

## Effect of Educational Program based on the Theory of Planned Behavior on Prostate Cancer Screening: A Randomized Clinical Trial

### Abstract

**Background and Aims:** Prostate cancer screening applied for early diagnosis of prostate cancer. But it is not usually pursued by men. This study was conducted to determine the effect of educational program based on the Theory of Planned Behavior (TPB) on prostate cancer screening. **Methods:** A randomized clinical trial was carried out on 68 middle-aged men referring to community houses in Iran. Samples were selected consecutively considering the inclusion criteria. Then block randomization was used to assign the participants into two groups. Data collection included demographic characteristics, knowledge and construct of TPB (Attitude towards the behavior, Subjective norms, Perceived behavioral control, behavioral intention) and behavior. The participants in the intervention group attended a theory based program 4 session twice per week. The participants were evaluated before and two month after the intervention.  $P < 0.05$  was considered statistically significant. **Results:** After the 2 months intervention, the pretest-posttest changes in the intervention group compared to the control group were in the Knowledge  $9.26 \pm 3.5$  vs.  $0.03 \pm 1.68$ , Attitude  $11.46 \pm 3.5$  vs.  $-0.16 \pm 1.39$ , Subjective norms  $3.16 \pm 2.6$  vs.  $0.29 \pm 1.3$ , Behavioral control  $6.76 \pm 4$  vs.  $0.12 \pm 1.60$  and Behavioral intention  $1.4 \pm 1.54$  vs.  $0.00 \pm 1.00$  ( $P < 0.05$ ). While none of the subjects in control group performed the prostate screening, 10 people (33.2%) performed it in the intervention group. ( $P < 0.001$ ). **Conclusions:** Educational program based on TPB has a positive effect on prostate cancer screening. It is recommended to set up regular training programs based on TPB to encourage middle-aged men for prostate cancer screening.

**Keywords:** Early detection of cancer, prevention and control, prostate neoplasms

### Introduction

Prostate cancer is one of the leading causes of cancer related death in men.<sup>[1]</sup> Prostate cancer is the 8<sup>th</sup> cause of death due to cancer in Iran. The incidence and mortality of prostate cancer have had an increasing trend in men.<sup>[2-4]</sup> Factors such as increased age, genetics, low physical activity and obesity, environmental factors, ethnicity, family history, diet, unhealthy lifestyle, chronic prostatic inflammation or infection, behavioral factors like alcohol consumption, UV exposure, and occupational exposures may contribute to the progression of this cancer.<sup>[5-8]</sup>

Evidence showed that prostate cancer lowers the quality of life and causes tension for patients and their families<sup>[9]</sup> and places a huge financial burden on the patients and health care system.<sup>[1,2,10]</sup> Therefore, screening tests should be applied for early diagnosis and management of prostate

cancer since early diagnosis is associated with increased odds of survival in prostate cancer patients.<sup>[11-13]</sup> The goal of screening for prostate cancer is to increase the chance of treatment through diagnosis of new cases in early stages.<sup>[1,2,12]</sup> Center for Disease Control and Prevention (2018) has found that many men with prostate cancer never have experienced symptoms and, without screening, would never know they had the disease.<sup>[14]</sup> Evidence shows that screening programs may also prevent approximately 3 cases of metastatic prostate cancer per 1000 men screened.<sup>[15]</sup>

Behavioral, psychological, biological, social, and cultural factors may facilitate participation in prostate cancer screening.<sup>[16]</sup> According to the findings, the frequency rates of performing PSA and DRE are 21.6% and 5.7%, respectively, in Iran, showing an inappropriate condition.<sup>[17]</sup> Prostate cancer screening is not usually pursued by men due to males are traditionally viewed as the stronger gender.<sup>[18,19]</sup> The effectiveness of

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health education for change behavior depends on the skills of benefiting from appropriate theories.<sup>[20]</sup>

