Effectiveness of an mHealth Intervention to Increase Participation in Breast Cancer Screening (Breast Cancer ATICA Study): A Pragmatic Randomized Controlled Trial

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ABSTRACT

Implementation of invitation systems has been shown to increase breast cancer screening rates. However, implementation of active outreach strategies in Latin American programs is limited. We conducted a pragmatic randomized controlled trial—the breast cancer ATICA study—to evaluate the effectiveness and implementation of a digital messaging–based intervention to increase breast cancer screening. A total of 248 Argentinian women ages 50+ years were recruited from 10 health care centers in Santa Fe, Argentina, and randomly assigned (1:1) to the intervention ($n = 123$) or control group ($n = 125$). The intervention included up to four Short Message Service (SMS) messages inviting participants to schedule an appointment for mammography through WhatsApp or the usual care control group ($n = 125$). Effectiveness outcomes were the proportion of women who underwent mammography within 105 or 45 days of enrollment. The reach, effectiveness, adoption, implementation, and maintenance framework was used to evaluate the implementation of the intervention. Our results showed that women in the intervention group ($n = 123$) were significantly more likely than women in the control group ($n = 125$) to undergo a mammography within 105 days (23.6% vs. 6.4%, difference 17%, 95% confidence interval, 7.7%–27.0%) and within 45 days (15.4% vs. 3.2%; difference 12%, 95% confidence interval, 4.3%–20.0%; $P = 0.02$). Our results also showed high acceptability and appropriateness of the intervention. Our study demonstrates that sending consecutive SMS messages, including a WhatsApp number to ask for an appointment, effectively increased breast cancer screening. This mobile health intervention could be an excellent option to improve access to breast cancer screening in low- and middle-resource settings in which active invitation systems are challenging to implement.

Prevention Relevance: Breast cancer remains a significant public health concern, and strategies to improve access to screening are urgently needed. This study is one of the first pragmatic randomized controlled trials in Latin America that demonstrate the effectiveness and real-world implementation of an SMS-based intervention to increase participation in breast cancer screening.

Introduction

Breast cancer is the most common cause of cancer-related death among women worldwide (1). In Latin America, 220,000 new cases are diagnosed each year, and 59,000 women die because of this cancer (1). Access, early detection, and appropriate treatment are needed to reduce the burden of this disease. According to the World Health Organization guidelines (2), in countries with well-established health systems, one mammography every 2 years is effective in reducing mortality in women ages 50 to 74 (2).

Evidence has shown that active invitation systems increase breast cancer screening (3, 4). This means implementing systems that ensure that all target women are invited and access mammographic services irrespective of their socioeconomic condition and past use of health services. Evidence has shown that in high-income countries, sending letters or making calls to invite women increases screening coverage (3–5). However, there are limits to implementing these active search strategies in Latin American programs (6), mainly because of insufficient human, physical, and financial resources to make calls or send letters.

The use of mobile health (mHealth) interventions has been proven to be an effective communication channel between health services and the population (7, 8). mHealth refers to

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Cancer Prev Res 2025;18:757–68

doi: 10.1158/1940-6207.CAPR-25-0225

the use of mobile wireless technologies for public health. mHealth is an important part of eHealth, which refers to the cost-effective and secure use of information and communication technologies in support of heath care. Mobile wireless technologies are particularly relevant due to their ease of use, broad reach, and wide acceptance (7). In particular, digital messaging–based interventions can effectively increase cancer screening uptake and improve other screening-related outcomes such as knowledge and awareness about screening (4–7). Digital messages can be automated, require less staff time, and are simple to use (6). Regarding breast cancer screening, evidence has shown that Short Message Service (SMS) could increase screening coverage compared with other invitation strategies such as letters or calls (4, 5, 9–12). However, all these studies were conducted in high-income countries (e.g., United States, United Kingdom, and Spain). A recent scoping review of reviews carried out by Schliemann and colleagues (4) about the use of mHealth technologies to improve the uptake of cancer screening also showed that few studies were carried out in Latin American countries. For example, Halake and colleagues (13) found that among 15 studies on the use of mobile technology–based interventions designed to support cancer prevention (any cancer), only one was conducted in Latin America (Mexico). To our knowledge, no pragmatic randomized controlled trial (RCT) has been conducted to evaluate the effectiveness of digital messaging–based interventions in increasing breast cancer screening in Latin American countries.

Argentina is one of the countries with the highest incidence and mortality rates in the region, with around 22,000 new cases and 6,500 deaths annually. In addition, 50% of new cases were in women ages 50 and over, and around 70% of death occurs in this population (Supplementary Table S1; ref. 1). Breast cancer screening is opportunistic, and despite several efforts to promote mammography, screening coverage remains low, at around 40% among women with public health insurance (14). Therefore, digital messaging is a strategy that could make a huge difference in the implementation of invitation systems to increase access to mammography.

The cervical cancer ATICA study was a hybrid type I trial that combined a cluster RCT with a mixed-methods evaluation (15). It aimed at assessing the effectiveness and implementation of a multicomponent mHealth intervention that included SMS messages to women and community health workers to increase adherence to triage among human papillomavirus (HPV)-positive women. The cervical cancer ATICA study involved the development of an automated messaging system (MATYS, for its initials in Spanish) connected to the National Information System on Screening (SITAM, for its initials in Spanish) to identify women who sent messages (women with HPV-positive results). The cervical cancer ATICA study showed a 20.5% point improvement in the proportion of women with a triage Pap by day 60 relative to the control group, showing that sending SMS was effective in increasing adherence to triage (15).

Based on this result, we hypothesized that using SMS messages to invite women to undergo mammography could make a real difference in breast cancer screening coverage. The main idea was to adapt the ATICA intervention, which was initially developed for cervical cancer screening, to breast cancer prevention. The use of the cervical cancer ATICA approach was based in several methodologic and practical considerations. First the ATICA intervention demonstrated real-world effectiveness in improving adherence within the cancer care continuum, supporting its applicability to other preventive health areas such as breast cancer screening. Second, the ATICA study is theoretical grounded in the Health Belief Model (HBM), a widely used framework for designing intervention aimed to modifying health preventive practices. Finally, the operational advantages of using a validated and automated platform (MATYS) enabled a rapid and low-cost adaptation and implementation, an essential factor in a resource-limited setting. Therefore, we conducted the breast cancer ATICA study to evaluate a digital messaging–based intervention to increase breast cancer screening.

Materials and Methods

Study design

We conducted a mixed-methods study comprising three phases: (i) formative research using a qualitative approach to inform the design and content of the SMS messages; (ii) a pragmatic RCT (16) to assess the effectiveness of the SMS intervention in increasing breast cancer screening under real conditions using real-world infrastructure, participants, and procedures, and (iii) a post-implementation evaluation.

We used the conceptual approach applied in the cervical cancer ATICA study (15, 17, 18). Thus, the study was guided by the reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework, specifically developed to assess interventions beyond efficacy across multiple public health criteria (19). The RE-AIM framework was integrated into all stages of the research process, including conceptualization (e.g., selecting implementation processes that would be evaluated), data collection, and analysis (18). In addition, we used Proctor's taxonomy of implementation outcomes (20) to measure acceptability and appropriateness, which are essential for understanding the success (or failure) of the implementation of an intervention from the user's perspective.

Our study was conducted in accordance with the Declaration of Helsinki, and it was approved by the Bioethics Review Committee of Santa Fe Ministry of Health. All women signed an informed consent form. The trial was registered with the National Register of Health Research (RENIS, for its initials in Spanish) S003141 and ClinicalTrials.gov NCT06500936.

Setting

The study was conducted in Santa Fe, the capital of the province of Santa Fe, which is located in the central region of

Argentina. It is the third most populated province in the country, with 3,556,000 inhabitants (Censo 2022: https://censo.gob.ar/index.php/datos_definitivos/) of which 30% are women ages 50 and over and around 20% have public health insurance. Approximately 90% of the households have cell phones (21).

The city of Santa Fe has 178 primary health centers, 33 hospitals, and three mammography centers. The screening, diagnosis, and treatment of breast cancer are free of charge. Information about women's characteristics (age, telephone number, residence, health insurance, and previous use of health services) was recorded in the provincial health information system (SICAP, for its initials in Spanish). All information about breast cancer screening in the public health system is recorded in the SITAM.

Participant eligibility and recruitment

A woman was eligible if she was 50 years or older, had not undergone mammography in the past 2 years, had no breast cancer diagnosis, and could provide a mobile phone number. The healthcare center staff invited all eligible women to participate and signed informed consent forms. Recruitment was conducted by trained staff at 10 primary health care centers in Santa Fe City. The healthcare center staff was invited to participate by local stakeholders.

Sample size

In the original study protocol proposed in 2019, before the COVID-19 pandemic, we planned to recruit 800 women (400 allocated to each group) in a second-level hospital over 12 months (March 2020–February 2021). Assuming a breast cancer screening participation rate of 42% in the control group (estimated based on a national survey of risk factors, 2018; ref. 14), the original sample size provided >80% power to detect a 10% point increase in the screening participation rate in the intervention group (two-sided test, $\alpha = 0.05$). On March 19, 2020, a nationwide lockdown was established in Argentina because of the COVID-19 pandemic (22), and all health research activities were suspended. Upon resuming research activities in 2021, recruiting this number of women has become unfeasible, because routine care and cancer screening services in the public health system were still affected during the recovery period. We changed the recruitment strategy and recalculated the sample size. Recruitment was conducted across 10 selected primary healthcare centers over 6 months, in which 248 women were recruited. This sample provided 80% power to detect an 18% point increase in the screening participation rate in the intervention group (two-sided test, $\alpha = 0.05$).

Randomization and masking

Blinding allocation was guaranteed because neither the recruiters nor the field coordinator knew the group to which women would be assigned. The local field coordinator sent a list of recruited women to the study coordinator on a weekly basis. After recruitment, the women were randomly allocated to either the intervention or the control group (1:1 ratio) using a computer-generated random number list created by the study coordinator.

Intervention

The intervention was designed with the participation of women and Santa Fe health authorities in consultation with the staff of the Agency for Cancer Control of Santa Fe. Following the cervical cancer ATICA study approach (17, 18), we conducted formative research to design SMS content (23).

The HBM (24, 25) guided our study. This framework, which is widely used in behavior change interventions (26, 27), has six constructs: (i) perceived susceptibility of getting a disease, (ii) perceived severity of contracting the disease, (iii) perceived barriers to address a recommended behavior, (iv) the individual's evaluation about the benefits–costs of doing it, (v) perceived self-efficacy relating to the confidence in the capacity of attending a health issue, and (vi) external factors that enhance the readiness to follow a new behavior (cues to action; refs. 24, 25, 28). The foundations of the model are the belief in the health-improving or illness-preventing consequences of a specific action and the modification of this belief by sociodemographic characteristics (e.g., age, gender, or educational level). In addition, external action cues, that could be events, individuals, or elements acting as catalysts, can prompt shifts in behavior (24, 25).

