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Department of Public Health

COMMUNITY-BASED CLINICAL TRIAL AMONG YEREVAN WOMEN TO DETERMINE
THE EFFECT OF A BREAST CANCER INTERVENTION PROGRAM

(Research Grant Proposal)

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EXECUTIVE SUMMARY

Breast cancer is the most commonly diagnosed cancer among women all over the world. It is the leading cause of death from cancers among Armenian women. Growth in the rate of incidence of breast cancer in the country is observed among younger women. The rate of death increased from 9.4 (per 100,000) in 1994 to 11.8 in 1998. It is believed that the mortality rate actually is higher because the overall population figures are lower than those officially reported. This increase is primarily due to a lack of access to health care services, fewer screening opportunities, and delays in seeking treatment. The screening rate is extremely low despite existing services.

To increase screening utilization, it is necessary to identify factors associated with women's decisions to have mammogram/breast self-examination (BSE)/clinical breast examination (CBE). This is a grant proposal designed to conduct a community-based, crossover clinical trial among 400 women from ages 35 to 65 years to determine breast cancer related knowledge levels, perceived mammography/BSE/CBE benefits and barriers, and the stage of adoption of screening practices as well as to conduct and evaluate breast cancer education classes among these women.

Goals of the education program: Increase of breast cancer related knowledge, woman-to-woman promotion of screening, and actual participation in screening.

Objectives: This study will assess whether a breast cancer education program results in favorable, replicable, and sustained outcomes. Principal outcome of the study is the use of screening methods, and secondary outcomes are the stage of mammography adoption and talking with friends/relatives about breast cancer and breast cancer screening methods.

Intervention: Six education classes will meet three times a week for two-hours during a 2-week period. After education classes; consultations are available for two-month period.

Study population: Women between ages 35 to 65 years.

The duration of the program is 3 years.

Methods: After baseline interviews, Group I will receive the education program, and Group II will act as the comparison group. Year 2 will be the crossover year in which Group II women will receive the program. Year 2 survey data from the Group I will be compared to year 3 data from group II to determine whether Group I findings could be replicated in year 3.

Statistical analysis: Chi square and t-test with 95% CI will be used to examine baseline characteristics and outcomes of the cohort of women interviewed at all three data collection periods. To model positive, negative or no change, ordinal logistic regression analysis will be used. To determine whether the subjects' responses to the health belief model scale items are associated with staging, a multiple logistic regression analysis will be performed.

SPECIFIC AIMS AND OBJECTIVES OF THE STUDY

This paper proposes to develop, conduct and evaluate breast cancer education classes among Yerevan women from ages 35 to 65 years. The goals of the education classes are to increase breast cancer related knowledge, woman-to-woman promotion of screening, and actual participation in screening. The program is designed to impart some basic breast cancer knowledge, which is deemed necessary for being screened themselves and for promoting screening among their friends/relatives. Breast health education course curriculum is provided in **Appendix A.**

The research questions addressed by this proposal are:

- What is the level of knowledge, perceived mammography benefits and barriers, and stage of adoption of screening practices among women from ages 35 to 65 years before intervention?
- What is the level of knowledge, perceived mammography benefits and barriers, and stage of adoption of screening practices among women from ages 35 to 65 years after intervention?
- Will the changes in knowledge, perceived mammography benefits and barriers, and adoption of screening practice among women from ages 35 to 65 years be sustained during study period?
- Will Group I findings be replicated in year 3?

The evaluation objectives of the program are the following:

Objective I: At the end of 2-week breast health education classes of the baseline year, the mean difference of pre-post knowledge scores in the intervention group will be at least 20% higher compared to the non-intervention group.

Indicator of Objective I: The difference of post- and pre-test mean scores for knowledge, divided by the expected total for right answers and multiplied by 100%.

Objective II: After attending 2-week breast health educational classes, the proportion of women reporting change in breast health behavior in the intervention group will be on 20% higher compared with the proportion of women reporting change in breast health behavior in the non-intervention group at the baseline year.

Objective III: After conducting 2-week breast health educational classes the mean agreement score for health belief model (HBM) variables in intervention group will be at least 20% higher compared to the non-intervention group.

Indicator of Objective III: The difference of post- and pre-test mean agreement scores for HBM variables, divided by the expected total for desired answers and multiplied by 100%.

Objective IV: After completion 2-week breast health educational classes between the year 2 and year 3 post intervention changes in Group II will be similar to Group I.

Objective V: The sustained intervention effect will be demonstrated in Group I with no decrease in knowledge scores in year 3.

BACKGROUND INFORMATION

Breast cancer (BC) is the most common cancer among women all over the world [1]. The disease has been increasing at an alarming rate and is considered to be of epidemic proportions in the United States, with current estimates indicating that 1 in 8 women will develop breast cancer during their lifetimes, according to American Cancer Society [2]. According to the World Health Organization, more than 1.2 million people will be diagnosed with breast cancer and 500,000 deaths from breast cancer will occur during 2001 throughout [2].

At present the cause of BC is not well understood and there are no immediate prospects for primary prevention. Advances in treatment have achieved only small increases in the survival of women with symptomatic disease. The survival rate is directly related to the disease stage at the time of diagnosis: women with early stage of disease at diagnosis have better survival prospects than those with more advanced BC [3]. This suggests that early detection, which includes mammography, breast self-examination (BSE) and clinical breast examination (CBE), provide the best way to reduce BC mortality.

Eight randomized controlled trials, including nearly half a million women from 4 countries (USA, Canada, Sweden, UK) [4-11] compared the breast cancer mortality of women, who were offered screening, to those who received standard care. The trials differed in the study population, study design, population recruitment procedures, and analysis of the outcomes. Unique features of the Canadian trial design were the prospective study of women aged 40 to 49 years, and the inclusion of clinical breast examination prior to randomization. Differences in design and analysis methodology created problems in comparing data from these trials. Based on these trials, there is general agreement that screening mammography for women aged 50 to 69 years is beneficial, at the population level. Mammography detects 40-70 percent of cancers

before they are evident on physical examination and reduces mortality from BC by 25-30 percent [1, 12]. The controversy arises regarding the recommendations for younger women. Women in their 40s have a relatively lower cancer incidence, but their clinically diagnosed cancers tend to be more aggressive. Premenopausal breast tissue is more likely to be dense, making interpretation of mammograms more difficult. Combining data from age 40 to 49 years subgroups of the other trials with data from the Canadian trial there may be a benefit in favor of screened women [13]. Although mammography is the primary screening modality, breast self-examination and clinical breast examination are recommended as a supplemental method of detecting breast cancer.

Monthly BSE is promoted as a low-cost, simple, non-invasive and non-hazardous means of detecting breast cancer at an early stage, which offers the best chance for treatment and cure. The identification of an abnormality by BSE can direct professionals to the relevant area of the breast, thus increasing the sensitivity of mammography and clinical breast examination. The impact of BSE on mortality or survival, rather than tumor size and stage at diagnosis, has not been assessed across studies [14-16]. Two randomized trials of BSE as a screening intervention to decrease mortality have been undertaken in Russia and in China.

A World Health Organization 15-year trial, initiated in Russia in 1985, compares the mortality experience of women exposed to BSE education intervention with women in control groups [14]. A randomized controlled trial of BSE was set up in Leningrad and Moscow with one experimental group and one control group in each city. Women between ages 40 and 64 years were enrolled in the study. As there were no differences in stage of diagnosis between the experimental and control groups, the authors commented that they did not expect any differences in mortality rates between the two groups. Five- and nine-year survival rates for breast cancer

patients in the two groups have been compared and although an absolute difference of 10 percent was found (65% survival among BSE group compared to 55% survival among controls) this difference was not significant. While the abstract does not indicate whether the proportion of tumors detected at an early stage differed between the two groups, it does indicate that the number of breast tumors detected at an early stage was greater in both the control and the BSE groups than in other parts of the former USSR. This finding suggests the possibility that the control group may have engaged in some form of early detection and indicates, that the data needed to be examined more closely. Results will be difficult to interpret, as it is also known that compliance in the study group was low. This study, therefore, has not provided an adequate evaluation of the efficacy of BSE.

The Shanghai study is the second randomized controlled trial examining the effectiveness of BSE in reducing breast cancer mortality [15]. Unlike the Russian study, women in this study were not just taught BSE, but also had this behavior reinforced through supervised practice sessions and refresher courses. After a five-year follow-up period, the study found no difference in the breast cancer mortality rates between the BSE instruction group and the control group. However, the authors suggested that this may not be unexpected, as some studies investigating the effectiveness of mammography in reducing breast cancer mortality did not find a significant difference in the cumulative breast cancer mortality rates between screened and unscreened groups until after the fifth year of the study.

Inferences about the benefits of BSE could be based on the results of observational studies. Foster and Costanza observed a 5-year survival rate of 75 percent for self-examiners compared to 57 percent for non-examiners. Five year survival rates from breast cancer were 78 percent for women, who examined themselves once a month; 84 percent for women, who

examined themselves every other month; and 61 percent - for non-examiners [17]. Most investigators found that compared with nonexaminers, self-examiners had smaller primary tumors and fewer involved axillary lymph nodes [18, 19]. The interest on BSE continues and may be justified by several factors: most cancers are discovered by women themselves; and BSE may enhance detection of "interval" cancer, which occur between screening examinations and may be the only screen available for women who do not have access to experts for economic and geographic reasons [20].

Clinical breast examination (CBE) is the third recommended screening method and may reveal breast cancers that are not detected by the patient or by other screening methods [21]. Data about the effectiveness of CBE alone or in combination with mammography are inconclusive. No randomized trials of CBE as a single screening modality have been done. The Health Insurance Plan of Greater New York trial compared annual mammography plus annual CBE with no screening in women from ages 40 to 64 years [22]. At 18 years of follow-up, there was a 20 percent reduction in breast cancer mortality in the screened group. Although the incremental benefit of CBE cannot be directly determined from this trial, modeling studies have suggested that two-thirds of the effectiveness may have been due to CBE [23]. The Canadian National Breast Screening Study compared CBE plus mammography to CBE alone in women aged 50 to 59 years. The frequency of cancer diagnosis, stage, interval cancers, and breast cancer mortality were similar in the 2 groups, and compared favorably with other trials of mammography alone. The explanation for this finding is the careful training and supervision of the health professionals performing CBE [24].

Treatment of breast cancer and survival rate. A specific attempt to communicate the benefits and limitations of early diagnosis involved the characterization of breast cancer as a heterogeneous disease. It was proposed 3 grades of BC: those of low malignancy, which were usually cured; those of high malignancy, which were usually lethal; and an intermediate group. As Kreyberg wrote in 1953, the speed of diagnosis was of little importance for both grade I tumors, which were "very slowly growing and late metastasizing", and grade III tumors, which were "very quickly growing and very early metastasizing". He argued, "The grade II tumors are an intermediate position, and there are the tumors where the question of earliness in diagnosis is of paramount importance" [25].

Identifying the cancer stage is one of the most important factors in selecting of appropriate treatment options. Several tests may be performed to help stage breast cancer including clinical breast exams, biopsy, and certain imaging tests such as a chest x-ray, mammogram, bone scan, CT scan, and MRI scan. The American Joint Committee on Cancer stages the breast cancer using the TNM classification system: T (tumor size), N (palpable nodes), and/or M (metastasis) [26] [see **Appendix B**]. Based on the determined stage of breast cancer the health care professionals are able to predict a patient's survival rate.

Table 1 shows a 5-year survival rate from breast cancer at different stages of the disease [26]. Almost 100% of women will survive 5-years if the disease is discovered at an early stages and successfully treated.

Table 1: Staging of breast cancer and survival rate

Stage	Tumor Size	Tumor (T)	Node (N)	Metastasis (M)	5 [*] -year Relative Survival Rate (%)
Stage 0	* *	Tis	N0	M0	100
Stage 1	Less than 2 cm	T1	N0	M0	98
Stage IIA	Between 2-5 cm	T0	N0	M0	88
		T2	N0	M0	
Stage IIB		T2	N1	M0	76
		T3	N1	M0	
Stage IIIA	More than 5 cm	T0	N2	M0	56
		T1	N2	M0	
		T2	N2	M0	
		T3	N1, N2	M0	
Stage IIIB		T4	Any N	M0	49
		Any T	N3	M0	
Stage IV	Not applicable	Any T	Any N	M1	16

Source: American Joint Commission on Cancer and International Union Against Cancer (year 2001);

* Source: American Cancer Society (year 2001)

Breast cancer survival continues to decline after five years. At least 71 percent of all women survive 10 years after diagnosis, but 48 percent or almost half, die from breast cancer within 20 years of diagnosis [2].

While breast cancer is less common in women in their twenties, they tend to have more aggressive breast cancers than older women, which may explain why survival rates are lower among younger women (Tab. 2).

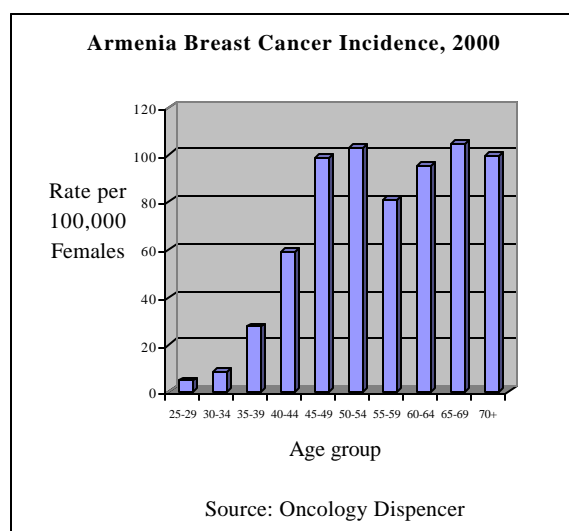
Table 2: Five-year survival rate by age.

Younger than 45	81%
Ages 45-64	85%
Ages 65 and older	86%

Source: American Cancer Society

Situation in Armenia. Breast cancer is the most prevalent malignant tumor and it is the leading cause of death from cancers among Armenian women. Each year in Armenia, about 700 new cases of breast cancer are identified and over 120 women die from the disease [27]. Cases were included as deaths from breast cancer if this was stated on the death certificate as the underlying cause of death. Growth in the rate of incidence of breast cancer in the country is observed among younger women. Statistics indicate [27], that the incidence of breast cancer rises dramatically at ages 35-39 years and continues to increase until at age 50-55 years, then decreases, but still remains high until ages 70-74 years [Fig. 1].

Figure 1. Incidence of breast cancer in Armenia



Age, as indicated in Figure 1, is the most important risk factor for breast cancer. Over 70% of breast cancer occurs in women over 50 years old; over 60% occurs in women over 60. According to official data, the rate of death increased from 9.4 (per 100,000) in 1994 to 11.8 in 1998 [27]. It is believed that mortality rate actually is higher because the

overall population figures are lower, than those officially reported. The increase of death from the disease is primarily due to lack of access to health care services, fewer screening opportunities, socioeconomic resources, and delays in seeking treatment.

In Canada and the US, breast cancer death has declined since 1980 [28]. The decrease in breast cancer death rates is partly due to the fact that more women are having mammograms. Heightened emphasis on monthly breast self-examination has facilitated the shift toward early

detection of breast cancer at an earlier, more curable stage. In Armenia more than 40 percent of all breast cancers go undetected without a mammogram [29].

Based on the results of a cross-sectional study conducted in Yerevan [30], which was aimed to obtain the general picture of BSE attitude, knowledge and practice patterns of women from ages 25 to 50 years and over 50 years of age, the proportion of women who practice BSE was found to be 20% and for those who have mammogram – 6%. The screening rate is extremely low despite of existing services.

The largest program carried out at Armenian American Mammography Center, which has been functioning in Yerevan since 1997. The Center provides reliable high-standard mammography and sonography, distributes short education materials on breast cancer and screening methods, but does not cover all the strata of the population. The cost of their services is rather high for the average woman.

A 1999 study [30] results show that there is a substantial lack of BC -related information among Yerevan women, which influences their late appeal or no appeal to health care facilities. In 1998-1999, only 11-12 percent of diagnosed Armenian patients were identified during the initial stage of cancer [31]. Because many breast cancers are detected in the late stages, only 50% of operated patients survive 5 years [27].

The Yerevan study [30] defined BSE performance or mammography utilization status dichotomously, by whether a woman has or has not ever had a mammogram/BSE. This concept is useful, but failed to address the issue of which factors influence consideration of mammography/BSE/CBE and repeat interval compliance. There is evidence that preventive health behavior such as mammography/BSE may be more appropriately conceptualized as processes of adoption. Stage models, which have been used for a variety of health behaviors [32,

33] employ this process by considering not only whether individuals have performed a preventive health action, but also the degree to which they considered the action and whether they have repeated it when appropriate. This approach allows identifying the variables, predicting adoption stages. People at different points in the health behavior decision process may behave in different ways, with different factors influencing their behavior, and needing different kinds of information to move them closer to taking preventive health action [34]. King and colleagues [35] found that women who believed that early-detected breast cancers could be cured were more likely to have mammograms. In addition, Champion [36] found, that perceived benefits such as relief from worry and feeling good about oneself were related to increased utilization and significant differences in benefit and barrier perceptions by mammography stage. Rimer [37] reviewed barriers linked to decreased use: these included fear of radiation, pain, cost and lack of knowledge.

No detailed research, aimed to identify perceived mammography/BSE/CBE benefits and barriers, and stage of adoption of screening practices has been conducted in Armenia, despite of public health importance of this issue. The proposed research study will fill some of the gaps and may increase breast cancer screening practices among Armenian women via a community and individually-oriented program.

THEORETICAL FRAMEWORK

Health Belief Model (HBM) and Transtheoretical Model are used in the study as the theoretical framework. The HBM was first introduced in 1950s by Hochbaum, Leventhal, Kegeles, and Rosenstock [38]. The original four concepts in the model were:

- Perceived personal vulnerability to or subjective risk of health condition (susceptibility);
- Perceived personal harm of the condition (seriousness);

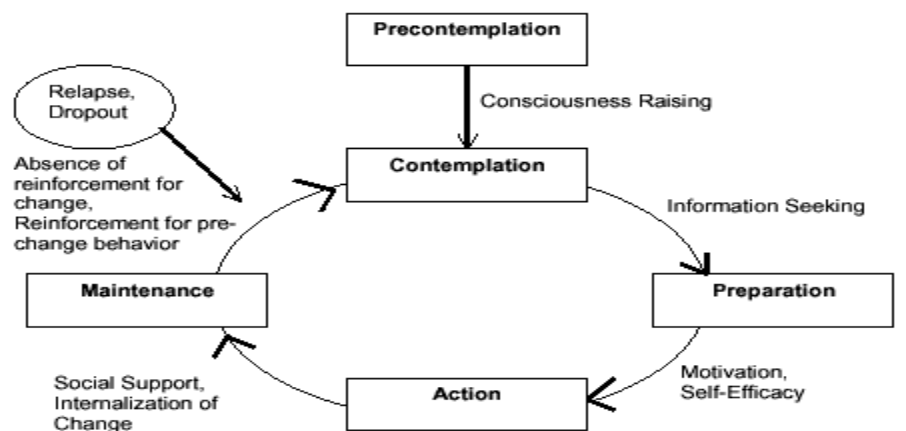
- Perceived positive attributes of an action (benefits);
- Perceived negative aspects related to an action (barriers).

In several studies, susceptibility, perceived benefits, self-efficacy and barriers have been found to be significantly related to BSE [39, 40, 41]. General health motivation was later an addition to the original HBM and also has been found to be positively related to BSE [42]. The most recent concept added to Health Belief Model is that of confidence [43], which is defined as “the belief that one can successfully execute a behavior that will then lead to a desirable outcome”. Thus, a woman who feels personally susceptible to BC and believes the condition is serious may be more likely to use screening methods. A woman, who recognizes screening benefits and experiences few barriers to performing BSE may increase practice. And finally, a woman’s general health motivation and perceived personal control over breast cancer theoretically should increase her practice of BSE and other screening methods.

A recent study [34] shows that perceived barriers and benefits vary by mammography stage. The study's [34] mammography stage model was adopted from Prochaska and DiClemente's Transtheoretical Model of smoking cessation [44]. The items determining the stage of mammography adoption have been included in the questionnaire of this proposed study. The Transtheoretical Model defines behavior change as a series of sequential stages. The degree of readiness to take behavioral action (Fig. 2) is operationalized by classifying women as precontemplators, contemplators, relapse precontemplators, relapse contemplators, action/maintenancers. Precontemplators are women who have never have a mammogram/BSE and are not thinking about the procedures. Contemplators have not have a mammogram/BSE but are consider action within the next six months. Relapse precontemplators had received a previous mammogram and performed BSE but were not thinking about getting the procedures in the

future. Relapse contemplators had received a previous mammogram/performed BSE and thinking about getting these procedures in the next six months. Action/ Maintenancers will receive one or more mammograms/perform monthly breast self -exam within two years.

Figure 2. Transtheoretical Model



Transtheoretical Model (Stages of Change Model)
(DiClemente et al., 1991; Prochaska & DiClemente, 1983)

PILOT STUDY

A small study was conducted to pilot the questionnaire and obtain preliminary information on women's knowledge related to BC screening methods, mammography/BSE benefits and barriers perception, and stage of adoption of screening practices. To validate the HBM scales and to pretest the questionnaire as a whole, the questionnaire was first administered to a group of 10 women, who were asked for feedback on the relevance and clarity of the questions. A revised questionnaire was used in the pilot study. Improvements of the questionnaire consisted mainly of simplifying the language, shortening sentences to facilitate better comprehension among women with little formal education, and adding several options for a few of the questions.

Forty-one women from ages 35 to 65 years (mean age was 47.9) were selected from the second Nork Massiv district. The first subject was conveniently selected from a neighborhood. Afterwards, the rest of the subjects were selected by visiting each third household in the area. If a person was not at home, the nearest house or apartment was selected. Of the 41 women, 2.4% had 8-year education, 31.7% 10-year education, 24.4% professional technical education and 41.5 percent university/institute education. About 76% of women were married, 6.7% single, 6.7 % divorced and 10% widowed. About 39 % of respondents reported their family income to be less than \$100.

Based on the data of the pilot study the prevalence of mammography, CBE, BSE was 4.9% (95% CI = -1.6%; 11.5%); 4.9% (95% CI = -1.6%; 11.5%); and 34% (95% CI = 19%: 48.5%) respectively. None of the women performed BSE or underwent mammography on a regular basis. Thirty percent of them had never heard about BSE, 66 percent about CBE, and 27 percent - about mammography. The mean knowledge score (SD) was 5.76 (2.08) (95% CI= 5.12; 6.4), indicating a BC-related knowledge deficit. The percentage of correct answers to each of 12 knowledge items is presented in **Appendix C**.

Susceptibility and confidence were extremely low. On a 5-point Likert-type scale (5 indicating that the respondent was “very sure” of her response), the mean agreement scores were 1.6 and 1.3 respectively (i.e., a summed score of 8.15 for 5 items and 14.3 for 11 items) (Table 3). Although these data could not be generalizable to the whole population, it provided justification to conduct a large-scale study.

Table 3: Mean summed scores for HBM variables

Variables	# of items	Mean	SD	95% CI
Susceptibility	5	9.7	3.8	8.5; 10.9
Seriousness	7	25.2	6.49	23.2; 27.2
Benefits (BSE)	6	12.2	4.85	10.7; 13.7
Barriers (BSE)	6	15.4	4.15	14.1; 16.7
Confidence	11	14.3	3.77	13.1; 15.5
Health motivation	7	22.8	3.46	21.7; 23.9
Benefits (Mammography)	6	13.8	4.00	12.6; 15
Barriers (Mammography)	5	9.7	3.63	8.6; 10.8

The results of the pilot study were used in calculation of appropriate sample size of the proposed study and to develop the first version of the curriculum for the education classes.

METHODOLOGY

Intervention. The research subjects will receive a two-week education course designed to increase their knowledge about breast cancer and to learn about screening methods to detect breast cancer during treatable phases.

The program is designed to impart basic breast cancer knowledge to participants, and to provide forum for the discussion of breast cancer and screening as well as communication tools for participants to use with their friends. The program was developed, using approaches from the several studies [46, 47]. Women will be invited to the six-core education classes based on the theoretical framework. The overall message of the program is that breast cancer screening and early treatment lead to increased hope for favorable outcomes and increased survival. Classes

will combine didactic and experiential educational strategies (i.e., combinations of short lectures followed by discussion or other interactive activities) that have been used to provide women with a base of health information and rationale for attitudinal and behavioral change. Each class will begin with a review of the previous class(es). Teaching materials will be both visual and tactile and could be used by persons with limited education. The first version of the education classes' curriculum is presented in **Appendix A**. The final version will consider the findings from the baseline interviews.

Study design. To evaluate the educational program's outcomes during a 3-year period, it is proposed to conduct a community-based crossover trial. After baseline interviews, that will be conducted among the women in both groups, Group I will receive the education program, Group II women will act as comparison group. Year 2 will be the crossover year in which only Group II women will receive the program. Year 2 survey data from the Group I will be compared to year 3 data from Group II. Both data will be collected at the same number of months after implementation of the breast health education program (Table 4).

Table 4. Study sequence

Study period (years)	Interviews	Education program implemented
Year 1	Group I and Group II	Group I only
Year 2	Group I and Group II	Group II only
Year 3	Group I and Group II	No program implementation

A crossover design is chosen, because this study design allows assessing the changes due to the intervention; determines whether Group I findings could be replicated in year 2 (at this

stage Group II findings will be compared to Group I findings); and exploring whether effects observed in Group I could be sustained beyond the implementation period (at this stage the long term effect of breast health education will be evaluated). Besides, this study design allows keeping high power of the study even when losses to follow-up will be relatively high.

Sample size. The ingredients for the sample size calculation are the following:

- Null hypothesis: At the end of 2-week breast health education classes of baseline year the mean difference of pre-post knowledge score in the intervention group will be the same as in the non-intervention group.

Alternative hypothesis: At the end of 2-week breast health education classes of baseline year the mean difference of pre-post knowledge score in the intervention group will be higher or lower compared with the non-intervention group.

Effect size: 1.2 (20% x 5.76)

a (two-tailed) = 0.05; **b** = 1 - 0.8 = 0.2

To determine sample size for two independent samples, whose mean values are to be compared the following formula will be used:

$$N = (Z\alpha + Z\beta)^2 \times 2 \times (SD)^2 / \Delta^2 ; N = (1.64 + 0.84)^2 \times 2 \times (2.08)^2 / (1.2)^2 = 36.9$$

Null hypothesis: After conducting 2-week breast health educational classes the mean agreement score for HBM variables in intervention group will be the same as in the non-intervention group.

Alternative hypothesis: After conducting 2-week breast health educational classes the mean agreement score for HBM variables in intervention group will be higher or lower compared with the non-intervention group.

Effect size:

1. Susceptibility: 1.94 (20% x 9.7)
2. Seriousness: 5.04 (20% x 25.2)
3. Benefits (BSE): 2.44 (20% x 12.2)
4. Barriers (BSE): 3.08 (20% x 15.4)
5. Confidence: 2.86 (20% x 14.3)
6. Health motivation: 4.56 (20% x 22.8)
7. Benefits (Mammography): 2.76 (20% x 13.8)
8. Barriers (Mammography): 1.94 (20% x 9.7)

α (two-tailed) = 0.05; β = 1 - 0.8 = 0.2

To determine sample size for two independent samples, whose mean values are to be compared the following formula will be used:

$$N = (Z\alpha + Z\beta)^2 \times 2 \times (SD)^2 / \Delta^2$$

Table 5. Sample size for each HBM variable

HBM variables	Mean	Effect size	SD	Sample size
Susceptibility	9.7	1.94	3.8	47.2
Seriousness	25.2	5.04	6.5	20.4
Benefits (BSE)	12.2	2.44	4.8	47.6
Barriers (BSE)	15.4	3.08	4.2	22.9
Confidence	14.3	2.86	3.8	21.7
Health motivation	22.8	4.56	3.5	7.2
Benefits (Mammography)	13.8	2.76	4.0	25.8
Barriers (Mammography)	9.7	1.94	3.6	42.4

The largest sample size is 47.6. It is planned to analyse the data using logistic regression technique. The model (see data analysis section) includes the following independent variables: screening method- related benefits and barriers, perceived risk and knowledge of breast cancer. Thus, sample size for each sample, which will allow performing the desired analysis, is 143 (47.6 x 4). Due to losses to follow-up, refuses to participate, the sample size is rounded up to 200 for each Group.

