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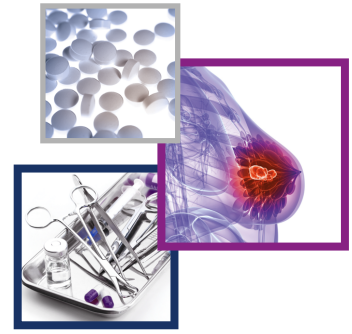

Acceptability and compliance with a breast cancer prevention campaign in the Northwest Region, Iran

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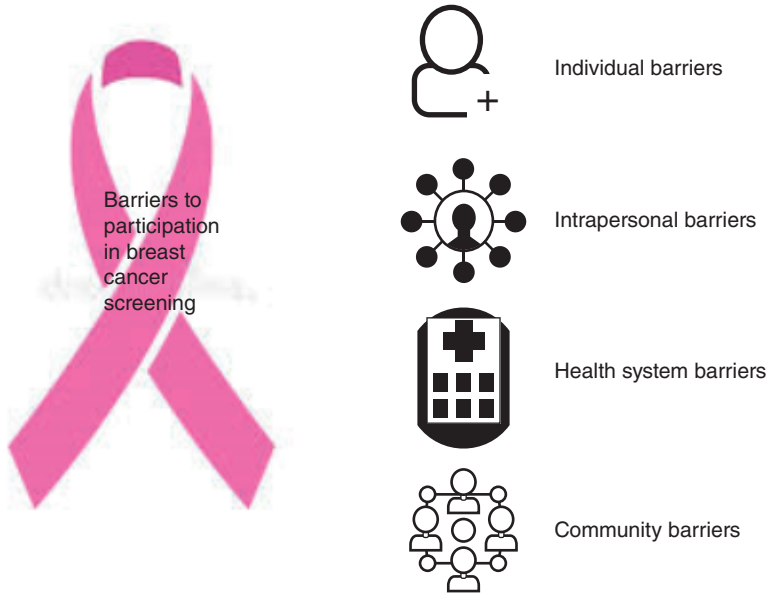
Aim: Breast cancer screening intended to improve survival and treatment outcomes. This study aimed to document the acceptability and compliance of the breast cancer prevention campaigns. **Materials & methods:** Healthy women aged 35–65 years were recruited from various regions of the Northwest of Iran. All women were invited to participate in self-examination training for the breast and then re-assessed by clinical examination and mammography. **Results:** A total of 321 healthy women were recruited, and volunteered to undergo at least one breast self-examination. The first and second clinical examinations were conducted on all women. Ultimately, 272 women (84.7%) underwent mammography. The most common barriers to screening were found to be fear of positive results, fear of cancer, lack of knowledge, fear of the mammography procedure and pain, travel distance and costs. **Conclusion:** The most critical challenge for implementing a breast cancer prevention program was the lack of knowledge and attitude.

Graphical Abstract:



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Keywords: barrier • breast cancer • clinical exam • mammography • screening

Future Medicine

According to the latest report from the International Agency for Research on Cancer in 2020, about 2.3 million new breast cancer cases have been reported in women worldwide accounting for one in four cancer cases in females [1]. Breast cancer now is the first most common cancer and has surpassed lung cancer globally. It is the most occurring and fatal cancer in women, and the 5th leading cause of cancer mortality in the world [1]. Based on recent reports from Iran, breast cancer is the most common cancer when both sexes and all ages are combined, comprising 12.5% of all cancer cases [2,3]. In the female population of the northwest of the country, the Age-Standardized Incidence Rate (ASIR) of breast cancer is estimated to be 31.1 per 100,000 women, with an increasing trend by Annual Percentage Change (APC) of 5.5%, over the past decade [4,5].

Screening and early diagnosis for breast cancer aims to improve survival and outcomes, as well as the morbidity associated with the treatment related to advanced stages of breast cancer [6,7]. Various methods have been introduced for early detection of breast cancer including NCCN (National Comprehensive Cancer Network) and ACS (American Cancer Society) Guidelines. Needless to say that implementing a systematic risk assessment of breast cancer by considering the target groups is the first step for any population based cancer preventive campaign [8].

