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AMIGAS: A Multicity, Multicomponent Cervical Cancer Prevention Trial Among Mexican American Women

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Abstract

BACKGROUND—Considerable efforts have been undertaken in the United States to reduce cervical cancer incidence and mortality by increasing screening; however, disparities in screening rates continue to exist among certain racial and ethnic minority groups. The objective of the current study was to determine the effectiveness of a lay health worker-delivered intervention—AMIGAS (*Ayudando a las Mujeres con Informacion, Guia, y Amor para su Salud* [helping women with information, guidance, and love for their health])—to increase Papanicolaou (Pap) test screening among 3 populations of women of Mexican origin.

METHODS—Six hundred thirteen women of Mexican origin in 3 treatment sites were randomized among 4 study arms: the full AMIGAS program with a video and a flip chart (n = 151), the AMIGAS program without the video (n = 154), the AMIGAS program without the flip chart (n = 155), and a usual care control group (n = 153). Six months after enrollment, women were surveyed and reported whether or not they had been screened.

RESULTS—Women in any of the intervention arms were statistically significantly more likely to report being screened than those in the usual care group in both an intent-to-treat analysis and a per-protocol analysis. In the intent-to-treat analysis, 25% of women in the control group and 52%

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in the full AMIGAS program group reported having had Pap tests ($P < .001$); in the per-protocol analysis, the percentages were 29% and 62%, respectively ($P < .001$).

CONCLUSIONS—AMIGAS was effective in increasing Pap test screening among women of Mexican descent when used in a 1-to-1 setting. Future research should compare the 1-on-1 intervention with the group-based intervention.

Keywords

uterine cervical cancer screening; Mexican origin; clinical trial; health education; Hispanic women

INTRODUCTION

Although both the incidence and mortality from cancer of the uterine cervix have decreased dramatically in the United States since the introduction of the Papanicolaou (Pap) test in the 1950s, in 2008, 12,410 US women were diagnosed with cervical cancer, and 4008 US women died from the disease.[1] Cervical cancer is curable if discovered early, and the Pap test can identify premalignant lesions before they become cancer.[2] Considerable efforts have been undertaken in the United States to reduce cervical cancer incidence and mortality by increasing screening; however, disparities in screening rates continue to exist among certain racial and ethnic minority groups.[3,4] Hispanic women have lower screening rates and higher cervical cancer morbidity and mortality than non-Hispanic white women.[1] Among Hispanic subgroups, Mexican women and Mexican American women reported the lowest rates of cervical cancer screening when asked about Pap test screening in the past 3 years.[4]

Hispanic women experience barriers to cervical cancer screening, including low levels of knowledge about screening guidelines, limited access to health care services, and culturally influenced barriers, such as embarrassment and partner influences.[5–7] Behavioral interventions are 1 method to increase screening behavior. Recommendations from the Community Preventive Services Task Force for increasing screening include interventions that use 1-on-1 education and the use of small-media materials.[8] Only a few of the studies referenced in the Guide to Community Preventive Services (available at: http://www.thecommunityguide.org [accessed September 3, 2012]) have focused on Hispanic populations. In addition, too few high-quality studies using lay health workers have been published to conduct a systematic review on this type of 1-on-1 intervention. Many studies determine efficacy without knowing the magnitude of effect that may be obtained in the real-world setting, known as *effectiveness*.[9] A recent study demonstrated the effectiveness of lay health worker-delivered interventions among older Hispanic women but did not explore the relative effectiveness of different components of the intervention.[7] In the current study, we sought to determine the effectiveness of a lay health worker-delivered intervention—*Ayudando a las Mujeres con Informacion, Guia, y Amor para su Salud* (AMIGAS [helping women with information, guidance, and love for their health])—to increase Pap test screening among 3 populations of women of Mexican origin (US/Mexico border, urban, and rural) using a randomized controlled design. A secondary objective was to characterize the relative effectiveness of the major small-media components of the intervention (video and flip chart) in increasing cervical cancer screening rates for the 3 populations.

