

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of an intervention based on I-Change model in comparison with existing health education methods on change of intention of women in utilizing preventive services of cancer (Cervical Cancer)

Protocol summary

Summary

Objective: Assess the effectiveness of a computer tailored intervention on encouraging women 30-75 in Iran to participate in preventive screening program of cervical cancer Type: Randomised Controlled Trial among women 30-75 in Tehran, main inclusion criteria is being sexually active and no history of cervical cancer, and main exclusion criteria is age <30 or >75 Sample size will be 300 in three groups, two for intervention and one for control. Case will randomly be allocated and study will be double blind. Participants will receive randomly intervention package which research team do not know about the content. Group A will receive available information about cervical cancer in national program, group B will receive tailored package and group C will not receive a package immediately, but after intervention phase will receive existing national package. Total duration of intervention and follow up will be 18 month, including 6 month enrollment and 12 month follow up. First outcome: change in behavior (making cervical cancer test or follow up) Second outcome: change in knowledge, attitude and plan of action

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092918120N1**
Registration date: **2014-09-29, 1393/07/07**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-09-29, 1393/07/07

Registrant information

Name

Kazem Zendeheel

Name of organization / entity

Cancer Research Center, Cancer Institute Iran

Country

Iran (Islamic Republic of)

Phone

+98 21 6656 1638

Email address

kzendeheh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tehran university of Medical Science

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-10-20, 1395/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of an intervention based on I-Change model in comparison with existing health education methods on change of intention of women in utilizing preventive services of cancer (Cervical Cancer)

Public title

Effect of an intervention based on I-Change model in comparison with existing health education methods on change of intention of women in utilizing preventive services of cancer (Cervical Cancer)

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Female; Adult age (30-75); Not virgin(considering sensitivity and privacy of this information, willingness item(item 5, below) with explanation about method of taking sample for Pap smear could cover this); Being resident of Tehran; Being available at least for next six month in that residence or other available address or telephone ;Not attending for Pap smear during last two years Exclusion criteria: Changing the residence address; Being in the list of preliminary cross sectional study (quantitative study) ;History of cancer; History of hysterectomy ; Illiteracy; Attended for Pap smear during last two years

Age
From **25 years** old to **75 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **900**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Committee of Tehran University of Medical Science

Street address
Tehran University of Medical Science

City
Tehran

Postal code

Approval date
2014-08-11, 1393/05/20

Ethics committee reference number
24890

Health conditions studied

1

Description of health condition studied

Cervical Cancer

ICD-10 code

N87

ICD-10 code description

Dysplasia of cervix uteri

Primary outcomes

1

Description

change in behavior (making cervical cancer test or follow up)

Timepoint

6-12 Month after intervention

Method of measurement

questionnaire and observation

Secondary outcomes

1

Description

change in knowledge, attitude and plan of action

Timepoint

4wks after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Group A intervention: will receive PHC available package for cervical cancer screening

Category

Behavior

2

Description

Group B: will receive tailored intervention package for cervical cancer screening

Category

Behavior

3

Description

group C: Will not receive a package before finishing intervention in groups A and B, then for ethical reasons will receive PHC package All packages will have information about cervical cancer screening, centers for referral and hot line number for questions

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Research Center, Cancer institute of I.R of Iran

Full name of responsible person

Rahim Taghizadeh Asl

Street address

Imamkhomeini Hospital, Keshavarz Blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tehran University of medical science

Full name of responsible person

Dr Masoud Younesian

Street address

Dameshgh Str., Keshavarz Blvd.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Tehran University of medical science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

CRC, Cancer Institute of Iran

Full name of responsible person

Rahim Taghizadeh Asl

Position

PhD student

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Position

MD

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Person responsible for updating data

Contact**Name of organization / entity**

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Position

MD, MPH

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty