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Strategies for Increasing Mammography Screening in Primary Care in Chile: Results of a Randomized Clinical Trial

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Abstract

Background—Breast cancer is the cancer with the highest incidence among women in Chile and in many Latin American countries. Breast cancer screening has very low compliance among Chilean women.

Methods—We compare the effects on mammography screening rates of standard care, of a low intensity intervention based on mail contact, and of a high intensity intervention based on mail plus telephone or personal contact. A random sample of 500 women 50 to 70 years registered at a community clinic in Santiago who had not had a mammogram in the past two years were randomly assigned to one of the three intervention groups. Six months after randomization, participants were re-evaluated for their compliance with mammography screening. The outcome was measured by self report and by electronic clinical records. An intention to treat model was used to analyze the results.

Results—Between 92% and 93% of participants completed the study. Based on electronic records, mammography screening rates increased significantly from 6% in the control group to 51.8% in the low intensity group, and 70.1% in the high intensity group. About 14% of participants in each group received opportunistic advice, 100% of participants in the low and high intensity groups received the mail contact, and 50% in the high intensity group received a telephone or personal contact.

Conclusion—A primary care intervention based on mail or brief personal contact could significantly improve mammogram screening rates.

Impact—A relatively simple intervention could have a strong impact in breast cancer prevention in underserved communities.

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Introduction

Breast cancer has emerged as the most significant cause of death from malignancies in Latin American women (1,2). Breast cancer has the highest incidence in the Chilean female population with a cumulative risk up to age 75 of 3.4% (3). Mortality rates from breast cancer in Chile (13.1/100,000) have remained stable during the last 10 years and are very similar to the ones reported in Brazil (14.1/100,000) but higher than the ones observed in Mexico (10,5/100,000) (1,4). Survival rates from breast cancer in South America are on average 20% lower than those reported in the United States, Western Europe or Japan (5,6). Later stage of diagnosis among South American women has been one of the factors associated with the differences observed in survival rates (5,6). In Chile, only 8% of breast cancer cases were diagnosed in situ stage in 2006 and, about 75% were diagnosed in stages II,III or IV (4).This low percentage of early detection among Chilean women is very similar to the percentages reported in other South American countries such as Brazil or Peru (6,7). Mammogram screening is an effective strategy to detect breast cancer in an early stage and reduce mortality rates when performed systematically to women 50 years and older (8).

Many countries in Latin America have begun to implement new health policies directed at improving breast cancer screening using mammography tests (9). In Chile, a national program for breast cancer prevention was initiated in 1995 that was based on clinical breast examination. Since 2005, the program has progressively incorporated a mammogram test for women aged 50 and older. The program includes universal financial coverage for complementary diagnostic tests and required therapy if breast cancer is detected (10). Increasing access to mammography can be an important facilitator for breast cancer screening. However, there is consistent evidence showing that mere availability of mammography to the population is not sufficient for improving breast cancer screening practices. (11–13).

Mammography screening rates are highly variable in diverse communities (14). The US National Health Interview Survey conducted in 2005 showed an average mammography use of 66% by women 40 years or older (15). However, screening rates varied from 38% to 75%. This variability has been associated with differences in socioeconomic status, race, ethnicity, cultural factors and regular contact with a general physician (11-13,15-17). Mammography screening rates in Latin American countries are very low and range between 10% and 35% (18). Numerous investigations conducted mainly in the US and Western Europe have focused on finding better interventions for improving breast cancer screening practices (14,19,20). A Cochrane systematic review concluded that active recruitment strategies such as invitation letters, mailed educational materials, telephone contacts and a combination of those strategies significantly increases the number of participants in breast cancer screening strategies compared with standard care (21). There is lack of information about the effects of different strategies to improve mammogram screening in Latin America. In this randomized controlled trial, we evaluate the effectiveness of three intervention strategies directed to increase mammogram screening among women 50 to 70 years old living in an underserved community in Santiago, Chile, and served by a free university clinic.

Methods

Setting

The study was conducted in El Castillo Oriente, an area of low socioeconomic status located in the Municipality of La Pintana in the Southeast area of Santiago, Chile. The population living in El Castillo Oriente is registered and receives free health care services at a university clinic. La Pintana has a high concentration of the poorest population of Santiago (22). The extent of education in La Pintana, as measured by years of schooling, is 30% lower than in the rest of the country.

In 2008, when the study started, 21,120 people were registered at the university clinic in El Castillo Oriente. Women between 50 to 70 within this population were able to receive free mammogram screening.

Study Population

Women eligible for participating in the study were those registered at the university clinic in El Castillo, aged 50 to 70 years, who had not had a mammogram in the last two years according to the electronic record, and who agreed to participate in the study. Women with a breast cancer diagnosis were excluded. A list of all eligible women was obtained from electronic records. Then, by using a computerized random number generator program, 500 women were randomly selected to participate in the study. Eligible women were contacted and invited to participate. Those who refused to participate were replaced according to the random sequence given by the program. Eligible women who agreed to participate, were asked to read and sign an informed consent and were interviewed using a structured questionnaire. Random selection continued until 500 women were included in the study. A complete data base with 500 eligible women interviewed at baseline was sent to the Fred Hutchinson Cancer Center in the US (i.e. the coordination center) to proceed with a random allocation to one of the two intervention arms or the control arm. A stratified randomization method blocking by age (50 - 59; 60 - 70) was used to allocate women to each group using a computerized random generator program. Blinding participants to their intervention group was not possible in this study.

Instruments and Intervention

A structured questionnaire was administered by trained interviewers at baseline and six months after randomization. The questionnaire had five sections and 59 questions. The main topics addressed in the questionnaire were health behaviors, reproductive health, breast cancer prevention beliefs, attitudes and practices, medical care practices and sociodemographic issues. The breast cancer prevention section evaluated mammography screening practices, motivational level and self efficacy to obtain a mammogram as well as predisposing, enabling and reinforcing factors related to having or not having a mammogram. Questions were based on the information obtained in the qualitative phase of the study (23). They evaluated barriers and facilitators to get a screening mammogram i.e. to get the test in an asymptomatic phase. Therefore, we excluded questions that addressed motivations of women to get a mammogram when having symptoms such as breast lumps.

Medical care practices were explored by assessing the number of contacts with physicians, nurses or midwifes during the last 12 months, as well as type of information and advice received for breast cancer prevention.

The project compared three different interventions that are described as follows:

Low intensity intervention: This strategy included two main components. The first component was the usual opportunistic advice given to women who contact their primary care provider at the clinic. The second component was a mail contact to the participant women with a letter from the primary care physician, an information booklet and a mammogram order with optional dates for getting the test.

High intensity intervention: This strategy included three components: The first two components were usual opportunistic advice and mail contact similar to the one described above. The third component was a telephone contact for those women who had not made an appointment for getting a mammogram after six weeks from the mail delivery. In case a telephone was not available or the women did not make an appointment for a mammogram in four extra weeks from the previous contact, participants in this intervention arm received an in home visit from a lay health educator. The content of the messages delivered in the information booklet and personal contact (telephone or home visit) to the participants followed the Predisposing, Enabling, and Reinforcing model (PRECEDE) (16) that was used to explore barriers and facilitators in a previous phase of the investigation (23).Basically, predisposing factors such as fatalism related to cancer diagnosis, enabling factors such as clear information about the procedure and reinforcing factors such as timely feedback about the results of the test were included in the messages delivered to participants.

Standard care intervention: In this arm of the study, women received the usual opportunistic advice about getting a mammogram and information about breast cancer prevention when they contacted their primary care provider at the clinic. During the opportunistic contact, the health care provider (primary care physician or midwife) had the option to order a free mammogram for the women who seek care at the clinic. Three lay health educators from the community were trained as interventionists for the high intensity intervention arm of the study. They participated in a three day training session for learning motivational interviewing skills that they would apply when contacting women by phone or during the home visits. Women were supervised by a trained psychologist to assure that the basic competencies of motivational interviewing were applied properly during the contacts. A standard protocol for the personal contacts was developed to analyze the process of the intervention. Staff at the clinic and at the radiology unit where participants got their mammograms were blinded to the allocation group.

Statistical Methods and Analysis

The main outcome of the study was compliance with mammogram screening. We measured mammogram screening by self report at baseline and six months after randomization. Mammography screening was also measured using electronic records. Two sources of electronic records were used. The first source was the electronic database containing the reports of all tests conducted during the study at the radiology unit affiliated with the university clinic. The second source was the electronic chart where the results of all tests are registered.

To determine the sample size for the study, we defined a point difference (δ) in the screening rate for each arm compared to the control arm of at least 10%, a power (β) of 0.8 and an alpha level of 0.05. Since participants were interviewed at two time points, we estimated an inter-person correlation (ρ) of 0.7.

