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The risk of developing colorectal cancer in individuals aged 50-70 years and behavioral changes in high-risk individuals regarding a fecal occult blood test

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Ethics Committee Approval

The study protocol was approved by the Ethics Committee of Ege University Faculty of Nursing (Number: 14.12.2015-147). All procedures in this study involving human

participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest No conflict of interest was declared by the authors.

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Abstract

Background/Aim: The prognosis of colorectal cancer (CRC) is highly associated with its stage; therefore, it is important to determine the risk factors. Risk determination tools such as CRC-PRO are patient-friendly since they are non-invasive, and highly successful in predicting the cancer risk. This study aimed to determine the risks of getting CRC in individuals aged 50-70 years and the early diagnosis behaviors of individuals, who were deemed at high risk based on a Fecal Occult Blood Test (FOBT).

Methods: This single-group quasi-experimental follow-up study was conducted in a family health center in Turkey between December 2016-December 2017. The data were collected using the "CRC Predicted Risk Online (CRC-PRO)" and "stages of change form." The patients were educated at the risk determination stage. Along with telephone counseling conducted with individuals in the first and sixth months, the changes in FOBT were noted.

Results: The CRC-PRO mean risk scores of the males and females were 1.37 (0.74), and 0.79 (0.40), respectively. Among them, 33.5% of males and 25.8% of females had a risk of CRC. After they were educated for FOBT, their behaviors positively and significantly changed from the risk determination stage until the 6th-month follow-up.

Conclusion: With the use of risk determination tools, individuals' lifestyle characteristics can be determined, and health education can be provided to change them.

Keywords: Colorectal cancer, Fecal occult blood test, Stage of change

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Introduction

According to Global Cancer Statistics (GLOBOCAN) [1], cancer is the second leading cause of death globally, and colorectal cancer (CRC) is the fourth most common cancer in both males and females worldwide. CRC is also the second most common cause of death due to cancer. According to the data of Turkey Statistical Institute (TSI) [2], it constitutes 8.1% of female cancers and 8.9% of male cancers. In Turkey, CRC is the third and fourth most common cause of death due to cancer in females and males, respectively [2].

The prognosis of CRC is highly associated with its stage. It is possible to detect and treat premalignant adenomatous polyps and early-stage localized cancers with early diagnosis programs [3]. CRC is preventable and treatable when diagnosed early. Informing the society, risk determination and the implementation of screening programs are significant for detection of cancer in the asymptomatic period. Studies showed that risk determination and screening reduced CRC mortality [3, 4].

CRC screenings include a fecal occult blood test (FOBT) every two years, a sigmoidoscopy every 5 years, and a colonoscopy every 10 years between the ages of 50-70 years in Turkey [5]. Although colonoscopy is known to reduce cancer mortality, it has certain disadvantages such as cost, anxiety, and rarely, intestinal perforation [6]. Moreover, screening programs such as colonoscopy in countries with limited resources are not considered cost-effective. These screening programs are generally implemented on individuals who are indicated to be at risk [7]. The determination of risk factors and conducting screenings for early diagnosis in high-risk individuals, instead of screening programs, are considered more effective [8]. The rate of CRC varies according to the type of risk factors and lifestyle characteristics [4]. Being at high risk for CRC is considered as having a family history of colon cancer and being above the age of 50 years. Although the highest increase in risk for CRC is genetically based, more than 50% of CRCs develop due to lifestyle. Therefore, it is important to determine the risks of cancer development by taking into account other risk factors, as well [4, 6].

