Results of a Community-Based Randomized Trial to Increase Colorectal Cancer Screening Among Filipino Americans

Objectives. We conducted 1 of the first community-based trials to develop a multicomponent intervention that would increase colorectal cancer screening among an Asian American population.

Methods. Filipino Americans (n=548) nonadherent to colorectal cancer (CRC) screening guidelines were randomized into an intervention group that received an education session on CRC screening and free fecal occult blood test (FOBT) kits; a second intervention group that received an education session but no free FOBT kits; and a control group that received an education session on the health benefits of physical activity.

Results. Self-reported CRC screening rates during the 6-month follow-up period were 30%, 25%, and 9% for participants assigned to intervention with FOBT kit, intervention without the kit, and control group, respectively. Participants in either of the 2 intervention groups were significantly more likely to report screening at follow-up than were participants in the control group.

Conclusions. A multicomponent intervention that includes an educational group session in a community setting can significantly increase CRC screening among Filipino Americans, even when no free FOBT kits are distributed. (Am J Public Health. 2010;100:2228–2234. doi:10.2105/AJPH.2009.176230)

Colorectal cancer (CRC) is the second leading cause of cancer death in the United States.1 Screening using a fecal occult blood test (FOBT), sigmoidoscopy, or colonoscopy is recommended for adults older than 49 years to reduce CRC mortality. However, population-based surveys have documented low rates of CRC screening among Asian Americans.2 For example, data from the 2005 California Health Interview Survey show that only 46% of Filipino Americans are up-to-date with CRC screening compared with 59% of non-Hispanic Whites.3 Low rates of CRC screening contribute to late-stage diagnosis and poor survival outcomes among Asian Americans compared with non-Hispanic Whites.4 Despite these disparities, very few interventions to increase CRC screening have been developed and rigorously tested for Asian Americans.5

The Task Force on Community Preventive Services, a group of public health and prevention experts that oversees systematic reviews of studies, recommends implementation of the following interventions to increase CRC screening on the basis of strong evidence of effectiveness: (1) brochures and other small media that describe screening tests and contain indications for, benefits of, and ways to overcome barriers to screening; (2) interventions to reduce structural barriers, such as distribution of free FOBT kits; and (3) client reminders to advise people they are due or late for screening. The Task Force determined that there is insufficient evidence to determine the effectiveness of small-group education.6

Small-group educational sessions had been popular among the Filipino community in 1 of our prior studies;7 therefore, we again offered small-group educational sessions in community settings. In keeping with the Task Force recommendations, we also used print materials and a reminder mailing. In addition, we distributed free FOBT kits in 1 arm of the intervention. In a second intervention arm, we did not distribute free FOBT kits, as this distribution may not be feasible for community organizations that want to continue similar programs after the end of the study. A control arm offered small-group education and print materials on the health benefits of physical activity. We report the effect of the multicomponent intervention on CRC screening rates among Filipino Americans. This is 1 of the first community-based randomized trials designed to increase CRC screening among Asian Americans and the first trial among Filipino Americans.

METHODS

In collaboration with 45 Filipino American community-based organizations and churches, we recruited 906 Filipino Americans who each completed a baseline interview (Figure 1). Participants who were nonadherent to CRC screening guidelines (n=548) were randomized into 1 of 3 arms. Two intervention arms consisted of a small-group CRC education session, print take-home materials, a reminder letter, and a letter to the physician, with the only difference being that participants in 1 arm received a free FOBT kit, but those in the other arm did not. A third control group consisted of a small-group session promoting physical activity. Another 55 participants who were not adherent to CRC screening were not entered into the randomized trial because insufficient numbers or schedule conflicts prevented the scheduling of small-group sessions. A total of 103 small-group sessions were conducted; each session lasted 60 to 90 minutes and was led by a trained Filipino health professional, usually a nurse. Telephone interviews 6 months after the session assessed the outcome—self-reported receipt of any CRC screening during the follow-up period—among all participants who were randomized. We also validated self-reported CRC screening in a subsample.
Recruitment, Eligibility Criteria, and Randomization

Liaisons with community-based organizations and churches distributed recruitment flyers for the Filipino Health Study, invited church and organization members to participate, and gave a list of potential participants to study staff. In addition, recruitment ads were posted on the bulletin boards and in newsletters of our partner organizations. During recruitment phase I (July 2005–October 2006), a person was eligible to participate in the study if he or she was of Filipino heritage (any part), aged 50–70 years, and had no history of CRC. Baseline interviews were conducted with participants who were adherent or nonadherent to CRC screening guidelines to compare the 2 groups.8 In this phase, community liaisons provided a list of 732 names, all of whom were contacted, and 598 interviews were completed (82% response rate). During recruitment phase II (November 2006–November 2007), we limited recruitment to participants who were nonadherent to CRC screening guidelines. We used a short screening questionnaire to exclude people who had had FOBT screening within the past 12 months, a sigmoidoscopy within the past 5 years, or a colonoscopy within the past 10 years. In this phase, we received from our community liaisons lists of 683 names, of whom 256 were ineligible and 64 could not be reached by phone. Of the 363 eligible potential respondents that we were able to contact, 308 completed the baseline interview (85% response rate). Thus, 906 baseline interviews were completed from 1,159 eligible potential participants, for an overall response rate of 83%.

Participants who were nonadherent to CRC screening guidelines (no FOBT within the past 12 months, no sigmoidoscopy within the past 5 years, and no colonoscopy within the past 10 years) were randomized in small groups of 6 to 10 participants to take advantage of existing bonds between members of the same organization. Couples and multiple members of the same household were assigned to the same small group. Six unique study arm sequences (ABC, ACB, BAC, BCA, CAB, and CBA, where A, B, and C represent the 3 study conditions) were each assigned a number from 1 to 6. For each community organization, the sequence of the groups offered was determined by selecting a number from 1–6 using a table of random numbers.

Intervention

The multicomponent intervention was developed with input from key informants and community members who participated in 3 focus groups. The intervention consisted of a small-group session to encourage CRC screening along with take-home print materials, a reminder letter, and a letter to participants’ providers. The Health Behavior Framework9,10 guided the intervention content and format. As shown in Table 1, we attempted to influence individual factors of the Health Behavior Framework that are usually associated with cancer screening, including knowledge, attitudes, barriers, social norms and support, communication with provider, and cultural factors.11,12

Small groups of 6–10 participants met at community organizations for a 60- to 90- minute educational session facilitated by a trained Filipino American health educator. Following a curriculum, facilitators and participants discussed incidence and mortality of CRC among Filipino American men and women, risk factors and symptoms, benefits of prevention and early detection, recommended screening tests (FOBT, sigmoidoscopy, colonoscopy), where to obtain screening tests, and myths versus facts about CRC and screening. Examples, illustrations, and graphics were used, and interaction among the participants was encouraged as much as possible. The health educator demonstrated how to do an FOBT (using peanut butter and an FOBT kit) and showed a drawing of a scope inserted in the colon and a picture of a polyp. The health educator addressed barriers to screening that were pertinent to any of the group members by inviting opinions and advice from other group members. As with other populations, common barriers included not knowing how to do an FOBT, feeling that collecting stool samples is unpleasant, and being embarrassed to get an endoscopy or worrying about the discomfort. Using an established response format, the health educator counseled the group members on how to deal with each of these barriers. The session was an opportunity for the participants to discuss their thoughts and concerns about

Note. FOBT = fecal occult blood test.

FIGURE 1—Participant flow for colorectal cancer (CRC) screening trial; Filipino Health Study, Los Angeles, CA, 2004–2009.

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Participants randomized to the control arm attended a small-group education session in which they discussed exercise and physical activity. Following a curriculum that we used in a previous study with Filipino American women, participants discussed and practiced aerobic, strengthening, and flexibility exercises and received print information (“Exercise! Ten Tips to Get You Started” and “I Walk Because . . . ” from Journeyworks Publishing) in English and Filipino.

The educational sessions were conducted from July 2005 through November 2007. Participants were members or parishioners of 45 community-based organizations and churches with predominant or significant Filipino American membership. The CRC education sessions were facilitated by 6 health educators; the exercise sessions were led by 2 health educators. During the 103 educational sessions that were conducted, 36 groups received CRC education and free FOBT kits, 37 received CRC education without FOBT kits, and 30 received exercise and physical activity education. Health educators were recruited from and through the Philippine Nurses Association of Southern California. They completed a 4-to-6-hour training session on how to conduct the intervention or the control group session.

### Baseline and Follow-up Interviews
All respondents were interviewed at baseline by telephone (70%) or in person (30%) in Filipino (40%) or English (60%). Each interview was completed in 22 minutes, on average, and assessed CRC screening history as well as demographic characteristics, including acculturation, access to health care, and doctor CRC screening recommendations. We also assessed knowledge of screening guidelines and CRC risk factors and attitudes regarding screening that will be reported in a future paper. All participants who completed the baseline interview received a $20 incentive and were contacted for a telephone follow-up interview 6 months after the small-group session. The follow-up interview was completed in 23 minutes, on average, predominantly by telephone (98%) and in English (86%), and assessed CRC screening during the follow-up period—either by FOBT, sigmoidoscopy, or colonoscopy—and correlates of CRC screening that were also

### TABLE 1—Selected Health Behavior Framework Factors Addressed by the Colorectal Cancer Screening Intervention: Filipino Health Study, Los Angeles, CA, 2004–2009

<table>
<thead>
<tr>
<th><strong>Intervention</strong></th>
<th><strong>Knowledge</strong></th>
<th><strong>Beliefs</strong></th>
<th><strong>Barriers</strong></th>
<th><strong>Social norms and support</strong></th>
<th><strong>Communication with provider</strong></th>
<th><strong>Cultural</strong></th>
<th><strong>Practice pattern</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Individual factors</strong></td>
<td>CRC information, all types of screening tests, and guidelines are discussed in the small-group session</td>
<td>Mortality of CRC among Filipino Americans is graphically shown to be higher than mortality of other cancers</td>
<td>Barriers such as cost, not knowing that the test is needed, concern about finding CRC, and absence of symptoms are discussed interactively</td>
<td>Discussion group format among peers establishes positive social norms and social support for CRC screening</td>
<td>Strong recommendation from health educator to discuss CRC screening with provider</td>
<td>CRC is discussed in small groups that know each other with opportunity for socializing and refreshments</td>
<td>Provider is informed that patient received CRC education and FOBT kit and urged to recommend screening</td>
</tr>
</tbody>
</table>

*Note. CRC = colorectal cancer; FOBT = fecal occult blood test.*
assessed at baseline. Up to 9 callbacks (on different days and times) were attempted to reach a participant. Participants who completed the follow-up interview received a $20 incentive, and their names were entered into a lottery with a chance to win a $500 prize. The large proportion of English-language interviews at follow-up is because of the fact that unlike at baseline, staff members who conducted follow-up interviews were more comfortable in English than in Filipino and most participants were able to answer questions in either language.

Provider Validation
During the first face-to-face contact (either at the baseline interview or at the group session), participants were asked for permission to contact their health care providers to confirm receipt of CRC screening during the study period. Of the 432 participants who completed the follow-up interview, 324 (75%) provided complete contact information for their providers and signed a release form. After completion of the follow-up interview, validation packets were mailed to providers of 110 participants who self-reported any screening during the follow-up period (FOBT, sigmoidoscopy, or colonoscopy) and 98 randomly selected nonscreeners. We received provider validations for 141 patients (86 of 110 [78%] self-reported screeners and 55 of 98 [56%] self-reported nonscreeners).

Statistical Analysis
To assess baseline balance across the study arms, we tested for differences in baseline demographics, acculturation, health, health care access, and CRC screening history among the 3 groups by using the $\chi^2$ test and analysis of variance. To assess the potential for follow-up bias, we tested for differences between study completers and noncompleters by using the $\chi^2$ test and the 2-sample t test.

The primary outcome was self-reported receipt of any CRC screening (FOBT, sigmoidoscopy, or colonoscopy) between the session and the follow-up interview. We conducted an intent-to-treat analysis of all randomized participants that used self-reported outcomes and assumed participants without outcome data had a “not screened” outcome. The analysis used mixed effects logistic regression with random intercepts to account for clustering by organization and session within organization and included language of the baseline interview as a covariate to adjust for baseline imbalance across study arms.

The study was powered to detect a 15-percentage-point difference between intervention and control groups with 80% power.

RESULTS
At baseline, study participants were, on average, aged 59 years and had lived in the United States for 18 years; 66% were women (Table 2). All study participants were foreign-born. More than two thirds were married, had a college education, and had an annual income less than $50,000. Most considered themselves more Filipino than American (60%) or equally Filipino and American (36%), and only 19% spoke mainly Filipino with their friends. Although most had health insurance (70%) and a regular doctor (79%), only 25% had ever received any CRC screening test in the past, but they were nonadherent to CRC screening guidelines. Participants in the control group were more likely to have completed the baseline interview in English (69%) as compared with participants in the 2 intervention arms (57%; $P<.04$). No other significant differences among study arms were found.

