Effectiveness of a Breast and Cervical Cancer Screening Promotion Program for Low-Income Puerto Rican Women

Vivian Colón-López[1,2,3], Camille Vélez[3], Marievelisse Soto-Salgado[3,4], Ileska M. Valencia-Torres[5], Lara Savas[5], Natalie Fernández-Espada[5], William A. Calo[6], Angela Pattatuci[7], María E. Fernández[5]

1. Department of Health Services Administration, Graduate School of Public Health, Medical Sciences Campus, University of Puerto Rico, San Juan, Puerto Rico. 2. Division of Cancer Control and Population Health, University of Puerto Rico Comprehensive Cancer Center, San Juan, Puerto Rico. 3. UPR-MDACC Partnership for Excellence in Cancer Research Program, University of Puerto Rico, Medical Sciences Campus, San Juan, Puerto Rico. 4. Department of Biochemistry, School of Medicine, Medical Sciences Campus, University of Puerto Rico, San Juan, Puerto Rico. 5. The University of Texas School of Public Health, Center for Health Promotion and Prevention Research, Houston, Texas. 6. Penn State College of Medicine, Department of Public Health Sciences, Hershey, Pennsylvania. 7. Retired

Corresponding Author: María E. Fernández, PhD. Email: Maria.E.Fernandez@uth.tmc.edu
University of Texas Health Science Center at Houston, Center for Health Promotion and Prevention Research.
7000 Fannin Street, Suite 2080, Houston, Texas 77030
Phone: (713) 500-9626 | Fax: (713) 500-9750

Funding: This work was supported by the NCI/National Institutes of Health under Grant [U54CA096297]; NCI through a Community Networks Program Center under Grant [U54 CA153505]; and the National Institute on Minority Health and Health Disparities of the National Institutes of Health under Award Number [2U54MD007587].

Conflicts of Interest/Competing Interests: The authors have no relevant financial or non-financial interests to disclose.

Ethics approval: The institutional review boards of the University of Puerto Rico Medical Sciences Campus and the University of Texas Health Science Center approved the study protocol.

Abstract: 236 words **Main text:** 3498 words

Abstract

The purpose of the study was to assess the effectiveness of a Lay Health Worker (LHW) delivered intervention to increase mammography and Papanicolaou (Pap) screening among non-adherent Hispanic women. We conducted a randomized controlled trial in Puerto Rico using a pre-post comparison group design. Eligible women (40 and older and non-adherent to mammography or Pap test screening recommendations) completed a baseline survey and were randomly assigned to the intervention or to a comparison condition. The intervention consisted of an LHW delivered session in which participants received mammography and/or Pat test screening education, and referral to local breast and cervical cancer screening providers. Among the 444 women recruited, 302 and 267 were non-adherent to mammography and Pap test respectively. Lay Health Workers delivered the intervention in women's homes and administered follow-up surveys. Women who received the intervention were 2.4 (95% CI: 1.2, 5.1) times more likely to report having had a Pap than those in the comparison group. Secondary analyses on intermediate impact variables showed that the intervention group had significantly higher self-efficacy scores for Pap test screening. There were no statistically significant differences in mammography screening between groups (OR= 0.94; CI 0.52-1.75). The intervention was effective for increasing Pap screening, but not for mammography. Possible reasons for failure to detect screening differences between the intervention and comparison group for mammography include a potential measurement effect, the possibility that the intervention was insufficiently culturally-adapted, and other factors.

ClinicalTrials.gov Identifier: NCT04617236

Keywords: Breast and cervical cancer, BCCS screening, Hispanic/Latina, Lay Health worker intervention, Puerto Rico

Introduction

Breast cancer is the primary cause of cancer mortality among women in Puerto Rico (PR), and cervical cancer is the seventh most commonly diagnosed and sixth most common cause of cancer-related death in PR.[1] Although evidence-based guidelines recommend breast and cervical cancer screening (BCCS), mammography and Papanicolaou (Pap) screening remain underutilized among Hispanic women including Puerto Ricans; representing missed opportunities for prevention and early detection. Despite the availability of *Vital*, a government-sponsored health insurance for individuals at or below 200% of the federal poverty level which provides primary care coverage to 63% of the women older than 21 years in PR[2], BCCS rates remain suboptimal.

Among age-eligible PR women, mammogram (70.4%) and cervical cancer screening (79.3%)[3] rates for 2020 fell below the Healthy People 2020 goal of 81.1% and 93%, respectively. Frequently reported screening barriers for Puerto Ricans[4, 5] are similar to those reported among Hispanics. These include lack of health insurance,[5-6] regular source of health care,[5,7-8] physician referral,[5] transportation,[8] cost,[6-8] time,[5] low health literacy,[6] procrastination,[5] fear of exam or diagnosis,[5] and confusion about recommendations due to inconsistencies in screening guidelines[4].