Low awareness, knowledge, and understanding about the screening process (e.g., how to get an appointment; refs. 5, 6, 11, 29, 30) are shown as a common barrier to breast cancer screening uptake, and thus the implementation of active invitation systems and reminders is recommended for improving screening coverage (31). Studies have evaluated the effectiveness of SMS messages in improving screening and treatments adherence, as well as (4–6) in reducing nonattendance rates in low- and middle-income countries (6). The advantages of SMS messages include simultaneous delivery to different populations, suitability in case of low–Internet signal areas, and less staff needed (11). Following the HBM, sending an SMS would work as a cue to promote breast cancer screening. In this sense, the SMS must address beliefs, values, and shared perceptions to encourage prevention behavior (23, 32, 33). Nevertheless, sending invitations through SMS may be challenging, as it could evoke emotional reactions that could act as barriers rather than facilitators for action (23).

Evidence underscores the importance of ensuring that SMS messages are culturally appropriate, concise, comprehensible, and carefully worded to avoid causing discomfort to recipients (34–36). Failing to incorporate patients' perceptions in the design of message content may compromise the acceptability and effectiveness of the intervention. Thus, to design the ATICA intervention, we conducted four online focus group discussions to explore women's preferences regarding message content by assessing their perceptions of the positive and negative aspects of each element of the message. Each linguistic component was analyzed based on its potential

to enhance the persuasive impact of the message, encouraging women to undergo mammography. To design persuasive SMS messages, we conducted participatory methods (37). The steps proposed by Abroms and colleagues (38) were taken into account during the design of our health communication strategy. In addition, following Muench and colleagues (39), the SMS was divided into five structural elements (23):

Opening: In the case of ATICA breast cancer, women mentioned that the opening phase would include clear content to capture attention without wasting the recipient's time and selected "*Health information*."

Recipient: The advantages and disadvantages of personalizing the message by including the recipient's name were evaluated. Women indicated that including their name was important to capture greater attention.

Sender: The source of the message was defined to provide legitimacy to its content. In this case, a well-known health institution, such as the "Cancer Control Agency," was considered the most appropriate option.

Focus of the message: We explored how to invite women to participate in breast cancer screening. Women agreed that the message should have an imperative tone, clearly indicating the action to be taken. An informal question was also incorporated to engage the recipients and serve as a reminder: "Women ages 50 to 69 should have a mammogram every two years. Have you already made your appointment?"

In addition, information about how to schedule an appointment was included: "Send a WhatsApp to xxx or an email to xxxx." This information is a key element of the intervention, as it facilitates access to mammogram appointments and aims to reduce one of the main barriers to access in the province.

Closing and call to action: A final sentence was included to reinforce the message's relevance and serve as a cue to action for scheduling a mammogram. This sentence highlights the importance of self-care: "Make your appointment today. It is important!"

The final version of the SMS message is shown in Supplementary Fig. S1.

We also adapted the automated messaging system (MATYS) to send SMS messages inviting women to undergo mammography. MATYS was designed to register data on the delivery and reception of SMS messages; a phone number was considered valid if MATYS did not kick back an error notification signaling that the number was nonexistent.

Women assigned to the intervention group received two series of SMS messages (up to four SMS messages). First, after enrollment, they received a weekly SMS message for 2 weeks. Women who did not have a mammography recorded in the SITAM 45 days after the second message received the second series of one weekly SMS messages over 2 weeks. The 45-day period was based on an average of 30 days to obtain an appointment and perform mammography, plus 15 days to upload the report in the SITAM. Messages were stopped if mammography was registered in the SITAM. Supplementary Fig. S2 shows the outline of the intervention. Women in the intervention group could make appointments through WhatsApp or via email. The staff at the Agency of Cancer Control received WhatsApp messages and assigned appointments.

Women in the control group received standard care, which in this context implied opportunistic screening. This usually involves two visits to the health establishment: one to obtain a mammography referral by a health professional and ask for an appointment, and second, a visit for mammographic screening.

Procedures

Administrative staff of 10 health care centers (recruiters) identified potentially eligible women who attended the health center for any reason. Trained recruiters provided standardized information to all women. They explained the study's objectives and procedures, informed the women that they would be randomly assigned to the intervention or control group, and invited them to participate. As this was a blinded study, both the control and intervention groups received the same initial information. Then, the intervention group additionally received the digital message via SMS. The control group did not receive any further communication. Those who agreed to participate provided informed consent before being enrolled.

The recruiters attended a 1-day training session in November 2021 (Supplementary Fig. S3). The session included presentations about the study design, methods, and ethical considerations, training on recruitment strategies, obtaining informed consent, and registering data in the SICAP, the provincial health information system. These sessions were delivered by ATICA researchers (M. Paolino and V. Sánchez Antelo) and the staff of the Agencia del Control del Cancer de Santa Fe (A. Furia, S. Correa, and G. López De Degani).

Data collection

The pragmatic trial women's recruitment took place between December 2021 and July 7, 2022. Recruiters collected data on women's characteristics and registered the data in the SICAP, the provincial information system: age, place of residence, telephone number, health insurance, name and region of the health center, and date of recruitment. Data on breast cancer screening were extracted from the SITAM. We linked the data from both systems by using each woman's national identity document number.

Effectiveness outcomes (RCT outcomes)

The effectiveness of the intervention (up to four messages) was measured as the percentage of women with mammography recorded in the SITAM within 105 days of recruitment. We also reported the percentage of women with mammography recorded within 45 days of recruitment, which only measured the effect of the first two messages.

Implementation evaluation

Data collection

We evaluated women's perspectives on implementation through a telephone survey among intervention group participants. A list of women in the intervention group and their contact details were extracted from the RCT database. All women in the intervention group were contacted by trained interviewers for phone interviews. Interviews were conducted between September and November 2022. We interviewed 73 (59%) women; 46 women could not be reached, and four refused to answer the telephone survey. The questionnaire included open-ended questions about women's perceptions of the acceptability and appropriateness of the SMS message content.

Implementation outcomes

We evaluated the implementation of the intervention using selected dimensions of the RE-AIM framework (outcome definitions and data sources are presented in **Table 1**; ref. 19).

Reach is the proportion of individuals who receive or are affected by a policy or program. In our study, reach was measured as the percentage of eligible women included in the study and their characteristics.

Effectiveness of the intervention (RCT outcomes) was defined as the percentage of women with mammography 45/105 days after the date of recruitment in the intervention group versus the control group.

Implementation refers to the extent to which an intervention is delivered as intended. In our study, we evaluated the implementation of the intervention using the following indicators: (i) percentage of healthcare centers that enrolled at least one eligible woman, (ii) percentage of SMS messages that reached women's valid phone numbers, (iii) percentage of women in the intervention group who scheduled an appointment, and (iv) percentage of surveyed women who mentioned that they did not receive or did not remember receiving the SMS message.

In addition, following Proctor's taxonomy of implementation outcomes (19), we measured acceptability and appropriateness from the user's perspective. The evaluation of the intervention from the user's perspective is important to identify potential implementation barriers that may have affected the screening uptake (e.g., low acceptability, inappropriate fit, or confusing content). Not considering users' perceptions of the content, design, and context are documented barriers to the acceptability and effectiveness of SMS-based health interventions in other settings (6, 40, 41).

Acceptability was defined as women's perception that the mHealth intervention (SMS message) was either agreeable or satisfactory. We evaluated acceptability by measuring the level of agreement with the statement "An SMS message is a good communication channel to promote breast cancer screening."

Appropriateness was defined as women's perceived fit, relevance, or compatibility with the SMS message as a communication channel to promote breast cancer screening. To evaluate appropriateness, we measured the level of agreement with statements related to different aspects of the intervention: usefulness, frequency and number of messages, confidentiality, comprehension, and pertinence of the content. We used a 5-category response option to measure the level of agreement (strongly agree, agree, neutral, disagree, and strongly disagree) with a set of statements related to the acceptability and appropriateness dimensions (**Table 2**).

Data analysis

Effectiveness

All statistical analysis were conducted on an intention-to-treat basis (42), ensuring all participants were included in the analysis according to their original group allocation, regardless of SMS message reception. Therefore, the estimated effect of ATICA breast cancer reflects the real-world effectiveness of implementing it. We report the percentage of participants who underwent mammography at 105 and 45 days in each group and the difference in percentages between the intervention and control groups alongside 95% confidence intervals (CI) and χ^2 test P values. For each effectiveness outcome, we explored potential effect modification using the following baseline factors: age (50–60 and 60+), health insurance (private and public), health center region (north and south), previous breast cancer screening in the past 10 years (yes and no), and annual average health care visits (≤7 and >7). A logistic model was fitted for each outcome and factor, including the group (intervention and control), factor, and interaction factor × group. We report the estimated effect of the intervention within levels of the modifier and the difference in effect between levels of the modifier and 95% CIs.

Reach and implementation

We conducted a descriptive analysis using frequencies and percentages for each variable included in the reach and implementation dimensions. To measure acceptability and appropriateness for women who mentioned that they had received SMS messages, we reported the percentage of women who strongly agreed or agreed with the acceptability and appropriateness statements out of the total number of women who responded.

We used R Project for Statistical Computing (RRID: SCR_001905) and SAS Statistical Analysis System – SAS (RRID: SCR_008567) version 9.4 for the analysis.

Results

Reach

Figure 1 shows the flowchart of the study. A total of 264 women were invited to participate in this study. Sixteen women were excluded because they did not meet the eligibility criteria (had a mammography in 2021). A total of 248 (93.9%) eligible women were included in the study (123 were allocated to the intervention group and 125 to the control group). The mean age was 57 years old (IQR, 53–62), 77.4% had public health insurance, and 58·1% had not undergone

Table 1. Measurements and data sources for the implementation evaluation based on RE-AIM.

RE-AIM dimension	Indicator	Data source
Reach	% of eligible women that were included in the study	Trial database
Effectiveness	% of women with a mammography recorded in the SITAM within 105 days from recruitment in intervention vs. control groups	Trial database
	% of women with a mammography recorded in the SITAM within 45 days from recruitment in intervention vs. control groups	Trial database
Implementation	% of health care center that enrolled at least one eligible woman in the study	Trial database
	% of SMS messages that reached women's valid phone number	Automated messaging system (MATYS)
	% of women in the intervention group who asked an appointment	Trial database
	% of surveyed women who mentioned that they did not receive or did not remember that they received the SMS message	Women's survey
	Acceptability: % of agreement with the statement "An SMS message is a good communication channel to promote breast cancer screening"	
	Appropriateness: % of agreement with the following appropriateness statements:	
	Usefulness of the SMS as a reminder: "The SMS messages were useful to remind me to get the appointment"	
	Frequency and number of messages : "It bothered me that the SMS messages were many" and "The hours in which I received the SMS messages seemed adequate to me"	
	Confidentiality concerns: "I do not like to receive a SMS message regarding health issues as someone in my family can read it"	
	Pertinence of the content: "When I read the SMS message, I felt that it was intended for me"; "The SMS message had enough information to the schedule the appointment"; and "The SMS message made me aware of the importance of having a mammography"	
	Comprehension: "The SMS was cut off" and "The SMS content was confusing"	

breast cancer screening in the past 10 years. There were no significant differences between the groups in sociodemographic and health system use characteristics (**Table 2**).

Effectiveness

The percentage of women with mammography within 105 days from recruitment was significantly higher in the intervention group (23.6%) than in the control group (6.4%), with 17% point improvement (95% CI, 7.7%–27.0%; $P < 0.001$; **Table 3**).

The percentage of women who underwent mammography within 45 days of recruitment was also significantly higher in the intervention group than in the control group [intervention: 15.5%, control: 3.2%, difference: 12% (95% CI, 4.3%–20.0%); $P < 0.001$; **Table 3**].

Table 4 shows the effect of the intervention (105 and 45 days) on the levels of the different women's characteristics. We observed a higher intervention effect of 105 days among women who were 60 years or older, had undergone cancer screening in the past 10 years, and were more frequent users of the health system. However, the effect modification was not significant for all factors considered (possibly due to a lack of power).

Implementation

All healthcare centers were able to enroll at least one woman in the study (range, 3–88; average 25 per center; **Table 5**).

During the intervention implementation, MATYS reached 110 (89%) valid phone numbers out of the 123 women in the intervention group. Most women (57%) received the whole sequence (four messages). In cases in which fewer messages were delivered, it was because a mammogram was recorded in the SITAM after the first, second, or third message—indicating early uptake of the intervention. When the phone number was not reached, it was because of the registration of an invalid phone number or issues with the network connection.

In total, 61.5% ($n = 75/123$) of women in the intervention group scheduled an appointment. Among them, 53 women used the WhatsApp number provided in the SMS message, whereas 22 women scheduled appointments at the healthcare center.

In the post-implementation survey, 58.9% ($n = 43/73$) of women reported that they did not receive or did not remember receiving the SMS message. Of the 43 women who reported not receiving an SMS, 39 had a record of receiving one message in MATYS. Of these, 13 underwent mammography registered in the SITAM. The other four had an error message recorded in the system.

Regarding *acceptability*, all women who remembered that they had received at least one SMS message ($n = 30$) agreed that SMS messages were a good communication channel for promoting breast cancer screening (**Table 5**).

Table 2. Characteristics of women by study group.

	Total		Intervention		Control		
	n	%	*n*	%	*n*	%	
	248	**100**	**123**	**100**	**125**	**100**	***P* value[a]**
Age							
Median (IQR)	57 (53–62)		57 (53–63)		56 (52–61)		
Age[a]							
(0, 55)	92	37.1	40	32.5	52	41.9	0.2
(55, 60)	68	27.4	36	29.3	32	25.8	
(60, 65)	50	20.2	23	18.7	27	21.8	
(65, 120)	37	14.9	24	19.5	13	10.5	
Health insurance							
Social security[b]	56	22.6	30	24.4	26	20.8	0.5
Public	192	77.4	93	75.6	99	79.2	
Health center region							
North	109	44.0	52	42.3	57	45.6	0.6
South	139	56.0	71	57.7	68	54.4	
Previous breast cancer screening (past 10 years)							
No	144	58.1	70	56.9	74	59.2	0.7
Yes	104	41.9	53	43.1	51	40.8	
Annual average health care visits (any reason)							
Up to 7	120	48.4	62	50.4	58	46.4	0.6
7.1+	128	51.6	61	49.6	67	53.6	

[a]χ^2 test.
[b]Social security" refers to health insurance programs administered by employers (Obras sociales), typically covering workers in the formal employment sector.

Regarding *appropriateness*, nearly all women ($n = 29/30$) agreed that SMS messages were useful in reminding them to schedule appointments. In addition, only three women agreed with the statement "It bothered me that the SMS messages were many," and most women reported that the message timing was appropriate. The pertinence of the SMS content was high, with more than 90% of interviewed women agreeing with positive statements about the SMS content. Message comprehension was also high: only two women mentioned that the SMS content was confusing and that the SMS message was cut off (**Table 5**).

Discussion

To our knowledge, this study is the first pragmatic RCT in Latin America to evaluate the effectiveness and implementation of an SMS-based intervention to increase participation in breast cancer screening in a real-world context. The study was implemented in the public health system using an mHealth evidence-based intervention that was proven effective in increasing access to cervical cancer prevention. Our study showed that sending consecutive SMS messages, including a WhatsApp number to ask for an appointment, was effective in increasing breast cancer screening. Our results also showed that the intervention was highly acceptable and appropriate. Thus, ATICA intervention could be an excellent option to improve access to breast cancer screening in low- and middle-resource settings in which active invitation systems are challenging.

The percentage of women who underwent mammography within 105 and 45 days from recruitment was significantly higher in the intervention group than in the control group. Our results are similar to those of other studies that evaluated the effectiveness of diverse SMS-based strategies to promote breast cancer screening (i.e., SMS messages delivered as reminders of cancer screening appointments, alone or in combination with other communication strategies; refs. 4, 5, 9–12) In these studies, increases in absolute screening rates ranged from 4.5% to 15% (4, 5, 9–12). For example, Kerrison and colleagues (11) showed the effect of a single text message sent 2 days before a breast cancer screening appointment in the United Kingdom. The authors found that women in the SMS group had a 5.3% absolute increase in mammography uptake compared with controls. Another RCT in Spain (10) assessed the impact of an SMS message on mammography screening in a single-blinded trial and found that women who received the intervention were 4.5% more likely to undergo breast cancer screening. Another study in Spain (12) showed that 74.9% of the women who received the SMS reminder and 65.0% of the women who only received the invitation letter attended their appointments. In addition, it showed that women who lived in areas with less reliable postal services benefited more from SMS intervention. In contrast to these studies, which were conducted in organized screening programs, the effectiveness of our strategy was evaluated in the context of an opportunistic program. The main difference between the studies mentioned above is that they assessed the use of SMS messages as reminders of previously assigned appointments. In our research, the message was used to invite women to schedule appointments and provide a

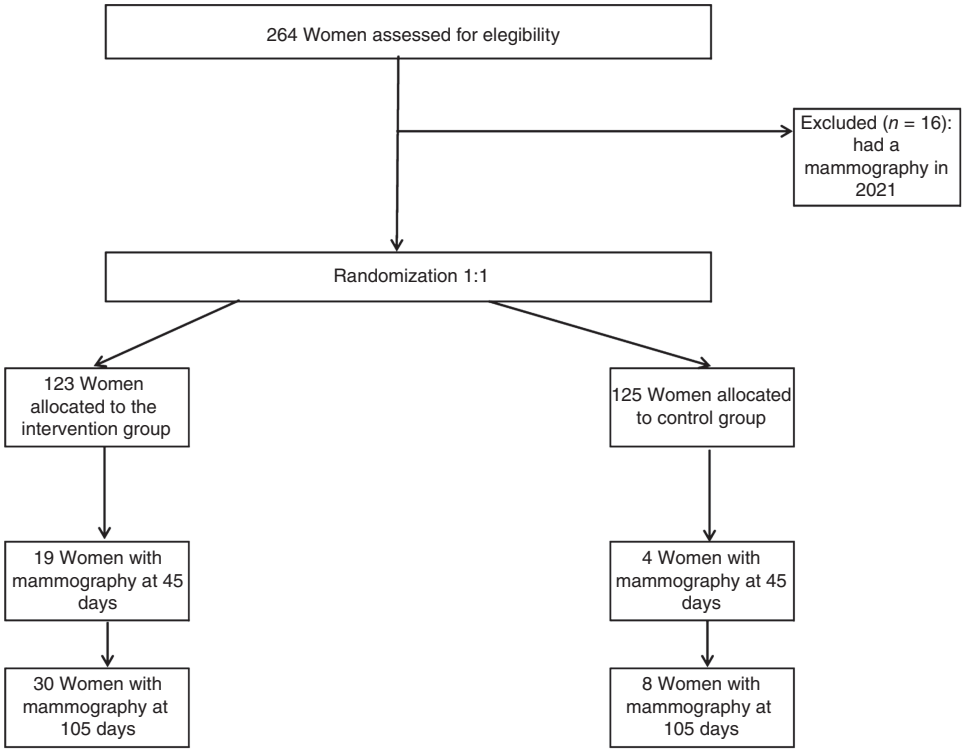

Figure 1.
Trial flow diagram. This figure shows the number of participated women (intervention and control) and number of women with mammography at 45/105 days (intervention and control).

mechanism to do so (WhatsApp number). Despite this difference, the effectiveness observed in our study reinforces the potential of SMS messages to reach populations in contexts in which other invitation methods—such as mailed letters or phone calls—are not feasible. Our results could be helpful in developing strategies that make a difference in access to screening and could contribute to the reduction of breast cancer mortality in Latin America. An additional consideration for future research is whether continued implementation of the intervention could help maintain or even improve long-term adherence to cervical cancer screening. Whereas our study demonstrates the short-term effectiveness of the intervention, sustained screening practices over time are crucial to maximize public health impact. Evaluating the effects of ongoing or booster interventions could provide valuable insights into strategies that support consistent engagement in preventive care.

Evidence has shown that text messages are particularly effective in increasing screening rates among populations living in socioeconomically deprived (11) or hard-to-reach areas (12) or among women in the lower secondary education level (10). In our study, the effect of the intervention was higher among women with public health insurance (i.e., population with low access to health care services); however, these differences were not statistically significant. This may be explained by the lack of statistical power to detect this difference.

However, the high proportion of participants with public health insurance in both groups (78%) reflects that the study was conducted in public health centers primarily serving lower-income populations. As such, whereas the sample may not fully represent the broader provincial population, it is representative of women who are most likely to receive care in these settings and thus most likely to benefit from the intervention. Further research is needed to explore the effects of digital messaging–based interventions on more vulnerable women.

In our study, the higher screening percentages in the intervention group might be related to the high acceptability of the intervention. In our post-implementation survey, all women who received SMS messages agreed that SMS messages were a good communication channel for promoting breast cancer screening. The acceptability reported in our study is consistent with results from the cervical cancer ATICA study (43) and other studies that showed that SMS-based interventions were an acceptable way of providing reminders for medication or appointments (44, 45). This high acceptability is probably explained by the fact that the content and tone of the message were designed collaboratively with target women, taking into account their needs and preferences (23). However, providing information or reminders without addressing institutional barriers to access breast cancer screening is unlikely to reduce disparities (46). A WhatsApp number to ask for an appointment was included in the message. This eliminated an additional visit to schedule the mammography appointment. In the context of middle- and low-income countries with opportunistic programs with low screening coverage, evidence has shown that

Table 3. Intervention effect on effectiveness outcomes.

					Intervention vs. control		
	N	***n***	**%**	**95% CI**	**Difference**	**95% CI**	***P* value**[a]
Mammography within 105 days							
Intervention	123	30	23.6%	(17.0%–32.0%)	17%	7.7%–27.0%	<0.001
Control	125	8	6.4%	(3.0%–13.0%)			
Mammography within 45 days							
Intervention	123	19	15.4%	(9.8%–23.0%)	12%	4.3%–20.0%	0.002
Control	125	4	3.2%	(1.0%–8.5%)			

[a]χ^2 test *P* value.

reducing the number of visits to complete the screening/diagnosis/treatment process is essential to increasing women's adherence to the cancer care continuum. The breast cancer ATICA strategy allowed women to connect with health institutions and reduced the need for additional visits to schedule appointments, reducing travel time, costs, and logistical barriers. Its implementation in routine practice can contribute to increasing the screening coverage.

Despite MATYS reaching 89% of valid phone numbers, 58% ($n = 43$) of women interviewed in the post-implementation survey reported that they had not received or did not remember receiving the messages. Records from MATYS indicate that 39 of these 43 women had, in fact, received at least one message. This suggests that the messages were likely delivered but not remembered. Interestingly, more than 30% of these women (13 of 39) scheduled an appointment and had a mammogram recorded in the SITAM, indicating that the SMS may have had some effect—even if it was indirect or not consciously recalled. This result could be explained by multiple reasons (e.g., women deleted the message before reading it, ignored it, or discarded it). Although the performance of MATYS was similar to that obtained in the cervical cancer ATICA study (15, 23), women's recollection level was lower. One possible explanation lies in the objective of the intervention. In our study, messages were sent to promote breast cancer screening, whereas in the cervical cancer ATICA study, messages were sent to inform women who had already undergone screening that the HPV test results were available in the health center. Thus, these women probably waited for the message, paying more attention to its reception and content.

Although approximately 60% of women in the intervention group scheduled an appointment, the remaining 40% did not. Studies that analyzed the social determinants of access to breast cancer screening found that lack or inadequate knowledge

Table 4. Intervention effect by level of baseline characteristics.

	Mammography within 105 days			Mammography within 45 days		
Characteristic	**Intervention vs. control**	**95% CI%**	***P* value**	**Intervention vs. control**	**95% CI%**	***P* value**
Age						
50–59	16.5%	(5.9% to 27.1%)	0.002	9.6%	(1.1% to 18.2%)	0.027
60+	18.0%	(3.1% to 32.9%)	0.018	16.7%	(4.4% to 28.9%)	0.008
Difference of effect between levels	−2%	(−19.9% to 16.7%)	0.869	−7.0%	(−21.9% to 7.9%)	0.357
Health insurance						
Public	18.6%	(−8.9% to 28.2%)	0.000	12.0%	(4.0% to 20.0%)	0.003
Private	11.8%	(−7.7% to 31.3%)	0.236	12.8%	(−2.5% to 28.1%)	0.099
Difference of effect between levels	6.8%	(−14.9% to 28.6%)	0.539	−0.8%	(−18.0% to 16.4%)	0.928
Breast cancer screening in the past 10 years						
No	11.7%	(1.5% to 22.0%)	0.024	7.4%	(−1.3% to 16.1%)	0.097
Yes	24.2%	(9.7% to 38.8%)	0.001	18.8%	(7.2% to 30.4%)	0.001
Difference of effect between levels	−12.5%	(−30.3% to 5.3%)	0.169	−11.4%	(−25.9% to 3.1%)	0.122
Health center region						
North	16.1%	(2.8% to 29.3%)	0.017	15.6%	(4.7% to 26.4%)	0.005
South	18.1%	(6.7% to 29.5%)	0.002	9.7%	(0.2% to 19.1%)	0.045
Difference of effect between levels	−2.0%	(−19.5% to 15.5%)	0.822	5.9%	(-8.5% to 20.3%)	0.423
Annual average number of health care visits (any reason)						
7+	23.5%	(10.8% to 36.3%)	0.000	18.3%	(7.3% to 29.4%)	0.001
Up to 7	10.8%	(−0.7% to 22.4%)	0.065	6.3%	(2.5% to 14.9%)	0.162
Difference of effect between levels	12.7%	(−4.5% to 29.9%)	0.148	12.1%	(−2.0% to 26.2%)	0.092

For each characteristic, intervention effects within levels of the characteristics and comparisons between levels were estimated from a logistic model including intervention characteristics and their interaction.

Table 5. Implementation evaluation: reach, effectiveness, and implementation measurements.

RE-AIM dimension	Indicator	Value
Reach	% of eligible women that were included in the study	93.9%
Effectiveness	% women with mammography 105 days from recruitment in intervention vs. control groups	23.6% vs. 6.4%
	% of women with mammography 45 days from recruitment in intervention vs. control groups	15.4% vs 3.2%
Implementation	% of health care center that enrolled at least one eligible woman in the study	100% (n = 10/10)
	% of SMS messages that reached women's valid phone numbers	89% (n = 110/123)
	% of women in the intervention group who scheduled an appointment	61.5% (n = 75/123)
	% of surveyed women who mentioned that they did not receive or did not remember that they received the SMS message	58.9% (n = 43/73)
	Acceptability: "An SMS message is a good communication channel to promote breast cancer screening"	100% (30/30)
	Appropriateness:	
	"The SMS messages were useful to remind me to get the appointment"	96.7% (29/30)
	"It bothered me that the SMS messages were many"	10.0% (3/30)
	"The hours in which I received the SMS messages seemed adequate to me"	90.0 (27/30)
	"I do not like to receive a SMS message regarding health issues as someone in my family can read it"	6.7% (2/30)
	"When I read the SMS message, I felt that it was intended for me"	90.0 (27/30)
	"The SMS message had enough information to the schedule the appointment"	93.3% (28/30)
	"The SMS message made me aware of the importance of having a mammography"	93.3% (28/30)
	"The SMS was cut off"	6.7% (2/30)
	"The SMS content was confusing"	6.7% (2/30)

