transmitted infections in women of reproductive age in Tehran

Design

This study was a randomized controlled trial (RCT) with a parallel control group.

Settings and conduct

According to the inclusion criteria, the target group is women aged at reproductive (18-35 yrs.), which will be announced through an internet call on several common social networks for participation in the study.

Participants/Inclusion and exclusion criteria

The inclusion criteria being married (at least one experience); being residence in Tehran; at least 18 years old, having at least one sexual relationship experience; having a smartphone and the ability to use it. The exclusion criteria Lack of interest in the subject of the curriculum Having a mobile phone under IOS Accommodation outside Tehran Being single and having no sexual experience

Intervention groups

Individuals receive the HESTIA intervention program The control group does not receive anything during the study.

Main outcome variables

Preventive behaviors of sexually transmitted infections including: The intention for safe sex (using condom) The intention for doing a screening test (pap-test, genital examination)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181205041861N1**

Registration date: **2019-03-20, 1397/12/29**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-20, 1397/12/29**

Update count: **0**

Registration date

2019-03-20, 1397/12/29

Registrant information

Name

Sara Kazemi

Name of organization / entity

Tarbiat Modares University

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-20, 1397/10/30

Expected recruitment end date

2019-05-20, 1398/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing and evaluating a theory-based educational intervention using mobile app for promoting preventive

behaviors of sexually transmitted infections in women.

Public title

Mobile Phone Applications Education In STIs

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Married women (once married) living in Tehran At least 18 years old Having a smartphone and the ability to use it

Exclusion criteria:

Unwillingness to continue to participate in the study

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **72**

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 Randomize.com site. The envelopes will be closed and its 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 the 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)

Single 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 of Medical Sciences

Street address

Tehran , Jalal Ale Ahmad , Nasr, Tarbiat Modares University

City

Tehran

Province

Tehran

Postal code

1411713116

Approval date

2018-11-18, 1397/08/27

Ethics committee reference number

IR.MODARES.REC.1397.154

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

Promoting preventive behaviors of sexually transmitted infections (STIs)

ICD-10 code

A50-A64

ICD-10 code description

Infections with a predominantly sexual mode of transmission

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

Preventive behaviors of sexually transmitted diseases

Timepoint

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

Method of measurement

Use of preventive behaviors questionnaire for sexually transmitted diseases

Secondary outcomes

empty

Intervention groups**1****Description**

First, after receiving the ethics code from the Ethics Committee of the Vice-Chancellor of Research in Tarbiat Modares University, an online call for participating to a mobile based educational program designed and required women at reproductive aged which had eligibility for the study. After initial phone re-checking the inclusion criteria the main researcher had simple randomized allocation for categorizing the participants in two separate intervention and control groups. Moreover,

the researcher explained about the study goal and asked them for a contact way such as email or phone number for sending the consonant form and the pre-test questionnaire for both intervention and control groups as the same time. After receiving the completed pre-test questionnaire from both groups, the intervention group was announced for receiving an application download link via e-mail or a registered number on one of the online social networks. After receiving and installing the application (HESTIA), they can use the educational contents about preventive behavior of STIs one month. The educational content of this app was in various appearances, including games, flashcards, and animated short films, quiz questions, and texts. Theoretically, the content has been developed based on the principles of protected motivation theory. Furthermore, the educational content was based on the latest national and international (CDC) guidelines for the prevention of sexually transmitted diseases. After one month of the first download, HESTIA will be deactivated automatically and users will not have access to educational content through the app. The first post-test immediately after the end of the intervention will start by sending the online questionnaire, then the second post-test one month after the zero tests. The last but third post-test will be done three months after the end of the intervention. The measurement and evaluation tool is the same at all stages before and after the intervention.

Category

Behavior

2**Description**

Control group: The control group will not receive intervention and at the end of the study to follow the ethics, a training booklet will be placed in the control group.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faculty of Medical Sciences, Tarbiat Modares University

Full name of responsible person

Fatemeh Zarei

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Tehran ,Jalal Ale Ahmad ,Nasr, Tarbiat Modares University

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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

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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

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

Fatemeh Zarei

Position

Ms student of health education

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

Contact

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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

Demographic information is confidential, but information about the outcome of the people's knowledge, attitude and behavior is shareable.

When the data will become available and for how long

A week after receiving the request via email to the corresponding researcher

To whom data/document is available

Researchers in academic institutions

Under which criteria data/document could be used

Deputies of health in Medical Universities

From where data/document is obtainable

Contact with Dr.Fateme Zarei as the corresponding researcher via email: f.zarei@modares.ac.ir

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

A week after receiving the request via email the corresponding researcher

Comments