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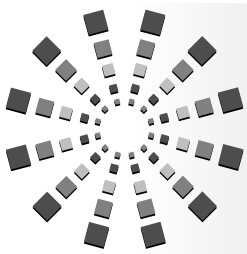

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The Effect of the Breast Cancer Risk Reduction Program on Women With High Breast Cancer Risk in Terms of Their Participation in Screening and Their Health Beliefs and Behavior

A Study Protocol for a Randomized Controlled Trial

KEYWORDS
Breast cancer screening
Genetic counseling
Health behaviors
Health beliefs
Relatives of women with breast cancer

Background: First-degree biological relatives of individuals with breast cancer have a higher risk of breast cancer. **Objective:** The purpose of this study was to create a protocol for evaluating the effect of the Breast Cancer Risk Reduction Program (BrCaRRP) on the participation of women at risk in screening and on their health beliefs and risk reduction behaviors. **Methods:** The research was planned as a single-site, single-blind randomized controlled experimental study with a parallel group. Participants will be assigned to intervention and control groups using the Stratified Permuted Block Randomization method. The BrCaRRP will be applied to the intervention group within the theoretical framework of the Health Belief Model and the Health Promotion Model. The BrCaRRP is a 12-week program that encompasses 6 meetings, the first being face-to-face and the others via phone. Multidisciplinary experts calculated the content validity index of BrCaRRP as being 0.954 (high); its weighted kappa statistic is 0.70 (high). **Results:** The

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difference in the likelihood of participation in breast cancer screening between the BrCaRRP and control groups will be evaluated after the interventions. Findings will be presented in terms of our hypotheses. **Conclusions:** The BrCaRRP is a nurse-led program based on the Health Belief Model and the Health Promotion Model. The BrCaRRP has high content validity and interrater reliability. **Implications for Practice:** This protocol can be tested as an intervention in a randomized controlled study.

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The risk of developing breast cancer among women with a family history of breast cancer is at least twice that of the population of women of the same age.[1–4] This risk increases with the diagnosis of breast cancer at early ages (≤50 years).[1,5] In Turkey, breast cancer screening is organized by the Cancer Early Diagnosis, Screening and Education Centers (Turkish acronym, KETEM) and targets women 40 years and older. The Centers offer mammograms every 2 years, after which women receiving a diagnosis of breast cancer are closely monitored. On the other hand, the high-risk group of first-degree relatives is not taken into any kind of monitoring program. The National Comprehensive Cancer Network in the United States recommends annual mammograms and magnetic resonance imaging (MRI) for this risk group.[5,6] The Breast Cancer Family Registry closely monitors individuals at high risk at their centers in Australia; New York, California, Pennsylvania, and Utah in the United States; and in Ontario, Canada.[4]

Although some authors have reported that relatively more women with a family history of breast cancer are now participating in screening,[7,8] there are studies that reported contrary results.[9,10] In Turkey, researchers point to an increase in the screening rate in one study,[11] but there are more studies asserting that there has been no difference in participation.[12–14]

Researchers emphasize the great need to determine cancer risk in women with first-degree relatives who have had cancer. It is suggested that these women be informed adequately about healthy lifestyle behaviors and screening processes,[12,15,16] but this issue is being addressed only to a limited degree.[17,18] The health behaviors of individuals with a family history of cancer have been shown to be similar to those of the general population, and it has been seen that interventions have been successful in increasing screening behaviors.[14,19]

Five risk reduction strategies are recommended for women at high risk due to a family history of breast cancer. The first step in developing risk reduction strategies is to promote genetic counseling. The second recommendation related to reducing the risk of breast cancer involves increasing physical activity, weight control, limiting alcohol consumption, considering a combined hormone treatment of estrogen and progesterone (limited to a maximum of 3-5 years), and breastfeeding. Other strategies include clinical interventions such as chemoprophylaxis and surgery.[5,6]

Studies indicate that nurses have a role in implementing risk reduction strategies.[20–22] In the limited number of studies conducted in Turkey,[14,19] it has been reported that nurses are engaged in only one of the aspects of educating, counseling, or monitoring the behavioral change processes of women at high risk. It also has been stated that there is no theoretical framework for behavioral change. Only screening rates have been measured in studies, whereas lifestyle changes and genetic counseling have been neglected.

In the creation of the protocol in this study, the content of the program designed for the intervention group was planned around the theoretical framework of the Health Belief Model (HBM) and the Health Promotion Model (HPM). The HBM is the oldest model that has been used to understand and predict health behaviors. It contains several key concepts that predict why people will take action to prevent, screen, or control disease, and examines how patients respond to symptoms and medical treatments.[23] The HPM provides perspective into the background of factors affecting health behaviors. It was first developed in 1982 and later underwent revisions. The revised third edition is based on 11 beliefs that should be evaluated by the nurse.[24] The conceptual, theoretical, and empirical structuring of the study is provided in Figure 1.

In addition to the planned theoretical framework, to improve the screening participation rate of women at high risk of breast cancer and to promote risk-reducing behavior, the functions of educating, counseling, case management, and monitoring-associated functions are performed together. The functions are summarized in Table 1. Unlike other interventions, 2 theoretical backgrounds were used in this protocol to develop both screening behavior and risk-reducing behaviors. Moreover, the content of the initiative is based on the consensus of the relevant experts.

The aim of this study protocol was to develop a Breast Cancer Risk Reduction Program (BrCaRRP) that encompasses multiple interventions of education, counseling, case management, and surveillance. The aim was to evaluate whether such a program will be effective in promoting risk reduction behaviors and increasing participation in screening programs for women at high risk because of breast cancer in the family.

■ Hypotheses

Four hypotheses were generated:

H_1: When compared with the control group, the women in the BrCaRRP group will have a higher rate of participation in breast cancer screening (mammograms), breast MRI, and breast ultrasound (US).
H_1: When compared with the control group, the women in the BrCaRRP group will display a change in their beliefs regarding breast cancer.

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	Health Belief Model			Health Promotion Model		
Conceptual C	Perceived Susceptibility	Health Motivation	Perceived Seriousness (Breast Cancer Fear)	Health Responsibility	Physical Activity	Diet
Theoretical T	Perceived sensitivity/susceptibility towards a health problem increases the probability of an individual's health behavior related to breast cancer screening.	An individual with high health motivation is more likely to increase health behavior	The perceived seriousness towards the health problem increases the probability of an individual's health behavior.	Individuals with high health responsibility are more likely to increase in health behaviors related to modifiable risk factors (physical activity, healthy diet, smoking cessation).	It is assumed that an individual with a high level of physical activity will have a lower risk of inactivity and obesity	The positive health behavior of an individual with a high nutritional level increases.
Empirical E	*Breast cancer screening *Genetic counselling *Susceptibility subscale of Champion's Health Belief Model (HBM) Scale in Breast Cancer Screenings	*Breast cancer screening *Genetic counselling * Health Motivation subscale of Champion's HBM Scale in Breast Cancer Screenings *Health Responsibility subscale of Healthy Lifestyle Behavior Scale II (HLBS-II) *Physical Activity subscale of HLBS-II *Diet subscale of HLBS-II	*Breast cancer screening *Genetic counselling *Champion's Breast Cancer Fear Scale (CBCFS)	*Breast cancer screening *Genetic counselling *Health Responsibility subscale of HLBS-II *Physical Activity subscale of HLBS-II *Diet sub-factor of HLBS-II *Smoking cessation attempt	*Physical Activity subscale of HLBS-II * The International Physical Activity Questionnaire (IPAQ) *Body Mass Index (BMI)	*Diet subscale of HLBS-II

Figure 1 ■ Conceptual, theoretical, and experimental structure of the study according to health belief model and health promotion model (CTE structure).

H_1: When compared with the control group, the women in the BrCaRRP group will have higher levels of healthy lifestyle behaviors.
H_1: When compared with the control group, the women in the BrCaRRP group will display a higher rate of receiving genetic counseling.

■ Study Design

The research was planned as a single-site, single-blind, parallel-group randomized controlled experimental study. It was registered on https://clinicaltrials.gov (trial number: NCT04304404).

■ Sample/Participants

A trial was conducted in the province of Antalya at Akdeniz University Medical Oncology Clinic. The clinical records of patients were used for identifying patients with breast cancer. The inclusion criteria were the following: (1) The consent of the patient aged 50 or younger with breast cancer to contact and invite a first-degree biological relative (participant) to join the study as a participant, (2) the consent of the participant for joining the study, (3) participant's residing in the province of Antalya, (4) being the 25 years or older, (5) not having had a mammogram and/or a breast MRI taken in the last 18 months, and (6) knowing how to read and write. The exclusion criteria were the following: (1) participant's (first-degree relative) has been diagnosed with breast cancer too and (2) being pregnant or breastfeeding. The disqualification criteria were the following: (1) participants in the BrCaRRP intervention group who do not continue with the telephone meetings after the face-to-face interview, and (2) participants older than 40 years who become pregnant during the intervention and need to have a mammogram taken.

■ Sample Size

The study population consisted of the first-degree biological relatives of the patients with breast cancer who met the inclusion criteria and had applied to the Medical Oncology Department during the period 2019-2020. In calculating sample size, the basic outcome measurement taken into consideration was the participation rate in breast cancer screenings. We applied the analysis performed in a previous study[14] that compared rates of having mammograms before (56%) and after (80%) an education program, and according to the McNemar test, our calculations yielded an 18.6 odds ratio, a mismatch ratio of 0.28, a margin of error of 0.05 at a power of 0.80, indicating that the minimum sample size would be 33. The power analysis was performed on the G*Power 3.1 program.[25] Taking into consideration previous studies that reported that dropouts could occur,[14,26,27] the sample size was enlarged by 15% to 38 individuals.

■ Randomization

The prestudy conducted to create the potential participant pool was launched on January 1, 2019, in the Medical Oncology Clinic. The universe of the study comprised first-degree biological relatives of patients with breast cancer. To create the universe, face-to-face interviews were held with patients with breast cancer who were younger than 50 for the purpose of tracing their biological relatives. The ages of the consenting first-degree biological relatives (mother, daughter, or sister) of the individuals with breast cancer were noted, as well as whether they had received a mammogram/MRI in the last 18 months. The pretests and informed consent of the participants were collected via a link to a questionnaire sent to their telephones. The participants sending in the pretest were assigned to intervention and control groups according to their ages (age 50 and below, age 51 and above) on a stratified basis and through 1:1 block randomization using a mobile application. This procedure was undertaken by a statistics expert and a researcher who did not play an active role in the interventions and measurements. The "Statistics and Sample Size" program was used to block out ages in the assignment of the participants to the intervention and control groups. Based on the recommendations in the relevant literature

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Table 1 • Content, Duration, and Theoretical Background of Applied Intervention to the BrCaRRP Group

Time Duration Intervention	Theoretical Background According to HBM and HPM	Content of Intervention	Intervention Categories of Nursing With the OMAHA System		
			Education, Counseling, Consultancy	Case Management	Surveillance
Zeroth week 60 min	4, b	Reminding the place and time by calling 1 day before the face-to-face meeting appointment		*	
Face-to-face meeting	1, 2	Assessment of breast cancer risk using the Tyrer-Cuzick risk assessment tool with the participant Talking about breast cancer risk brought by family history	*		*
	1, 5	Explaining individual modifiable risk factors for breast cancer, using a power point presentation Explain the behavior to be taken to reduce risk Talking about what the individual can change (such as alcohol, smoking, oral contraceptive use) and referral to the relevant specialist if necessary	*	*	*
	1	Referral to genetic counseling if a first degree relative with breast cancer was diagnosed aged 45 and under		*	
	1, 5	Measuring height and weight, calculating BMI, explain what the calculated result means for the participant, talk about obesity as a modifiable risk factor for breast cancer	*		*
	1	If the BMI is 30 or more, referral to the obesity unit that provides free services in primary care		*	
	5	Informing on healthy eating and physical activity	*		
	1	Identifying an individual's activity level with IPAQ and explaining the effect of being active on both weight control and breast cancer risk reduction	*		*
	3, 5, a	Recommending walking at least 150 min/wk	*		
	5, d	Giving and teaching a physical activity chart to record walking time	*		
	5, d	To be gifting a pedometer ensured of Provincial Health of Directorate to record her walk and teaching her to use it	*		
	1	If she is smoking, explaining effect of smoking on increasing the risk of breast cancer	*		
	3, 5, a	If she smokes and is considering quitting, referral to CEDSEC, which provides this service free of charge, or to another health institution of her choice, smoking cessation polyclinic		*	
	1	Referring those aged 40 and over to CEDSEC for screening mammography, and those aged 39 and under to the general surgery outpatient clinic		*	
	1, 4, 5, b	Making together a mammography appointment from CEDSEC		*	
	1, 3, 5, a	Giving an information note that includes modifiable risk factors to reduce breast cancer, screening recommendations for the high-risk group, addresses where screening can be done, and units that can support risk reduction (CEDSEC, general surgery outpatient clinic, medical genetics polyclinic, dietitian, smoking cessation polyclinic)	*		
		Giving the "Early diagnosis saves lives" magnet, bookmark and brochure of the Ministry of Health Giving the "Don't let breast cancer be your destiny," "Don't be late, stay healthy," "A good breakfast," "Adequate and balanced diet is the basis of health," "Purchasing food," "Eat healthy and act for health," "Exercises for desk workers," "obesity," "100% smoke-free air space" brochures of the Ministry of Health			
		Planning the next phone call			*

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Table 1 • Content, Duration, and Theoretical Background of Applied Intervention to the BrCaRRP Group, Continued

Time Duration Intervention	Theoretical Background According to HBM and HPM	Content of Intervention	Intervention Categories of Nursing With the OMAHA System		
			Education, Counseling, Consultancy	Case Management	Surveillance
Second week 15 min	4, 5, 6, b, c	Asking about mammography or MRI and talking about obstacles, if any	*		
Calling by phone	5, 6, c, d	Talking about physical activity chart and pedometer, answering questions, supporting the positive changes	*		
	5, 6, c, d	Taking the photo of the physical activity chart with a message, supporting use of the pedometer and the individual walking plan			*
	5,6, c, d	Talking about healthy choices in their diet, appreciating positive changes	*		
	5, d	If redirection has been made, follow-up and support of genetic counselor, general surgeon, dietician, and smoking cessation outpatient clinic controls			*
		Planning the next phone call			*
Third week 10 min	4, 5, 6, b, c	Asking about mammography or MRI and talking about obstacles, if any	*		
Calling by phone	2, 5	If mammography or MRI is taken, learning the result, referral to the general surgery department if advanced examination is required		*	
	5, 6, c, d	Taking the photo of the physical activity chart with a message, supporting using of the pedometer and the individual walking plan	*		
	5, 6, c, d	Talking about healthy choices in their diet, appreciating positive changes	*		*
	5, 6, c, d	If redirection has been made, follow-up and support of genetic counselor, general surgeon, dietician, and smoking cessation outpatient clinic controls			*
		Planning the next phone call			*
Sixth week 10 min	4, 5, 6, b	Asking about mammography or MRI and talking about obstacles, if any	*		
Calling by phone	5, 6, c	If mammography or MRI is taken, learning the result, referral to the general surgery department if advanced examination is required		*	
	5, 6, c, d	Taking the photo of the physical activity chart with a message, supporting using of the pedometer and the individual walking plan	*		
	5, 6, c, d	Talking about healthy choices in their diet, appreciating positive changes	*		
	5, 6, c, d	If redirection has been made, follow-up and support of genetic counselor, general surgeon, dietician and smoking cessation outpatient clinic controls			*
		Planning the next phone call			*
Ninth week 10 min	4, 5, 6, b, c	Asking about mammography or MRI and talking about obstacles, if any	*		
Calling by phone	5	If mammography or MRI is taken, learning the result, referral to the general surgery department if advanced examination is required		*	
	5, 6, c, d	Taking the photo of the physical activity chart with a message, supporting using of the pedometer and the individual walking plan	*		

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Table 1 • Content, Duration, and Theoretical Background of Applied Intervention to the BrCaRRP Group, Continued

Time Duration Intervention	Theoretical Background According to HBM and HPM	Content of Intervention	Intervention Categories of Nursing With the OMAHA System: Education, Counseling, Consultancy	Case Management	Surveillance
	5, 6, c, d	Talking about healthy choices in their diet, appreciating positive changes	*		
	5, 6, c, d	If redirection has been made, follow-up and support of genetic counselor, general surgeon, dietician, and smoking cessation outpatient clinic controls			*
		Planning the next phone call			*
Twelfth week	1	Measuring weight			*
30 minutes	5, 6, c	If referral has been made, learning the latest status of genetic counselor, general surgeon, dietician, and smoking cessation outpatient clinic follow-ups			*
Calling by phone					

Abbreviations: BMI, body mass index; BrCaRRP, Breast Cancer Risk Reduction Program; CEDSEC, Cancer Early Diagnosis and Education Centers; HBM, health belief model; HPM, health promotion model; IPAQ, International Physical Activity Questionnaire; MRI, magnetic resonance imaging.
HBM 1: perceived susceptibility, 2: perceived seriousness, 3: perceived benefits, 4: perceived barrier, 5: health motivation, 6: self-efficacy.
HPM a: perceived benefits, b: perceived barrier, c: self-efficacy, d: interpersonal influences.

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suggesting the inclusion of 6 to 12 subjects in each block,[28] blocks of 8 were created.

■ Blinding

Because the intervention was being conducted by the researcher, blinding was not possible. On the other hand, the participants were blinded as they were not aware of which group they had been assigned to. The data on the electronic questionnaire were encoded as groups A and B on the SPSS program. The encoding was performed by a consultant researcher who had no role in the interventions and measurements. The statistician (assessor) who performed the analysis of the data belonging to the encoded groups was also blinded and did not know who had been assigned to either the intervention or the control group. The intervention and control groups were announced after the researcher had written out the study report. Assignment bias, statistical bias, and reporting bias were thus avoided.