The results of current interventions based on theories show that theories can positively affect prostate cancer preventive behaviors of individuals by improving their knowledge level and leaving positive effects on perceived susceptibility and severity as well as considering the perceived barriers, benefits and health motivations and self-efficacy, but the intention to behavior and engagement in that behavior is not clear.<sup>[21-23]</sup> Therefore there is a need for the interventions based on theories that, in addition to promoting knowledge and attitude, can lead to tangible change in behavior. The theory of planned behavior (TPB), an extension of the theory of reasoned action, is widely applied to predict adoption of health behaviors.<sup>[9,24,25]</sup> According to TPB, the intention to behavior is a direct predictor of engagement in that behavior. Intention in turn is predicted by a person's attitude towards the behavior, subjective norms, and perceived behavioral control.<sup>[25]</sup> The attitude toward behavior is defined as the degree to which the person treats the behavior as positive or negative. The subjective norms means social perceived pressure to engage or not to behave. Finally, perceived behavioral control means perceived ability to conduct a successful behavior.<sup>[25,26]</sup> The TPB has been used successfully to predict and explain a wide range of health behaviors and intentions. The TPB states that behavioral achievement depends on both motivation (intention) and ability (behavioral control).<sup>[25]</sup>

Many studies have used TPB as a theoretical framework in order to behavioral change that led to effective change in their participant's behavior.<sup>[26-30]</sup> However, studies that show the effect of educational interventions based on theories for changing behavior in screening prostate cancer were not observed.

Considering the increasing trend of prostate cancer in the world and the effective role of correct screening in early detection and management of these patients, it is necessary to reflect on this problem and design educational interventions based on appropriate models. Therefore, this study was conducted to determine the effect of educational program based on the TPB on prostate cancer screening behavior in middle-aged men.

## Methods

### Study design

This randomized clinical trial was of pre-test-post-test design, conducted to determine the effect of education based on the theory of planned behavior on prostate cancer screening behavior in middle-aged men.

### Participants and randomization

The research population was all middle-aged men (30-59 years of age) referring to community houses in Tehran. Community houses is a place where the neighbors

are gathered there for education, recreation and social activity. It was located in the center of the neighborhood and was easily accessed by all residents.

The sample size was calculated using the difference between two proportions formula, with 95% confidence level, 90% statistical power, and  $P1-P2 = 0.35$ ; Considering 10% attrition rate the sample size was 34 men per group. In current study, doing Prostate Cancer Screening was primary outcome and other variables (Knowledge, Attitude, Subjective norms, behavioral control, and behavioral intention) were secondary outcome. Therefore, the sample size was calculated based of difference in proportion.

Of the 75 eligible participants, 6 participants declined and one of them excluded due to relocation. Sixty-eight individuals were selected consecutively considering the inclusion and exclusion criteria. The selected samples were randomly assigned to intervention ( $n = 34$ ) and control groups ( $n = 34$ ) using blocked randomization with a block size of 4 until the required sample size was achieved. The inclusion criteria were age 45-59 years, lack of a history of participation in similar educational programs; no having a history of screening for prostate cancer until now; lack of severe mental and physical disorders and exclusion criteria were non-participation in two consecutive sessions and withdrawal from the study.

### Assessments

Data collection tools were demographic characteristics, knowledge of prostate screening and questionnaire with TPB constructs (Attitude towards the behavior, Subjective norms, Perceived behavioral control, behavioral intention) and behavior.

- **Demographic characteristics questionnaire:** It includes age, the education level, income, and number of family members, diseases, history of medication, general health status and history of prostate cancer in family
- **Knowledge of prostate cancer and screening questionnaire:** The 2<sup>nd</sup> questionnaire was applied to assess the knowledge of prostate cancer and screening for it (12 questions). A correct answer scored 2 and an incorrect answer scored 0. Score 1 was assigned to "I don't know". The total score of the questionnaire ranged from 0 to 24, with higher scores indicating higher levels of knowledge.
- **TPB constructs questionnaire:** The 3<sup>rd</sup> questionnaire contained questions on TPB constructs, including attitude (13 Item), Subjective norms (6 Item), behavioral control (9 Item) and behavioral intention (2 item), Performing the behavior was 1 Item. The score of the sections of attitude, subjective norms, behavioral control, and behavioral intention ranged from 0 to 52, 0 to 24, 0 to 36, and 0 to 8, respectively, with higher scores indicating higher levels of attitude, subjective norms, behavioral control, and behavioral intention.