In Iran, there is no national screening program for breast cancer, and limited data available on the acceptability and compliance of breast prevention programs in women. In addition, there are no guidelines for breast cancer screening. For that we are planning to set up a comprehensive breast cancer preventive campaign in the region. This study was performed as a first step to explore the options for the implementation of a comprehensive breast cancer preventive program in the northwestern region, Iran. For that, we aimed to document the acceptability and compliance of the campaign among the participating healthy women.

Materials & methods

Design & methods

This study was a feasibility study in which mixed methods were applied. Screening was implemented in a group of healthy women from different regions of East Azerbaijan (Northwest of Iran) during one year, from 1st April 2018 to end of April 2019 after obtaining informed consent. Uptake of our intervention and outcomes were registered. In addition, the participating women were interviewed about their participation. Volunteer sampling was applied. Women eligible to participate (n = 321) in the study were voluntarily recruited. By cooperating with health care centers, clinics, hospitals and Non-Government Organizations (NGOs), eligible women were invited by general invoices, telephone calls, posters and advertisements on social media in the study area. All participants were followed by well-trained research medical students.

Intervention

The intervention consisted of three parts.

Part 1: All women were invited to participate in an individual and/or group training for breast self-examination. Two trained medical students (PJ, SP) educated women to perform breast self-examination monthly. In addition, an educational illustrative pamphlet was given women after training session. Data for breast self-examination were collected from women self-reported results.

Part 2: Clinical breast examination was performed every three months by a family physician resident (ZA) and the two trained medical students at the regional Oncology Clinic, according to clinic's routine guideline.

Part 3: All women were screened with two-view mammography, including bilateral craniocaudal (CC) and mediolateral oblique (MLO) views. For that, women were referred to the mammography section of referral Imam-Reza university hospital. The mammographic screening was performed by an expert radiologist in mammography (MR). Information and mammogram reports were collected and recorded based on the Breast Imaging-Reporting and Data System (BIRADS) risk assessment tool [9,10]. This tool was developed by American College of Radiology and provides standardized terminology for reporting schema and ranking according to mammography imaging of breast and ranking as:

- BIRADS 0: Incomplete, need additional imaging evaluation
- BIRADS 1: Negative, no additional intervention needs
- BIRADS 2: Benign mass, probability of malignancy is 0%
- BIRADS 3: Probably benign, probability of malignancy is <2%, short interval follow-up suggested
- BIRADS 4: Suspicious for malignancy, probability of malignancy is 2–94%, biopsy should be performed

- BIRADS 5: Highly suggestive for malignancy, probability of malignancy is >95%, appropriate action should be taken
- BIRADS 6: Known biopsy-proven malignancy

During the clinical breast examination and/or the breast self-examination, if any suspicious finding was present, the woman was referred to the oncologist (ZS) for further evaluation. The oncologist examined the woman again, and if indicated, the woman was referred for mammography test. Women were followed up for one year (2018–19). All respondents should be referred us every 3 months, and for clinical examination as well. In the absence of any clinical finding during the examinations, mammograms were requested in the last quarter of the follow-up period.

All the interventions were free of any cost for participants. Research team students provided some facilities for women including coordination with a physician (SP) in referral mammography center for scheduling and facilitating of mammography and tracking the imaging results. They also coordinated the facilities for women with any positive findings at any follow-up time, and referring them to oncologist and/or needle biopsy and tracking the pathology results.

Number of women included in this study

As this was a feasibility study, a small cohort of 310 women was estimated. We aimed to include three women with a diagnosis of breast cancer, and the expected incidence in this age cohort is 31 cases of breast cancer per 100,000 women per year [4].

The eligibility criteria were based on last NCCN Guideline for Breast Cancer Screening [8], including:

- Asymptomatic women at average risk of BC, aged 40–65
- Asymptomatic women at increased risk of BC, based on previous positive findings and/or positive family history aged 35–65

All participants entered the study voluntarily after obtaining consent form.