Sampling procedures. Because of the high concentration of the population in Yerevan, the city is the primary target for the breast health education program. A multistage sampling procedure is used in the study. Assuming that socio-economic status of the population living in the central area and the outlying area are different. The first stage of sampling is the division of Yerevan on two areas: central area and outlying area.

Second stage: From the list of polyclinics of Yerevan (see **Appendix D**) polyclinics# 4, 7; Second Med. Unit and 17 from the central area and polyclinics# 14, 13, 19 and 20 from the outlying area were randomly chosen for the study.

Assumption 1. Polyclinics in central area are homogeneous.

Assumption 2. Polyclinics in outlying area are homogeneous.

Third stage: Two hundred women will be randomly chosen for Group I and 200 women for Group II. In order to control for possible dissemination of the information between these two groups, randomly two polyclinics (PC) in each area will be selected for each group.

YEREVAN

Central area

PC# 4; PC# 17
PC# 7; **Second Med. Unit**

Group I. (100) Group II. (100)

Outlying area

PC# 14; PC# 19
PC# 13; PC# 20

Group I. (100) Group II. (100)

Study population. As was noted earlier, the incidence of breast cancer rises dramatically at ages 35-39 years. Thus, women between ages 35 to 65 years will be selected as the *study population*.

Sampling frame: List of the women who are registered in polyclinics #4, 7, 14, 17, 13, 19, 20, Second Med. Unit.

Sampling element: Women at age 35 to 65 two are registered in polyclinics# 4, 7, 14, 17, 13, 19, 20, Second Med. Unit.

Inclusion criteria:

- Women on the polyclinic registries between 35 to 65 years of age;
- Women who are willing to participate in the study;
- Women, who have Yerevan residence.

Exclusion criteria: Pregnant women, women with benign breast disease, and women with different forms of cancer.

Group I: From the list of women on the polyclinics (# 4, 7, 14, Second Med. Unit) registries using simple random sample the sample elements will be selected.

Group II: From the list of women on the polyclinics (# 13, 17, 19, 20) registries using simple random sample the sample elements will be selected.

INTERVIEW AND MEASURES

An interviewer-administered survey will be conducted, taking into consideration the following factors. First, the topic under investigation is not very sensitive as discovered during the pretest. Second, the method will allow a high level of response rate. Third, the personal interviews will give opportunity to have questionnaires of longer length and to control the sequence of response to questions. Fourth, interviewers will more accurately follow the special instructions included in the questionnaires. Finally, the «don't know» option will not be read by interviewers and will be circled only when the respondent does not provide an answer.

Female interviewers will conduct the interviews. Before conducting the interviews, the women will receive six hours of group training.

The interviews will measure mammography/BSE/CBE use as the primary outcome and stage of screening methods adoption and talking with friends as secondary outcomes.

The survey instrument is designed to make its use easy and convenient. All questions are numbered to provide clear reference to every item in the questionnaire. To reduce interviewer bias, general questions are stated first and continued with more specific. When a new topic is introduced, transitional phrases are used to make respondent understand and think about the topic. The median interview length is 25 minutes. The English version of the questionnaire is provided as **Appendix E**.

The questionnaire comprises 103 questions, out of which 12 questions related to respondent's personal data (name, address, age, education, medical background, employment status, marital status, physical health, source of regular medical care, number of medical visits in previous year, monthly income, etc.). Twelve knowledge items, 5 susceptibility, 7 seriousness, 11 benefits and barriers for mammography, 12 benefits and barriers for breast self-exam, 6

confidence and 7 health motivation statements are included in the questionnaire. Statements are anchored on a five-point summated Likert scale with markers ranging from "strongly agree" to "strongly disagree" and don't know (DK) option is added. Within the questionnaire, the following types of scales are applied as well: verbal frequency, ordinal, numerical and checklists. Fifteen items will determine the stage of screening methods adoption. Participants will be asked a series of questions to measure their stage of mammography/BSE/CBE adoption, including if they had ever heard of a mammogram/BSE/CBE, if they had thought about having a mammogram/BSE/CBE within the next six months, and the number of mammograms they had received in the previous years. The responses to these items will determine the assignments of study subjects to 1 of 3 stages (precontemplation, contemplation and action/maintenance) at each data collection point. The rest of the questions assess BSE proficiency and talking with friends about breast cancer screening methods.

Women will be asked to record their monthly BSE frequency and proficiency steps on their personal BSE Cards during the three years period (**Appendix F**). To minimize self-reported bias, at the ninth month of each three years skilled nurses will observe and score participants as they will demonstrate BSE on a model.

Breast cancer knowledge and attitudinal scale were adopted from validated measures developed by Champion [45]. Table 1 gives the information on internal consistency and test-retest reliability. Cronbach's alphas for internal consistency ranged from 0.75-0.88.

Table 6. Internal consistency and test retest reliability of the HBM scales.

	Alpha	Test/Retest	M	SD	# of items
Susceptibility	.93	.70	2.54	.81	5
Seriousness	.80	.45	3.25	.68	7
Benefits (BSE)	.80	.45	3.88	.52	6
Barriers (BSE)	.88	.65	2.02	.60	6
Confidence	.88	.65	3.31	.57	11
Health motivation	.83	.67	3.78	.59	7
Benefits (Mammography)	.79	.45	23.86	3.17	6
Barriers (Mammography)	.75	.65	11.02	3.26	5

Another questionnaire that comprises 19 knowledge questions will be used to evaluate women's knowledge change at the end of education classes (see **Appendix G**).

SCORING

The knowledge items will be scored dichotomously as correct or incorrect, and the number of correct responses will be summed. For each individual, the ideal total score for knowledge, from summing up all possible scores to knowledge questions is 12. Health Belief Model scales, measuring beliefs related to breast cancer is measured on a 5 point Likert scale with the following coding: strongly disagree (1); disagree (2); neutral (3); agree (4); and strongly agree (5). Scales will be summated for the analysis.

Women will check off the BSE proficiency steps that they will complete each month. These steps will include examining both breasts, looking at their breasts in the mirror holding hands at their sides and with hands over their head, and using the pads of the fingers for circular palpation of the breasts. Participants will receive one point for each item performed each month. The BSE proficiency scale consists of six items. Thus, the highest possible score will be 72 (i.e., 12 x 6).

STUDY LIMITATIONS

- Self-reported frequency and proficiency of BSE could be inflated by a self-report bias. To minimize recall bias the study requires participants to complete monthly BSE cards. In addition at the ninth month of each year during 3-year period four skilled nurses will observe and score participants, as they will demonstrate BSE on their own breast. However, even if a self-report bias will be presented, it should be randomly spread throughout all groups.
- It is possible that some factor not associated with the breast cancer education program will contribute to the postintervention differences.

ETHICAL ISSUES

The important characteristic of ethical research is the scientific worth of the study and the appropriateness of the selected methods. The purposes of this study are to increase BC-related knowledge among women and improve their breast health behavior and will be achieved through education intervention. The program is anticipated to have two groups. Recruitment procedure will be carried out using multistage sampling. The probability of selection at each stage will be

specified in a way that ensures equal likelihood overall. The next characteristic concerns informed consent. Consent will be provided prior to the interview, so, that participants will have the opportunity to ask questions, get answers, and to think about whether they want to be involved in the research (**Appendix H**). Providing a unique identifier to each interview will ensure the confidentiality of participants. Only the study investigators will have access to the names and identification numbers of participants.

The women will be informed of the aims, methods, intervention, anticipated benefits of the study and also that they are free to withdraw their consent to participate at any time. The program does not contain any sensitive topics and will not touch on private issues. Any problems discovered during the programs will be referred for follow up.

The study received approval from the Departmental Institutional Review Board (IRB) committee within the College of Health Sciences.

DATA ANALYSIS

All reported tests should be 2-sided and the statistical analysis of the data will be carried out using the STATA computer program.

Data analysis will proceed in two steps:

1. Chi square and t-test (for categorical and numerical variables, respectively) with 95% CI will be used for examining baseline characteristics and outcomes of the cohort of women interviewed at all three data collection periods.
2. To determine whether subjects' responses to the HBM scale items are associated with staging, a multiple logistic regression analysis will be performed, using a backward selection procedure. All variables will be initially screened using

univariate logistic regression. Those variables that will yield a p -value less than 0.3 will be included in the multivariable model. Variables will be individually removed beginning with the least significant variable having p -value greater than 0.05. This process will be continued until all variables in the model will be significant at the 0.05 levels. The following independent variables such as screening method-related benefits and barriers; perceived risk and knowledge of breast cancer will be included in the model. Covariates; namely age: ≤ 50 versus > 50 , education: = professional technical education versus $>$ professional technical education, and income: = \leq \$100 versus $>$ \$100 will be also included in the model. Baseline comparison groups are: Action/Maintenance; age > 50 ; education = professional technical education (PTE); income = \leq \$100. All possible interactions will be considered.

Multiple logistic regression analysis will use change=Action/Maintenance as the reference category for change. The STATA output will show two simultaneous logistic regression equations:

$$\log(P(Y=\text{precontemplators})/P(Y=\text{Action/Maintenance})) = \beta_0 + \beta_1(\text{HBM_vars}) + \beta_2(\text{age}) + \beta_3(\text{income}) + \beta_4(\text{edu}) + \beta_5(\text{knowledge}).$$

$$\log(P(Y=\text{contemplators})/P(Y = \text{Action/Maintenance})) = \beta_0 + \beta_1(\text{HBM_vars}) + \beta_2(\text{age}) + \beta_3(\text{income}) + \beta_4(\text{edu}) + \beta_5(\text{knowledge}).$$

The next step is to test whether β_1 are the same when change is, say, precontemplators vs. contemplators. H_0 : the β 's for the two are different.

The same thing will be done for β_2 , β_3 , β_4 and β_5 . If their p -values are > 0.05 , so the conclusion is that these β 's are essentially the same for the two logistic regressions. In order to cut down the number of coefficients, it's best to add this constraint to the model and run it again.

Mammography stage, a 3- level ordinal variable, will be recorded as positive change, no change, or negative change between adjacent time periods. For example, movement from precontemplation (not thinking about mammogram/BSE/CBE) to contemplation (thinking about having a mammogram/BSE/CBE) or action (recently screened) is a positive change; there is forward stage movement. Regressing from contemplation to precontemplation is negative change with backward movement. To model positive, negative, or no change the ordinal logistic regression analysis will be used.

The data will be coded as following: +1=positive change, 0=no change, -1=negative change, creating new variable-“change”. The *cutpoints* describe when the regression equation predicts that a woman will fall into the three categories, for example:

$$\begin{aligned}\text{logit}(P(Y>_{\text{cut1}})) &= \beta_0 + \beta_1(\text{had mammogram}) + \beta_2(\text{age}) \\ \text{logit}(P(Y>_{\text{cut2}})) &= \beta_0 + \beta_1(\text{had mammogram}) + \beta_2(\text{age})\end{aligned}$$

Stata defines these two equations with the same β_1 and β_2 . There are two types of interpretations one can make from this:

- Interpret the β 's: β_1 is the log odds ratio for a mammogram where the outcome is having a “change” value one level higher or if a woman had a mammogram at baseline, she has e^{β_1} times greater odds of having a higher change in contemplation than a woman who had not had a mammogram at baseline, assuming the two women are the same age, have the same education and income level.

β_2 is similar: β_2 is the increase in the log odds of falling into a higher change category that corresponds to a single year increase in age, after adjusting for baseline mammogram status.

- Interpret the predicted values themselves. First step to find the probability that a woman will fall into each category of change. Then, based on the Stata output, it will be possible

to show a) what change category a woman is most likely have b) describe how well the model fits the observed data (by comparing the predicted and observed change values for each woman).

TIME-TABLE

During the first month of the baseline year and the two follow-up years, all women in both groups will attempt to be interviewed, data will be analysed, and reported. Group I women will participate in education classes in the third month of the baseline year and Group II women – in third month of the first follow-up year. At the end of the third month the knowledge change assessment will be done. The oncologist's consultations will be organized for two-month period after the education classes, so the women will be able to visit the doctor with different breast health problem that may arise after education classes. Each ninth month of the study years nurses will score participants' BSE performance. The overall duration of the study is three years.

The following **Gantt** chart shows the schedule of each activity by months.

<i>MONTH</i>	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	4	5	9	
<i>ACTIVITY</i>																									
Education materials development, translation, pretesting, production																									
Training of trainers, interviewers, data entries, nurse																									
Baseline data collection, data entry, analysis, report																									
Education classes, knowledge evaluation																									
Consultations																									
Check- ups																									
Knowledge and behavior change evaluation (training course, data collection, data entry, analysis, report)																									

LOGISTIC CONSIDERATION

Budget and resources. Implementation of the breast health educational program will require financial expenditures and resources. The program coordinator will be paid a salary for 23 months (working period). Two assistants will be needed for 5 months. The program coordinator and the assistants will supervise and maintain logistical flow of the program, entry the data, perform statistical analysis of the data, interpret the findings and report the results. Five female interviewers will be hired to conduct the interviews. Each interviewer will conduct total 240 interviews (at the baseline year –80, at the first follow-

up year-80, at the second follow-up year –80). The cost of a filled questionnaire is \$2 US.

The interviewer will be paid for training sessions $\$25 @ 3(\text{times}) = \75 US.

- A surgeon will be paid a salary \$25 US for each the four education classes. A radiologist and assistants will be paid \$25 US and \$15 US correspondingly for an education class. A nurse for BSE class will be paid \$15.
- Two oncologists will be available during two months for any follow-up.
- At the ninth month of each the three years four skilled nurses will observe and score participants, as they will demonstrate BSE on their own breast.
- The questionnaire is 13 pages of length. The total expenditures for printing and copying the questionnaires and the one page consent form are $\$0.04 @ 14(\text{pp}) @ 400(\text{copies}) @ 3(\text{years}) = \672 . For assessing only the knowledge change after education program 3 pages questionnaire will be distributed: $\$0.04 @ 3(\text{pp}) @ 400(\text{copies}) = \48 . It is assumed that 30 pages of educational materials (handouts) and 13 pages of BSE Cards during two week period will be distributed among 400 women: $\$0.04 @ 30(\text{pp}) @ 400 + \$0.04 @ 13(\text{pp}) @ 400 = \688 .
- Two education films for two-week period will be purchased. The maximum possible price is taken to avoid underestimation of the budget. Videocassette Recorder (VCR) with TV will be rented for \$20 per day: $\$20 @ 2(\text{VCR}) @ 2(\text{days}) = \80 and $\$20 @ 1(\text{projector}) @ 2(\text{days}) = \40 .

Women will be supplied with notebook and pen for note taking and wooden bead

necklaces: $\$1.25 @ 400 = \500 , $\$0.30 @ 400 = \120 and $\$3 @ 400 = \1200 .

- Drivers (3), a car and 2 buses will be rent for the program.

- Accountant will receive \$50 per month for bookkeeping, accounts preparation, financial statement preparation and analysis.
- Miscellaneous expenses and contingencies are mentioned in the budget.

The overall estimated budget is **\$45,090 US (Appendix K)**.

PROJECT FEASIBILITY

The proposed project is feasible due to several considerations:

Technical considerations. The study will be conducted by a special team, including Public Health specialists, trained interviewers, and health care professionals who possess necessary skills and knowledge to conduct and evaluate have breast cancer education classes. The office room and supplies, rooms for education classes as well as the availability of equipment and statistical packages for data entry and analysis will support the technical feasibility.

Logistical considerations. To assess whether education program results sustainable outcomes women have to be surveyed at least three year.

Financial considerations. The proposed project is not excessively expensive. However, the accomplishment of the project depends on the donor NGO's financial support. Considering the importance of the problem, it is anticipated that there are organizations, which will be interested in the proposed study.

Administrative considerations. Having a Public Health specialist as a project manager will support and simplify the project conduction. The head of the project should have both good managerial, administrative interpersonal skills and working experience.

Political considerations. Considering the importance of the problem health policy makers of the Ministry of Heath should be interested in and contribute to the project implementation.

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.Appendix A: Breast health education course curriculum.

OVERVIEW

Education program's Goal: To increase breast cancer related knowledge, woman-to-woman promotion of screening and actual participation in screening.

The program is designed to impart some basic breast cancer knowledge to attendants, to provide forum for the discussion of breast cancer and screening as well as communication tools for participants to use with their friends. Women will be invited to six-core education classes that will base on the theoretical framework -Health Belief Model (HBM). The overall message of the program is that breast cancer screening and early treatment seeking lead to increased hope for favorable outcomes and increased survival. Classes will combine different methods of teaching (i.e., combinations of short lectures followed by discussion, or other interactive activities such as small group discussions) that have been used to provide women with a base of health information and rationale for attitudinal and behavioral change. Each class will begin with a review of the previous class(es). Teaching materials are both visual and tactile and could be used by persons with limited education.

Woman population: Two hundred women on the polyclinic registries between 35 to 65 years of age who are willing to participate in the study and who have Yerevan residence.

A total of 6 breast health education classes will be conducted. Expected number of groups is 10 (20 women in each group).

Time: The breast health education program meets three times a week for two-hours during a 2-week period. The total amount of time for the classes is 12 hours.

Setting: One large classroom equipped with portable videotape equipment and five small classrooms.

Learning objectives for six education classes:

At the end of 2-week breast health education classes woman will be able:

- To recognize, that breast cancer screening is effective for finding early cancer;
- To be aware of increased likelihood of favorable outcomes with early detected breast cancer;
- To recognize that a number of factors may act as barriers to breast cancer screening;
- To identify questions that can be used to determine women's perceived benefits and barriers to breast cancer screening;
- To feel increased confidence that she can encourage breast cancer screening among friends/relatives.
- To identify the maximum number of nodules in silicon breast models.

Class Coordinators/Instructors: Surgeon-oncologists and radiologists/assistants and nurses from Oncological Scientific Center will carry out the education classes after attending the training of trainers course. Manual for trainers is presented as **Appendix L**.

Class Materials/Resources

- Videocassette recorder
- Educational video tapes
- Syllabus/Lecture handouts
- Slides/Mammography Slides/Three dandelion slides/ Slides of collages
- Wooden Bead Necklaces
- Posters
- BSE Cards/ BSE checklists.
- Markers/Pencils/paper
- Silicon breast models for practical sessions (BSE)
- Projector
- Chalkboards

BREAST HEALTH EDUCATION COURSE CURRICULUM

TOPIC	TEACHER ACTIVITIES	WOMAN ACTIVITIES	TIME	S
<i>FIRST CLASS</i>				
Introduction	Instructor distributes syllabus. Coordinator provides the rationale for teaching and describes the course goals, related teaching activities, and methods for evaluation.	Women listen and ask questions.	½ hour	I c
Introduction	Instructor asks women to introduce themselves.	Women introduce themselves.	1 hour	I c
The structure of glandule mammary.	Instructor distributes handouts. Coordinator lectures on the structure of glandule mammary, using different visual techniques, such as slides and posters, answers questions and discuss next class activities.	Women listen and ask questions.	½ hour	I c
<i>SECOND CLASS</i>				
Review of the previous class.	Coordinator reviews the previous class and answers the questions.	Women listen and ask questions.	1/6 hour	I c
Breast diseases	Coordinator lectures on benign breast diseases, highlights the signs of breast cancer, and the risk	Women listen, ask questions and	2/3 hour	I c

	<p>factors of breast cancer. During the lecture he rises the following questions for discussion:</p> <ul style="list-style-type: none"> • What role do diet and nutrition play in reducing one's breast cancer risk? • How does exercise influence one's breast cancer risk? • Are women who have fibrocystic changes in their breasts at higher risk for breast cancer? • What are the signs of breast cancer? • What are the signs of a breast cancer recurrence? 	participate in the discussion.		
<i>Coffee-break</i>			1/4 hour	
« Who is at risk of breast cancer?»	<p>Coordinator shows slides of collages, including men, women, teens, and children. Instructor guides the discussion about the topic in small groups of five women.</p> <p>Coordinator sends the message that all adult women are at current breast cancer risk and that teenage and little girls could be at risk when they became adults.</p> <p>Coordinator shows slides of collages, including adult women of various ages and apparent lifestyles (e.g., a woman wearing clerical robes; a "loose-looking" woman in a tight, low-cut dress). Instructor guides the discussion about the topic in small groups of five women.</p> <p>Coordinator sends the message that all women depicted are at risk, but older women are at a higher risk than younger women and women who are sexually chaste are at no lower risk than those who are perceived to have "loose morals."</p>	Women discuss the topic and a member of each group presents the answer with possible justification in the blackboard.	2/3 hour	I c
	Coordinator summarizes activities; answer questions, discusses next class activities and assign reading materials.	Women listen and ask questions.	1/4 hour	I c
<i>THIRD CLASS</i>				

Review of the previous class.	Coordinator reviews the previous class and answers the questions.	Women listen and ask questions.	1/6 hour	I c
Benefits of screening methods	Coordinator lectures on mammography/CE/BSE's efficacy and benefits. Throughout the session, lecturer ask questions to spur discussion: <ul style="list-style-type: none"> • What do you see in the X ray? • How would you describe it? • How many of you think you would know if a lump this size will be in your breasts? 	Women listen, ask questions and participate in discussion.	1/2 hour	I c
Illustration of the difference in the size of breast lumps that can be felt versus those a mammogram can detect.	Coordinator asks questions (questions are printed on slides): <ul style="list-style-type: none"> • "What size lump can you feel?" • What size lump can your doctor feel? • What size lump can a mammogram find?" Instructor guides the discussion in small groups of five women.	Women studies the beads, and decides what size lump they could feel in their own breasts, what size lump can doctor feels and what size lump can mammogram find. A member of each group presents the answers in the blackboard.	1/3 hour	I c
<i>Coffee-break</i>			1/4 hour	
Efficacy of screening methods.	Coordinator highlights the efficacy of mammography, clinical breasts examination and breast-self examination. Coordinator encourages women to use the beads to share information with their friends.	Women listen and ask questions.	1/4 hour	I c
Reason for finding cancer early.	To communicate a reason for finding cancer early, Coordinator use a dandelion analogy. He shows a series of three dandelion slides. After each slide, Coordinator asks women what would happen. Coordinator shows videotape, illustrating cancer spreading inside the body.	Women provide the answers and discuss the issue. Women comprehend the importance of "taking care of the cancer before it can spread in your body and make you	1/4 hour	I c

		sick." Women watch the videotape.		
Increase of the response and self-efficacy expectations.	Coordinator summarizes activities; answer questions, discusses next class activities and assign reading materials.	Women listen and ask questions.	¼ hour	I c
<i>FOURTH CLASS</i>				
Review of the previous class.	Coordinator reviews the previous class and answers the questions.	Women listen and ask questions.	1/6 hour	I c
Demystification of the workup and treatment process to reduce the barrier of fear and further stress the benefit of early detection.	Coordinator briefly explains the difference in surgery and treatment types in connection to cancer stage. Coordinator emphasizes choice in treatment decisions and tells the women that, if a problem was found, they could take time to decide on medical options that they need not feel rushed.	Women listen and ask questions.	½ hour	I c
"What would happen if you found you had cancer?"	Coordinator shows the slide with the question for discussion. Instructor guides the discussion about the topic in small groups of six women. Coordinator sends the message to find cancer before it "makes you sick" and that cancer can sometimes be treated without necessitating a nights in the hospital.	Women discuss feelings and problems in small groups. Class as whole discusses the topic to reach greater consensus.	1/3 hour	I c
<i>Coffee-break</i>			1/4 hour	
Skill building for spreading the messages emphasized in previous classes	To promote rehearsal and interaction, Coordinator uses the following questions (presented on slides): <ul style="list-style-type: none"> • Do you feel that you have learned important information? Why is it important? • Is it going to be easy to share what you have learned with your friends? • Why or why not? 	Class as whole discusses these questions.	1/6 hour	I c
Sharing Partner Exercises	To practice finding out what women' friends/relatives are thinking about mammogram and developing appropriate responses, Coordinator divides women into	In the first, women determined the main reason their	1/4 hour	I c

	<p>pairs for two exercises. Instructor writes down the identified reasons on the blackboard as well as the suggestions (during First exercise).</p> <p>Coordinator describes the second exercise: the second exercise paires women into sharing partners for four role-playing scenarios. Coordinator gives women 5 minutes to respond to the following objections (presented on slides) to breast cancer screening:</p> <ul style="list-style-type: none"> • "I am afraid to have a mammogram because it might show that I have breast cancer." • "Breast cancer is something I do not talk about with other people. It is too personal." • "If I have breast cancer, I would rather not know about it. Why go looking for trouble?" • "I do not need a mammogram. If I have lived this long without breast cancer, I am not going to get it now." <p>Instructor writes down the identified responses on the blackboard. In conclusion, Coordinator sends message that «we do not have to know exactly what to say before the</p>	<p>partner would not want to have a mammogram and then the main reason the partner would want to have a mammogram. Then class elicits suggestions for effective and appropriate responses to barriers and communication and reinforcement of benefits.</p> <p>Women provide the responses to the objections to breast cancer screening. Women report to the group the responses they had used.</p>	<p>1/3 hour</p>
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I
c

	conversation starts. Rather, instead of beginning the conversation by telling friends what we think they need to know, we should find out what they think. Respond to what your friend says is important to her. Talk to her about her special reasons."			
<i>FIFTH CLASS</i>				
Review of the previous class.	Coordinator reviews the previous class and answers the questions.	Women listen and ask questions.	1/6 hour	I c
Breast Self-Examination	Coordinator shows videotape: «The most effective method to exam your breasts is a three-step procedure».	Women watch the procedure and ask questions.	1/6 hour	I c
Benefits and barriers of BSE	Coordinator asks women to think about benefits and barriers of BSE. Instructor writes down the identified by women barriers on the blackboard and then guides the discussion about overcoming these barriers in small groups of five women.	Each woman writes down benefits and barriers of BSE. Women in small groups discussed about overcoming these barriers.	1/3 hour	I c
	Instructor distributes individual BSE cards and explain women how to use it.	Women listen and ask questions.	1/12 hour	I c
<i>Coffee-break</i>			1/4 hour	
Introduction	Instructor sets ground rules for providing constructive feedback and distributes BSE checklists. Then, he introduces four nurses who will teach women to BSE.	Women listen and ask questions.	1/6 hour	I c
BSE skills development.	Five nurses meet with small groups of four women in different classrooms. Nurses explain and demonstrate effective BSE on the model. Nurses rate women' BSE performance using checklist. After each demonstration nurses provide feedback, identifying areas that need to be improved.	Women listen and ask questions. Four women meet. One woman demonstrate BSE skills the second third and fourth women observe	1/6 hour 2/3 hour	I c I c

		using checklist. Women switch the roles and repeat the process. Woman who received negative feedback repeats the process.		
<i>SIXTH CLASS</i>				
Review of the previous class.	He thanks women for participation. Explains the methods for knowledge and BSE skills assessment and aim of the assessment.	Women listen and ask questions.	1/12 hour	I c
Breast cancer related knowledge assessment	Instructor distributes the questionnaires.	Women fill the questionnaires.	1/3 hour	I c
<i>Coffee-break</i>				
BSE skills assessment	To assess BSE skills Coordinator asks women to identify the maximum number of nodules in each breast during 5 min period. Coordinator gives a point for each nodule identified.	Women in order of priority came and perform BSE on the model and leave to continue coffee break.	5/3 hour	I c

Appendix B: TNM classification system

T: Tumor Size. The letter **T** followed by a number from 0 to 4 describes the tumor's size and whether it has spread to the skin or chest wall under the breast. Higher T numbers indicate a larger tumor and/or more extensive spread to tissues surrounding the breast.

- **T0:** No evidence of a tumor
- **Tis:** Cancer may be lobular carcinoma in situ (LCIS), ductal carcinoma in situ (DCIS) or Paget's disease
- **T1:** Tumor is 2 cm or less in diameter
- **T2:** Tumor is between 2 and 5 cm in diameter
- **T3:** Tumor is more than 5 cm in diameter
- **T4:** Tumor is any size, has attached itself to the chest wall and spread to the pectoral (chest) lymph nodes

N: Palpable Nodes. The letter **N** followed by a number from 0 to 3 indicates whether the cancer has spread to lymph nodes near the breast and, if so, whether the affected nodes are fixed to other structures under the arm.

- **N0:** Cancer has not spread to lymph nodes
- **N1:** Cancer has spread to the movable ipsilateral axillary lymph nodes (underarm lymph nodes on same side of breast cancer)
- **N2:** Cancer has spread to ipsilateral (same side of body as breast cancer) lymph nodes fixed to one another or to other structures under the arm
- **N3:** Cancer has spread to the ipsilateral mammary lymph nodes or the ipsilateral (same side of body as breast cancer) supraclavicular lymph nodes

M: Metastasis. The letter **M** followed by a 0 or 1 indicates whether or not the cancer has metastasized (spread) to distant organs (i.e., the lungs or bones) or to lymph nodes that are not next to the breast.

- **M0:** No distant metastasis to other organs
- **M1:** Distant metastasis to other organs

According to TNM classification system stage I cancer can be described as T1N0M0; stage IIA –T0N0M0, T2N0M0; stage IIB- T2N1M0, T3N1M0; stage IIIA- T0N2M0, T1N2M0, T2N2M0, T3N1 (N2) M0; stageIIIB- T4 anyNM0, anyTN3M0; stageIV- anyT anyNM1.

The treatment of stage I cancer includes breast conserving therapy (BCT): lumpectomy (removal of cancerous lump and small margin of surrounding normal tissue) and axillary node dissection (removal of underarm lymph nodes) followed by radiation, modified radical mastectomy (removal of the affected breast) and axillary's node dissection. Stage II cancer treatment is usually the same as stage I treatment. Radical mastectomy, radiation and systemic therapy such as chemotherapy: cyclophosphamide, methotrexate and 5-fluoruracil (CMF-6 cycles) or cyclophosphamide and adriamycin (CA-4 cycles) or hormonal therapy often following surgery are used for stage

III cancer. The treatment of stage IV breast cancer focuses on extending survival time and relieving symptoms. Systemic treatment (treatment that affects the entire body) such as chemotherapy, hormonal therapy or both is often recommended. Radical mastectomy or the use of the drug tamoxifen may provide symptom relief in some cases.

Appendix C: Breast Cancer Knowledge and Attitude among Nork Masive's women

Questionnaire Item	%Answering Correctly
• Do you think women who have close relatives with breast cancer are more likely to get it themselves?	41.5%
• Are older women more likely to get breast cancer than younger women?	34%
• Do breast lumps almost always turn out to be cancer?	75.6%
• Do women with breast cancer almost always have to have their breast removed?	56.6%
• Can bumping or bruising the breasts lead to breast cancer?	41.5%
• Can touching or squeezing the breasts lead to breast cancer?	51.2%
• Are women with large breasts more likely to get breast cancer than women with smaller breasts?	58.5%
• Is breast cancer usually painful when it is in the early stage of development?	48.8%
• Do you think the treatment for breast cancer is worse than the cancer itself?	39%
• Does breast cancer diagnosed at an early stage have a good chance of being cured?	75.6%
• If you have breast cancer, is it better not to know about it?	39%
• Does the treatment for breast cancer work better for younger than for older women?	17%

Appendix D: The list of polyclinics in Yerevan

Outlying area of Yerevan	Central area of Yerevan
<i>Policlinic# 2</i> <i>Policlinic# 3</i> <i>Policlinic# 5</i> <i>Policlinic# 6</i> <i>Policlinic# 8</i> <i>Policlinic# 9</i> <i>Policlinic# 11</i> <i>Policlinic# 12</i> <i>Policlinic# 13</i> <i>Policlinic# 14</i> <i>Policlinic# 15</i> <i>Policlinic# 16</i> <i>Policlinic# 18</i> <i>Policlinic# 19</i> <i>Policlinic# 20</i> <i>Policlinic# 21</i> <i>Policlinic# 22</i> <i>Policlinic of Noragavit</i> <i>Malatia Medical Center</i> <i>8-th Med. Unit</i> <i>2-th Med. Unit</i> <i>6-th Med. Unit</i> <i>4-th Med.San. Station</i> <i>5-th Med.San.Station</i>	<i>Policlinic# 1</i> <i>Policlinic# 4</i> <i>2-th Med. Unit</i> <i>Policlinic# 7</i> <i>The Center of primary Health Care</i> <i>Policlinic# 10</i> <i>Special University Polyclinic</i> <i>Policlinic# 17</i>

Source: The Ministry of Health

Appendix E :

**QUESTIONNAIRE TO EVALUATE THE OUTCOMES OF THE BREAST HEALTH
EDUCATION PROGRAM**

ID NUMBER: 1 _ _ _ _ _

DATA: MM_ _ DD_ _ YY_ _

INTERVIEWER'S NAME: _____

***The coding for ID number:**

<i>Digit 1</i>	<i>Code of Yerevan</i>
Digit 2-6	<i>Code of interviewee (policlinic number, group number, year)</i>
Digit 7	<i>Code of interviewer</i>

START TIME : ___ ___ : ___ ___

1. What is your name _____

2. What is your current address? _____

3. What is your date of birth?

MM__ __ DD__ __ YY__ __

4. How old are you now? _____ (*Record age in years*)

5. What is your level of education?

- 1). Incomplete secondary (8 years or less)
- 2). Complete secondary (10 years)
- 3). Professional technical education
- 4). University education

6. Do you have a medical background (graduated from medical university or medical college)?

- 1). Yes
- 2). No

I have some questions about breast cancer. Different people have different ideas. We want to know what you think.

7. Do you think women who have close relatives with breast cancer are more likely to get it themselves?

- 1). Yes
- 2). No
- 88). DK

8. Are older women more likely to get breast cancer than younger women?

- 1). Yes
- 2). No
- 88). DK

9. Do breast lumps almost always turn out to be cancer?

- 1). Yes
- 2). No
- 88). DK

10. Do women with breast cancer almost always have to have their breast removed?

- 1). es
- 2). No
- 88). DK

11. Can bumping or bruising the breasts lead to breast cancer?

- 1). Yes
- 2). No
- 88). DK

12. Can touching or squeezing the breasts lead to breast cancer?

- 1). Yes
- 2). No
- 88). DK

13. Are women with large breasts more likely to get breast cancer than women with smaller breasts?

- 1). Yes
- 2). No
- 88). DK

14. Is breast cancer usually painful when it is in the early stage of development?

- 1). Yes
- 2). No
- 88). DK

	<i>1.Yes, definitely</i>	<i>2.Yes, most likely</i>	<i>3.No, most likely</i>	<i>4.No, definitely</i>	
15. Do you think the treatment for breast cancer is worse than the cancer itself?					
16. Does breast cancer diagnosed at an early stage					

have a good chance of being cured?					
17. If you have breast cancer, is it better not to know about it?					
18. Does the treatment for breast cancer work better for younger than for older women?					

19. Has any of your female blood relatives had breast cancer?

- 1). Yes
- 2). No
- 88). DK

Please mention the degree of agreement with the following statement.

<i>SUSCEPTIBILITY</i>	<i>Strongly disagree</i>	<i>Disagree</i>	<i>Neutral</i>	<i>Agree</i>	<i>Strongly agree</i>	<i>D</i>
20. It is extremely likely I will get breast cancer in the future	1	2	3	4	5	8
21. I feel I will get breast cancer in the future.	1	2	3	4	5	8
22. There is a good possibility I will get breast cancer in the next 10 years.	1	2	3	4	5	8
23. My chances of getting breast cancer are great.	1	2	3	4	5	8
24. I am more likely than the average woman to get breast cancer.	1	2	3	4	5	8

<i>SERIOUSNESS</i>	<i>Strongly disagree</i>	<i>Disagree</i>	<i>Neutral</i>	<i>Agree</i>	<i>Strongle agree</i>	<i>D</i>
25. The thought of breast cancer scares me.	1	2	3	4	5	8

26. When I think about breast cancer my heart beats faster.	1	2	3	4	5	8
27. I am afraid to think about breast cancer.	1	2	3	4	5	8
28. Problems I would experience with breast cancer would last a long time.	1	2	3	4	5	8
29. Breast cancer would threaten a relationship with my boyfriend, husband, or partner.	1	2	3	4	5	8
30. If I had breast cancer my whole life would change.	1	2	3	4	5	8
31. If I developed breast cancer, I would not live longer than 5 year.	1	2	3	4	5	8

Now I have some questions about mammograms. A mammogram is an x-ray of the breast that is most often done to find out if a woman might have breast cancer.

32. Have you ever heard of mammogram before now?

- 1). Yes
 2). No \longrightarrow (SKIP TO Q# 53)
 88). DK \longrightarrow (SKIP TO Q# 53)

33. Have you ever had a mammogram?

- 1). Yes
 2). No \longrightarrow (SKIP TO Q# 37)
 88).DK \longrightarrow (SKIP TO Q# 37)

34. About how many mammograms have you had? _____

35. Where did you have your last mammogram?

- 1). Armenian American Mammography Center
- 2). Oncology Dispenser
- 3). Erebuni Hospital
- 4). Other _____

36. How long ago did you have your last mammogram?

(DO NOT READ OPTIONS BUT USE THEM AS PROBES AND TO CLARIFY)

- 1). Fewer than six months ago (*SKIP TO QUESTION 8*)
- 2). More than six months; not yet a year
- 3). Just about a year ago
- 4). More than a year ago, not 2 years yet
- 5). Just about 2 years ago
- 6). More than 2 years
- 88).DK

37. Do you plan to have a mammogram in the next six months?

- 1). Yes
- 2). No
- 88). DK

38. Do you plan to have a mammogram in the next month?

- 1). Yes
- 2). No
- 88). DK

39. How often do you think a woman your age should have a mammogram?

- 1). More than once a year
- 2). Every year
- 3). Every two years
- 4). Once every 5 years
- 5). Never unless she has pain or detects a lump in her breast
- 88). DK

	<i>1. Yes, definitely</i>	<i>2. Yes, most likely</i>	<i>3.No, most likely</i>	<i>4. No, definitely</i>	<i>88. DK</i>
40. Do you know where to go to get a mammogram?					

41. How common is it for a woman to have an abnormal mammogram?

- 1). Very common
- 2). Somewhat common
- 3). Not common
- 4). Very uncommon
- 88). DK

42. Has a friend ever talked to you about having a mammogram?

- 1). Yes
- 2). No
- 88). DK

Please, mention the degree of agreement with the following statements

<i>BENEFITS AND BARRIERS FOR MAMMOGRAPHY</i>	<i>Strongly disagree</i>	<i>Disagree</i>	<i>Neutral</i>	<i>Agree</i>	<i>Strongly agree</i>	<i>L</i>
43. When I (would) get a mammogram, I (would) feel good about myself.	1	2	3	4	5	8
44. When I (would) get mammogram, I (would not) don't worry as much about cancer.	1	2	3	4	5	8
45. Having a mammogram or X-ray of the breasts will help me find lumps early.	1	2	3	4	5	8
46. Having a mammogram or X-ray of the breasts will decrease my chances of dying from breast cancer.	1	2	3	4	5	8

47. Having a mmogram or X-ray of the breasts will decrease my chances of requiring radical or disfiguring surgery if breast cancer occurs.	1	2	3	4	5	6
48. Having a mammogram will help find a lump before it can be felt by myself or a health professional.	1	2	3	4	5	6
49. Having a routine mammogram or x-ray of the breasts would be embarrassing.	1	2	3	4	5	6
50. Having a mammogram or x-ray of the breasts would take too much time.	1	2	3	4	5	6
51. Having a mammogram or x-ray of the breasts would be painful.	1	2	3	4	5	6
52. Having a mammogram or x-ray of the breasts would cost too much money.	1	2	3	4	5	6

Now I have some questions about breast examinations done by a doctor. This would be when you lie down on the table and the doctor feels for lumps in your breast.

53. Have you ever heard about breast exam by a doctor?

- 1). Yes
 2). No \longrightarrow (SKIP TO Q# 61)
 88). DK \longrightarrow (SKIP TO Q# 61)

54. Have you ever had a breast exam by a doctor?

- 1). Yes
 2). No \longrightarrow (SKIP TO Q# 56)
 88). DK \longrightarrow (SKIP TO Q# 56)

55. How long ago did you have your last breast exam by a doctor?

- 1). Fewer than six months ago (*SKIP TO QUESTION 5*)
- 2). More than six months; not yet a year
- 3). Just about a year ago
- 4). More than a year ago, not 2 years yet
- 5). Just about 2 years ago
- 6). More than 2 years
- 7). Never
- 88).DK

56. Have you thought about having a breast exam by a doctor in the next six months?

- 1). Yes
- 2). No
- 88).DK

57. Have you thought about having a breast exam by a doctor in the next month?

- 1). Yes
- 2). No
- 88). DK

58. How often do you think a woman your age should have a breast exam by a doctor?

- 1). More than once a year
- 2). Every year
- 3). Every two years
- 4). Once every 5 years
- 5). Never unless she something like pain or lump in her breast
- 88). DK

	<i>1. Yes, definitely</i>	<i>2. Yes, most likely</i>	<i>3. No, most likely</i>	<i>4.No, definitely</i>	<i>DK</i>
59. Is having a breast exam by a doctor too embarrassing?					

60. Has a friend ever talked to you about having breast exam by a doctor?

- 1). Yes
- 2). No
- 88). DK

Now I have some questions about breast self-examination. This would be when you feels for lumps in your breast.

61. Have you ever heard about breast self-exam?

- 1). Yes
- 2). No \longrightarrow (SKIP TO Q# 87)
- 88). DK \longrightarrow (SKIP TO Q# 87)

62. Have you ever performed breast self-exam?

- 1). Yes
- 2). No \longrightarrow (SKIP TO Q# 87)
- 88). DK \longrightarrow (SKIP TO Q# 87)

63. Are you currently practicing breast self-exam?

- 1). Yes
- 2). No \longrightarrow (SKIP TO Q# 65)

64. What components of breast self-exam do you usually perform? (MENTION ALL THAT APPLY)

- 1). Visual examination
- 2). Three digits used
- 3). Finger pads used
- 4). Circular palpation
- 5). Most of breast is examined
- 6). Axillae examined
- 7). I don't exam my own breast
- 8). Other _____

65. At what time during a month should breast self-exam is performed?

- 1). Before menses
- 2). After menses
- 3). At any time
- 88).DK

66. Have you thought about performing breast self-exam in the next six months?

- 1). Yes
- 2). No
- 88). DK

67. How often do you think a woman should perform breast self-exam?

- 1). More often than once a month
- 2). Every month
- 3). Every three months
- 4). Once a years
- 5). Never unless she something like pain or lump in her breast
- 88). DK

68. Has a friend ever talked to you about performing breast self-exam?

- 1). Yes
- 2). No
- 88). DK

Please, mention the degree of agreement with the following statements

<i>BENEFITS (BSE)</i>	<i>Strongly disagree</i>	<i>Disagree</i>	<i>Neutral</i>	<i>Agree</i>	<i>Strongly agree</i>	<i>D</i>
69. When I do breast self-examination I feel good about myself.	1	2	3	4	5	8
70. When I complete monthly breast self-examination I don't worry as much about breast cancer	1	2	3	4	5	8
71. Completing breast self-examination each month will allow me to find lumps early.	1	2	3	4	5	8
72. If I complete BSE monthly during the next year I will decrease my chance of dying from breast cancer .	1	2	3	4	5	8
73. If I complete BSE monthly I will decrease my chances of requiring radical or disfiguring surgery if breast cancer occurs.	1	2	3	4	5	8
74. If I complete monthly BSE it will help me to find a lump which might be cancer before it is detected by doctor or nurse.	1	2	3	4	5	8
<i>BARRIERS (BSE)</i>	<i>Strongly disagree</i>	<i>Disagree</i>	<i>Neutral</i>	<i>Agree</i>	<i>Strongly agree</i>	<i>D</i>

75. I feel funny doing BSE.	1	2	3	4	5	8
76. Doing BSE during the next year will make me worry about breast cancer.	1	2	3	4	5	8
77. BSE will be embarrassing to me.	1	2	3	4	5	8
78. Doing BSE will take too much time.	1	2	3	4	5	8
79. Doing BSE will be unpleasant.	1	2	3	4	5	8
80. I don't have enough privacy to do BSE.	1	2	3	4	5	8

<i>CONFIDENCE</i>	<i>Strongly disagree</i>	<i>Disagree</i>	<i>Neutral</i>	<i>Agree</i>	<i>Strongly agree</i>	<i>D</i>
81. I know how to perform BSE.	1	2	3	4	5	8
82. I am confident I can perform BSE correctly.	1	2	3	4	5	8
83. If I were to develop breast cancer I would be able to find a lump by performing BSE.	1	2	3	4	5	8
84. I am able to find a breast lump if I practice BSE alone.	1	2	3	4	5	8
85. I can use the correct part of my fingers when I examine my breasts.	1	2	3	4	5	8
86. When looking in the mirror, I can recognize abnormal changes in my breast	1	2	3	4	5	8

Now, in this question, I am going to ask you to compare yourself to other women your age.

87. Would you say your chances of getting breast cancer are

- 1). Lower than average?
- 2). About average? —————▶ *(SKIP TO Q# 89)*
- 3). Or higher than average?
- 88). DK

88. Why are your chances of getting breast cancer (lower/higher) than average, compared to other women your age? (DO NOT READ RESPONCES BUT PROBE TO DETERMINE CATEGORIES AND CHECK ALL THAT APPLY)

- 1). family history
- 2). general health
- 3). religious faith
- 4). Estrogens
- 5). birth control pills
- 6). breast size
- 7). bumps/bruises
- 8). Diet
- 9). mental attitude
- 10). smoking status
- 11). age of child birth
- 12). number of children
- 13). age of menarche
- 14). breast feeding
- 15). sexual activity
- 16). Other _____

Now I have some general questions about you

89. What is your marital status?

- 1). Single
- 2). Married
- 3). Divorced
- 4). Widowed

90. At the present time, would you say that your physical health is

-
- Excellent Good Fair Poor

Please, mention the degree of agreement with the following statements

<i>HEALTH MOTIVATION</i>	<i>Strongly disagree</i>	<i>Disagree</i>	<i>Neutral</i>	<i>Agree</i>	<i>Strongly agree</i>
91. I want to discover health problem early.	1	2	3	4	5

92. Maintaining good health is extremely important to me.	1	2	3	4	5
93. I search for new information to improve my health.	1	2	3	4	5
94. I feel it is important to carry out activities which will improve my health.	1	2	3	4	5
95. I eat well-balanced meals.	1	2	3	4	5
96. I exercise at least 3 times a week. →	1	2	3	4	5
97. I have regular health check-ups even with I am not sick.	1	2	3	4	5

You talk to your friends about lots of things

98. Have you ever talked with a friend about having a mammogram?

- 1). Yes
- 2). No
- 88). DK

99. Have you ever talked with a friend about having breast exam?

- 1). Yes
- 0). No
- 88). DK

100. Where do you go for your regular medical care?

(DO NOT READ OPTIONS BUT PROBE TO CLASSIFY)

- 1). No regular place where I usually go
- 2). Neighborhood clinic
- 3). Hospital
- 4). Other_____

101. About how many times did you go to see a doctor since this time last year?

(DO NOT READ OPTIONS BUT PROBE TO CLASSIFY)

- 1). 0
- 2). 1
- 3). 2-5
- 4). more than 5
- 88). DK

102. Are you currently employed?

- 1). Employed
- 2). Unemployed
- 3). Retired

103. On average, how much money does your household spend monthly?

- 1). Less than \$50 (< 25,000 AMD)
 - 2) \$50-99 (25,000-50,000 AMD)
 - 3) \$100-300 (51,000-150,000 AMD)
 - 4) Above \$300 (> 150,000 AMD)
- 88). DK

That's the end of the questions I have to ask you. Is there anything you would like to add?

Thank you for sharing your thought with us. Thank you for spending time and effort!

END TIME: __ __: __ _____

DATA ENTRY # 1 _____

DATA ENTRY # 2 _____

Appendix F: BREAST SELF-EXAM CARD



BREAST SELF-EXAMINATION

Women twenty years of age or older should examine their breasts at least once a month, every month. The last day of your menstrual period is the best time for BSE, because by then any premenstrual changes will have subsided. If you are no longer menstruating, check your breasts on the first day of each month. By practicing BSE you will become familiar with how your breasts normally feel, and you will be more aware when a change does occur in your breasts. The purpose of BSE is to discover any change in your breast. The most effective method to exam your breasts is a three-step procedure: (1) Mirror Inspection, (2) Soaping the Breasts and (3) Palpation

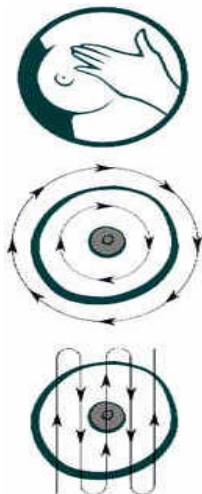
1. MIRROR INSPECTION: VISUAL INSPECTION

Inspect your breasts with your arms at your sides. Check for anything unusual, such as any discharge from the nipples, puckering, dimpling, or scaling of the skin. Next, raise your arms high overhead. Look for any changes in the contour of each breast. Look first at the front and then turn to each side. Finally, place your hands on your hips and press down firmly to flex your chest muscles, and again check the front and side views. Your left and right breasts will not exactly match-few women's breasts do. Only be concerned if there has been an unusual increase in the size or change in position of one breast. Regular inspection of your breasts will show what is normal for you and will give you confidence in your examination.

2. SOAPING THE BREASTS

During your bath or shower examine your breasts. Wet, soapy skin makes this step easier. Raise your left arm over your head, with your fingers held flat, feel the left breast with your right hand. Beginning at the outer edge, press the flat part of your fingers in small circles, moving the circles slowly around the breast. Gradually work toward the nipple. Be sure to check the complete breast. Examine very carefully the area between the breast and the armpit, including the armpit itself.

3. PALPATION



- *Look and feel for changes in your breasts about one week after your period. It is best to feel for changes when lying on a flat surface. Put a pillow under your right shoulder. Put your right arm comfortably behind your head.*
- *Using the pads of three fingers, press lightly, moderately and then firmly on your breast. Slide three fingers over to another area on your breast and repeat the levels of pressure.*
- *Using your left hand, examine your right breast either in a circular or up and down pattern (see diagrams to the left).*
- *Using your right hand, examine your left breast in the same way.*

Perform BSE today!

It is one of the best things you can do for yourself!

What components of breast self-exam did you perform? (<i>MENTION ALL THAT APPLY</i>)						
<input type="checkbox"/> . Visual examination <input type="checkbox"/> . Finger pads used						
<input type="checkbox"/> . Three digits used <input type="checkbox"/> . Most of breast is examined						
<input type="checkbox"/> . Circular palpation <input type="checkbox"/> . Axillae examined						
JANUARY						
1	6	11	16	21	26	
2	7	12	17	22	27	
3	8	13	18	23	28	
4	9	14	19	24	29	
5	10	15	20	25	30	

Remember, if a lump or change is discovered during BSE, it is important to see your doctor as soon as possible. Do not be frightened. Most breast lumps or changes are benign (not cancerous), but only your doctor can make that diagnosis.

Oncologist's Name: _____

Telephone number: _____

(For Comments) _____

Appendix G:

QUESTIONNAIRE TO ASSESS THE BREAST CANCER RELATED KNOWLEDGE CHANGE

WOMAN'S ID _____

START TIME: __ __: __ __

1. Is breast cancer usually painful when it is in the early stage of development?

- 1). Yes
- 2). No
- 88). DK

2. Are older women more likely to get breast cancer than younger women?

- 1). Yes
- 2). No
- 88). DK

3. If you have breast cancer, is it better not to know about it?

- 1). Yes
- 2). No
- 88). DK

4. Do breast lumps almost always turn out to be cancer?

- 1). Yes
- 2). No
- 88). DK

5. Are women with large breasts more likely to get breast cancer than women with smaller breasts?

- 1). Yes
- 2). No
- 88). DK

6. Are women who have close relatives with breast cancer more likely to get it themselves?

- 1). Yes
- 2). No
- 88). DK

7. Can bumping or bruising the breasts lead to breast cancer?

- 1). Yes

- 2). No
- 88). DK

8. Can touching or squeezing the breasts lead to breast cancer?

- 1). Yes
- 2). No
- 88). DK

9. Would you please to mention the risk factors of breast cancer?

_____	_____
_____	_____
_____	_____
_____	_____

10. Can mammogram find a breast lump before it is big enough for you or your doctor to feel it?

- 1). Yes
- 2). No
- 88). DK

11. How common is it for a woman to have an abnormal mammogram?

- 1). Very common
- 2). Somewhat common
- 3). Not common
- 4). Very uncommon
- 88). DK

12. Are women whose breast cancer found early often having a choice about what kind of treatment they will have?

- 1). Yes
- 2). No
- 88). DK

13. Do women with breast cancer almost always have to have their breast removed?

- 1). Yes
- 2). No
- 88). DK

14. Are women whose breast cancer found early often having a choice about what kind of treatment they will have?

- 1). Yes
- 2). No

88). DK

	<i>1. Yes, definitely</i>	<i>2. Yes, most likely</i>	<i>3. No, most likely</i>	<i>4. No, definitel y</i>	<i>88.DK</i>
15. Do you think the treatment for breast cancer is worse than the cancer itself?					
16. Does breast cancer diagnosed at an early stage have a good chance of being cured?					
17. If you have breast cancer, is it better not to know about it?					
18. Does the treatment for breast cancer work better for younger than for older women?					
19. Is it very hard to know how to encourage a friend to get a mammogram or a breast exam by a doctor?					

That's the end of the questions I have to ask you. Is there anything you would like to add?

Thank you for sharing your thought with us. Thank you for spending time and effort!

END TIME: __ __: __ __

DATA ENTRY # 1 _____

DATA ENTRY # 2 _____

Appendix H:**American University of Armenia****Department of Public Health**

Institutional Review Board/Committee on Human Research

CONSENT FORM TEMPLATE

CHR#

Title of Research Project: The impact of breast health education intervention: community based clinical trial in Yerevan.

A graduate student as part of her course requirement at the American University of Armenia, Master of Public Health Course is conducting a study to evaluate the breast health education program's outcomes. The purposes of the study are to 1) increase knowledge about breast cancer, 2) promote screening techniques, 3) participate in education application classes, and 4) establish a sustainable and replicable practice of breast cancer screening interventions. Women between ages 30 to 65 years may participate in the study: two-week education classes and two months consultations, led by health care professionals. The classes will be organized to promote understanding about breast cancer and screening methods. Women will be able to apply to oncologists for consultations about different breast health problems that may arise after education sessions.

A class will also organized to teach women how to perform breast self-exam. We anticipate your participation in the study. Periodically over a three-year timeframe, we plan to contact you to determine the effects of the training. The nurses at the ninth month of each three years will observe and score participants as they will demonstrate BSE on a model.