The Community Preventive Task Force (CPSTF) recommends the implementation of effective interventions focused on increasing screening practices among underinsured, uninsured, or low-literacy minority women include mass media, group education, small media, and one-on-one, community health worker (CHW) or lay health workers (LHW) delivered interventions, or a combination of these strategies.[9-11] Among Hispanic women, research shows that effective cancer prevention programs have employed Spanish-language media,[12] combined peer role models in media with positive social reinforcement,[13] "small media",[14] and LHWs.[7, 12,15] The LHW model uses peer health education, delivered by community members to educate other members in a culturally appropriate manner. This interpersonal method facilitates culturally appropriate communication and a more natural connection between health services and the community. Research supports the effectiveness of LHW programs for increasing BCCS among diverse populations and a recent systematic review and meta-analysis led to a new US Preventive Services Task Force recommendation for use of LHW for BCCS.[9] The review indicated that, compared with no intervention or usual care, LHW interventions increased cervical cancer screening by a median of 12.8 percentage points[16] and breast cancer screening by a median of 12.7 percentage points.[17] The review also showed that LHW programs that focused both on increasing education and motivation for screening as well as improving access to screening services, showed the highest impact on screening and that the LHW programs were cost-effective.

Despite evidence about the effectiveness of LHW programs for BCCS in general, there are no published studies of interventions to increase BCCS among women living in PR. Additionally, it is unclear whether interventions developed for other Hispanic populations could be effective for increasing screening in PR. The purpose of this study was to evaluate the effectiveness of a minimally-adapted evidence-based intervention known as *Cultivando la Salud* (Cultivating Health) on increasing mammography and Pap screening among women in PR.

Methods

Cultivando la Salud (CLS), is an LHW-delivered BCCS educational intervention that was first developed in 2005 through funding by the Centers for Disease Control and Prevention by the National Center for Farmworker Health and the UTHealth Center for Health Promotion and Prevention Research.[18-19] The purpose of the intervention was to increase BCCS among low-income Hispanic women living in farmworker communities in Texas and California. Intervention materials included an LHW training curriculum, a DVD with a novella style video, and a flip chart. The CLS program was effective in increasing BCCS among women aged 50 or older in the original trial.[18] The program was later updated and adapted to be more appropriate for the general population of low-income Hispanic women in the US and found to be effective in populations in Houston and in El Paso. Although adapted and updated based on recommendations, the program has thus far only been tested among women Hispanic women who were primary of Mexican and/or Central American descent in Texas and not other Hispanics such as Puerto Ricans.[20-21]

The team used IM Adapt, a process based on Intervention Mapping to plan the adaptation of evidence-based interventions.[22-23] Research staff conducted focus groups to identify factors influencing BCCS among women in PR. Findings indicated that many psychosocial factors influencing BCCS among these women were similar to those already addressed in latest version of CLS. Factors included knowledge about recommended screening, self-efficacy, attitudes about screening, risk perceptions, and social norms. External factors such as access to low-cost or free screening, were different in PR, since *Vital* is available to virtually all PR women (as compared to low-income US Hispanic women) and it provides regular preventive care, diagnostic tests, treatment, medication, and referral to specialist services as needed.[24]

Guided by IM Adapt, we set out to create a second adaptation to CLS, with the aim of tailoring the intervention to a different population (Hispanic women in PR vs. the target population of original and 1st adaptation versions – women of Mexican descent living in the US). We first created a logic model of change taking into consideration the new contextual and psychosocial factors influencing screening.

We systematically mapped the performance objectives and psychosocial determinants of screening. We then created performance objectives matrices and compared these to the original program's objectives, and further compared the methods and practical applications used in CLS to determine if they were appropriate for the PR population. Following this process, we determined that, because the specific actions and the determinants that seemed to be influencing BCCS were very similar to those addressed in the original program, only a minimal content adaptation would be required. Specifically, we would need to include information regarding access to screening and the steps required to get an appointment. While the analysis described above addressed the "deep structure" changes necessary in the intervention, it did not address the "surface structure" adaptation needs (i.e. changes in the look and feel of the intervention to match cultural preferences).[25] For example, we did not believe that the video would be appropriate primarily because it depicted women of Mexican origin living in farmworker communities in the US. Our previous research[23] showed that physical ethnic similarity influences attitudes towards media and health promotion messages among PR women. While we were cognizant of the fact that PR women may not identify with some of the images, because of budgetary constraints, we could only make the following changes: 1) omit the video since the images and characters were clearly Mexican American farmworker women; 2) maintain use of the training curriculum to prepare LHWs for implementation, adding a list of local resources, 3) use the implementation protocol and the flipchart, and 4) modify the original program's inclusion of breast self-exam instruction (due to changes in recommendation guidelines). Instead, the LHWs discussed "breast health awareness", talked about noticing changes, and emphasized the importance of mammography.

Study design. We conducted a randomized controlled trial using a pre-post comparison group design (Fig. 1) in Canóvanas. This urban municipality has a higher breast and moderate cervical cancer incidence and mortality rates, than other municipalities in PR.[1] Another factor influencing this selection was the presence of *Taller Salud, Inc.*, a community-based organization experienced in providing LHW-delivered interventions to medically underserved women in the area.

Eligibility criteria included ages 21 and older for the Pap cohort and 40 and older for the mammography cohort, non-adherence to American Cancer Society breast and/or cervical cancer screening guidelines at the time of the study (women ages 21-65 with no Pap in the past three years; and aged 40 and older with no mammography in the past year), not currently pregnant, and no history of cancer or hysterectomy.

Staff visited each household within randomly selected census blocks, screened potential participants, completed informed consent, and conducted baseline surveys on one eligible woman per

household. If more than one was eligible, the woman with the most recent birthday was invited to participate. Prior to interviewing, we randomly assigned recruited women to a study group (intervention/control). All data collection procedures were conducted over a 12-month period (July 2012 to June 2013); including follow-up data 4-6 months post education session (intervention) or post-baseline survey (control). All participants received breast or cervical cancer screening educational brochures and a $20 incentive after completing the baseline and follow-up interviews. Data were collected using REDCap. Study protocol was approved by the University of Puerto Rico Medical Sciences Campus Institutional Review Board.

Once recruited, participants in the intervention group were scheduled for face-to-face session at their homes. Sessions consisted of an individualized presentation and discussion using CLS flipchart. LHWs delivered sessions according to non-adherence status: breast, cervical, or both. Each session lasted between 45-90 minutes (longer for participants who received both mammography and Pap education). At the end of each session, participants were provided with information about local BCCS providers.

We adapted all data collection instruments from the original CLS study.[18-19] These included validated measures of the psychosocial constructs targeted by the intervention: perceived pros and cons of mammography screening, mammography self-efficacy and subjective norms, and Pap test self-efficacy and subjective norms. All psychosocial items were assessed with 5-point Likert-type scales. The internal consistency scores (Cronbach alpha) of these scales at baseline were: perceived pros and cons of mammography = 0.63 and 0.56, respectively, self-efficacy for mammography and Pap test screening = 0.79 and 0.82, respectively, and subjective norms for mammography and Pap test screening = 0.72 and 0.73, respectively. Screening behavior status at baseline and 6-month follow-up were assessed by asking women the month and year of their last mammogram and Pap test.

The mammography cohort was composed by 301 participants, of which 176 were unique participants (only non-adherent to mammography) and 125 women were non-adherent to both screening guidelines. For the Pap cohort, 253 women were not adherent to Pap guidelines. This cohort includes a total of 120 participants who were not adherent to both screening guidelines. For the purpose of analysis, only two groups are considered (Mammography and Pap Cohorts). Both groups include participants who are unique to the cohort screening and those that might be non-adherent to both guidelines.

Analyses. We conducted descriptive analyses using frequency distributions to assess categorical variables and summary measures to assess continuous variables. We conducted univariate analyses

using logistic regression to determine which variables would be included in the multivariable models. For determining the effect of the intervention on screening completion, we used multivariable logistic regression. We tested for interactions in both models using the Likelihood Ratio (LR) test.

***Mammography cohort*:** The multivariable logistic model was adjusted by age at interview, education and health insurance given that these variables were associated with the outcome ($p<0.25$) in the univariate logistic regression model. All possible interaction terms among study group, age, education and health insurance were not significant (LR test: 10.79, $p=0.21$).

Pap cohort: The model was adjusted by marital status given that this was the only variable that reached significance ($p<0.25$) in the univariate logistic regression model. Interaction terms among study group and marital status were not significant (LR test: 2.10, $p=0.35$).

We conducted all analyses by cohort with each including women who were non-adherent; women non-adherent to both types of screening were included in both cohorts. We conducted both per-protocol and per intent-to-treat analyses. We first included only women reached for follow-up for per protocol analysis; then included all women enrolled at baseline, regardless of whether they were reached for follow-up surveys (intent-to-treat analysis). To assess the impact of the intervention on potential treatment mechanisms (e.g., self-efficacy, subjective norms), we first calculated scale scores for each construct then compared scores at follow-up (posttest) between the intervention and control groups using a generalized linear mixed model adjusting for the mean pre-test score.

Results

Demographic characteristics of each cohort are summarized in Table 1. The average age in the mammography and Pap cohort was 54 and 46 years, respectively. In both cohorts, the majority of women reported having annual household income below $15,000 and having private or government-sponsored health insurance coverage. Half of the study population had not completed high school. Most reported no family history of either breast or cervical cancer. In the mammography cohort, both intervention and control groups were comparable in terms of demographic characteristics and psychosocial constructs measured at baseline. In the Pap cohort, the control group had significantly lower income compared to the intervention group (P=.035); no other differences were observed. We controlled for income in both per-protocol and intent-to-treat analyses. LHWs completed intervention sessions with 90% of the women assigned to intervention groups. The overall study follow-up rate was 91%. In the mammography cohort, follow-up rates were 95% and 88% for control and intervention groups, respectively, while in the Pap cohort rates were 96% and 86% for control and intervention,

respectively. There were no statistically significant differences in demographic characteristics between participants contacted for follow-up and those lost to follow-up.

In both, the per-protocol and intent-to-treat analyses, we observed no difference in mammography screening completion between intervention and control groups (Table 2). In the Pap cohort, a significantly higher percentage of women in the intervention group than in the control completed screening (Per-protocol analysis: 21.7% vs 11.7%, respectively). This difference in Pap completion among study groups was retained in the intent-to-treat analysis. After adjusting for marital status, women who received the intervention were 2.14 (95% CI: 1.02, 4.46) times more likely to report having had a Pap test compared to those in the control group. We found no significant interactions in the multivariate model for mammography (LR X^2 =10.79, p=0.21) or Pap test (LR X^2 =2.10, p=0.35).

Analyses of the intervention effect on psychosocial variables were studied. Mean scores for mammography self-efficacy and perceived mammography "pros" were higher for women in the intervention group than the control group at baseline, but these differences were not significant. There were also no significant posttest differences between the intervention and control groups in perceived mammography "cons" and subjective norms. For Pap test, subjective norm was significantly higher for women in the intervention group as were Pap test self-efficacy score (Table 3).

Discussion

This study aimed to evaluate the impact of a minimally adapted version of the CLS LHW-delivered BCCS program. Findings indicate that the program was effective for increasing Pap screening among PR women. It was not effective, however, for increasing mammography screening. Upon further examination of findings, it appears that there was a substantial increase in mammography screening among women in both the intervention and the control conditions. That is, in both the mammography and Pap intervention groups, about 21% of women completed screening. But, while the screening-completion rate of the Pap-intervention-group was significantly higher compared with the Pap-control group, in the Mammogram cohort the screening completion rate for both intervention- and control-groups was materially the same (with both achieving increases in screening completion rate, compared to baseline). This may have been due to other mammography education and community-based efforts being implemented in PR during the time of the study. For example, the community-based organization, *Taller Salud* and others local community-based efforts at breast cancer awareness may have obscured our ability to detect an intervention-effect on mammography screening due to the CLS program.

Another potential factor that may have influenced higher uptake of mammography but not Pap test screening in the control group is differences in how resistant unscreened women were to each

behavior. The prevalence of mammography during the study period (2012 & 2014) was 76.6% and 79.9%, respectively.[3] Given this prevalence of mammography at a population level, there were likely more women in the mammography cohort who were not necessarily resistant to getting screened but simply needed information about guidance on where get screened. By contrast, there is a lower population prevalence of Pap screening at a population level in PR. The prevalence of pap during the period of our study (2012-2014 (was 70.9% vs. 74.4%)[3]. Therefore, women who continue to be non-adherent to Pap screening recommendations (and recruited into our study) likely represent individuals who are more resistant to screening and may require more intensive interventions (such as CLS) to motivate and facilitate Pap screening. In other words, the threshold for changing the behavior of women who were not in up-to-date with mammography recommendations could have been lower (compared to this 'threshold' for women who were not up-to-date with Pap). Therefore, women who did not receive the Pap screening intervention (control group) were significantly less likely to get screened as those in the intervention group. For mammography, on the other hand, because there may be more individuals who are non-adherent simply because they were not aware of recommendations or had questions about where to get screened, more women in the control group received screening.

The CPSTF recommends for the implementation of one-on-one community health worker-delivered interventions using small media, such as CLS, to increase mammography in underserved communities.[17] Perhaps, these women may simply need a "cue to action" provided by the surveys and the basic educational information given to all women. In future efforts, CLS educational materials including small media, should be fully adapted to address the aforementioned barriers and include cues to action that motivate this group of women to complete their cervical and breast cancer screenings.

Our study aimed to determine whether a minimally adapted intervention would be effective for increasing mammography and Pap screening in PR. Using needs assessment data collected in PR and applying a systematic analysis and planning process for needed adaptations, we determined that many of the factors influencing screening among PR women were similar to those identified and addressed in the original evidence-based program. While we would have preferred to include more images of PR women and materials that reflected PR culture, there was no funding available to make these "surface structure" changes. Because of limited resources in many public health settings, the question about whether or not minimally adapted intervention is effective in different settings and in this case, across Hispanic subgroups, is an important one; our study demonstrated that it was effective, at least in the case of cervical cancer screening. It is plausible that the factors described above limited our ability to detect differences between intervention and comparison conditions for mammography.

Regardless of whether or not a more extensive adaptation would have increased effectiveness of the program for mammography screening, there is a clear preference for materials that reflect population characteristics and settings. Following the conclusion of the study, we convened a roundtable meeting with community partners, collaborators, recruiters, health promoters, and the research staff to discuss the CLS study, educational materials used, and preliminary study results. Attendees felt that the study flipchart was an excellent tool and that it was both useful and effective in guiding the discussion with study participants. Nevertheless, they suggested adapting some of the flipchart's images to better reflect the cultural reality of the participants. More research is needed to explore the effectiveness of adapted interventions across groups and settings and the need for in-depth cultural adaptation. This is particularly relevant when adapting interventions developed for one Hispanic cultural group, to another, particularly when the content of the intervention does not need to change much (because psychosocial factors influencing the health behaviors are similar).

In PR, although existing programs provide services to low income women for both breast and cervical cancer including the National Breast and Cervical Cancer Early Detection Program, to our knowledge, BCCS interventions using LHWs have not previously been used. However, now there is a specific recommendation from the CPSTF for interventions using LHWs for increasing both BCCS. The findings of this study - related to the effectiveness of LHWs for increasing cervical cancer screening - are consistent with the CPSTF recommendation based on a systematic review of 29 studies that evaluated intervention effects on cervical cancer screening.[16] The data from this study and mounting evidence from the CPSTF systematic review support the important role that LHW interventions can have on reducing the cancer burden among Hispanic populations. In PR specifically, despite broad availability of healthcare coverage, using LHWs to both increase demand for BCCS and improve access has substantial promise.

Strengths and Limitations

This study has substantial strengths, including: the use of a systematic process for program adaptation; the conduct of the study in a real-world setting implemented by community-based LHWs employed by a community-based organization, and; high rates of follow-up. A critical step in the adaptation of the intervention was to determine what content needed to change and what should be maintained. This was done using a systematic process that includes careful analysis of the needs of the target community, a detailed description of the components of the existing program and a systematic comparison between the two.[22-23] The fact that the intervention was delivered by a local community-

based organization improves the external validity of findings and the potential sustainability of the program.

Nevertheless, the study was limited in several ways: (1) Limited funds were available for adaptation of the visual elements of the program; (2) A rigorous assessment of ongoing community-based prevention work – which could have influenced behaviors – was not performed; the sample size was relatively small.

Table 1. Demographic characteristics of study participants: CLS Intervention

	Mammography cohort n=301*			Pap Cohort n=253*		
	Control n (%)	Intervention n(%)	p-value**	Control n (%)	Intervention n(%)	p-value**
Age (mean ± SD)	55.8 ± 10.4	54.8 ± 10.8	0.31	46.5 ± 15.3	46.3 ± 15.2	0.95
Education (years)			0.54			0.70
≤ 12	79 (57.3)	87 (53.7)		61 (51.7)	66 (49.3)	
> 12	59 (42.7)	75 (46.3)		57 (48.3)	68 (50.7)	
Marital status			0.46			0.91
Never married	21 (15.2)	21 (12.9)		28 (23.7)	29 (21.5)	
Married or living together	74 (53.6)	99 (60.7)		67 (56.8)	79 (58.5)	
Divorced, separated or widowed	43 (31.2)	43 (26.4)		23 (19.5)	27 (20.0)	
Income			0.20			0.05
< $15,000	94 (71.7)	99 (64.7)		89 (79.5)	85 (68.0)	
≥ $15,000	37 (28.2)	54 (35.3)		23 (20.5)	40 (32.0)	
Health insurance coverage			0.49			0.72
Private	52 (37.9)	69 (42.3)		45 (38.8)	54 (40.3)	
Public	69 (50.4)	81 (49.7)		56 (48.3)	67 (50.0)	
None	16 (11.7)	13 (8.0)		15 (12.9)	13 (9.7)	
Family history of breast cancer			0.67			0.12
Yes	30 (21.9)	32 (19.9)		30 (26.1)	23 (17.8)	
No	107 (78.1)	129 (80.1)		85 (73.9)	106 (82.2)	
Family history of cervical cancer			0.71			0.14
Yes	21 (15.6)	27 (17.2)		19 (16.5)	13 (10.1)	
No	114 (84.4)	130 (82.8)		96 (83.5)	116 (89.9)	

*120 participants were in both cohorts (non-adherent to both behaviors).

**p-value from Chi-square or Fisher's exact test for categorical variables and Mann-Whitney test for continuous variables.

Table 2. Screening completion by study group: CLS Intervention and Logistic regression models to evaluate the effect of the intervention on mammography and Pap test screening adjusted by income

	Intervention Group N (%)	Control Group N (%)	$POR_{unadjusted}$ (95% CI)	$POR_{adjusted}$* (95% CI)
Mammography cohort				
Per-protocol-analysis	29/136 (21.3%)	27/122 (22.1%)	0.95 (0.53 – 1.72) N=258	0.97 (0.53 – 1.78) N= 243
Intent-to-treat	29/163 (17.8%)	27/138 (19.6%)	0.89 (0.50 – 1.59) N= 301	0.98 (0.53-1.78) N= 283
Pap test cohort				
Per-protocol-analysis	25/115 (21.7%)	13/111 (11.7%)	**2.09 (1.01 – 4.34)** N= 226	**2.14 (1.02 – 4.46)** N= 208
Intent-to-treat	25/135 (18.5%)	13/118 (11.2%)	1.84 (0.89 – 3.78) N= 253	1.85 (0.89 – 3.83) N= 234

Notes:

Intent-to-treat: represents the percentage of women who reported having completed screening among all non-adherent women regardless of follow-up.

Per-protocol-analysis: represents the percentage of women who reported having completed screening for each behavior outcome among those reached for follow-up.

Variations in the sample size between unadjusted and adjusted models were due to missing information in the covariates.

**Mammography cohort*: The model was adjusted by age at interview, education and health insurance given that these variables reached significance ($p<0.25$) in the univariate logistic regression model. All possible interaction terms among study group, age at interview, education and health insurance were not significant (LR test: 10.79, $p=0.21$).

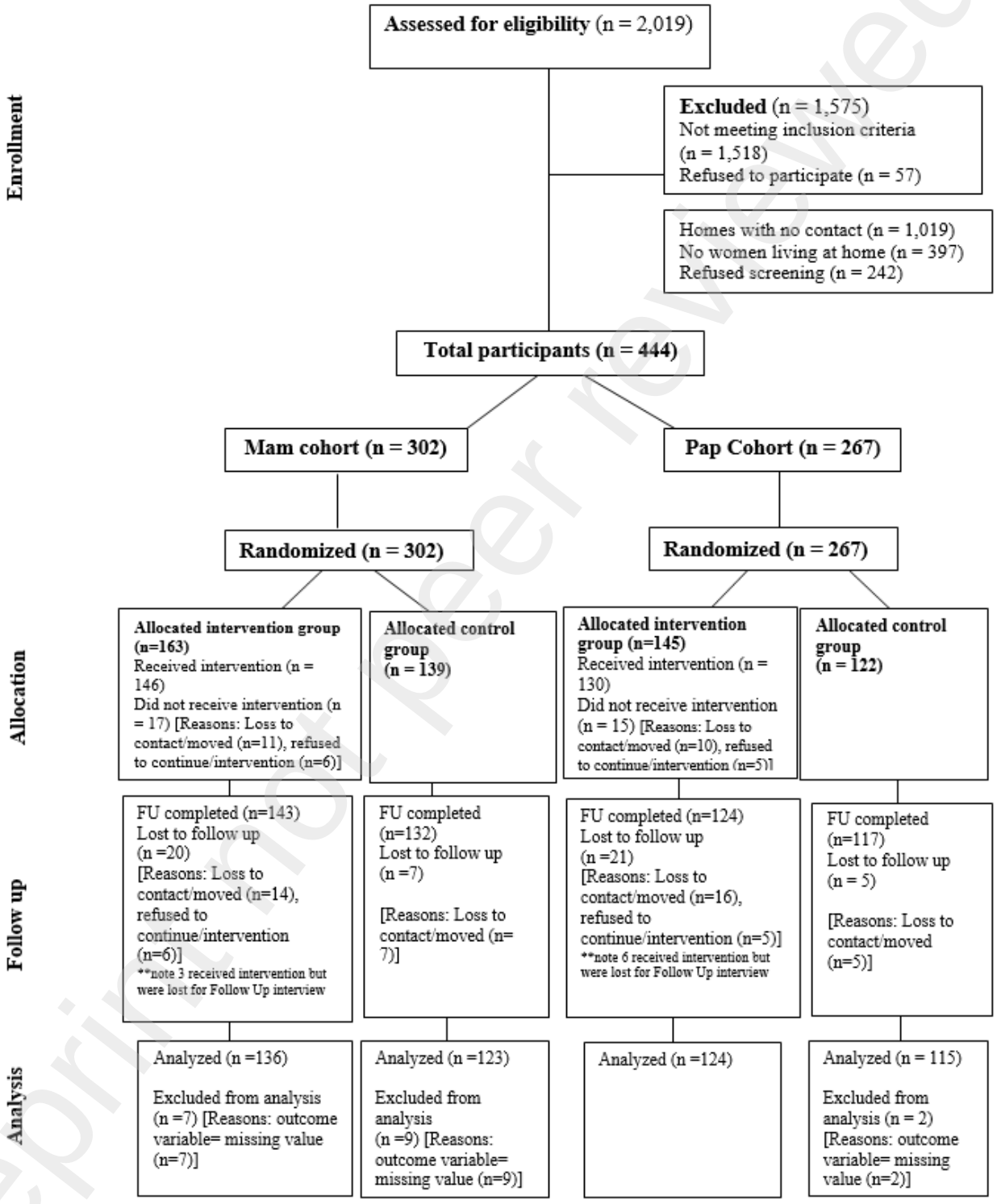
**Pap cohort:* The model was adjusted by marital status given that this was the only variable that reached significance ($p<0.25$) in the univariate logistic regression model. Interaction terms among study group and marital status were not significant (LR test: 2.10, $p=0.35$).

Table 3. Effect of the intervention of intermediate impact variables: CLS intervention

	Control Mean (SD)	Intervention Mean (SD)	p-value*
Mammography-related variables			
Self-efficacy	4.48 (0.78)	4.64 (0.64)	0.14
Decisional balance (pros)	4.67 (0.57)	4.74 (0.42)	0.26
Decisional balance (cons)	2.49 (1.10)	2.37 (1.02)	0.30
Subjective norms	17.02 (6.70)	16.43 (6.74)	0.63
Pap test- related variables			
Self-efficacy	4.33 (0.92)	4.62 (0.65)	**0.01**
Subjective norms	12.70 (4.99)	13.29 (4.23)	0.48

*p-values from the generalized linear models with the pretest score serving as a covariate.

Figure 1. Consort Flow Diagram



References:

1. Torres-Cintrón CR, Alvarado-Ortiz M, Román-Ruiz Y, Ortiz-Ortiz KJ, Zavala-Zegarra D, Tortolero-Luna G (2020). Cancer in Puerto Rico, 2012-2016. Puerto Rico Central Cancer Registry. San Juan, PR.

2. Santiago D PRHIA. Datos Asegurados del Plan del Gobierno de PR - Mi Salud. Velez C, editor. 2014. https://estadisticas.pr/en/inventario-de-estadisticas/asegurados-y-elegibles-por-region-y-municipios Accessed: November 25, 2020.

3. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Population Health. BRFSS Prevalence & Trends Data [online]. 2020. URL: https://www.cdc.gov/brfss/brfssprevalence/ Accessed: January 21, 2022.

4. Ayala-Marín AM, Colón-López V, Vélez-Álamo C, Fernández-Espada N, Pattatucci A, Fernández ME. Never Screened: Understanding Breast Cancer Nonadherence in Puerto Rico. Health Educ Behav. 2021;48(5):559-566. doi:10.1177/1090198120988248

5. Miranda-Diaz C, Betancourt E, Ruiz-Candelaria Y, Hunter-Mellado RF. Barriers for Compliance to Breast, Colorectal, and Cervical Screening Cancer Tests among Hispanic Patients. Int J Environ Res Public Health. 2015;13(1):ijerph13010021. Published 2015 Dec 22. doi:10.3390/ijerph13010021

6. Pagán JA, Brown CJ, Asch DA, Armstrong K, Bastida E, Guerra C. Health literacy and breast cancer screening among Mexican American women in South Texas. *J Cancer Educ*. 2012;27(1):132-137.

7. Abraído-Lanza AF, Martins MC, Shelton RC, Florez KR. Breast Cancer Screening Among Dominican Latinas: A Closer Look at Fatalism and Other Social and Cultural Factors. *Health Educ Behav*. 2015;42(5):633-641.

8. Shelton RC, Jandorf L, Thelemaque L, King S, Erwin DO. Sociocultural determinants of breast and cervical cancer screening adherence: an examination of variation among immigrant Latinas by country of origin. *J. Health Care Poor Underserved.* 2012;23(4):1768-1792.

9. Guide to Community Preventive Services. Cancer Screening: Interventions Engaging Community Health Workers – Cervical Cancer. https://www.thecommunityguide.org/findings/cancer-screening-interventions-engaging-community-health-workers-cervical-cancer. Page last updated: May 25, 2021. Accessed: January 25, 2022.