MATERIALS AND METHODS

Our research protocol was approved by the University of Texas Health Science Center-Houston Committee for the Protection of Human Subjects and the Fred Hutchinson Cancer Research Center Institutional Review Board. To develop the AMIGAS intervention, we used a systematic process for developing theory-based and evidence-based health promotion interventions known as *intervention mapping*.[10] We also incorporated input from a community advisory board that participated throughout program development and testing.[11] Theoretical constructs from Social Cognitive Theory,[12] the Health Belief Model,[13,14] the Transtheoretical Model,[15,16] and the Theory of Reasoned Action[17] were identified as potential determinants of screening behavior and guided intervention development. The AMIGAS intervention was designed for delivery by trained lay health workers (*promotoras de salud* or *promotoras*) in either English or Spanish either in a group setting or individually. The AMIGAS intervention includes a *promotora* instruction guide, which provides detailed steps for *promotoras* on how to deliver the intervention, along with a set of small-media materials *promotoras* can use to increase participants' knowledge. These materials include a video that uses role modeling by women from the community to address common barriers and beliefs about cervical cancer and screening, a flip chart that reinforces the video and adds more in-depth information, and games and handouts that can be used by the *promotora* at her discretion to reinforce the messages in the video and flip chart. Initial testing and validation of the educational material and lesson plans were done through 2 half-day workshops with bilingual and bicultural *promotoras* who worked with women in the priority population. Further pretesting was done in 3 pilot sessions which were observed by members of the investigator team. In these sessions, the *promotoras* demonstrated that they were able to use the lesson plans successfully and that the materials were clear and easy to use.[11]

Eligibility Criteria

Eligible participants were women of self-reported Mexican origin aged ≥21 years with no previous history of cancer, no hysterectomy, and no cervical cancer screening within the past 3 years. Eligibility was ascertained using a screening survey, which was conducted either by telephone or in-person.

Description of Sites

The study was conducted in 3 diverse sites: El Paso, Texas, on the US/Mexico border; Houston, Texas, a large urban center; and Yakima Valley, Washington, a rural farming community. According to the Texas Department of State Health Services,[18] the population of El Paso County is approximately 749,000 with 83% of Hispanic origin; and the majority is Hispanic of Mexican origin. According to data from the 2005 local Behavioral Risk Factor Surveillance System, the last year for which city-level data are available, 39.5% of the El Paso population is without insurance coverage, and 46.4% of Hispanic respondents reported having no insurance coverage.[19]

Houston, Texas is a large urban in Harris County area with approximately 41% of its 4.6 million residents who identify themselves as Hispanic.[20] Of these, approximately 79% are

Mexican or Mexican American.[21] Approximately 29% of the Harris County population has no health insurance, and 44% of Hispanic residents report no health care coverage.[20]

In Washington State, much of the Hispanic population is concentrated in Yakima County (population, 243,231), the home of the Yakima Valley, where almost 45% of the population is Hispanic.[22] The Lower Yakima Valley is a region that includes many small agricultural communities, and an estimated 94% of Hispanics in the region are Mexican-origin.[23] According to Yakima County Behavioral Risk Factor Surveillance System data from 2007, 22% of the general Yakima County population and 52% of Hispanics in the county lack health care coverage.[24]

Recruitment

Recruiting underserved populations can be challenging and often requires extensive time and effort.[26–28] All 3 sites used flyer distribution and in-person recruitment. Personnel delivering flyers and conducting recruitment were research assistants (Houston), local *promotoras* (El Paso), or project staff (Yakima). We used a variety of locations to recruit participants, including beauty salons, jewelry stores, bakeries, schools, community centers, churches, and retail stores. In Houston, where recruitment was most difficult, in-person attempts to recruit eligible participants were made in over 40 different locations, and the most successful venue was laundromats.

All women were asked standard screening questions to determine eligibility. Eligible women who agreed to participate were contacted by an interviewer who administered both the consent and the survey.

Intervention

The AMIGAS intervention was developed by a planning group of researchers, community members, and *promotoras* in El Paso with funding from the Centers for Disease Control and Prevention. The intervention was subsequently revised and updated by a multidisciplinary group of researchers from the Centers for Disease Control and Prevention, Battelle Centers for Public Health Research and Evaluation, the University of Texas, and health care agency administrators and *promotoras* from El Paso, Texas; San Diego, California; Hood River, Oregon; and Yakima, Washington. The final program included a video novella using role models to discuss barriers to and facilitators for cervical cancer screening; a flip chart reviewing the information in the video; games and activities, including a set of cards developed to help *promotoras* understand the woman's stage of change; a contract sheet titled "mi promesa" (my promise), on which women wrote their promise to themselves to get screened or to think about screening, depending on their readiness to change, and a *promotora* training manual.[11] In the current study, we tested the effectiveness of the AMIGAS program delivered to individual women by *promotoras* who were also of Hispanic origin and of similar socioeconomic status to the women in our priority population.