This scale was scored from 0 (strongly disagree) to 4 (strongly agree). A yes-no answered question was developed to measure prostate screening in the last two months (I did screening tests for prostate cancer.).

Face and content validity of the tool was evaluated by 10 faculty members and experts in the field of TPB and S-CVI (Scale-Content Validity Index)<sup>[31]</sup> was determined 0.98. For reliability according to the test-retest method, the score of knowledge questionnaire and attitude, subjective norms, behavioral control, and behavioral intention (TPB constructs) was 0.83, 0.95, 0.88, 0.95, and 0.9, respectively, which were acceptable. The Cronbach's alpha of the knowledge, attitude, subjective norms, behavioral control, and behavioral intention was 0.7, 0.84, 0.85, 0.84, and 0.9, respectively, which were satisfactory and acceptable.<sup>[32]</sup>

### Intervention

After obtaining written informed consent, a pre-test was first administered in the both groups. The participants in the intervention group attended a theory based program include 4 session about 120-minute twice per week. Intervention were information about anatomy and structure of prostate gland, its function, common diseases, symptoms and complication of it, risk factors, prevention strategies of prostate cancer, screening exams, cost of it and how to do a screening test. All sessions were conducted based on improvement of knowledge and based on TPB constructs (attitude, subjective norms, behavioral control and behavioral intention). Educational methods were selected according to model constructs. Small groups were formed, group discussions and question and answer were conducted to promote knowledge and attitudes. Participants actively expressed their experiences and discussed their beliefs in these program. To intervention for subjective norms, since it was not possible to access a large number of key relatives of the participants in person, telephone calls were used to contact them two times during the intervention. Of the 30 participants, 10 key relatives (Significant others) were not willing to be involved in a conversation regularly or were not available. Of 20 key relatives, 15 were wives and 5 were children who participated regularly in telephone conversations. Each conversation was about 15 minutes. They were taught about the importance of prostate cancer screening, and they were asked to encourage participants to cancer screening. After intervention, Posttest was applied two months after the last interventional session. At this stage, it was asked about performing prostate screening in the last two months. Conforming to research ethics, at the end of research, the participants of both groups were given an educational booklet about prostate cancer and importance of screening it.

### Ethical consideration

The Ethics Committee of Tehran University of Medical Sciences approved the study (ethics code: IR.TUMS.FNM.

REC.1395.1124) and the study was registered in the Iranian Registry of Clinical Trials (IRCT2016112631118N1). They were also assured of the data confidentiality. Informed consent was obtained from all participants prior to the study.

### Statistical analysis

Descriptive statistics, including frequency distribution, mean, standard deviation, median, and interquartile range, and inferential statistics such as chi square, independent *t* test, Mann-Whitney test, paired *t* test and Fisher's exact test were applied to analyze the data. The normality of the quantitative variables was checked using the Kolmogorov-Smirnov test. Some variables (Attitude, behavioral control and behavioral intention in the before intervention and knowledge, behavioral intention after intervention) were not normally distributed ( $P < 0.05$ ). Therefore, we used median and interquartile range instead of mean and standard deviation.  $P < 0.05$  were considered statistically significant. All statistical analyses conducted using the Statistical Package for Social Science version 18 (SPSS Inc., Chicago, Illinois, USA).

### Results

The number of samples in each group was 34 subjects. But 4 subjects of the intervention group and 3 subjects of the control group were excluded because they were very busy and unwillingness to continue the study. Finally, data analysis was done with 61 subjects [Figure 1].

The distribution of demographic variables in the study population shows in Table 1. There was no significant difference in demographic variables between intervention and control groups and two groups were homogeneous.