Analysis

Compliance with the monthly breast self-examinations and findings during the examinations were collected and recorded by follow-up and by calling the women. This was done by two medical students. Information and findings during the clinical breast examination were also collected and recorded by them. All print reports of the mammographic screening were sent to the research team. A comprehensive review and checking of the data were performed by the family medicine resident (ZA), and rechecked with principal investigator (RD). All analysis were performed using SPSS software (IBM SPSS Advanced Statistics 26.0), and results were provided as descriptive analysis and frequency and percentages, with 95% confidence intervals (CI).

Results

A total of 321 women were included, with a mean age of 45 ± 8.52 (range 35–65 years). All women in the study performed the first breast self-examination; 145 women (45.1%, 95% CI: 39.7–50.6) did the second, 151 (47.0%, 95% CI: 41.5–52.5) third and 21 (6.5%, 95% CI:3.8–9.2) women performed their fourth self-examination of the breast. For an overview Flowchart of screening processing in 321 healthy women was provided (Figure 1).

The first clinical breast examination was performed by physicians for everyone in the study. Because of some symptoms at the first clinical examination, 73 (22.7%, 95% CI: 18.1–27.3) were referred to the oncologist for further evaluation. The similar figures in the second and third visit were 30 (9.3%, 95% CI: 6.1–12.5) and 121 (53.0%, 95% CI: 46.5–59.5), respectively.

In total, 272 women (84.7%, 95% CI: 80.8–88.6) underwent mammography from which mammography was requested by the oncologist due to any suspicious finding during clinical breast examination for 111 cases (40.8%, 95% CI: 34.9–46.6). A total of 161 women (59.1%, 95% CI: 53.3–65.0) underwent mammography after one year from follow-up. The main reasons for referring of women were: breast mass (73.6%, 95% CI: 67.8–79.4), bloody or pushy discharge (14.2%, 95% CI: 9.7–18.8), pain (12.0%, 95% CI: 7.7–16.3). Most women (74.6%, 95% CI: 69.4–79.8)) had a BIRADS score of 1 or 2 (Table 1). After mammography, nine women (3.3%, 95% CI: 1.1–5.4) underwent additional diagnostics with fine needle aspiration as they had BIRADS score of 3 or 4. All of them turned out to be benign, and no cancer was found.