Women responded to a survey about Pap test history and attitudes and beliefs about screening and cervical cancer (perceived susceptibility, perceived barriers, perceived benefits, and self-efficacy). We used a computer-generated randomization scheme to

randomly assign 613 women to 1 of 4 study arms that differed by the types of materials the *promotoras* used to deliver the program: the full AMIGAS program (video and flip chart; n = 151), the AMIGAS program without the video (n = 154), the AMIGAS program without the flip chart (n = 155), and the usual care control group (n = 153). The 3 intervention arms also included the cards, handouts, and the mi promesa handout mentioned above. Women in the control group received no *promotora* education but may have received education about cervical cancer screening delivered by clinics and the media. Six months after intervention delivery, women were visited by data collectors and completed a follow-up interview. After the final follow-up, women in the control group were offered the full AMIGAS program (Fig. 1).

The primary endpoint was cervical cancer screening measured by self-report on the follow-up survey and validated through medical records review. During recruitment, women were asked to provide their usual source of health care and for consent to examine their medical records for Pap test history.

Analyses

Two analytic approaches were used to assess completion of screening. The first was a more conservative “intent-to-treat” analysis, which included all women who responded to the baseline survey. This analysis strategy assumes that women who did not complete the follow-up survey were not screened. The second approach was a “per-protocol” analysis, which included only women who responded to both the baseline and the follow-up surveys. This analysis strategy assumes that women who were lost to follow-up were missing at random and were not different from those who completed follow-up. For each analysis, a comparison of the proportions of the 4 study arms at follow-up was conducted using the Fisher exact test. If the overall test was statistically significant, then we conducted further Fisher exact test analyses to detect where significant differences occurred. P values ≤ .05 were considered statistically significant. An additional comparison of screening rates was conducted within each site. In addition, we compared the per-protocol and intent-to-treat conditions of all sites and across treatment arms for those women who reported having a Pap test. We also compared self-report by the women with clinic records to assess the accuracy of self-report. Finally, we compared self-report and medical record-validated receipt of Pap test by site, although the sample sizes for women who had medical records available were too small in the El Paso community to do meaningful analysis.

Attitude and belief variables included at least 2 items (perceived susceptibility, 2 items; perceived barriers, 10 items; perceived benefits, 6 items; self-efficacy, 9 items), and each item was scored using a 4-point Likert-type scale (from 1 [strongly agree] to 4 [strongly disagree]). Perceived barriers, perceived benefits, and self-efficacy items were tested for internal consistency reliability using Cronbach’s α, and all 3 had acceptable α values (.74, .70, and .92, respectively). Item responses were summed and averaged to develop a score for each variable.

We compared demographic and attitudinal data between women who were reached for follow-up and those who were lost to follow-up to test the “missing at random” assumption. We also compared these data among women in each study arm. All data were entered at a

single El Paso site. The primary statistical software used for data analysis was SAS (version 9.2; SAS Institute Inc., Cary, NC).

RESULTS

In total, 613 women of Mexican origin were included in the intent-to-treat analysis. The percentage of women who received a Pap test at the 6 month follow-up was 52.3% in the full AMIGAS arm, 41.3% in the video-only arm, and 45.5% in the flip chart-only arm compared with 24.8% in the control group. The difference between the control arm and the intervention arms was statistically significant based on Fisher's exact test analysis ($P < .0001$). There was no statistically significant difference among the 3 intervention arms (Table 1).

The per-protocol analysis was based on 513 women. The percentage of women who received a Pap test at the 6-month follow-up was 61.7% in the full AMIGAS arm, 56% in the video-only arm, and 50.8% in the flip chart-only arm compared with 28.6% in the control group. The difference between the control arm and the intervention arms was statistically significant based on Fisher exact test analysis ($P < .0001$). Again, there was no statistically significant difference among the 3 intervention arms (Table 2).

Within-site comparisons revealed statistically significant differences in screening completion at follow-up between the intervention groups and the comparison groups in El Paso and Yakima but not in Houston (Table 3). When we compared women who completed the study with those who were lost to follow-up, there were no differences in health care coverage, place of birth (United States vs Mexico), place of parent's birth, marital status, or years of education. Those who completed the study were almost 4 years older ($P = .0018$) than those who did not (mean age, 39.8 years vs 36 years) and had been in the United States longer (17 years vs 14.1 years; $P = .03$). There were no differences in scores for perceived susceptibility, perceived barriers, or self-efficacy when comparing these groups; however, women who were lost to follow-up scored significantly lower on perceived benefits than those who completed the study (possible score range, 6–24; mean score, 9.5 and 10.3, respectively).

We obtained medical records for 132 of 250 women who reported having a Pap test at the 6-month follow-up and for 98 of 262 women who reported not having a Pap test (Table 4). We were able to verify that a Pap test had been done for 79% of women who reported having had a Pap test. There was 100% agreement for a report of no Pap test.

DISCUSSION

Compared with usual care, self-reported Pap testing increased in all 3 AMIGAS intervention groups in both the intent-to-treat analysis and the per-protocol analysis, and these proportions were higher than expected based on other studies.[7,25] We did not observe a statistically significant difference among the 3 intervention arms. Although it was not statistically significant, the full AMI-GAS program appeared to be somewhat more effective in increasing screening compared with the video-only arm (a difference of approximately 6 percentage points), which appeared to be slightly more effective (by 6 percentage points)

than the flip chart-only arm. This suggests that delivering the full program may provide the optimal benefit for increasing screening among previously unscreened women based on our findings; compared with usual care, screening completion among rarely or never screened women could be increased using any of the 3 options (video, or flip chart, or both). From a practical perspective, this flexibility facilitates dissemination and adaptation of the program in community settings, where there may be variability in the time available for intervention delivery or financial constraints that may limit purchase of DVD players and/or reproduction of flip charts.

Site Comparisons

Within-site comparisons for El Paso and Yakima Valley also were statistically significant. Although the differences in the Houston sample did not reach statistical significance, the percentage of women screened in each group were similar to those in the other 2 sites. Although the magnitude of the increase was lower in Houston, there were 22% and 24% point differences between the full AMIGAS arm and the control arm and the video-only arm and the control arm, respectively. These differences were larger than those reported by the majority of studies that evaluated the impact of educational interventions to increase screening.[7,25] Two additional observations from the Houston data are noteworthy and deserve additional research. The difference observed between the flip chart-only arm and the control arm in Houston was less than that observed at the other 2 sites. This observation may indicate differences related to media preferences among urban women compared with rural women. Second, although the differences in the other 2 arms (full AMI-GAS and video-only) were >20 percentage points above the control arm, these differences still were markedly less than what was observed in the other 2 sites. On the basis of qualitative interviews conducted during follow-up data collection in Houston, we observed that women who sought appointments often were not able to obtain timely appointments or had difficulty paying the fee (even if it was minimal), suggesting that capacity and financial constraints remain barriers to receipt of care for this urban population. In Yakima, the Breast, Cervical, and Colon Health Program, which is funded by the Centers for Disease Control and Prevention, provided free screening and follow-up care to income-eligible and age-eligible women, raising the possibility that women at this site faced fewer structural barriers to Pap testing.

In focus group interviews held with women who were study participants after completion of the research, we observed that many women mentioned the *promotora* visits as the most memorable part of AMIGAS. It would be interesting to further study the effect of *promotora* visits with and without the educational pieces that were developed for AMIGAS.

Limitations

We were able to demonstrate that the AMIGAS program is effective in increasing Pap test screening in Hispanic women when used in a 1-to-1 intervention. Although the program was developed for use either in groups or with individuals, in this study, we did not evaluate the effectiveness of the program delivered in a group setting.