Risk assessment can be performed using the "Harvard Risk Index" [5], "United States National Cancer Association Index" [5] and the "Colorectal Cancer Predicted Risk Online (CRC-PRO)" [6], which was developed using the Cox proportional hazards model in the recent years. Risk determination tools are highly successful in predicting cancer risk [7-9]. While the total risk score for CRC can be calculated with these tools, the awareness of individuals regarding their lifestyle also increases. Primary prevention is important, for which healthy lifestyle behaviors, such as healthy nutrition, physical activity, non-smoking, and non-consumption of alcohol should be adopted [10]. Risk assessment tools such as CRC-PRO assess the healthy lifestyle behaviors of the individuals. Moreover, risk determination tools are patient-friendly since they are non-interventional [6]. These types of risk determination tools are also suitable for the use of health care professionals during consultations [9]. Health care professionals play a key role in alerting the community to the early detection of CRC since they usually have the closest contact with the community [11].

The conceptual framework of our study is based on the Transtheoretical Model (TTM), created by Prochaska and DiClemente. The TTM is used in the design of various health behavior change interventions [12], such as smoking cessation, exercising, protection from sun exposure, and sexually transmitted diseases, and then for identifying behavioral changes for early diagnosis tests such as mammography, Breast Self-Examination, PAP test, FOBT, and colonoscopy. Especially in recent years, researchers use the TTM in behavioral changes for the early screening of CRC [13-17]. The TTM is a dynamic, 4-6 stage process that evaluates the individuals' behavioral changes from precontemplation to relapse [13]. Some changes in stages were necessary for determining the behavioral changes in the early diagnosis of cancer, because smoking cessation or mammography do not require continuity. However, the FOBT must be repeated at certain periods [13, 14, 17, 18]. For CRC, the FOBT includes screenings that need to be repeated at certain periods. Therefore, the stages of change defined in the TTM are appropriate for use in explaining behavioral changes.

The purpose of this study was to determine the risks of developing CRC in individuals aged 50-70 years and the behavioral changes of individuals at risk regarding a FOBT.

Research questions

- 1. What is the risk of developing CRC in the next 10 years among females?
- 2. What is the risk of developing CRC in the next 10 years among males?
- 3. What are the behavior changes in individuals with high CRC risk after FOBT?

Materials and methods

This single-group quasi-experimental follow-up study was conducted between December 2016 and December 2017. A total of 4500 individuals aged between 50-70 years who were registered to a Family Health Center (FHC) in İzmir-Turkey constituted the study population. FHCs in the district were classified according to age, income status and the state of having a chronic disease, which were defined as CRC risk factors in the literature, and one was selected by the purposeful sampling method. The reason for carrying out the study in an FHC was to determine the risk of CRC in healthy individuals and to perform a fecal occult blood test freely on the groups at risk.

The selected FHC was in a middle socio-economic class district that allows immigrants from different regions, where the median age was 37.01 years [19]. In the calculation made with the sampling from a finite population formula, the required sample size was 445 individuals aged between 50-70 years. The inclusion criteria were as follows:

- Being 50-70 years old
- Having no medical conditions that prohibited the FOBT test
- Having health insurance
- Volunteering

The Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) checklist was used in the study design and manuscript drafting [20]. The research data were collected using the CRC-PRO for Men and Women, and the stages of change form was used for FOBT.

"CRC-PRO for Men" and "CRC-PRO for Women" are risk prediction tools created by Wells et al. [6] considering the risks of individuals diagnosed with CRC (n=2765) and using the Cox proportional hazards analysis. These tools calculate the risk of CRC in the individual online (Colorectal Cancer-10 year Predicted Risk Online) as a percentage within a 10-year period [21]. It consists of twelve questions for females and thirteen questions for males. The common questions are about weight, height, age, ethnicity, years of smoking, amount of daily alcohol use, educational level, family history of cancer, diagnosis of diabetes mellitus, and the use of multivitamins. In the form developed for men, the time spent actively by doing sports, the frequency and amount of red meat consumption, and the use of anticoagulants are asked additionally. In females, the use of estrogen and whether they take anti-inflammatory drugs are also questioned. The risk of CRC is between 0.2-15% for men and 0.1-20% for women. The median values were 1.0% and 1.6% for females and males, respectively. For males, low CRC risk indicates <1.6% while the high CRC risk indicates >1.6% risk. For females, the respective values are <1.0% and 1.0% [6, 21]. This tool needs to be tested for validity in different populations because it is an index questioning universally known risk factors and does not include the expressions that may vary individually, such as opinion and attitude. The accuracy of this tool in determining CRC risk was good, 0.681 in males and 0.679 in females [6, 21].