We expected potential confounding variables to be balanced between each group given the random allocation of participants. However, we considered multivariate analyses in case of subgroup analyses using logistic or linear regression models according to the dependent variable being analyzed.

An intention to treat analysis was conducted using electronic clinical records (24). They were reviewed for all women and compliance was estimated using the baseline denominators of each group. Figure 1 presents a flow diagram describing the enrollment, allocation, follow-up and outcome variables of the study. The analysis of the data was conducted by investigators of the coordination center at the Fred Hutchinson Cancer Research Center. They were blinded to the group assignment of participants.

The study was reviewed and approved by the Institutional Review Board at the Fred Hutchinson Cancer Research Center in Seattle and the School of Medicine at Pontificia Universidad Católica de Chile in Santiago. This investigation was supported by the U.S. National Institute of Health (NIH) -Fogarty International Center (R03TW007900) and by the National Cancer Institute (U01 CA114633).

Results

Table 1 presents the general characteristics of the population at baseline. Participants were of low socioeconomic status and had a low education level. The majority of them (56.2%) reported an income of less that Ch\$ 100,000 (US\$ 200) a month and only 22.4% of them completed more than 8 years of education (i.e. high school or university level education). About half of the women identified themselves as mestizo and 8.6% as indigenous. No significant differences were observed between groups in the demographic characteristics of the participants.

After 6 months, 92.4% (462/500) of the women completed the final survey. Lost to followup of participants were very similar between groups (i.e. 6.6% in the control group, 7.8% in low intensity group and 8.4% in the high intensity group). Main reasons associated with lost of follow-up were refusing to participate in the final survey (20/38 women) and not being

cardiovascular disease during the study.

The number of women who received the intervention in each group is presented in Figure 1. Brief advice about having a mammogram was delivered by a primary care provider to 15% (73/500) of participants. This intervention had a very similar distribution across groups. In addition to the clinical brief advice, all women in the low intensity group received the mail intervention. In the high intensity group, women received the mail intervention and those who did not get a mammogram were contacted by telephone, and subsequently (if they still did not get a mammogram) received a home visit (outreach intervention). Fifty percent (83/167) of the women in this group were contacted by telephone and/or received a home visit. The majority of them (72/167) received both interventions.

Table 2 shows the mammogram screening rates at baseline and after six months in the three groups. There was a significant increase in mammography screening in the low and high intervention arms of the study compared to the control arm. Percentage of screening according to the electronic registry of mammograms performed during the period of the study shows a significant increase from 6% (167) in the control arm, to 51.8% (86/166) in the low level intervention arm, and 70.1% (117/167) in the high level intervention arm.

Table 3 presents the beliefs and attitudes of women at baseline and after the intervention in the three arms. About 90% of women believed that blows to the breast could cause breast cancer and that they will only need a breast exam if they feel pain. These beliefs did not change significantly after the intervention. About 60% of participants perceived that if they have a mammogram they could find a disease that they would rather not to know about. However, about 90% recognized that a mammogram was a test to detect breast cancer earlier and that getting a mammogram regularly could reduce the risk of dying from breast cancer. A significant increase in the information of women about where and how to get a free mammogram after the intervention was observed in participants of the low and high intensity intervention arms compared to those in the control arm.

Discussion

This study shows that relatively simple interventions can significantly improve mammographic screening rates in a disadvantaged community in Santiago, Chile. A low intensity intervention based on mailing information could improve screening from about 6% to 50% for women 50 to 70 years old. If this intervention is complemented with a telephone or personal contact through a home visit, compliance could increase to 70%.

This study provides useful information to decision makers in many Latin American countries that, as in Chile, are starting to implement screening programs that incorporate mammography. International evidence shows that availability of mammography within the target population is not enough to achieve the recommended compliance rate of 70%–75% required to obtain significant impact on early detection and mortality rates (11, 12, 25,26). Moreover, screening programs that rely mainly on clinical opportunistic contacts from the primary health care provider to develop a breast cancer preventive program have achieved