Four interviews will be conducted: one in the baseline year, second immediately after education classes and two in the follow-up years. The initial interview will last 30-35 minutes; the total amount of time for the classes will be 12 hour.

We appreciate your participation in this study. Your responses are highly valuable to us.

RISKS/DISCOMFORT:

There is no known risk for the participants of the study. The research possesses risk, discomfort, and inconvenience the same as encountered in your daily life.

BENEFITS: You could directly benefit from this study. Due to the educational program you could increase your knowledge about breast cancer, screening methods and treatments. In addition, it is intended that you could positively change your breast screening practices. The information provided by you may also be very useful to reveal perceived risk, barriers and

benefits associated with breast cancer screening methods, which can lead to improvements.

CONFIDENTIALITY: Your name, address, telephone number will be taken in order to contact with you for follow-up. However, your identifiers will keep separately from other information you provide. These data will be accessible only for the principal investigators of the study. Your responses will be analyzed and stored at the Public Health Department of the AUA.

VOLUNTARINESS: It is your decision whether to participate or not in this study. You have the right to stop providing information at any time you wish or skip any question you consider inappropriate. Your refusal to participate in the study or your decision to withdraw from the study at any time will not affect your job.

WHOM TO CONTACT: You should ask the person in charge any question you may have about this research. You should ask him questions in the future if you do not understand something that is being done. Upon completion of the study, the results will be publicly available. The report will maintain in the Public Health Reference library at AUA.

If you want to talk to anyone about this research you should call the person in charge of the study, [Michael Thompson] at [phone number: (3741) 512592 / e-mail: mthompso@aua.am]

The person in charge of the study will answer your questions. If you want to talk to anyone about the research study because you feel you have not been treated fairly or think you may have been hurt by joining the study you should contact the American University of Armenia at (3741) 512512.

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Đ³ Ò³ È³ ñ³ Ý

Đ³ è³ ñ³ Ì³ Ì³ Ý ²éáÕÇ³ á³ ÑáóÁÙ³ Ý µ³ ÁÇÝ

Đ³ Ò³ Ó³ ÒÝ³. ÇÑ

Đ³ ñó³ ½ñáóÙóÇ Ýá³ Ì³ Ì³ Á³ . áñÍ»Éáó Ì³ ñ. Á

Đ³ Ò³ èì ³ ÝÇ ²Ù»ñÇÌÙ³ Ý Đ³ Ò³ È³ ñ³ ÝÇ Đ³ è³ ñ³ Ì³ Ì³ Ý ²éáÕÇ³ á³ ÑáóÁÙ³ Ý µ³ ÁÇÝÁ Ý»ñÌ³ ÒáóÙè °ñ³ ÝáóÙ ³ ÝóÌ³ óÝáóÙ ¿ "ÍñÍÙ³. »ÕÓÇ ù³ ÓóÍ»Õ ° Ýñ³ Ñ³ Òì Ý³ µ»ñÙ³ Ý Ò»Áá¹Ý»ñ" »ñÍáó Ò³ µ³ Áí³ ÍñÁ³ Ì³ Ý Íñ³. ñÇ ° »ñ»ù ³ Òèí³ ÍáÝèóÈì ³ óÇ³ ÒÇ ³ ñ¹ÒáóÝùÝ»ñÇ . Ý³ Ñ³ Ì³ Ò³ Ý áóèáóÙÝ³ èÇñáóÁÙáóÝÁ: Ìñ³. ñÇ Ýá³ Ì³ Ì³ Ý ¿ µ³ ñóñ³ óÝ»É Ì³ Ý³ Ýó . Çì »ÉÇùÝ»ñÇ Ò³ Ì³ ñ¹Ì³ Á ÇÝáá»è Ý³ ° áñáyÇÉ³ Ìì Çì Ñ»ì ³ ½áí áóÁÙáóÝÝ»ñÇ Ò³ èÝ³ ÍóáóÁáóÝÁ. ° èÁÝ¹³ óÝ»ñÁ ³ ÝóÌ³ óÝáóÙ »Ý Ò³ èÝ³. »ì Ý»ñÁ. ²Ù¹ Íñ³. ñÇ Ò³ ÇÝÁÝ¹. ñÍáóÙ »Ý 30 ° µ³ ñóñ³ Ì³ ñÇÇÇ Ì³ Ý³ ÒùÉ Đ»ì ³ ½áí áóÁÙáóÝÁ ÉÇÝ»Éáó ¿ Ò³ ñáóÝ³ Ì³ Ì³ ÝÉ Ø»Ýù ³ Ì³ Ý³ ÉáóÙ »Ýù Ò»ñ Ò³ èÝ³ ÍóáóÁÙáóÝÁ Ìñ³ Ý »ñÍáó Ì³ ñÇ Ñ»ì á ° èĐ³ ñó³ ½ñáóÙóÁ Ìì ° Ç 30-35 ñáá»é

Ò»ñ Ò³ èÝ³ ÍóáóÁÙáóÝÁ Ì³ Ò³ Íáñ ¿ áóù Çñ³ ÍáóÝù áóÝ»ù áá³ Ì³ èÉ³ Ý»É ó³ Ý³ ó³ Í Ñ³ ñóÇ ° Ì³ Ò³ ó³ Ý³ ó³ Í á³ ÑÇÝ Ññ³ Á³ ñí»É Ñ³ ñóÙ³ ÝÁ Ò³ èÝ³ Íó»ÉáóóÉ Ò»ñ á³ Ì³ èÉ³ ÝÝ»ñÁ á³ ÷ ³ ½³ Ýó Ì³ ñ³ áñ »Ý Ò³ Ñ³ Ò³ ñÉ Ì³ ÝÉ³ Ì³ Ñ³ Òì ÝáóÙ »Ýù Ò³ »ñ³ Èì ³. Çì áóÁÙáóÝÁÉ

èÇèÍ/Ù. áóì

Đ»ì ³ ½áí Ò³ Ý Ò³ èÝ³ Íó»ÉÁ áÇ »ÝÁ³ ñáóÙ ³ Í»ÉÇ Ò»Í éÇèÍ Ì³ Ò ³ ÝÑ³ ñÙ³ ñ³ Ì³ »ì áóÁÙáóÝ, ò³ Ý Ñ³ Ý¹ÇááóÙ ¿ ³ èóñÙ³ ÌÙ³ ÝùáóÙÉ áóù èì ³ Ý³ Éáó »ù ³ ÝÙÇÇ³ Ì³ Ý ù. áóì¹ . Çì »ÉÇù ° è»Ý³ Ì³ Ý ³ éáÓÇáóÁ³ Ý Ý³ Ì³ Ò³ Ý ×ÇÌì Ì³ ñ³ µ»ñÙáóÝù. Ò»ñ Ò³ èÝ³ ÍóáóÁÙáóÝÁ Ìù. ÝÇ Ñ³ Áì Ý³ µ»ñ»É áñáyÇÉ³ Ìì Çì Ñ»ì ³ ½áí áóÁÙáóÝÝ»ñÇ á¹ÇÙ»Éáó á³ Ì³ ×³ éÝ»ñÁÉ

¶³ Òì ÝÇáóÁÙáóÝÁ

Ò»ñ ³ ÝáóÝÁ, Ñ³ èó»Ý ° Ñ»é³ ÉáéÇ Ñ³ Ò³ ñÁ ³ ÝÑñ³ Á»Ìì »Ý¹ ÒÇ ò³ ÝÇ Ì³ ñÇ Ñ»ì á Ñ»ì ³ ½áí áóÁÙáóÝÁ Ò³ ñáóÝ³ Ì³»Éáó Ñ³ Ò³ ñÉ è³ Ì³ ÒÝ ³ ÝÓÁ Ñ³ èì ³ Ì³ áÓ ³ Ò¹ Ì³ Ì³ ÉÝ»ñÁ áóñÇÌ áá ÒÇ Ì³ »Õ á»Ý ù. Ì³. áñÍ ÍÇÉ ° ñ³ Ýù Ì³ á³ Ñí »Ý ÉÇèì . ³ Òì ÝÇ ° Ò³ Ì³ á»ÉÇ ÌÉÇÝ»Ý ÒÇ³ ÒÝ Ñ»ì ³ ½áí áóÁÙ³ Ý Ò»Í Ì³ Ì³ ñÇ Ñ³ Ò³ ñÉ Ò»ñ á³ Ì³ èÉ³ ÝÝ»ñÁ Ìì ñ»ÉáóÍ Ì³ Ý ° Ñáóè³ ÉÇáñ»Ý Ì³ á³ Ñá³ Ýì »Ý Đ³ Ò³ èì ³ ÝÇ ²Ù»ñÇÌÙ³ Ý Đ³ Ò³ È³ ñ³ ÝÇ Đ³ è³ ñ³ Ì³ Ì³ Ý ²éáÕÇ³ á³ ÑáóÁÙ³ Ý µ³ ÁÝáóÙÉ

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°Á» Ñ³ ñó»ñ Ì³. »Ý Ñ»ì ³ ½áí áóáÁÙ³ Ý Ì³ ñ³ µ»ñÙ³ É, áóù Ì³ ñáÓ »ù ¹ÇÙ»É Ñ»ì ³ ½áí áóÁÙ³ Ý Ò»Í Ì³ Ì³ ñÇÝ. Ø³ ÒùÉ ÁáÙèáÝ Ñ»é. 512592 / ¿. ÷ áèì mthomps@aua.am
°Á» áóù Ì³ ñÍ áóÙ »ù, áñ Ò³ Ñ»ì Ì³ ñí »É »Ý ³ ÝÑ³ ñ. ³ ÉÇó Ì³ Ò ³ Ý³ ñ¹³ ñ³ óÇ Ì³ ñáÓ »ù ½³ Ý. ³ Ñ³ ñ»É Ñ»ì ° Ò³ É Ñ»é³ Éáé³ Ñ³ Ò³ ñáí¹ 512512

Appendix L: Table 10. Budget

BUDGET LINE	UNIT PRICE IN USD	MONTHS	SUBTOTAL IN USD	TOTAL
1. Project staff:				
a. Program coordinator	400	23	9,200	
b. Research assistant (2)	250	10	5,000	
c. Research associates (5 interviewers)	505	3	2,525	
d. Drivers (3)	30	12 days	90	
e. Accountant	50	23	1,150	

Subtotal (taxes included)				17,965
2. Education program instructors:				
a. Surgeons (5)	25	10 days	1,250	
b. Radiologists (5)	25	2 days	250	
c. Assistants (6)	15	12 days	1,080	
d. Nurses (5)	15	2 days	150	
Subtotal (taxes included)				2,730
3. Consultants (2)	150	4	1,200	
4. Nurses (4)	80	12	3,840	
5. Training of trainers	10	2 days	420	
Subtotal (taxes included)				5,460
Materials and supplies				
a. Copying of training materials, study instruments,			688	
b. Notebooks, pens, wooden bead necklaces, videocassettes, recorder, TV			1,940	
c. Expenses for food during the training program	0.5/per person	12 days	1,200	
d. Incentives	2/per person	3	2,400	
e. Office supplies	100	36	3,600	
Subtotal				9,828
Capital assets				
a. Computers (2)	1600	36	1,600	
b. Printer	200	36	200	
c. Statistical package	150	12	150	

Subtotal				1,950
Operating cost				
a. Office rent	100	36	3,600	
b. Electricity	30	36	1,080	
c. Transportation: bus (2) and car (1) rent and maintenance	50	12 days	150	
d. Fuel	5	12 days	180	
Subtotal				5,010
9. Miscellaneous				2,147
Total				45,090

Appendix M: Manual for trainers.

INTRODUCTION

There are few things more fearful and panic provoking than finding a lump or a change in your breast. Your immediate thought will probably be of cancer. Everyone reacts differently when this happens to her. Some will call their doctor at once, others might be afraid of confirming their fears and delay making an appointment.

It is only normal for you to feel upset and fearful if you find a lump in your breast. But fear will not make the lump disappear. The earlier you find a lump in its development and the smaller it is, the greater the chance it is curable if it is cancer. Not all breast lumps are malignant. Only a doctor can accurately diagnose if a breast lump is benign (not cancerous) or malignant (cancerous). Do not try to diagnose it yourself.

BENIGN BREAST LUMPS

Breasts are made up of ducts, lobes, fibrous tissue, and underlying bone; therefore, they can feel lumpy or uneven. Before your menstrual period begins, and sometimes during your period, you can have some tenderness, pain, or lumps in your breasts. This could be due to the extra fluid that collects in the breast tissue (cyst) as well as changes in the body's hormonal levels. This is normal. But if the lumps do not disappear before your next period, contact your doctor as soon as possible. Any noticeable change, thickening or localized swelling in your breast that was not there before may be a lump. Eighty-five percent of all breast lumps found are benign. Some common benign breast problems that appear as lumps are:

Cystic Disease (fibrocystic breast disease) is the most common cause of breast lumps in women. These lumps or cysts are fluid-filled sacs that enlarge and become tender and painful before the menstrual cycle. This condition is responsible for at least half of all breast biopsies performed. It tends to involve both breasts. These lumps are movable, and if large may feel round and firm. Cystic disease usually disappears after menopause.

Lipomas develop as single, painless lumps. They can vary in size. Lipomas consist of fatty tissue and are commonly found elsewhere in the body.

Fibroadenomas, single solid tumors, appear most often in young women. These breast lumps are firm, rubbery, movable, often oval-shaped, and usually painless.

Papillomas are small, wart-like growths in the lining of a mammary duct near the nipple. These can produce a bloody discharge of the nipple.

Injury to the breast, or **trauma**, may result in blood accumulation (hematoma) or destruction of fatty tissue (fat necrosis). Both conditions can appear as lumps. Sometimes the skin around these areas appears red or bruised. No evidence exists that traumas can cause breast cancer.

There are other, not as common benign breast lumps caused by a variety of breast problems such as sclerosing adenosis, etc.