Stages of change form: Behavioral changes of individuals regarding FOBT were created according to the Stages of Change Form developed by Prochaska and Diclemente (1982) [12]. In the literature, the stages of behavioral change regarding FOBT within the framework of the TTM were evaluated differently: The TTM stages of Bui et al. [13] and Kwak et al. [15] were used in this study. The stages were classified as follows:

- 1. Precontemplation: The individual has not taken this test and does not consider taking it in the future.
- 2. Contemplation: The individual has not taken the FOBT but is thinking of taking it.
- 3. Action/Maintenance: The individual took the FOBT at least once within 2 years and is thinking of taking it again within the next 2 years.
- 4. Relapse risk: The individual has previously taken the FOBT on time but does not think of repeating it in the future.
- 5. Relapse: The individual took the FOBT more than 2 years ago but does not think of taking it within the next 2 years.

The CRC-PRO for Men and CRC-PRO for Women was applied by face-to-face interviews conducted with individuals in the FHC where the study was conducted. The individuals were given individualized information for 20 minutes with a standard education brochure on the same day. The Education Brochure is a two-page education tool prepared by the researchers with reference to the training prepared by the National Health Directorate [22]. This brochure includes information about the definition, causes and symptoms of CRC, the measures to be taken in high-risk individuals, and the early diagnosis of the disease. It was used to provide standard education to all individuals interviewed in the risk determination stage. This standard education was conducted in a meeting room in the FHC.

After the implementation of the CRC-PRO for Men and CRC-PRO for Women, the behavioral changes of high-risk individuals in terms of FOBT were followed with the questions in the stages of change in the FOBT behaviors form, which was prepared based on the TTM, by face-to-face interviewing at Time 0 and tailored telephone counseling conducted one month later (Time 1) and after 6 months (Time 2) [13, 15] (Figure 1).

While the behavior of taking the FOBT is the outcome variable of the study, the score for men and women obtained from the CRC-PRO for Men and CRC-PRO for Women is the main independent variable.

Permission was obtained from Dr. Michael Kattan, who developed the tool, to use the CRC-PRO for Men and CRC-PRO for Women. Written permissions were obtained from Ege University, Faculty of Nursing Ethics Committee (Number: 14.12.2015-147), the Provincial Directorate of Health, and the individuals participating in the study.

Statistical analysis

Data were analyzed using the SPSS 17.0 statistical software. Number, percentage distribution and mean were used in the analysis of data. For repeated measures, the Friedman test was used to examine and compare the time periods and the Bonferroni correction test. A level of P < 0.05 was considered statistically significant.

Results

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Among all, 47.3% of the participants were males (n=193), and 52.7% were females (n=252), and all were Caucasian. The mean age and the mean years of education of the males were 59.80 (7.36) years (50-70 years) and 8.88 (3.75) years (0-15), respectively. Their mean body mass index (BMI) was 27.86 (3.57) kg/m² (21- 38 kg/m²). Among them, 54.9% smoked, and 13.5% consumed alcohol. 9.3% of males were using multivitamins while the study was conducted, and 22.3% had Diabetes Mellitus (DM). 23.8% of the family members of the males had received the diagnosis of cancer at any stage of their life. 37.3% of the males were exercising, 24.9% used aspirin, 53.6% regularly consumed red meat, and 45.0% consumed red meat once a week (Table 1).