10. Sharma N, Harris E, Lloyd J, Mistry SK, Harris M. Community health workers involvement in preventative care in primary healthcare: a systematic scoping review. *BMJ Open*. 2019;9(12):e031666. Published 2019 Dec 17. doi:10.1136/bmjopen-2019-031666

11. Wells KJ, Luque JS, Miladinovic B, et al. Do community health worker interventions improve rates of screening mammography in the United States? A systematic review. *Cancer Epidemiol Biomarkers Prev*. 2011;20(8):1580-1598. doi:10.1158/1055-9965.EPI-11-0276

12. Fleming K, Simmons VN, Christy SM, et al. Educating Hispanic Women about Cervical Cancer Prevention: Feasibility of a Promotora-Led Charla Intervention in a Farmworker Community. Ethn Dis. 2018;28(3):169-176. Published 2018 Jul 12. doi:10.18865/ed.28.3.169

13. Nápoles AM, Santoyo-Olsson J, Stewart AL, et al. Nuevo Amanecer-II: Results of a randomized controlled trial of a community-based participatory, peer-delivered stress management intervention for rural Latina breast cancer survivors. Psychooncology. 2020;29(11):1802-1814. doi:10.1002/pon.5481

14. Salgado O, Medina L, Rivera M, Ortiz L, et al. Increasing breast cancer knowledge in Puerto Rico through partnerships [abstract]. In: Proceedings of the Twelfth AACR Conference on the Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved; 2019 Sep 20-23; San Francisco, CA. Philadelphia (PA): AACR; Cancer Epidemiol Biomarkers Prev 2020;29(6 Suppl_2):Abstract nr B022.

15. Savas LS, Atkinson JS, Figueroa-Solis E, et al. A lay health worker intervention to improve breast and cervical cancer screening among Latinas in El Paso, Texas: A randomized control trial. Prev Med. 2021;145:106446. doi:10.1016/j.ypmed.2021.106446

16. Guide to Community Preventive Services. Cancer Screening: Interventions Engaging Community Health Workers – Cervical Cancer. https://www.thecommunityguide.org/findings/cancer-screening-interventions-engaging-community-health-workers-cervical-cancer. Page last updated: May 25, 2021. Accessed: February 3, 2022.

17. Guide to Community Preventive Services. Cancer Screening: Interventions Engaging Community Health Workers – Breast Cancer. https://www.thecommunityguide.org/findings/cancer-screening-interventions-engaging-community-health-workers-breast-cancer. Page last updated: December 22, 2021. Accessed: February 3, 2022

18. Fernández ME, Gonzales A, Tortolero-Luna G et al. Effectiveness of Cultivando la Salud: A breast and cervical cancer screening promotion program for low-income Hispanic women. *Am. J. Public Health*. 2009;99(5):936-943.

19. Fernández ME, Gonzales A, Tortolero-Luna G, Partida S, Bartholomew LK. Using Intervention Mapping to develop a breast and cervical cancer screening program for Hispanic farmworkers: Cultivando La Salud. *Health Promot. Pract.* 2005;6(4):394-404.

20. Savas LS, Atkinson JS, Figueroa-Solis E, Valdés A, Morales P, Castle PE, Fernández ME. A lay health worker intervention to improve breast and cervical cancer screening among Latinas in El Paso, Texas: A randomized control trial. Prev Med. 2021 Apr;145:106446. doi: 10.1016/j.ypmed.2021.106446. PMID: 33548363.

21. Savas LS, Heredia NI, Coan SP, Fernández, ME. Effectiveness of a community health worker-delivered intervention to increase breast and cervical cancer screening among medically underserved Hispanics. E-Poster, Oral Presentation presented at World Cancer Congress; October 4, 2018; Kuala Lumpur, Malaysia.

22. Bartholomew LK, Markham C, Ruiter RAC, Fernández ME, Kok G, Parcel G. Planning Health Promotion Programs. An Intervention Mapping Approach. 4th ed. San Francisco: Jossey Bass, 2016.

23. Highfield L, Hartman MA, Mullen PD, Rodríguez SA, Fernández ME, Bartholomew LK. Intervention Mapping to Adapt Evidence-Based Interventions for Use in Practice: Increasing Mammography among African American Women. *Biomed Res. Int*. 2015; https://doi.org/10.1155/2015/160103.

24. Ortiz-Ortiz KJ, Ramírez-García R, Cruz-Correa M, Ríos-González MY, Ortiz AP. Effects of type of health insurance coverage on colorectal cancer survival in Puerto Rico: a population-based study. *PLoS One* 2014;9(5):e96746.

25. Resnicow, K., Soler, R., Braithwaite, R.L., Ahluwalia, J.S. and Butler, J. (2000), Cultural sensitivity in substance use prevention. J. Community Psychol., 28: 271-290. https://doi.org/10.1002/(SICI)1520-6629(200005)28:3<271::AID-JCOP4>3.0.CO;2-I