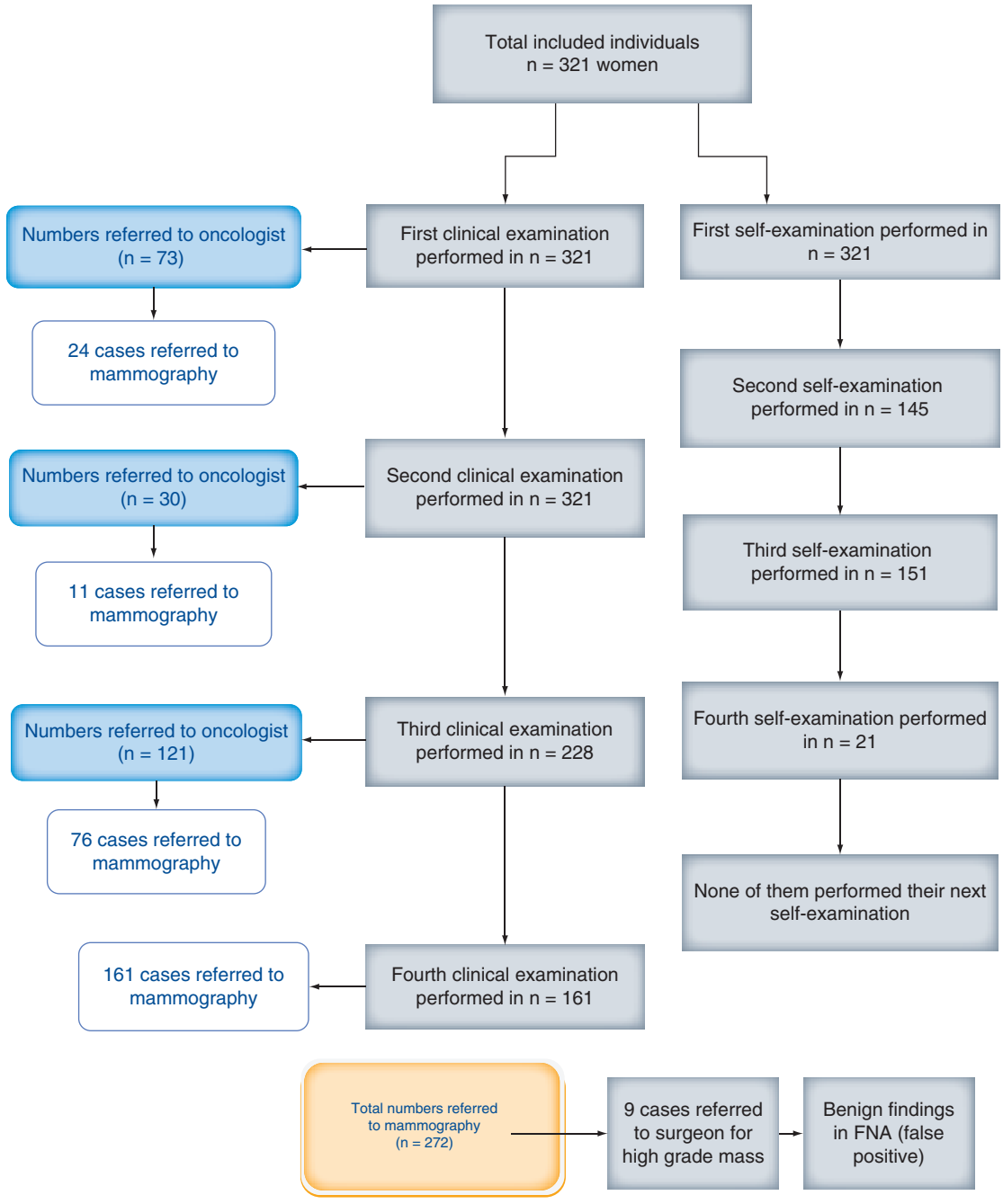

Figure 1. Flowchart of screening processing in 321 healthy women.
FNA: Fine needle aspiration.

Table 1. Distribution of BIRADS scores for the mammograms performed as found during mammography.

Mammographic reports[†]	BIRADS 0	BIRADS 1	BIRADS 2	BIRADS 3	BIRADS 4
n (%)[‡]	60 (22.0)	99 (36.3)	104 (38.2)	8 (2.9)	1 (0.3)
95% CI	17.1–26.9	30.6–42.1	32.4–44.0	0.9–4.9	0–1

[†]For 63 women there were differences between the left and the right breast in the BIRADS score. Those women were classified based on their highest BIRADS score.
[‡]Percentages are within 272 cases that underwent mammography.
BIRADS: Breast Imaging-Reporting and Data System.

49 women (15.2%, 95% CI: 11.3–19.1) stopped their participation during the one year of follow-up and were not referred for mammography. Main reasons were lack of knowledge about the aims and benefits of screening programs (11.5%, 95% CI: 8.0–15.0), fear of mammography (9.0%, 95% CI: 5.8–12.1), travel distance and costs (7.4%, 95% CI: 4.5–10.3) and family/personal problems (4.9%, 95% CI: 2.6–7.3). Some women refused to attend due to fear of positive findings during mammography and fear of cancer (12.7%, 95% CI: 9.1–16.4). In some other cases, they had even fear of the breast self-examination. A number of women also thought that as they had no problems, they did not need mammography or any other screening modality (4.3%, 95% CI: 2.1–6.5). However, we overcame most of the barriers by providing some facilities and information about screening benefits, and by good relationship with the study women, regular post-follow-up contacts, so that most of them accepted to perform their screening process by mammography.