The mean age and the mean years of education of the females were 56.82 (6.73) years (50-70 years) and 6.25 (3.23) years (0-15), respectively. Their mean body mass index (BMI) was 29.88 (5.30) kg/m² (17-44 kg/m²). Among them, 21.8% smoked, and none consumed alcohol. 20.3% of females were using multivitamins while the study was conducted, and 38.5% had Diabetes Mellitus (DM). 30.2% of the family members of the females had received the diagnosis of cancer at any stage of their life, 83.4% did not use nonsteroidal anti-inflammatory drugs (NSAIDs), and 92.9% had never received estrogen supplements (Table 2).

Table 1: Men' risk factors for colorectal cancer development according to CRC-PRO (n=193)

| (11-175) | | |
|-------------------------------|-----|--------------|
| Risk factors | n | % |
| Age (Mean)(SD) | 193 | 59.80 (7.36) |
| Education years (Mean)(SD) | 193 | 8.88 (3.75) |
| Body mass index (Mean)(SD) | 193 | 27.86 (3.57) |
| Smoking | | |
| Yes | 106 | 54.9 |
| No | 87 | 45.1 |
| Alcohol intake | | |
| Yes | 26 | 13.5 |
| No | 167 | 86.5 |
| Regular use of multivitamins | | |
| Yes | 18 | 9.3 |
| No | 175 | 90.7 |
| History of diabetes | | |
| Yes | 43 | 22.3 |
| No | 150 | 77.7 |
| Family history of cancer | | |
| Yes | 46 | 23.8 |
| No | 147 | 76.2 |
| Physical activity per day | | |
| Yes | 72 | 37.3 |
| No | 121 | 62.7 |
| Regular use of aspirin | | |
| Yes | 49 | 24.9 |
| No | 144 | 75.1 |
| Red meat intake | | |
| Regular | 111 | 53.6 |
| No | 82 | 46.4 |
| CRC-PRO risk score (Mean)(SD) | 193 | 1.37 (0.74) |
| | | |

SD: Standard deviation

Table 2: Women' risk factors for colorectal cancer development according to CRC-PRO tool (n=252)

| Risk factors | n | % |
|-------------------------------|-----|--------------|
| Age (Mean)(SD) | 252 | 56.82 (6.73) |
| Education years (Mean)(SD) | 252 | 6.25 (3.23) |
| Body mass index (Mean)(SD) | 252 | 29.88 (5.30) |
| Smoking | | |
| Yes | 55 | 21.8 |
| No | 197 | 78.2 |
| Alcohol intake | | |
| Yes | 0 | 0.0 |
| No | 252 | 100.0 |
| Regular use of multivitamins | | |
| Yes | 51 | 20.3 |
| No | 201 | 79.7 |
| History of diabetes | | |
| Yes | 97 | 38.5 |
| No | 155 | 61.5 |
| Family history of cancer | | |
| Yes | 76 | 30.2 |
| No | 176 | 69.8 |
| Regular use of NSAIDs | | |
| No | 210 | 83.4 |
| Yes, but not currently | 23 | 9.1 |
| Yes, currently | 19 | 7.5 |
| Use of estrogen | | |
| Yes, currently | 12 | 5.0 |
| Yes, previously | 5 | 2.1 |
| No | 235 | 92.9 |
| CRC-PRO risk score (Mean)(SD) | 252 | 0.79 (0.40) |

According to the CRC-PRO for men and CRC-PRO for women, the mean risk score of CRC development within the next 10 years were 1.37 (0.74) (0.3-4.5) and 0.79 (0.40) (0.2-2.1), respectively (Tables 1 and 2). Therefore, 33.5% of men and 25.8% of women in the study group were at high risk for CRC.

The behavioral changes of high-risk individuals in terms of FOBT were followed with the questions in the stages of change in the FOBT behaviors form. In the first test (Time 0) (n=131), it was determined that 35.9% of the high-risk individuals had previously heard about the FOBT but did not take it and were not thinking of taking it in the future (precontemplation), 34.3% had not taken the FOBT but were thinking of taking it (contemplation), 19.9% had previously taken the FOBT in time and were thinking of taking it in the future (action/maintenance), 5.3% had previously taken the FOBT (relapse risk), and 4.6% had previously taken the FOBT, but did not want to repeat it (relapse) (Table 3).

