Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Design, Implementation and Evaluation of a Cervical Cancer Prevention Behavior Training Program for Women of Reproductive Age 18-49 in Andimeshk in 1399-1998

Protocol summary

Study aim

Design, implementation and evaluation of the effect of training program on cervical cancer screening behavior in women of reproductive age 18-49 years

Design

Sample size obtained using the formula n = ((Z_ (1-α / 2) + Z_ (1-β)) ^ 2 (δ_1 ^ 2 + δ_2 ^ 2)) / (μ_1-μ_2) ^ 2 Thirty-six patients were included, accounting for 15% of the probability of loss for the 42 group. Randomization of the samples will be done to maintain equilibrium in the number of subjects belonging to the control and intervention groups and to obtain the maximum power in the study using a randomized block design with four blocks. These duplicate random blocks will be performed for each cluster individually.

Settings and conduct

At this stage, to obtain a random sample that represents all women in the city; a sample of Andimeshk women in order to achieve the status of knowledge, attitude, self-efficacy, and performance of women in Pap smear screening, setting up, and providing targeted educational content. The second phase will be studied.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Women of childbearing age 18-49 (who have been married at least once, regardless of their current marital status), Resident of Andimeshk 3. Minimum literacy reading and writing 4. Has a minimum age of 18 years and a maximum of 49 years 5. Written consent to participate in the study Exclusion criteria 1. Cervical cancer or other STDs 2. Opt out of study 3. Inability to read and write

Intervention groups

All women who qualify for the study will be given a pre-test. After completing the questionnaire, individuals will be divided into intervention and control groups according to their evaluation and mean score. The control group will not be given specific action or training.

Main outcome variables

Promoting Knowledge, Attitude, Self-efficacy, and Practice About Cervical Cancer Screening

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191206045626N1**
Registration date: **2020-02-12, 1398/11/23**
Registration timing: **prospective**

Last update: **2020-02-12, 1398/11/23**
Update count: **0**

Registration date

2020-02-12, 1398/11/23

Registrant information

Name

shahnaz ghalavandi

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 61 4269 0656

Email address

ghalavandishahnaz@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-19, 1398/12/29

Expected recruitment end date

2020-06-18, 1399/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, Implementation and Evaluation of a Cervical Cancer Prevention Behavior Training Program for Women of Reproductive Age 18-49 in Andimeshk in 1399-1998

Public title

Design, Implementation and Evaluation of a Cervical Cancer Prevention Behavior Training Program for Women of Reproductive Age

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 Andimeshk Minimum literacy Minimum 18 years and maximum 49 years Written consent to participate in the study

Exclusion criteria:

Cervical cancer or other STDs 2.Opt out of study 3.Inability to read and write

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: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of the samples will be done in order to maintain equilibrium in the number of subjects belonging to the control and intervention groups and to obtain maximum power in the study using a randomized block design with 4 blocks. These duplicate random blocks will be performed for each cluster individually.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This is a two-stage study; the first stage is a cross-sectional descriptive study with the aim of determining knowledge, attitude, self-efficacy and practice about cervical cancer of women of reproductive age 18-49 in Andimeshk. The second phase of an experimental study with a control group with the overall aim of evaluating a cervical cancer screening training (Pap smear) training program in women of reproductive age 18-49 years in Andimeshk. First, all women who met the inclusion criteria. After completing the questionnaire, the subjects will be divided into two intervention and control groups according to their evaluation and mean score.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tarbiat Modarres University

Street address

Jalal Al Ahmad Street,district Nasr,Tarbiat Modares University,Faculty of Medical Sciences

City

Tehran

Province

Tehran

Postal code

14115-111

Approval date

2020-01-21, 1398/11/01

Ethics committee reference number

IR.MODARES.REC.1398.200

Health conditions studied

1

Description of health condition studied

Screening for cervical cancer(Pap smear)

ICD-10 code

C53

ICD-10 code description

Malignant neoplasm of cervix uteri

Primary outcomes

1

Description

Improve cervical cancer screening behavior

Timepoint

Before the intervention, one month and three months after the intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group in this study consisted of 42 people who scored less than average after the pre-test; the intervention in this study will be educational. After completing the first phase of the study (cross-sectional) and assessing the educational needs of the questionnaire, the educational content will be formulated in 4 constructs of knowledge, attitude, self-efficacy and performance. And will be delivered in 3 training sessions for one month.

Category

Behavior

2

Description

Control group: The control group in this intervention consisted of 42 subjects who received a mean and higher score after the pre-test; no intervention for the control group. Post-test will be performed by Pap smear screening questionnaire from both intervention and control groups. This post-test will also be repeated 3 months after the end of training for both groups.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Andimeshk city health and treatment network

Full name of responsible person

Alireza Heidarnia

Street address

Jalal Al Ahmad Street, Nasr district, Tarbiat Modares University, Faculty of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modarres University, Vice Chancellor Research

Full name of responsible person

Yaghoub Fathollahi

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Jalal Al Ahmad Street, Nasr district, Tarbiat Modares University, Faculty of Medical Sciences

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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 Modarres University, Vice Chancellor Research

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

Alireza Heidarnia

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Alireza Heidarnia

Position
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Latest degree
Ph.D.
Other areas of specialty/work
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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
No - There is not 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
In this study, data can be shared after people are unrecognizable. Statistical analysis and intervention program reporting will also be shared.
When the data will become available and for how long
+Access to study documentation will begin 6 months after the results are published.
To whom data/document is available
Study documentation will be available to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
Study documentation will be available only to researchers working in academic and scientific institutions and will not be available to others.
From where data/document is obtainable
1. Dr. Alireza Heidarnia, Professor of Health Education, Tarbiat Modares University email: hidarnia@modares.ac.ir 2- Shahnaz Ghavavandi MSc Student of Health Education, Tarbiat Modarres University email: ghalavandishahnaz@modares.ac.ir
What processes are involved for a request to access data/document
Writing the request clearly defines what part of the applicant's actual need is to study the documentation. Submit request via email provided in the study.
Comments