There was no significant difference between the two groups before the intervention. However, a significant difference in the score of these variables was observed between groups after the intervention ( $P < 0.05$ ). After the 2 months intervention, compared with the control, Knowledge ( $42 \pm 7.25$  vs.  $28 \pm 13$ ,  $P < 0.001$ ), Attitude ( $41.6 \pm 5.12$  vs.  $30.06 \pm 7.6$ ,  $P < 0.001$ ), Subjective norms ( $14.9 \pm 3.1$  vs.  $10.94 \pm 4.1$ ,  $P < 0.001$ ), Behavioral control ( $25.33 \pm 5.4$  vs.  $18.19 \pm 6.2$ ,  $P < 0.001$ ) and Behavioral intention ( $6 \pm 4$  vs.  $4 \pm 3$ ,  $P < 0.019$ ) (Knowledge and Behavioral intention are based on median  $\pm$  IQR). Also, the pretest-posttest changes in the intervention group compared to the control group were in the Knowledge  $9.26 \pm 3.5$  vs.  $0.03 \pm 1.68$ , Attitude  $11.46 \pm 3.5$  vs.  $-0.16 \pm 1.39$ , Subjective norms  $3.16 \pm 2.6$  vs.  $0.29 \pm 1.3$ , Behavioral control  $6.76 \pm 4$  vs.  $0.12 \pm 1.60$  and Behavioral intention  $1.4 \pm 1.54$  vs.  $0.00 \pm 1.00$  ( $P < 0.05$ ) Table 2.

According to Table 3, there was no change in performing the behavioral in the control group after the intervention while it have done by 10 subjects (33.2%) in the intervention group. Fisher's test showed a significant

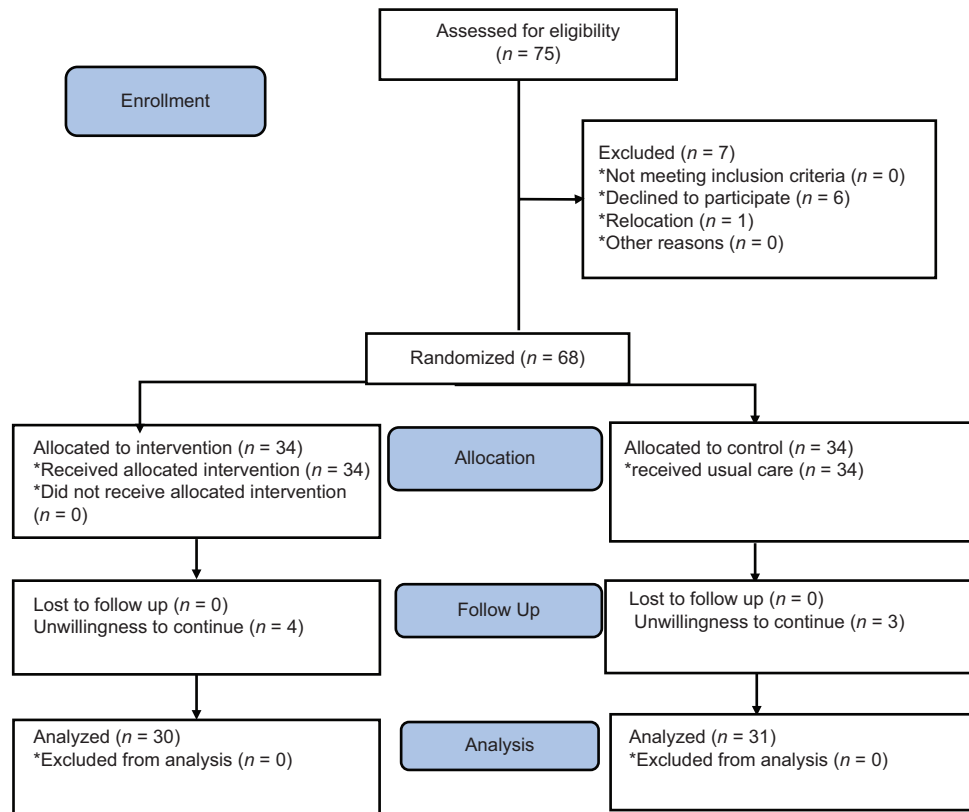


Figure 1: CONSORT flow diagram of the participants

difference in performing the behavior between intervention and control groups after the intervention ( $P < 0.001$ ).

## Discussion

This study was conducted to evaluate the effect of education based on the theory of planned behavior on prostate cancer screening in middle-aged men. The results showed that education based on TPB has a positive effect on the constructs of this model, enhancing prostate cancer screening, and performing these tests in middle-aged men.