During the 1^{st} -month follow-up (Time 1) (n=98), 29.6% of those who needed to take the FOBT were in the

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precontemplation stage, 14.3% were in the contemplation stage, 45.9% were in the action/maintenance stage, 8.2% were in the relapse risk stage and 2.0% were in the relapse stage (Table 3).

During the 6th month follow-up (Time 2) (n=45), 2.2% of the individuals who needed to take the FOBT were in the precontemplation stage, 2.2% were in the contemplation stage, 77.8% were in the action/maintenance stage, and 17.8% were in the relapse risk stage. The stages the individuals were in changed significantly from baseline until the 6th-month follow-up (x^2 =113.968, P<0.001). The effect size was 1.534 in terms of FOBT behavior between the follow-ups (Table 3).

Table 3: The stages of change for FOBT according to the follow-ups of individuals who are at high risk for CRC

| Stages of change | Time 0 | | Time 1 (1 st month) | | Time 2 (6 th month) | | Significance test ^a | | Effect size (d) (Time 0- |
|--------------------|--------|-------|--------------------------------------|-------|--------------------------------------|-------|--------------------------------|---------|--------------------------------|
| | n | % | n | % | n | % | x ² | P- | Time 2) |
| | | | | | | | | value | |
| Precontemplation | 47 | 35.9 | 29 | 29.6 | 1 | 2.2 | | | |
| Contemplation | 45 | 34.3 | 14 | 14.3 | 1 | 2.2 | 113.968 | < 0.001 | 1.534 |
| Action/Maintenance | 26 | 19.9 | 45 | 45.9 | 35 | 77.8 | | | |
| Relapse risk | 7 | 5.3 | 8 | 8.2 | 8 | 17.8 | | | |
| Relapse | 6 | 4.6 | 2 | 2.0 | 0 | 0.0 | | | |
| Total | 131 | 100.0 | 98 ^b | 100.0 | 45 ^b | 100.0 | | | |

^a: Friedman analyses with Bonferroni correction, Cronbach Alpha: $0.025 (\alpha/2 = 0.025)^{b}$: Individuals who did not take the FOBT test previously (follow-up).

Discussion

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In our study, according to the CRC-PRO for Men and Women tool, one out of every three people in the whole sample group had CRC risk within the next 10 years and men had a higher risk than women, per the total risk score (33.5% vs. 25.8%). This result is consistent with the GLOBOCAN [23] data, according to which, men get colorectal cancer 1.5 times more than women. In study by Ries et al. [24], men had a higher CRC risk than women. The modifiable risk factors examined in CRC-PRO are obesity, smoking and alcohol use, exercise, red meat consumption, nonsteroidal anti-inflammatory drugs and estrogen use, and the presence of DM. The mean BMIs of men and women in our study were in the overweight range and 38.5% of women and 22.3% of men had DM. The prevalence of obesity and DM in our country is almost twice the world average [25, 26]. Among our patients, alcohol consumption was low in men (13.5%), and women did not drink alcohol. Nearly half of men and one-fifth of women were smokers. Retrospective studies in which the risk factors for CRC were assessed reported that obesity was responsible for 3.9% of CRC development, having DM increased the risk by 1.20-1.22 times, and alcohol use increased the risk between 1.17-1.44 times [27, 28]. De Rosa et al. [29] determined that the presence of CRC in the first-degree relatives of individuals increased the risk by 2-4 times. While the incidence of CRC in family members is between 9-11% in the world, it is between 10.3-25.2% in Turkey [29]. In our study, the incidence of CRC in family members was high, found in 17.2% of men and 32.4% of women. It can be said that the incidence of CRC is higher in family members in our country. In our study, NSAID and aspirin use were higher, and the use of estrogen was lower compared to those reported in the literature [7, 27]. More than one-third of the individuals in our study were physically active every day. Various studies reported that the use of NSAIDs or aspirin decreased CRC development by 16-38% and that the use of estrogen and doing physical activity decreased the risk by 0.4-0.8 times and 1.06 times, respectively [27, 28]. In our