Discussion

In this study, a group of healthy women regardless of their family history for breast cancer were recruited from northwest of Iran. They were followed up for one year. A total of 321 Healthy women eligible to participate in the study were voluntarily recruited, and all underwent at least one breast self-examinations, and 145 (45%) at least two. The first and second clinical examinations were conducted in all women and in 228 (71.0 %) at least three times. Finally, 272 women (84.7 %) underwent mammography. Nine women (3.3%) underwent additional diagnostics with fine needle aspiration as they had BIRADS score of 3 or 4. All of them turned out to be benign, and no cancer was found. Forty-nine women (15.2%) stopped their participation during the one year of follow-up and were not referred for mammography. Main reasons were fear of positive findings during mammography and fear of cancer (12.7%), lack of knowledge about the aims and benefits of screening programs (11.5%), fear of mammography procedure and pain (9.0%), travel distance and costs (7.4%) and family/personal problems (4.9%).

Our findings showed a high compliance rate for interventional methods. However, although most participated women had breast symptoms, none of them had visited a doctor for their breast symptoms and only 10% visited the clinics for routine breast checkups. Lack of knowledge and awareness about screening programs might have had a role to this matter. Most women believe that they would only need screening programs when they have symptoms. Similar findings have been reported from other Asian and Low-resource countries around [11–14].

Our study showed a high participation rate, much higher than in some other Asian surveys [11,15–17]. Summary results of related reviewed studies were provided in Table 2 (Table 2). In a cross-sectional study performed in six Jordanian areas, the self-reported uptake for breast self-examination, clinical examination and periodic mammography screening was 35, 17 and 9%, respectively [18]. Compared to previous reports from Iran, our uptake rate was higher. In the study reported from South-East of Iran, breast self-examination was reported in 5% of participants and clinical examination and mammography were both around 1% only [19]. Another similar study revealed that the rates for breast self-examination, clinical examination and mammogram were 4, 5 and 4%, respectively [20].

As indicated before, lack of knowledge and awareness was the main barrier and problem in this study, which might lead to negative attitude about screening programs and fear of positive findings during mammography [18,25,26]. In addition, women are not aware of the opportunity of screening programs and the benefits and timeliness of early detection of breast cancer [25,26]. The other barrier for screening in our study was living in rural areas and travel costs, which is comparable to findings in other studies [18,22,23]. Higher socio-demographic status and higher income and education increase the breast cancer screening uptake, not only because of better accessibility to screening modalities and health care systems, but also because of better knowledge and attitude regarding the breast cancer and mammography screening [18,24]. Another barriers was the limited referral centers for clinical examination and mammography, and the related costs of the screening procedures [27,28]. Providing several organized screening centers, providing information and encouraging women to undertake mammography screening may then lubricate early detection programs for at risk groups [29,30].

We found that the most common symptom was breast mass followed by bloody or pushy discharge and/or pain. The occurrence of symptoms is similar to the results reported from Iran, but is somehow different with other studies in which pain was the common symptom followed by breast mass or lump, breast shape or size and breast discharge [18,21]. After mammography, in our study, nine women (3%) underwent additional diagnostics with fine needle aspiration because of high score BIRADS findings, and no cancer was detected.

Clinical breast examination was performed every three months by a family physician resident and the two trained medical students at the regional Oncology Clinic, according to clinic's routine guideline. All the 321 women referred

Table 2. Summary of the results of related studies.