The current results are based largely on self-report; because, despite efforts to make arrangements with the clinics before starting the study, and obtaining signed Health Insurance Portability and Affordability Act (HIPAA) release forms, we had difficulty getting patient information from the clinics. For example, 1 of the sites was a community center where a local health care clinic provided Pap tests. On the HIPAA form, the women reported the name of the community center rather than the clinic name, and the legal team at the clinic refused to grant us access to those records. In addition, several of the private physicians did not comply with our request for records, because they each have a form that they use in their own practice, and they did not recognize the signed HIPAA release as valid. Nevertheless, from those records obtained, the results indicated that the validity of self-report in our current study was as good as or better than that in other studies in which self-report of Pap test screening was compared with clinic records.[29,30]

The objective of this study was to assess the effectiveness of the AMIGAS program over the short term. We were not funded for a long enough period to examine maintenance. Long-term follow-up for cervical cancer screening has become more complicated, because the guidelines have changed, and the interval between screening tests has been extended to 3 to 5 years; however, being screened on a regular basis according to guidelines is an important issue for program decision-makers that should be examined in future studies.

In conclusion, the AMIGAS intervention is effective in increasing Pap test screening among women of Mexican descent residing in border, urban, and rural locations when used in a 1-to-1 setting. Future research should focus on the feasibility of adapting this intervention for other populations in these regions of the country, screening maintenance, and the effectiveness and cost-effectiveness of group versus 1-to-1 interventions. The complete AMIGAS intervention will be distributed by the Centers for Disease Control and Prevention and will include an Administrator's guide to facilitate the adoption and implementation of the program.

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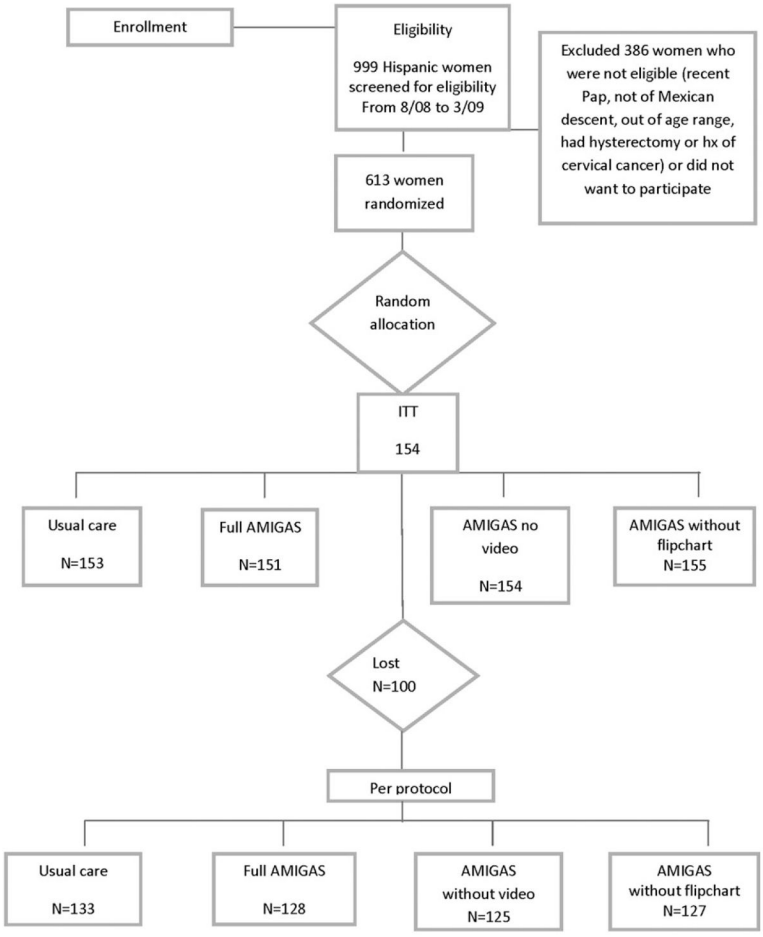

Figure 1.

The allocation of participants is illustrated for the study arms. Pap indicates Papanicolaou test; ITT, intent-to-treat analysis; AMIGAS, Ayudando a las Mujeres con Informacion, Guia, y Amor para su Salud (helping women with information, guidance, and love for their health).

TABLE 1

Percentage of Women Who Reported Having a Papanicolaou Test by Study Arm Across All Treatment Sites, Including Women Who Were Lost to Follow-Up: Intent-to-Treat Analysis, n = 613

Study Arm	Self-Reported, %	Validated, %[a]
Control group, n = 153	24.8	7.2
Full AMIGAS cohort, n = 151	52.3	17.9
Video-only group, n = 155	41.3	19.4
Flip chart-only group, n = 154	45.5	22.7
P		
For comparison of all 4 study arms	< .001	.008
For comparison of the 3 intervention arms only	.1499	.55

Abbreviations: AMIGAS, *Ayudando a las Mujeres con Informacion, Guia, y Amor para su Salud* (helping women with information, guidance, and love for their health).

[a]Validated results were those for which medical records information could be obtained.

TABLE 2

Percentage of Women Who Completed the Study and Reported Having a Papanicolaou Test by Study Arm Across All Treatment Sites: Per-Protocol Analysis, n = 514

Study Arm	Self-Reported, %	Validated, %[a]
Control group, n = 133	28.6	8.27
Full AMIGAS cohort, n = 128	61.7	21.1
Video-only group, n = 125	56	23.6
Flip chart-only group, n = 128	50.8	28
P		
For comparison of the 4 study arms	< .0001	.0002
For comparison of the 3 intervention arms only	.2169	.4382

Abbreviations: AMIGAS, *Ayudando a las Mujeres con Informacion, Guia, y Amor para su Salud* (helping women with information, guidance, and love for their health).

[a]Validated results were those for which medical records information could be obtained.

TABLE 3

Percentage of Women Who Reported Having a Papanicolaou Test by Study Arm According to Treatment Site

	Percentage of Women (No.)					
	Per-Protocol Analysis, n = 514			Intent-to-Treat Analysis, n = 613		
Study Arm	**El Paso**	**Houston**	**Yakima**	**El Paso**	**Houston**	**Yakima**
Control group	28 (50)	23.3 (43)	35 (40)	28 (50)	17.9 (56)	29.8 (47)
Full AMIGAS cohort	62.5 (48)	45.4 (44)	80.6 (36)	60 (50)	39.2 (51)	58 (50)
Video-only group	50 (46)	36.8 (38)	62.8 (43)	46 (50)	24.6 (57)	56.2 (48)
Flip chart-only group	47.9 (48)	47.5 (40)	75.7 (37)	46 (50)	35.2 (54)	56 (50)
P						
For comparison of the 4 study arms	.0070	.0833	.0001	.0145	.0553	.0150
For comparison of the 3 intervention arms only	.3276	No test[a]	.1970	.2712	No test[a]	1.000

Abbreviations: AMIGAS, *Ayudando a las Mujeres con Informacion, Guia, y Amor para su Salud* (helping women with information, guidance, and love for their health).

[a]No Fisher exact test was done with the 3 intervention arms in this group, because the test across all 4 arms was not significant.

TABLE 4

Percentage of Women With Validated Papanicolaou Tests by Study Arm According to Treatment Site

	Percentage of Women (No.)					
	Per-Protocol Analysis, n = 514			Intent-to-Treat Analysis, n = 613		
Study Arm	**El Paso**	**Houston**	**Yakima**	**El Paso**	**Houston**	**Yakima**
Control group	8 (50)	9.3 (43)	7.5 (40)	8 (50)	7.2 (56)	6.4 (47)
Full AMIGAS cohort	0 (48)	27.3 (44)	41.7 (36)	0 (50)	23.5 (51)	30 (50)
Video-only group	10.9 (46)	18.4 (38)	41.9 (43)	10 (50)	12.3 (57)	37.5 (48)
Flip chart-only group	4.2 (48)	32.5 (40)	54 (37)	4 (50)	24.1 (54)	40 (50)
P						
For comparison of the 4 treatment arms	.0836	.0457	< .00011	.1042	.0344	.0002
For comparison of the 3 intervention arms	No test[a]	.3797	.4766	No test[a]	.2024	1.0

Abbreviations: *AMIGAS, Ayudando a las Mujeres con Informacion, Guia, y Amor para su Salud* (helping women with information, guidance, and love for their health).

[a]No Fisher exact test was done with the 3 intervention arms in this group, because the test across all 4 arms was not significant.