

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Randomised clinical trial of evaluating the effect of education based on the theory of planned behavior on prostate cancer screening behavior in middle-aged men

Protocol summary

Summary

This clinical trial aimed to evaluate the impact of education based on the theory of planned behavior on prostate cancer screening in middle-aged men who referred to health care centers in south of Tehran. Research population is all middle-aged men are covered by this centers. Also research setting is health care centers affiliated to Tehran University of Medical Sciences. First, a center will be selected randomly and sampling will be continued in the target center until sample size reaches to sufficient number and in case of failure to collecting the desired sample size, another center will be selected randomly in order to collecting remaining samples. According to the determined sample size (68 subjects) and inclusion criterias (age 45 to 59 years, no history of prostate cancer screening and Non-participation in similar researches) study samples randomly assigned into intervention and control groups. In order to randomised allocation, Permuted block randomization will be used and octet blocks consisting of 4 participants in the intervention group and 4 participants in the control group are considered to complete the sample. For the control group pre-test will be conducted in the first week and for the intervention group pre-test and educational intervention will be carried out in the second week. educational sessions will be conducted based on the theory of planned behavior in 4 sessions. eight weeks after the intervention post-test will be taken from the two groups and these groups will be compared according to the objectives of the study, then implementation of screening will be examined.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016112631118N1**
Registration date: **2017-04-18, 1396/01/29**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-04-18, 1396/01/29

Registrant information

Name

Hesam Rezaee

Name of organization / entity

Tehran University of Medical Sciences/School of Nursing & Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 21 4485 2461

Email address

h-rezaee@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomised clinical trial of evaluating the effect of education based on the theory of planned behavior on prostate cancer screening behavior in middle-aged men

Public title

Educational program about screening and prevention of prostate cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criterias: The age range of 45 to 59 years; The ability to speak and understand and write the Persian language; No history of attending similar educational programs; No history of prostate cancer screening; Non-participation in similar researches Exclusion criterias: Non-participation in one of the educational sessions; Withdrawing from the research

Age

From **44 years** old to **59 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences, School of Nursing and Midwifery

Street address

Community Health Department, Building #1, School of Nursing and Midwifery, Nosrat St, Tohid Square, Tehran

City

Tehran

Postal code

1419733171

Approval date

2016-11-26, 1395/09/06

Ethics committee reference number

IR.TUMS.FNM.REC.1395.1124

Health conditions studied

1

Description of health condition studied

Prostate Cancer

ICD-10 code

C61, D07.5

ICD-10 code description

Malignant neoplasm of prostate, Carcinoma in situ: Prostate, Benign neoplasm: Prostate, ant neoplasm of prostate, Carcinoma in situ: Prostate, Benign neoplasm: Prostate

Primary outcomes

1

Description

Prostate cancer screening behavior

Timepoint

Before and 8 weeks after intervention

Method of measurement

Researcher-made questionnaire

2

Description

Attitude toward prostate cancer screening behavior

Timepoint

Before and 8 weeks after intervention

Method of measurement

Researcher-made questionnaire

3

Description

Subjective norms of prostate cancer screening behavior

Timepoint

Before and 8 weeks after intervention

Method of measurement

Researcher-made questionnaire

4

Description

Perceived control of prostate cancer screening behavior

Timepoint

Before and 8 weeks after intervention

Method of measurement

Researcher-made questionnaire

5

Description

Behavioral intention of prostate cancer screening behavior

Timepoint

Before and 8 weeks after intervention

Method of measurement

Researcher-made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

For the intervention group educational sessions will be conducted based on the theory of planned behavior in 4 one-hour sessions. Educational intervention methods will include lecture, group discussion, question and answer and PowerPoint presentation. Educational materials include orientation with prostate cancer, its signs, symptoms and complications, its risk factors, necessity of screening and orientation with current screening tests. Also group discussion is about subjective beliefs, consequences of the behavior, facilitating and inhibiting factors of the behavior, motivation of conformity from the significant others, subjective norms and modification of incorrect beliefs.

Category

Prevention

2

Description

The control group will not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran's South Health Centers

Full name of responsible person

Hesam Rezaee (MSc student of community health nursing)

Street address

Community Health Department, Building #1, School of Nursing and Midwifery, Nosrat St, Tohid Square, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences, School of Nursing and Midwifery

Full name of responsible person

-

Street address

Community Health Department, Building #1, School of Nursing and Midwifery, Nosrat St, Tohid Square, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences, School of Nursing and Midwifery

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

Tehran University of Medical Sciences, School of Nursing and Midwifery

Full name of responsible person

Hesam Rezaee

Position

MSc student of Community Health Nursing

Other areas of specialty/work

Street address

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences, School of Nursing and Midwifery

Full name of responsible person

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Contact

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Full name of responsible person

Hesam Rezaee

Position

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Other areas of specialty/work

Street 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