Author/year of publication/region	Number of women included	Inclusion/exclusion criteria	Age/range (years)	Main outcome	Main results	Ref.
Shakor *et al.*, 2018, Sulaimani, Iraq	40,491	Inclusion: healthy women (aged ≥40 years) and high–risk women (aged 35–40 years with family history of BC or nullipara Exclusion: girls younger than 14 years with clear sonography	35–55	Breast cancer detection rate	The CDR of the Iraqi program was 8.2 per 1000 screened women, and that of the mammograms was 42.02 per 1000 mammograms. Women mostly participated in the program by the self-referral method (77.54%)	[11]
Alirmaei et *al.*, 2009, Sanandaj, Iran	759	Inclusion: all women referred to the breast clinic	41–50	Mammography screening	A total of 68% of the women didn't have any positive finding, 48 (6.3%) had benign mass and 3 (0.39%) had cancer	[21]
Abu-Helalah et al., 2015, six governorates in Jordan	507	Inclusion: women aged 40–69 years, speak Arabic fluently and permanently live in Jordan Exclusion: outside the age range of 40–69 years, does not speak Arabic fluently, not living permanently in Jordan	40–69	Knowledge, barriers and attitudes towards breast cancer mammography screening	BSE, doctor examination and periodic mammography screening were reported by 34.9, 16.8 and 8.6% of study participants, respectively The most commonly reported symptoms were breast mass (43.5%) followed by changes in breast shape or size (16.5%) and unusual nipple secretions (15.0%)	[18]
Ozman *et al.*, 2017, Turkey	7234	Inclusion: eligible women living in Bahçeşehir county in Istanbul, in 2009	40–69	Cost–effectiveness of breast cancer screening	– The overall cancer detection rate was 9.3 per 1000 women (67 out of 7234) – 48% of the women diagnosed with breast cancer were women aged 40–49 years while 59% of the screened women were in the age group of 40–49 years – BMSP led to an average saving of 4.17 life years per woman diagnosed with cancer	[15]
Radi *et al.*, 2013, Jeddah, Saudi Arabia		Inclusion: adult Saudi females, aged 20 years and older, living in Jeddah city, no personal history of any type of cancer, not working in the medical field Exclusion: females who were not willing to participate in the study	≥20	The level of breast cancer awareness among Saudi females in Jeddah, focusing on knowledge of breast cancer warning signs, risk factors, screening programs and BSE	Out of 200 participants, 50.5% were aware of breast lump as a warning sign of breast cancer, 57.5% claimed that family history was risk factor, 20.5% had undergone breast screening, 79% had heard about BSE, and 47.5% knew how to perform BSE. Findings indicated that Saudi females level of awareness of breast cancer is very inadequate	[16]
Al-Naggar *et al.*, 2012, Malaysia	200	Inclusion: female, aged 40 years or older, voluntary, ability to speak Malay or English	≥40	Practice and barriers of mammography among Malaysian women in the general population	– The most important barriers were lack of time, lack of knowledge, not knowing where to go for the test and a fear of the test result (42.5, 32, 21 and 20%; respectively) – Age, regular medical check-up and knowledge about mammography testing were statistically associated with the practice of mammography	[17]
Heidari *et al.*, 2008, Zahedan, Iran	384	Inclusion: married women, selected as an improbability sample from women referred to Qouds Maternity Hospital in Zahedan, southeast Iran, during summer 2003	15–60	Knowledge and practices of women about breast cancer screening	– Overall knowledge of breast cancer screening was insufficient in 67.4%. About 21.6% and 3.4% had good knowledge about BSE and mammography, respectively – Only 4.5% of women performed BSE on a regular basis, 4.1% had had a clinical breast examination and 1.3% had had a mammography at some point during their life	[19]
Salimi Pormehr *et al.*, 2010, Ardebil, Iran	300	Inclusion: women referring to Ardabil's Health and Medical Centers were chosen by multistage sampling	15–64	Determine the breast cancer screening tests performance and affecting factors in women	The percentage of screening tests including self-examination, clinical examination and mammography consequently were 4, 4.7 and 3.7%	[20]

BC: Breast cancer; BMSP: Bahcesehir Mammographic Screening Program; BSE: Breast self-examination; CDR: Cancer detection rate; NA: Not available.

Table 2. Summary of the results of related studies (cont.).