A significant change in the median score of knowledge in the intervention group indicated the effectiveness of intervention in knowledge improvement. Many studies showed the impact of an intervention based on TPB on knowledge of behavioral.<sup>[11,24,33,34]</sup> Implementation of a health education intervention as an effective way to enhance levels of knowledge and promote positive health perceptions regarding colorectal cancer and screening recommendations.<sup>[35]</sup>

In present study, the educational intervention could improve the attitude towards screening and diagnostic tests. The results of a some studies showed same results.<sup>[26,28]</sup>

We found significant difference in the mean score of subjective norms between intervention and control groups after the intervention ( $P < 0.001$ ). Although access to key persons was not satisfactory and their participation

in the educational sessions was not possible, it was tried to contact them by telephone and distribute educational pamphlets for family members and relatives to modify subjective norms. Moreover, the researcher, as an influential person (health care provider) had a direct effect on subjective norms through education and improved this construct via encouraging the participants to take informed actions. In this regard, the results of a study by Williams *et al.* (2015) on promoting walking through education based on the TPB showed significant difference in the mean score of subjective norms between the two groups immediately, 6 weeks, and 6 months after the intervention.<sup>[29]</sup> Motivation and education by healthcare workers are important factors for increasing cancer screening rates.<sup>[36]</sup> The association between education and cancer screening behavior may be moderated by social support. Practitioners and researchers should focus on interventions that activate social support networks as they may help increase cancer screening compliance.<sup>[37]</sup>

The results showed a significant increase in the mean score of behavioral control in the intervention group. It seems that the intention to perform screening behaviors becomes stronger in men when they have more knowledge about prostate cancer and its screening, develop a positive attitude towards controllability of cancers upon early detection, feel capable of doing these behaviors, and believe they can control environmental factors, which results in improved health-seeking behaviors. Different methods were used to

**Table 1: Comparison of demographic variables in the intervention (n=30) and control (n=31) groups.**

Variable	Level	Control	Intervention	P
		n (%)	n (%)	
Age	45-49	9 (29)	4 (13.3)	P=0.24*
	50-54	10 (32.3)	9 (30)	
	55-60	12 (38.7)	17 (56.7)	
Education Level	Under Diploma	5 (16.2)	4 (13.3)	P=0.81*
	Diploma	17 (54.8)	15 (50)	
	Upper Diploma	9 (29)	11 (36.7)	
Married Status	Single	3 (9.7)	4 (13.3)	P=0.71**
	Married	28 (90.3)	26 (86.7)	
number of family members	<=4	14 (45.2)	18 (60)	P=0.56*
	>4	17 (54.8)	12 (40)	
Income adequacy	Yes	11 (35.5)	12 (40)	P=0.72*
	No	9 (29)	6 (20)	
History of diseases	Somewhat	11 (35.5)	12 (40)	P=0.76*
	No diseases	19 (61.3)	15 (50)	
	Cardiovascular System	6 (19.4)	7 (23.5)	
	Respiratory System	0 (0)	1 (3.3)	
	Urinary System	1 (3.2)	0 (0)	
	Diabetes	3 (9.7)	2 (6.6)	
	Prostate hypertrophy	1 (3.2)	1 (3.3)	
	Other diseases	1 (3.2)	4 (13.3)	
History of medication	Yes	12 (38.7)	13 (43.3)	P=0.45**
	No	19 (61.3)	17 (56.7)	
General health status	Excellent	6 (19.4)	2 (6.7)	P=0.95**
	Very good	11 (35.5)	15 (50)	
	Good	7 (22.5)	11 (36.7)	
	Fair	5 (16.1)	1 (3.3)	
	Weak	2 (6.5)	1 (3.3)	
History of prostate cancer in family	Yes	4 (12.9)	4 (13.3)	P=0.76*
	No	5 (48.4)	17 (56.7)	
	I don't know	12 (38.7)	9 (30)	

\*Chi- Square. \*\*Fisher's exact test

**Table 2: Comparison of the mean/median and interquartile range score of the middle-aged men's knowledge, attitude, subjective norms, behavioral control and behavioral intention before and after intervention in the intervention and control groups.**