NIPPLE DISCHARGE

Many women will have during their lifetime a nipple discharge. It can be either in one breast or both. Most nipple discharge are not serious. A clear nipple discharge is considered normal and most of the time will not require further work-up. If it persists or increases, your physician will probably want to investigate the matter further. A bloody nipple discharge is different. Although most women with a bloody nipple discharge will be found to have a benign tumor inside one of the milk duct (intraductal papilloma), it has to be proven. A bloody nipple discharge can occasionally be the symptom of a breast malignancy and should be thoroughly investigated. Some surgeons will first order a

Galactography which is an Xray of the ductal system of the breast. This may help clarify the cause of the discharge. Most of the time a breast biopsy is warranted to obtain the diagnosis.

MALIGNANT BREAST LUMPS

Malignant lumps develop most often from mammary ducts or lobules. Unlike benign lumps, malignant lumps continue to grow in an uncontrolled manner and in time, if left untreated, will spread beyond the breast.

The basic structure of the breast is composed of:

- lobules, which when appropriately stimulated will produce and secrete milk,
- ducts, which carry the milk from the lobules to a network of ducts and then eventually to the nipple, and
- supporting tissue.

Breast cancer can arise from each of these structures. The most common site is the ducts, and secondarily is the lobules. The terminology of ductal carcinoma and lobular carcinoma is derived from the location of their origin. When breast cancer begins within the ducts of the breast, this is referred to as intraductal carcinoma in situ (DCIS), and it is considered to be the earliest, detectable stage of breast cancer. The most common progression of DCIS is that it may, and in most cases, will become an invasive carcinoma. It will go beyond the duct into the breast tissue. Once this has spread through the breast, it will spread to the lymph nodes. From the lymph nodes it may spread to other parts of the body, such as the bones, lungs, liver or brain.

If the breast cancer originates in the lobules of the breast it is called lobular carcinoma in situ (LCIS). The evolution of this cancer is similar to DCIS, but it has specific characteristics. These characteristics are:

- It is not as aggressive as DCIS, and
- It is viewed as a marker for breast cancer. This means that in patients found with LCIS they are at increased risks of developing cancer in both breasts.

There are other forms of breast carcinoma that are not discussed at this setting because of their rare occurrence.

Early breast cancer can be a nonpalpable lesion or a very small tumor located within the breast. A breast cancer most likely has been growing for several years before it is large enough to be felt. Women who examine their breasts each month, go to doctor for routine breast examinations, and after age thirty-five have a mammogram, are more likely to detect an early breast cancer.

Advanced breast cancer is a tumor that has spread beyond the breast to the lymph nodes or to another part of the body. Cancer cells break off from the primary tumor and are carried in the lymphatic system and/or the bloodstream to a distant part of the body where they will grow into a new tumor or metastasis.

HOW A BREAST LUMP OR A MAMMOGRAPHIC LESION IS EVALUATED

It is important for any woman to understand the difference between a "palpable lump or breast mass or lesion" and a "non palpable or mammographic lesion".

A palpable lump or breast mass or lesion is a lump or mass that can be readily felt by palpation by your physician or by you.

A non palpable or mammographic lesion is a lump or mass (also be called a lesion) which cannot be felt by palpation by your physician. It is a lump or lesion, which has been detected by a routine, screening mammogram. If this lesion does not have the hallmarks of a benign lesion on mammogram, it will be called a suspicious mammographic lesion. The surgeon can evaluate a breast lump or a mammographic lesion in a variety of ways:

- **Palpation** is the physical examination of the breast. A surgeon is well trained to thoroughly examine your breasts in order to evaluate the tissue. Both breasts will be examined while you are lying down. The surgeon will also examine your underarm lymph nodes. If your examination is normal and there are no physical findings, your surgeon will suggest you schedule a follow-up appointment to reexamine the area you were concerned about. Until your next visit, it is important you continue to do your breast self-examination (BSE) on a routine basis.
- **Aspiration** allows the surgeon to know immediately if a lump is fluid-filled or is a solid mass. The procedure is done in the surgeon's office. The surgeon inserts a needle into the lump and, if it is a cyst, withdraws the fluid and collapses the cyst. The aspirated contents of the cyst are sometimes sent to pathology for a diagnosis.

This is not a painful procedure.

- **Fine Needle Aspiration.** This is performed once the surgeon has determined the mass is solid. A needle is inserted into the area in question in the breast, and cells are aspirated (taken out). A technician from the pathology department is present for this procedure and prepares slides with the aspirated fluid. A pathologist analyzes these slides. The procedure is brief and well tolerated by the patient.
- **Mammography or xeromammography.** This is an X-ray technique using low levels of radiation to create an image or picture of the breast on film or paper. Mammography has made it possible to detect breast cancer at very early stages. There are several types of mammographic lesions that are suspicious and associated with early cancer. Mammograms can be helpful in determining whether a lump is benign or malignant. In fact, at times it can detect cancer in the breast before a lump can be felt.

- **Ultrasound.** This is another method of evaluating the breast. This procedure creates a picture of the breast from sound waves. Although useful, this method is not reliable enough to be used alone. It is helpful when combined with other methods.
- **Stereotactic Breast Biopsy.** In some patients, some nonpalpable, suspicious (cannot be felt) breast lesions/masses can only be seen on mammography. This will now be called a suspicious mammographic lesion or mass. Using a special X-ray device (stereotactic biopsytable), a biopsy of this mass can be done under local anesthesia with a special needle.
- **Surgical Breast biopsy.** This is the most accurate way to diagnose a lump or a mammographic lesion. The breast biopsy is usually performed as an outpatient procedure in a hospital setting under general or local anesthesia. The surgeon removes the entire lump. The tissue is sent to the pathologist for microscopic analysis.

As mentioned before, many lumps are due to normal hormonal changes in the breast, and can be safely watched.

BREAST CANCER TREATMENT OPTIONS

Beginning with the time a breast lump or lesion is found, women have a number of treatment options. As developments occur, surgeons are continuing to learn about the advantages and disadvantages of these different treatments. Because of the different stages at which breast cancer is diagnosed, there is not one specific treatment that is best for all women. There are too many variables involved to have one standardized treatment plan for breast cancer.

Currently, the **basic types of treatment** for breast cancer are:

- surgery,
- radiation,
- chemotherapy,
- hormonal manipulation.

Surgery and radiation are considered local treatment as they treat and affect one area of the breast or body. Chemotherapy and hormonal manipulation are systemic treatment that applies to the entire body.

The options available to you will depend on a number of factors, including the type of tumor, the extent of the disease at the time of diagnosis, your age, and your medical history. But your personal feeling about the treatment, your self-image, and your lifestyle will also be important considerations in your surgeon's assessment and recommendations. You and your surgeon should discuss these treatment options and how they apply to your situation. Remember, of primary importance in determining the appropriate treatment is the cure rate. Your life should be your number one priority.

LOCAL TREATMENT: SURGICAL RESECTION

MODIFIED RADICAL MASTECTOMY

This procedure removes the entire breast including the nipple and some lymph nodes under the arm.

The **advantages** of the procedure: No chest muscle is removed and the patient retains normal use of her arm. Breast reconstruction is an option and may be performed at the time of the modified radical mastectomy or at a later date. The **disadvantages** of the procedure: The breast is removed. In some cases, there may be swelling of the arm because of the removal of the lymph nodes.

SIMPLE MASTECTOMY

This type of surgery removes only the breast tissue including the nipple. It may be followed by radiation therapy. The **advantages** of the procedure: Chest muscles are not removed and arm strength is not diminished. All of the underarm lymph nodes remain, so the risk of swelling of the arm is greatly reduced. Breast reconstruction is an option. The **disadvantages** of the procedure: The breast is removed. If cancer has spread to the underarm lymph nodes, it may remain undiscovered.

PARTIAL MASTECTOMY / LUMPECTOMY WITH AXILLARY DISSECTION

This procedure removes the tumor as well as a rim of tissue to obtain clear margins (healthy breast tissue). Once the diagnosis of breast cancer has been made, the patient undergoes a second surgical procedure at a later date for the removal of lymph nodes to check for the possible spread of cancer and to stage the disease. This is referred to as an axillary dissection. After surgery, once the patient has healed, they begin postop radiation therapy for approximately six weeks. This option is also referred to as Breast Conservation with Radiation Therapy.

The **advantages** of the procedure: The breast is preserved. There is little possibility of loss of muscle strength.

The **disadvantages** of the procedure: If a woman has extremely small breasts and the tumor is large, this procedure may noticeably change the shape of the breast. If the tumor involves the nipple, this procedure may not be feasible and a mastectomy should be done.

RADIATION THERAPY

Most patients who receive radiation therapy for breast cancer have the external form of radiation. It is usually given during outpatient visits to the hospital. This approach refers to the use of high-energy rays to destroy or suppress cancer cells by a

doctor who is a radiation oncologist. Radiation treatment of the chest area is occasionally used after surgery to destroy cells that may not have been removed by surgery. It is usually given once a day, five days a week for six to seven weeks in a dose that is based on the type and location of

your tumor. This therapy destroys both normal and malignant cells. However, since cancer cells grow and divide rapidly, they are affected more by radiation than normal cells are. In addition, normal cells appear to recover more fully from radiation effects than cancer cells. Doctors carefully limit the intensity of treatments and the amount of normal tissue being treated so that the cancer will be harmed more than you will.

BREAST CARE

Currently breast cancer strikes more than 700 Armenian women annually. Every woman should take the time to examine her breasts for signs of possible cancer. All women, not only those with prior breast lumps, benign or malignant, should learn and practice monthly breast self-examination (BSE). Breast cancer cannot be prevented;

therefore, early detection is your best protection against breast cancer. The consistency of breast tissue varies from woman to woman. By examining your breasts carefully at the same time each month, you will be able to notice any unusual changes, signs, or symptoms of breast cancer.

The following list will help you become aware of what to look for:

1. A lump or thickening of the breast
2. A discharge from the nipple
3. Dimpling or puckering of the skin
4. Retraction of the nipple
5. Scaly skin around the nipple
6. Other changes in skin color or texture, such as "Orange Peel" skin
7. Swelling, redness, or heat in the breast
8. A lump under the arm

The best approach to breast health care is three fold:

- Monthly BSE (Breast Self-Exam),
- A yearly exam by a doctor. An exception is for women with previous breast problems. These women should be examined by their doctor every three months.
- After age thirty a baseline mammogram is preferable to perform. A woman should have a mammogram every two years until age forty (our recommendation). Thereafter, it should be done annually, unless otherwise indicated by your doctor.

Mammography is the single most accurate screening tool available to detect cancer in its earliest and most curable stages. Mammograms are 80 to 85 percent accurate and can even detect lumps that are too small to be felt. In some instances a lump cannot be detected on the mammogram even though you or your surgeon can feel it. The reason for this is the lump is transparent and it will not appear on your mammogram. Mammograms are not 100 percent accurate; therefore, it is crucial to have a physical exam as well as a mammogram. Mammograms can detect very small lumps- less than one quarter of an inch. Most lumps can not be felt until they are at least a half an inch. Precancers can also be found on mammograms. These are the earliest demonstrable forms of breast cancer. It is best to have all your mammograms done at the same facility so that subtle changes can be detected more easily, and techniques, equipment and interpretation are less likely to vary.

Once again, even if you get a clean bill of health from a mammogram, you should still do monthly BSE at home on a regular basis. Remember the three "ams":

- 1) Mammogram,
- 2) Doctor's exam, and
- 3) Breast Self-Exam.

Certain women are at a greater risk for developing breast cancer. These women need to be identified and followed more closely. The risk factors for women most likely to get breast cancer are as follows:

MAJOR RISKS:

- Age:

Table 1: Probability of developing invasive breast cancer among women who are free from invasive breast cancer at their current age, shown as risk over specific intervals of time (based on an analysis of data from the *Surveillance, Epidemiology, and End Results (SEER) registry for 1987-1988*)

Current age (in years)	Risk interval (in years)					Eventually
	10	20	30	40		
30	0.43%	1.99%	4.29%	7.47%	12.80%	(1 in 8)
40	1.58%	3.91%	7.13%	10.28%	12.53%	(1 in 8)
50	2.41%	5.74%	9.01%	10.83%	11.33%	(1 in 9)
60	3.59%	7.10%	9.07%		9.62%	(1 in 10)
70	4.13%	6.45%			7.08%	(1 in 14)

- Women whose mother or sister has had breast cancer, particularly if the disease occurred when the patient was premenopausal;
- Women who have never had children;
- Women who had first child after age 30;
- Women who started first menstrual period at the age of 12 or younger;
- Women who have experienced menopause after 55;
- Women who are obese;
- Women who consumes large amount of alcohol

Each woman is a separate individual and her risk factors can be quite variable.

FOLLOW-UP CARE

Once you have completed your treatment, you have gone through a number of physical and emotional changes and are probably ready to get on with the rest of your life. However, you should be aware of your continuing need for follow-up care. It is important for you to return to your surgeon for scheduled examinations, continue to practice breast self-examination, and be aware of the signs of a possible recurrence.

Breast cancer is a disease that may recur. Recurrent breast cancer can be successfully treated if it is detected early. Recurrences happen to approximately 10% of women who have had

breast cancer. Any surgery leaves some residual breast cells, and any of these cells can be malignant. Sixty percent of all recurrences appear within the first 3 years after the initial treatment, 20 percent within the next 2 years, and 20 percent in later years. As a result, you should continue to be checked by your doctor as often as recommended.

Do not live in constant fear of a recurrence, but be aware that it can happen. As a cancer survivor you will gradually learn to trust your body again. Even though you should be careful to observe and to report any symptoms of recurrent disease to your doctor, do not let yourself become obsessed with finding a new cancer. Each year that passes without evidence of cancer substantially improves the chances that you are cured. The real hope for the future in regards to breast cancer is in earlier detection. More knowledge is considered a first step to help save more lives and to help lessen the fear of breast cancer. In addition to more knowledge, the key to saving more lives is earlier detection and treatment.

Performing Breast Self-Examination can save your life. Knowing how to examine your breasts is an important defense against breast cancer. Detecting breast cancer early, when the disease is in a more curable stage allows for more options in treatment and increases the chances for success and cure. The smaller the lump, the better your chances of being treated successfully. Nine out of ten women who receive early treatment for breast cancer are considered disease-free five years later.