Author/year of publication/region	Number of women included	Inclusion/exclusion criteria	Age/range (years)	Main outcome	Main results	Ref.
Kim *et al.*, 2011, China	770	Inclusion: women living in four cities (Beijing, Shanghai, Guangzhou and Xi'an) in China, those who agreed to participate in the study Exclusion: data with large missing responses or those out of age ranges were excluded	25–65	Breast cancer screening practice, health promoting behaviors, perceived benefits and perceived barriers	About 60% of Chinese women participated in some type of breast cancer screening practice, among them only 60 (7.8%) women used mammography, ultra sonogram and BSE. The main reason for carrying out breast cancer screening was "feeling screening was necessary". About 36% of the participants reported they did not perform any of the screening practices, because they "didn't feel it was necessary"	[22]
Akpinar *et al.*, 2011, Turkey	444	Inclusion: female health care professionals in various health care centers (between March–December 2007), who agreed to participate in the study	24–56	Knowledge and attitude about breast cancer and practice of breast cancer screening among different female health workers	The degree of feeling at risk of breast cancer among female health personnel was 31.3%. The majority (98.4%) perceived BSE as a beneficial method for the early detection of breast cancer. Although 81.3% of the participants stated that they did BSE, only 27.3% reported doing so on a regular basis (performed monthly or once per menstrual cycle). The most common reason for not doing BSE was the belief that it was not necessary (45.8%). Of the entire group, the rate of having a mammography was 10.1% and the rate of clinical breast examination was 24.8%	[23]
Schuler *et al.*, 2008, San Jose, United States	4,957,347	Inclusion: systematic quantitative review of the literature, English language papers published between 1988 and 2007	NA	Factors associated with mammography utilization	– Physician access barriers, such as not having a physician-recommend mammography (adjusted OR: 0.16; 95% CI: 0.08–0.33) and having no primary care provider (OR: 0.41; 95% CI: 0.32–0.53), were highly predictive of not obtaining mammography – Past screening behavior correlated strongly with receipt of mammography – Racial and ethnic differences were seen. Concerns about cost, mammography safety and pain were more important to African–American and Latina women, and having no insurance was more important to White and Chinese women	[24]
Rejali *et al.*, 2018, Isfahan Iran	9591	Inclusion: healthy women between 20–65 years, clustering random selection model Exclusion: history of breast cancer	20–65	Status of breast cancer screening	63.4% carried out BSE, and 61.5% mentioned no pain at breast site as the reason for the lack of BSE. 50.2% of women had at least one clinical breast exam in the past 3 years with the total average number of 1.9- ± 2.2-times. The most prevalent cause of failure to carry out a clinical exam (85.9%) was having no problems with breast, and the lowest prevalent cause (4.2%) was the cost of the practice. 15.7% of women already had at least once mammogram and the average frequency of mammography was 2.3- ± 2.4-times. Lack of breast problems was the main reason for canceling mammography procedure (80.8%)	[25]
Rezaee *et al.*, 2013, Tehran, Iran	900	Inclusion: healthy women aged >40 years referred to selected clinics Exclusion: history of previous mammography	40–60	Attitudinal barriers to mammography screening among women	Attitudinal barriers to mammography screening: having no symptoms of breast cancer (81.9%), 'lack of knowledge about breast cancer' (73.2%), 'lack of concern about breast cancer because of no family history' (71.8%), 'unnecessity of mammography' (62.3%)	[26]

BC: Breast cancer; BMSP: Bahcesehir Mammographic Screening Program; BSE: Breast self-examination; CDR: Cancer detection rate; NA: Not available.

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to 1st and second clinical breast examination, and n = 228 to 3rd, and 161 for 4th CBE. The most problem and barriers for women was like to other barriers that we mentioned for refereeing for mammography, including fear of positive results, fear of cancer and lack of knowledge, travel distance and costs. So based on this study results, we can offer an annually clinical breast examination for implementation on our center's protocol.