■ Outcome Measures

The main outcome measures created in line with the hypotheses of the study were measuring participation in breast cancer screenings, sensitivity, health motivation, fear of breast cancer, health responsibility, healthy eating behaviors, monitoring physical action, and appropriate referrals to genetic counseling. The outcome measures and measuring tools are shown in Table 2. The pretest is to be administered through self-reporting in the clinical setting, the posttest at the 12th week and the retest at the 24th week via online questionnaires.

Descriptive Form of Participants' Sociodemographic and Health Behaviors History

This form is made up of 2 parts. The participants' age, education, and relationship to the patient are the subjects of the questions in the first part. Height, weight, smoking status, alcohol intake, use of combined oral contraceptives, and hormone replacement therapy comprise the secondary measurements of the study to be queried in the pre- and posttests.[29] Questions about applying to a smoking cessation clinic and receiving counseling from a dietitian were added to the posttest.

Participation in Breast Cancer Screening Questionnaire

The pretest contains questions on whether the participants have been previously referred to breast cancer screening by healthcare professionals, whether they have received genetic counseling on breast cancer, and the time of their most recent breast cancer screening. The posttest queries whether the participants were screened during the BrCaRRP, and if so when, if not why, and whether they had referred other relatives to breast cancer screening, thus permitting a review of the full status of screening among the participants. With respect to the age of the participants, those younger than 39 years having a breast US or clinical breast examination (CBM) and/or breast MRI, those older than 40 who had a mammogram, mammogram–breast US, mammogram-CBM and/or MRI, if required,[6,30] will be considered to have been screened. If a participant is screened at a KETEM facility, those older than 40 years receive a mammogram and a CBM, whereas evaluations at a hospital are made on the basis of a mammogram and a US.

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Table 2 • Measurement of Results and Measuring Tools

Outcome Measures	Measuring Tools
Main outcome measures	
Participation in breast cancer screenings	• The investigation form on participation in breast cancer screening
Health beliefs	• Subscale of susceptibility (3 items) in the Champion Breast Cancer HBM Scale
	• Subscale of health motivation (5 items) in the Champion Breast Cancer HBM Scale
	• CBCFS (8 items)
	• Subscale of health responsibility (9 items) in the HLBS II
Physical activity	• Subscale of physical activity (8 items) in the HLBS II
	• IPAQ (7 items)
Diet	• Subscale of diet (9 items) in the HLBS II
Situation of receiving genetic counseling	• The investigation form on receiving genetic counseling
Secondary outcome measures	
BMI	• Measurement of height and weight
Behavior of smoking cessation	• Survey question
Behavior of alcohol withdrawal	• Survey question
Use of hormonal drug (COC and HRT)	• Survey question
24th week follow-up	
Participation in breast cancer screenings	• The investigation form on participation in breast cancer screening
Health beliefs	• Subscale of susceptibility (3 items) in the Champion Breast Cancer HBM Scale
	• Subscale of health motivation (5 items) in the Champion Breast Cancer HBM Scale
	• CBCFS (8 items)
	• Subscale of Health Responsibility (nine items) in the HLBS II
Physical activity	• Subscale of physical activity (8 items) in the HLBS II
	• IPAQ (7 items)
Diet	• Subscale of diet (9 items) in the HLBS II
Situation of receiving genetic counseling	• The investigation form on receiving genetic counseling

Abbreviations: BMI, body mass index; CBCFS, Champion's Breast Cancer Fear Scale; COC, combined oral contraceptive; HBM, Health Belief Model; HLBS II, Healthy Lifestyle Behavior Scale II; HRT, hormone replacement therapy; IPAQ, The International Physical Activity Questionnaire.

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Genetic Counseling Questionnaire

The United States National Comprehensive Cancer Network recommends that individuals with a family history of cancer (younger than 45 and a relative of a patient diagnosed with breast cancer) receive genetic counseling. In line with this recommendation, the posttest will also query whether or not the participant has received genetic counseling. The policy of the hospital where this study was conducted is not to administer a test to a relative before the administration of a genetic test to the patient. The relative is tested in the event a mutation is detected in the patient. For this reason, individuals (younger than 45 and relatives of patients diagnosed with breast cancer) will be duly informed of this in the BrCaRRP interventions, and those with a diagnosis of breast cancer will be queried as to whether they have applied to a genetic outpatient clinic. If so, they will be asked for their test results.[29]

The Champion Breast Cancer Health Belief Model Scale (Subfactors of Susceptibility and Health Motivation)

Champion developed the Health Belief Model Scale in 1984 based on the HBM; the instrument was revised 3 times.[31] In this study, we used the subfactors "susceptibility" and "health motivation" from Champion's Health Belief Model Scale, which had been adapted into Turkish.[32] In the Turkish adaptation, the Cronbach's alpha coefficients of susceptibility and the health motivation subfactors were .69 and .83, respectively. Health motivation and susceptibility increase as scores increase on the scale.