about the benefits of mammography, perceived absence of symptoms such as absence of disease, fear of disease, embarrassment, and possible stigma act as barriers to mammography screening (47). Other factors mentioned in several studies were lack of time due to the burden of caregiving and forgetting the appointment (47). Considering these barriers, future interventions should consider incorporating instant messaging apps such as WhatsApp to replace SMS text messaging because the number of users is increasing exponentially worldwide, and more educational information (e.g., videos, audio messages, or graphics) could be shared. In addition, our team is working on designing an app to provide information and support to HPV-positive women (48). Its implementation may not be limited to cervical cancer prevention. The app might be adapted to provide information and support regarding breast cancer prevention and could contribute to further increasing participation in breast cancer screening.

One study limitation relates to the potential for shared phone used. This is a common challenge in real-world mHealth interventions. Although we could not confirm that the intended recipient read the messages directly, MATYS provided delivery confirmation, indicating that the SMS message was sent to the designated phone number. Although delivery does not ensure exposure, evidence from the women's survey showed that only 15% of women share phones with any member of their family (11 of 73 women that participated in the women's survey), suggesting that in most cases, the messages likely reached the intended women. Another limitation of our study is that, to evaluate implementation, we conducted a telephone survey, which usually has lower response rates than face-to-face surveys. In addition, the fact that a low proportion of women remember that they had received the SMS message may be explained by recall bias or limitations in the survey design, particularly considering that the survey was conducted by telephone. It is possible that some participants saw and processed the message but did not recall it at the time of the interview. Thus, acceptability and appropriateness outcomes could only be measured in a limited group of women. This may have affected the results. However, the results on the acceptability and appropriateness of the intervention were consistent with the acceptability reported in the cervical cancer ATICA study and other studies that showed that tailored SMS content is highly acceptable to users.

An important strength of our study is that the effectiveness was measured under real conditions. The trial included a broad population without restrictive eligibility criteria, and the control group received usual care, reflecting standard practice. Outcomes were measured based on information registered in the National Screening Information System, in which all mammographies performed in the public health system are registered, and no attempts were made to enforce adherence to breast cancer screening. Finally, the analysis was conducted under an intention-to-treat approach, ensuring that findings reflect the real-world impact of offering the intervention rather than controlled scenarios.

In conclusion, sending SMS messages that include a WhatsApp number to schedule a mammography appointment effectively increases breast cancer screening. Our

study provides evidence on how an mHealth intervention can improve the quality and effectiveness of the breast cancer screening process in a Latin American country, which can be helpful in similar low- and middle-income settings.

Data Availability

Deidentified individual participant data, on which summary statistics and tables are based, and other study materials, such as forms and questionnaires, are available upon request from the corresponding author.

Authors' Disclosures

M. Paolino, V. Sánchez Antelo, J.D. Mazzadi, and S. Arrossi report grants from the NCI of Argentina (Asistencia Financiera a Proyectos de Investigación en Cáncer de Origen Nacional V) during the conduct of the study. No disclosures were reported by the other authors.

Authors' Contributions

M. Paolino: Conceptualization, Data curation, Supervision, Writing–original draft, Project administration. **V. Sánchez Antelo:** Conceptualization, Investigation, Writing–review and editing. **L. Orellana:** Data curation, Formal analysis, Writing–review and editing. **S. Correa:** Investigation, Writing–review and editing. **J.D. Mazzadi:** Data curation, Writing–review and editing. **A. Furia:** Investigation, Writing–review and editing. **M.E. Strochero:** Investigation, Writing–review and editing. **G. López De Degani:** Writing–review and editing. **S. Arrossi:** Conceptualization, Supervision, Writing–review and editing.

Acknowledgments

The breast cancer ATICA study was funded by the NCI of Argentina. M. Paolino, as principal investigator, received a grant from the NCI of Argentina (Asistencia Financiera a Proyectos de Investigación en Cáncer de Origen Nacional V). The content is the sole responsibility of the authors and does not necessarily represent the official views of the NCI of Argentina. The study was led by the Center for the Study of State and Society in collaboration with the Agency of Cancer Control of the Ministry of Santa Fe. The authors would like to thank all the staff of the Agency of Cancer Control of the Ministry of Health for their support and all the staff of the 10 primary health care centers who carried out the RCT recruitment. We also thank the interviewers who carried out the women's survey, Laura Livieri, Isabel Tripodi, and Paula Frejdkes, for their administrative support and Marisa D Alessandro for help with English edition. Finally, we thank the women who participated in this study.

While writing this manuscript, we used Grammarly to improve the English writing. After using this tool, the authors reviewed and edited the content as needed and took full responsibility for the content of the publication.

Note

Supplementary data for this article are available at Cancer Prevention Research Online (http://cancerprevres.aacrjournals.org/).

Received June 13, 2025; revised July 10, 2025; accepted July 22, 2025; posted first July 23, 2025.

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