study, about one-tenth of men consumed red meat every day. A meta-analysis concluded that red meat consumption increased CRC development by 1.12 times [30]. In our study, the rate of red meat consumption was low.

The early diagnosis of CRC with a FOBT is effective in decreasing morbidity and mortality [7, 8]. Screening programs with a FOBT are conducted in many countries, as well as in Turkey [5, 22]. The success of these screening programs surely depends on participants' continuity for taking the FOBT. In our study, the ratio of individuals who took the FOBT at least once at Time 0 was 29.8%. In a study conducted in 14 Asia-Pacific countries including 7915 individuals, 30.4% of the individuals had previously taken the FOBT [31]. Bronner et al. [32] determined that the rate of taking any early diagnosis test for CRC was 18-34% among the individuals in Israel. Our results and the data from the literature show that approximately onethird of individuals take the FOBT for the early diagnosis of CRC, without any health professional informing them about it. The early diagnosis behaviors of the individuals are associated with the welfare level of the countries. The cost of FOBT is a serious obstacle to showing early diagnosis behavior [13, 31]. However, the FOBT has been offered free of charge to individuals aged 50 years and older since 2014 in our country [22]. The behavioral change to take the FOBT can be achieved by education. Individuals show 5-15% increased early diagnosis behaviors in education-intervention studies [17].

While the rate of individuals who had taken the FOBT and were in the stage of taking it was 45.9% at Time 1 after education was provided, this rate increased to 77.8% at Time 2. In the Action and Maintenance stage, there was a 57.9% difference in the desired direction. The effect size in the stages of change in terms of taking the FOBT between Times 0-2 was high. In the study by Ilgaz and Gözüm [9] conducted on the agricultural workers in Turkey, the ratio of taking the FOBT was 7% before being informed and increased to 89% after information was given. Temucin and Nahcivan [33] determined that the navigator nurse program in Turkey was effective in CRC early diagnosis screenings. In the same study, the rates of taking the FOBT in the experimental group in the 3rd and 6th-month follow-ups were 82% and 84%, respectively. Hendren et al. [34] examined the effect of telephone counseling on CRC cancer screening and determined that individuals exhibited significant early diagnosis behaviors within 1 year compared to the control group (16.6% vs. 37.7%). Christie et al. [18] reported that the behavioral change for early diagnosis of CRC was not affected by any sociodemographic variables of individuals and that only providing information about the subject had a positive effect on changing the early diagnosis behavior of individuals. They concluded that there is a need for increased follow-up and informing the individuals to take the FOBT [9, 17, 18, 33, 34].

Limitations

Only the individuals who came to the FHC and volunteered to participate in the study were included. On the other hand, the FHC, where the research was conducted, had a relatively high population and socio-cultural diversity. The individuals with high risk who did not come to the FHC during the study may have been excluded. However, reaching a sufficient sample size increased the generalizability of our results. Self-reporting is a major limitation in our study. The follow-ups were performed within the framework of TTM.

Conclusions

In this study, according to the CRC-PRO for Men and Women tool, almost one in three men and one in four women were at risk of developing CRC in the next 10 years. After informing about the FOBT performed based on the TTM, a significant and positive change occurred from the risk determination stage (Time 0) until the 6th-month follow-up (Time 2) in taking the FOBT. The difference in the stages of change for taking the FOBT had a high effect size. These results revealed that health care professionals could promote desirable behaviors through education in the early diagnosis behaviors of individuals.

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