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low rates of screening. A meta-analysis of randomized trials published by Page and colleagues (19) found that control groups of no active intervention in the included trials had an average mammogram screening compliance rate of 13% to 16%. An invitation letter significantly increased mammogram screening by 1.98 times (95% CI:1.34-2.91) and the size effect was larger if the invitation letter was complemented with a follow-up telephone call (OR: 3.15, 95% CI: 2.06-4.83). This study found results leading in the same direction as those reported in the meta-analysis but with a larger size. The low intensity intervention in our study included a personal invitation letter plus an information booklet and a medical order to get the test. The components of this intervention focused on facilitating access, encouraging confidence and stimulating personal reward for taking self care. These were essential predisposing, enabling and reinforcing factors related with breast cancer screening identified by a group of Chilean women in a qualitative investigation (23). A direct contact invitation through a telephone call or a home visit produced a significant and incremental effect in mammography screening in our study. A meta-analysis conducted by Denhaervnck and colleagues (14) found that direct contact strategies that included telephone counseling and home visits significantly improved adherence to mammography from 21% (95% CI: 10%-34%) to 46% (95% CI:32%-61%). Our high intensity intervention group included both strategies and achieved an effect closer to the highest range of the meta-analysis mentioned. Most women in this arm of the study received both interventions. These interventions were conducted by trained lay health educators that followed the motivational interviewing model (27). The combination of interventions and the specific interviewing model applied probably explains part of the improvement observed.

Beliefs and attitudes related with breast cancer were similar among the three groups at baseline and did not experience significant changes at the end of the intervention. Most women considered breast self examination an essential part of cancer prevention and also valued the importance of having a mammography as a way to find breast cancer earlier and therefore, an increasing chance to live longer. However, women in the low and high intervention groups significantly improved their information on where and how to get a mammogram screening test. This is an important finding given the evidence that shows that one of the main barriers for mammogram screening is access to the procedure.(14,15). Our intervention was particularly focused on improving mammogram screening and the study succeeded in improving the information level of women in this key factor, facilitating their access to the test.

In Latin America there is lack of information about the effect of interventions directed to improve breast cancer screening. Caleffi and colleagues (28) are conducting a cohort intervention study to test the effectiveness and cost effectiveness of an intervention based on lay health workers for early detection and treatment of breast cancer The authors highlighted the low compliance of about 10%, of mammography screening for women 50 year and older at baseline and the need to implement a systematic intervention to improve screening and early treatment. Our study provides evidence that can contribute to designing effective intervention models to optimize the effectiveness and efficiency of breast cancer screening programs.

This study has limitations that are important to consider. First, generalizability of our results are restricted to populations similar to the one included in this research. We described the essential characteristics of the community, health setting and participants of the study to provide relevant information and define the scope where the findings of the study could be better applied.

Second, blinding was not possible for participants and interventionists; therefore, they knew the allocation arms. Lack of blinding in this study could have produced a certain level of cross contamination given that women, especially in the control arm, could have demanded more information than usual. This effect would most likely favor the screening rates in the control arm and therefore act in favor of the null hypothesis of no differences between groups. Mammography tests were free for the three groups and access for medical and midwife care was equivalent in all of them as well as shown in Figure 1.

Implementation of each component of the interventions was measured and allowed us to estimate the "doses" required to produce the effect observed. Finally, lack of compliance with the intervention can be another source of bias of randomized controlled trials. Compliance in this study was very high and the main outcome was analyzed using an intention to treat model based on information from the electronic records.

In conclusion, this randomized controlled trial shows that in a population of women living in an underserved community in Santiago, a mailed intervention alone or in combination with a personal contact (telephone or home visit) could produce a significant increase in the rate of mammogram screening compared with standard care. A personal contact plus a mail intervention achieves a higher effect than the mailing intervention alone. This study can contribute to better inform health decision makers about the magnitude of the effect expected when applying interventions with different intensity to populations similar to the one of this research.

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Figure 1. Study design and follow-up

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Table 1

Demographic characteristics of participants at baseline

		Interven	tion
	Control	High intensity Mail plus outreach	Low intensity Mail only
Characteristic	(n=167) N (%)	(n=167) N (%)	(n=166) N (%)
Age (years)			
50-59	120 (71.9)	122 (73.1)	108 (65.1)
60–70	47 (28.1)	45 (27.0)	58 (34.9)
Current marital status			
Single	16 (9.60)	28 (16.8)	33 (19.9)
Married	87 (52.1)	82 (49.1)	85 (51.2)
Living with partner	15 (8.9)	12 (7.2)	6 (3.6)
Separated/Divorced/Widow	49 (29.3)	45 (27.0)	42 (25.3)
Income (per month)			
<100,000 pesos	95 (56.9)	87 (52.1)	99 (59.6)
100,000 pesos	72 (43.1)	80 (47.9)	67 (40.4)
Ethnicity			
White	77 (46.1)	74 (44.3)	77 (46.4)
Mestizo	77 (46.1)	74 (44.3)	78 (47.0)
Indigenous	13 (7.8)	19 (11.4)	11 (6.6)
Occupation			
Homemaker/informal job	119 (71.3)	127 (76.1)	121 (72.9)
Maid	16 (9.6)	15 (9.0)	15 (9.0)
Merchant	18 (10.8)	12 (7.2)	8 (4.8)
Student/Other	14 (8.4)	13 (7.8)	22 (13.3)
Education (years completed)			
No schooling	11 (6.6)	16 (9.6)	16 (9.6)
1 – 7	101 (60.5)	93 (55.7)	93 (56.0)
8	18 (10.8)	15 (9.0)	25 (15.1)
9 – 12	20 (12.0)	30 (18.0)	14 (8.4)
12 +	17 (10.2)	13 (7.8)	18 (10.8)