Strengths & limitations

Strong points of our study was that we educated all participating women by the providing of educational booklets about the aims of breast cancer screening and the performance of breast self-examination, and that we contacted all participants in case of any dropout. For that, we had a very well trained and dedicated group of clinical researchers. Our study provides detailed information on uptake and compliance with screening in a country where there is no formal screening yet, and we were able to get more information on those women who did not participate for the whole program period of one year. Also we provided some facilities, including scheduling the mammography, coordination with additional referral centers, and paying the relevant costs. The job done by well-trained research medical students in scheduling, following and providing the appropriate knowledge and attitude, were other strengths of our study.

Most participated women for our 'Breast Cancer Screening Campaign' were symptomatic women. We referred 73 women to oncologist in their first clinical breast examination (CBE), n = 30 in their second CBE and n = 121 in their third CBE. Lack of availability and costs of breast cancer screening and/or diagnostic centers, many women referred us because we covered all screening modalities fees.

Despite the educational efforts for BSE, due to some barriers and fears, 145 women did their second BSE, n = 151 did the third, n = 21 did the fourth and none of the 321 women finalized their monthly breast self-examinations.

However, as the aim of this study was to evaluate the acceptability and compliance of breast screening among the participating women in East Azerbaijan, the intention was not to include a large cohort of women.

Conclusion

The barriers and problems mentioned in some of the participants were due to lack of knowledge, fear of screening and mammography, distance travel and costs, family problems and fear of possible positive findings during the tests. One of the most important challenges for the implementation of a breast cancer prevention program is to increase the knowledge and attitude, and to provide accurate and sufficient information about screening modalities. Priority should be given to guide women with breast symptoms to find proper medical care. Informing women through face-to-face learning, tracking and facilitating mammograms, as we did in this study, may be a preferred strategy to implement successful preventive screening programs. This approach needs to be implemented on a larger scale, first by developing and implementation of a systematic risk assessment tool, and then by providing well designed and rigorous research in well-resourced settings.

Summary points

- Screening and early diagnosis for breast cancer aims to improve survival and outcomes, as well as the morbidity associated with the treatment related to advanced stages of breast cancer.
- Our findings showed a high compliance rate for interventional methods.
- We provided some facilities, including scheduling the mammography, coordination with additional referral centers, and paying the relevant costs.
- However, although most women who participated had breast symptoms, none of them had visited a doctor for their breast symptoms and only 10% visited the clinics for routine breast checkups.
- Despite the educational efforts regarding breast self-examination (BSE), due to some barriers and fears, 145 women did their second BSE, 151 did the third, 21 did the fourth and none of the 321 women finalized their monthly BSEs.
- Based on these study results, besides using a protocol of clinical breast examination every 3 months, we can offer an annual clinical breast examination as part of our center's protocol.
- Main barriers for mammography were fear of positive findings during mammography and fear of cancer (12.7%), lack of knowledge about the aims and benefits of screening programs (11.5%), fear of mammography procedure and pain (9.0%), travel distance and costs (7.4%), and family/personal problems (4.9%).
- The most critical challenge for implementing a breast cancer prevention program was the lack of knowledge and attitude towards breast cancer screening.

Author contributions

(1) Conception and design: R Dolatkhah, S Dastgiri and GH de Bock; (2) Administrative support: R Dolatkhah, S Dastgiri and Z Sanaat; (3) Provision of study material or patients: R Dolatkhah, Z Sanaat and M Ranjkesh; (4) Collection and assembly of data: Z Abbasi, P Jabbaripour, S Pashaie and S Poorsaberi; (5) Data analysis and interpretation: R Dolatkhah, S Dastgiri and GH de Bock; (6) Manuscript writing: R Dolatkhah, S Dastgiri and GH de Bock; (7) All authors approved the final manuscript.

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Financial & competing interests disclosure

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No writing assistance was utilized in the production of this manuscript.

Ethical conduct of research

This study was accepted by the ethics committee of Tabriz University of Medical Sciences as a research project (ID: IR.TBZMED.REC.1396.756). Confirmed and signed consent forms were collected from all participants.

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