Breast Cancer Fear Scale

This scale was developed by Champion et al in 2004.[33] The adaptation of the scale into Turkish was executed in 2012.[34] In the Turkish adaptation study, the Cronbach's alpha coefficient was .90. The scale is made up of 8 items. It is a Likert-type instrument, and all items are positive. As the score increases, the fear of breast cancer rises, and when evaluated on the basis of the total score, a score of 8 to 15 is considered to indicate a low level of fear; 16 to 23, a moderate fear; and 24 to 40, a high level of fear.

The Healthy Lifestyle Behaviors Scale II (Subfactors of Health Responsibility, Physical Activity, and Diet)

The Healthy Lifestyle Behaviors Scale (HLBS) was developed by Walker et al[35] in 1987. It was revised in 1996 and renamed HLBS II.[35] The validity and reliability study of the Turkish adaptation of the HLBS II were executed by Bahar et al.[36] In the Turkish adaptation study, the Cronbach's alpha coefficients for the health responsibility, physical activity, and nutrition subfactors were .77, .79, and .68, respectively. The scale consists of 52 items and 6 subfactors. We will use the subfactors of

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"health responsibility," "physical activity," and "diet" in this study. All of the items on this Likert-type scale are positive. As the score increases, the levels of health responsibility, physical activity, and diet also rise.

The International Physical Activity Questionnaire (IPAQ) will be used in the detailed evaluation of the participants' physical activity. The adaptation of both the short and long forms of the questionnaire was first tested for validity and reliability in 2005,[37] and then a second time in 2010.[38] The IPAQ short form used in this study comprises 4 subfactors (vigorous physical activity, moderate physical activity, light physical activity, and resting periods) and 7 items. Although the test-retest reliability coefficient of the Turkish version of the IPAQ was .69 for all physical activities, it was .64 for vigorous physical activity, .50 for moderate physical activity, .67 for light physical activity (walking activity), and .78 for sitting. Calculations are made on the basis of the time and resting periods individuals devote to light, moderate, and vigorous activities and how much energy they spend on these activities.

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■ Study Procedure and Interventions

Program to Be Applied to the Intervention Group: BrCaRRP

The details of the BrCaRRP to be applied to the intervention group are set out in Table 1. The BrCaRRP is a 12-week program that encompasses 6 meetings, where the first is a face-to-face, 60-minute session, and the others are held by phone at weeks 2, 3, 6, 9, and 12. As reminders and in support of their changes in behavior, participants will receive more frequent telephone calls in the first weeks.

The interventions made according to the HBM and HPM were categorized in line with the OMAHA system of classification (education, counseling, consultancy, case management, and surveillance). The research-based Omaha System is a classification system. It consists of nursing diagnoses/client problems, interventions, and client outcomes. The association of each planned intervention with its related concept was achieved in consultation with experts in the field. According to the experts, BrCaRRP's content validity index was calculated as 0.954 (high); its weighted kappa analysis statistic was 0.70 (high). The content of the face-to-face individual education to be presented to the intervention group in the first week was drawn up in accordance with expert opinions taken from Akdeniz University Hospital Medical Genetics Outpatient Clinic, the General Surgery Outpatient Clinic, the Medical Oncology Outpatient Clinic, and KETEM.

INTERVENTION TO BE APPLIED TO THE CONTROL GROUP

To achieve blinding of the participants in the control group, an information sheet will be sent out via WhatsApp after the administration of the pretest. This 1-page information sheet will contain suggestions regarding reducing risk in women with a family history of breast cancer, locations where screening can be obtained, and the names of units that can support risk reduction (KETEM, general surgery outpatient clinics, medical genetics outpatient clinics, dieticians, and smoking cessation clinics). The posttest will be administered at the 12th week, and the retest at the 24th week. After the retest, the plan foresees that each participant is invited to the face-to-face education to be offered within the scope of the BrCaRRP. The study procedure is explained in Figure 2.

■ Data Analysis

The data obtained from the study will be statistically analyzed on the IBM SPSS: 23, G*Power and R programs. To complete the missing data on the posttest, an intention-to-treat (ITT) analysis will be made.[39] Mean imputation will be performed to complete continuous data, and a worst-case scenario will be considered for numerical data. We chose to plan for a worst-case scenario to avoid bias because breast cancer screening produces a straightforward result; an individual either has a screening or not. Accordingly, those who dropped out of the study were assumed to not have been screened. All data will be evaluated with ITT. The paired-samples t test will be used for continuous data showing normal distribution, and the Student t test for 2 independent groups. The McNemar test for 2 dependent groups will be applied to categorical variables, and the chi-square test for 2 independent groups (Table 3).

