Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 eduaction 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 wiil 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 are 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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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences, School of Nursing and Midwifery
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Person responsible for updating data

Contact

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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