Groups Variable/Time	Intervention group (n=30)				Control group (n=31)				P
	Before intervention	2 months After intervention	Change	P	Before intervention	2 months After intervention	Change	P	
Knowledge	11.33±5.09	42±7.25	9.26±3.5	<0.001**	11.87±4.3	28±13	0.03±1.68	0.9*	<0.001***
Attitude	29.5±6	41.6±5.12	11.46±3.5	<0.001**	28±12	30.06±7.6	-0.16±1.39	0.5*	<0.001***
Subjective norms	11.73±4.03	14.9±3.1	3.16±2.6	<0.001*	10.65±4.3	10.94±4.1	0.29±1.3	0.3*	<0.001***
Behavioral control	17.5±7.25	25.33±5.4	6.76±4	<0.001*	17±10	18.19±6.2	0.12±1.60	0.6**	<0.001***
Behavioral intention	4±3.25	6±4	1.4±1.54	<0.001**	4±2	4±3	0.00±1.00	0.07**	0.019***

\* paired-samples t-test. \*\*Wilcoxon W. \*\*\*Man-Whitney U. Before the intervention, the values of Attitude, Behavioral control and Behavioral intention and after intervention, Knowledge and Behavioral intention were non-normal and presented based on median±IQR.

improve behavioral control in men, including education about screening and diagnostic tests, costs of examinations and tests, guidelines of credible organizations and associations on screening for prostate cancer, facilitative

and preventive factors (economic, cultural, and social barriers). Duangpunmat *et al.* (2013) also reported similar findings.<sup>[27]</sup> Perceived behavioral control depend on society and culture. So, culturally-tailored education

**Table 3: Comparison of the frequency (%) score of the middle-aged men's behavior (Prostate Cancer Screening) after intervention in the intervention and control groups.**

Groups/Behavior	Intervention n=30	Control n=31	P*
	n (%)	n (%)	
Yes	10 (33.2)	0 (100)	0.001*
No	20 (66.8)	31 (0)	

\* Fisher's exact test

program is effective in improving knowledge, attitudes about and intentions to participate in cancer screening. It is important that culturally-tailored programs are developed in conjunction with communities to improve health outcomes.<sup>[38-40]</sup>

The results of our study also showed a significant increase in the mean score of intention in the intervention group. According to the structure of theory of planned behavior, an educational program affecting the constructs before intention will eventually leave its effects on intention, as well. According to TPB, a behavior occurs following intention, and intention to do a behavior has the highest correlation with performing the behavior. In present research, subjects who had the strongest intention performed the behavior (cancer screening), indicating that performing a behavior is most probable in subjects who have the highest intention. Education based on TPB improves behaviors related to prostate cancer screening, including counselling, examinations, and diagnostic tests for early detection of prostate cancer (like physical examination and blood test). This finding is consistent with the results of many studies.<sup>[9,20,28,34]</sup> When educated individuals are better informed, they are more likely to incorporate variation in risk factors. when they report their personal cancer risk, and as risk varies, the better educated will react more strongly by adopting preventive behaviors such as cancer screening.<sup>[41]</sup> Therefore, change behavior theories can be used as an interventional program to improve cancer screening.

But limitations of this study include low level of literacy and lack of completeness of questionnaires by some of the participants, as well as behavioral evaluation by self-report method, which can be a factor in misrepresentation of data. The main limitation of the study was the lack of placebo in control group. But, one of the strengths of the study is the study design that has been done according to the CONSORT Statement. The study also focused on current men's need for prevention of prostate cancer, which is now one of the health priorities. Also, the theory-based interventions can help assess the theory in solving health problems.

## Conclusions

Proper education about prostate cancer screening, a prevalent cancer in men, in a planned manner can result

in many positive outcomes, correct and develop positive attitude and beliefs, and facilitate decision-making in ambiguous situations. Health care providers as key members in the education and health services system are in a good position to address this issue through interventions. Hence it is recommended that nurses and primary health care providers set up regular training programs to encourage middle-aged men for cancer screening. Health policy-makers can take an important step in promoting awareness and behaviors through modeling these outcomes and developing theory-based programs.

## Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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## Conflicts of interest

There are no conflicts of interest.

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