■ Discussion

There are studies showing that women who have a family history of breast cancer do not differ from those who do not have such a history in terms of their participation in breast cancer screening and their health behaviors.[9,10,12] According to data compiled by the Turkish Ministry of Health, participation in breast cancer screening in the general population was 16.1% in the last 2 years.[40] It was found in a study conducted in Antalya that first-degree relatives of individuals with breast cancer apply for mammograms at a rate of 17%.[13] These rates indicate that women at high risk of breast cancer act no differently than those at moderate risk.

It can be seen from a review of the literature that some studies stress that the first-degree relatives of individuals with breast cancer need to receive education and counseling.[17,18] The health behaviors (such as breast cancer screening, physical activity, lose weight, decreasing body mass index, nutrition, and stress management) of high-risk women are similar to those of the general population. However, improving interventions has been found to be effective.[12,14,19,26,41–45] Researchers have studied the effects of increasing physical activity, preventing obesity, and maintaining weight control on reducing the risk of cancer.[41,44,46,47]

The literature reveals that nurses are effectual in identifying the risk of breast cancer[20,48,49] in referring women at high risk to genetic counseling,[22,49,50] helping women to make lifestyle changes,[14,51] counseling women to choose other risk-reducing methods (risk-reducing agents and surgery),[21,52] and ensuring that women participate in screening.[14,21,51,52] It is reported in a few studies conducted in Turkey[14,19] that nurses generally steer

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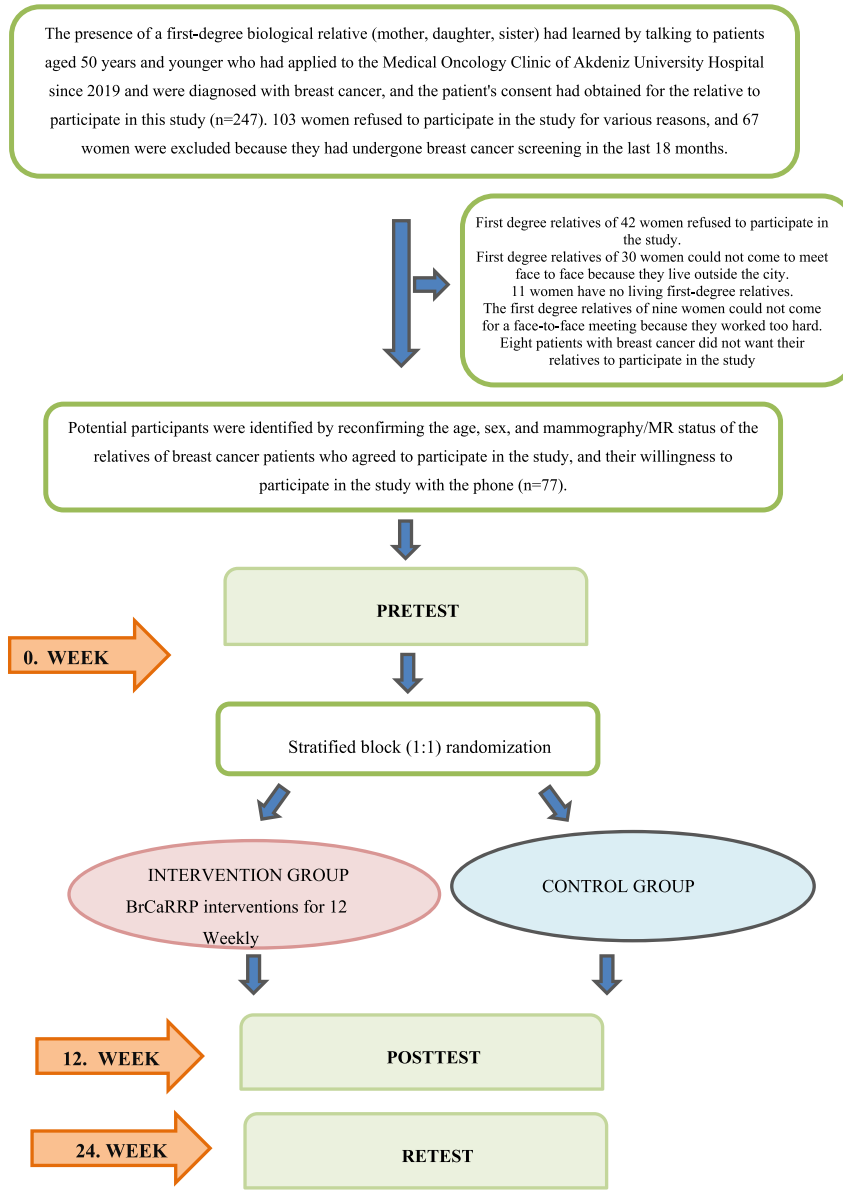