Table 2

Mammography screening behavior

Mammography screening		Intervention		Significance
	Control	Low Intensity Intervention	High Intensity Intervention	
	(1)	(1)+(2)	(1)+(2)+(3)	
	(n = 167) N (%)	(n = 166) N (%)	(n = 167) N (%)	
Self report				
Had a mammogram in the past 6 months	12/156 (7.7)	79/153 (51.6)	103/153 (67.3)	<i>a,b,c</i>
Electronic record				
Had a mammogram in the past 6 months (intention to treat)	10/167 (6.0)	86/166 (51.8)	117/167 (70.1)	<i>a,b,c</i>

(1) Opportunistic screening: brief advice

(2) Mail contact

(3) Personal contact: telephone contact or home visit

 a p value < 0.05 for low intensity intervention vs. control

 $^b{\rm p}$ value <0.05 for high intensity intervention vs. control

 c p value < 0.05 for low intensity intervention vs. high intensity intervention

kappa for electronic record and self report: 0.8

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Table 3

Beliefs and attitudes about breast cancer by intervention group at baseline (base) and differences at follow-up (FU)

	ට	ntrol	Low J	ntensity	High	Intensity	
	Base n = 167	Difference FU - Base	Base n = 166	Difference FU - Base	Base n = 167	Difference FU - Base	Significance
Beliefs (% who agree)							
Blows to the breast, specifically those that produce bruises, can cause breast cancer.	87.4	3,6	91.0	3,8	89.8	3	NS
If I have cancer, I will know because of pain, that is why I only need to get one exam in case I feel any pain.	65.3	-8,2	70.5	5.4	73.7	-16,2	NS
Breast cancer is a fatal disease. Once it is detected, it is probably that the person will die in a couple of years.	66.5	3,3	63.9	9-	59.3	13,9	S
Examining my breasts frequently is the best way to detect breast cancer at an early age.	83.8	0,8	88.6	-6,9	86.8	-5,1	NS
The mammogram is an exam that works to detect cancer in its early stages.	93.4	2,7	97.0	-2,9	93.4	1,4	NS
The person to whom breast cancer is detected in its early stage can recover from the disease.	82.0	5,2	79.5	7,4	80.2	3,5	NS
Attitudes							
Getting a mammogram may allow me to live longer.	91.0	0,7	95.8	-4,9	91.6	0,6	NS
Getting a mammogram may help detect cancer at an early stage.	95.8	-0,9	95.2	0,9	97.6	-0,9	NS
In getting a mammogram, disease that my be found that I prefer not to know about	66.5	-14,6	56.0	-11,9	63.5	-11,9	NS
I know where I should go if I want to get a mammogram.	42.5	15,8	37.4	41,5	32.3	52,6	a,b
I can get a free mammogram.	53.3	20,4	51.2	35,7	49.1	35,8	a,b
I have no problems in getting to the location where they give mammograms.	50.9	-9,2	45.2	7,1	53.3	-7,5	а
The cost of getting a mammogram is what keeps me from getting one.	68.9	2,3	68.7	-4,6	79.0	-5,8	NS
The time it takes in getting a mammogram is what keeps me from getting one.	17.4	6,3	19.9	-0,3	20.4	-2,1	NS
I am embarrassed of being touched and that is what keeps me from getting a mammogram.	17.4	-0,1	12.0	1,1	19.2	-12	b,c
$\frac{a}{b}$ value < 0.05 for low Intensity vs. Control.							

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 $^{\mathcal{C}}$ p value < 0.05 for Low Intensity vs. High Intensity

b p value < 0.05 for High Intensity vs. Control.