Figure 2 ■ Study procedure.

women at high risk toward either education, counseling, or behavioral change and that there is no theoretical framework that has been adopted to promote change. The roles and functions of providing education, counseling, consultation, case management, and monitoring for women at high risk of breast cancer must be implemented together. Working to increase the participation in screening programs of women at high risk of breast cancer, to provide referrals to genetic counseling, and to improve health beliefs and behaviors can be considered to be among the roles of the nurse. The feasibility of achieving these goals will be tested with the implementation of the BrCaRRP intervention.

Limitations

The self-reporting statements of the participants on whether or not they were screened or had genetic counseling may be considered a limitation. On the other hand, because both the screening and genetic counseling appointments will be organized by the researcher, the supervision provided will keep this limitation under control. The fact that the study was conducted at only one site and did not include those who could not read, write, or speak Turkish may be considered other limitations.

Ethical Considerations

Institutional approvals for the conduct of the study were obtained from Akdeniz University Faculty of Medicine Clinical Studies Ethics Committee (29.08.2018/596) and from Akdeniz University Hospital Medical Oncology Department (01.03.2019). Permission for use of all of the scales was obtained from their respective authors. A written informed consent will be collected from all the participants. The study data will be used only in published scientific articles; personal data belonging to the

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Table 3 • Statistical Analyses to Be Used in the Research

Variable/Outcomes	Hypothesis	Outcome Measure	Methods of Analysis
	Sample calculation and power analysis		G*Power program
	Concordance between expert opinions on the relevance of the content of the intervention	Expert opinions	Content validity index Weighted kappa analysis with R program
	Whether the data show a normal distribution		Skewness and kurtosis
Rate of screening participation at third month from baseline	H_1: When compared with the control group, the women in the BrCaRRP group will have a higher rate of participation in breast cancer screening such as mammogram, breast MRI, and US	Self-report and screening records	McNemar test, odds ratio and chi-squared test, relative effectiveness, ARR, ITT-worst case imputation
Difference in change in health beliefs compared with baseline at third month	H_1: When compared with the control group, the women in the BrCaRRP group will display a change in their beliefs regarding breast cancer a.They will become more sensitive to the issue b.Their health motivation will increase c.They will have less of a fear of breast cancer	- Susceptibility and health motivation subscales of Champion's HBM Scale in breast cancer screenings - Breast Cancer Fear Scale	Independent samples *t* test, paired samples *t* test, ITT-mean imputation, effect size, CI
Difference in change in health behaviors compared with baseline at third month	H_1: When compared with the control group, the women in the BrCaRRP group will have higher levels of healthy lifestyle behaviors a.Their health responsibility will be improved b.They will engage in more physical activity c.They will be eating a healthier diet	- Health responsibility, physical activity and diet subscales of HLBS II - IPAQ	Independent samples *t* test, paired samples *t* test, ITT-mean imputation, effect size, CI
Rate of receiving genetic counseling at third month from baseline	H_1: When compared with the control group, the women in the BrCaRRP group will display a higher rate of receiving genetic counseling	Self-report and genetic polyclinic records	McNemar test, odds ratio and chi-square test, relative effectiveness, ARR, ITT-worst case imputation

Abbreviations: ARR, absolute risk reduction; BrCaRRP, Breast Cancer Risk Reduction Program; CI, confidence interval; HBM, Health Belief Model; HLBS II, Healthy Lifestyle Behavior Scale II; IPAQ, International Physical Activity Questionnaire; ITT, intention to treat; MRI, magnetic resonance imaging; US, ultrasound.

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participants will be shared under no circumstances. If the BrCaRRP is successful, the same interventions will be applied to the control group.

■ Conclusion

The BrCaRRP is a nurse-led program based on the HBM and the HPM that is implemented with the aim of increasing the participation in screening of women with high breast cancer risk and achieving risk reduction. The education contains multiple interventions, including counseling, consultation, case management, and surveillance. The BrCaRRP has been found to have high content validity according to the feedback from experts (content validity index was calculated as 0.954; the weighted kappa statistic for interrater reliability was 0.70). The program can be used as an intervention in a randomized controlled trial.

■ Data Monitoring

The data of this study will be monitored by the research advisor and other members of the thesis monitoring committee within the framework of thesis monitoring procedures.

■ Auditing

The Akdeniz University Scientific Research Projects Coordination Unit will provide the financial coverage of the study. The researchers are providing 6-month reports of developments and expenditure.

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