Ninety-three percent of the participants attended the education session (Figure 1). Follow-up interviews were started 6 months after the session, and the average time period between the session and follow-up was 8.2 months (SD = 2.7 months). Follow-up interviews were completed with 79% of participants. A comparison of study completers (n = 432) and noncompleters (n = 116) indicated that completers were more likely to be college educated (72% vs 56% among noncompleters; $P<.001$), to have an annual income of $50,000 or more (36% vs 24%; $P<.02$), and to have completed the baseline interview in English (63% vs 51%; $P<.01$). Completers were also more likely than noncompleters to report receipt of a doctor’s recommendation to obtain FOBT or an endoscopy at baseline (29% vs 19%; $P<.03$, and 32% vs 22%; $P<.03$).

Based on intent-to-treat analysis with imputation of not screened for study noncompleters, self-reported CRC screening rates were 30%, 25%, and 9% for participants assigned to the intervention with a free FOBT kit, the intervention without an FOBT kit, and the control group, respectively (Table 3). Participants randomized to either of the 2 intervention arms were significantly more likely to report screening at follow-up than were control group assignees (odds ratios of 4.9 and 3.7 compared with the control group; both $P<.001$). The study was not powered to detect differences between the 2 intervention arms. After adjusting self-report for sensitivity and specificity as calculated according to provider validation data, the odds of screening in each intervention arm remained significantly higher than the odds in the control group (both $P<.001$; data not shown).

Of the intervention participants who reported CRC screening during the follow-up period (n = 61 in intervention A and n = 45 in intervention B), 73% received an FOBT only (74% and 71% in interventions A and B, respectively), 17% received an FOBT plus an endoscopy (15% and 20%), and 10% received an endoscopy only (11% and 9%), with no significant differences between the 2 intervention arms. Of the control group participants who reported CRC screening during the follow-up period (n = 14), 64% received an FOBT only, 14% received an FOBT plus endoscopy, and 21% received an endoscopy only.

DISCUSSION
To our knowledge, this is the first trial to test an intervention to increase CRC screening among Filipino Americans and one of the first trials testing an intervention to increase screening in a community rather than a clinic setting. The intervention consisted of several components, including a small-group educational session which was specifically tailored for Filipino Americans. Participants in the small-group session were members of churches or community organizations who often knew each other. The session offered an opportunity to socialize and to enjoy Filipino refreshments at the church or the community organization. Members of the same household were randomized to attend the same session so they could discuss the need to get screened and remind each other after the session. Leaders
### TABLE 2—Baseline Characteristics by Study Arm: Filipino Health Study, Los Angeles, CA, 2004–2009

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Doctor recommended any CRC screening</th>
<th>Ever had any CRC screening but not within guidelines</th>
<th>Doctor recommended FOBT</th>
<th>Ever had FOBT but not within last 12 mo</th>
<th>How likely to get FOBT in 6 mo</th>
<th>Doctor recommended endoscopy</th>
<th>Ever had endoscopy but not within guidelines</th>
<th>How likely to get endoscopy in 6 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention With FOBT Kit (n = 202)</td>
<td>88 (44)</td>
<td>60 (30)</td>
<td>59 (29)</td>
<td>48 (24)</td>
<td>33 (16)</td>
<td>64 (32)</td>
<td>19 (9)</td>
<td>83 (41)</td>
</tr>
<tr>
<td>Intervention Without FOBT Kit (n = 183)</td>
<td>79 (43)</td>
<td>42 (23)</td>
<td>51 (28)</td>
<td>39 (21)</td>
<td>33 (18)</td>
<td>32 (16)</td>
<td>8 (4)</td>
<td>73 (40)</td>
</tr>
<tr>
<td>Control (n = 163)</td>
<td>67 (41)</td>
<td>34 (21)</td>
<td>37 (23)</td>
<td>25 (15)</td>
<td>25 (15)</td>
<td>46 (28)</td>
<td>14 (9)</td>
<td>63 (39)</td>
</tr>
<tr>
<td>Total (n = 548)</td>
<td>234 (43)</td>
<td>136 (25)</td>
<td>147 (27)</td>
<td>112 (20)</td>
<td>91 (17)</td>
<td>163 (30)</td>
<td>41 (8)</td>
<td>219 (40)</td>
</tr>
<tr>
<td>( P^b )</td>
<td>.883</td>
<td>.117</td>
<td>.350</td>
<td>.131</td>
<td>.802</td>
<td>.742</td>
<td>.14</td>
<td>.854</td>
</tr>
</tbody>
</table>

**General demographics**

- **Age, y**: 59.2 ± 6.2
- **Years living in the United States**: 18.5 ± 12.5
- **Female**: 134 (66)
- **Married**: 135 (67)
- **Education**: Less than college (33), College or more (67)
- **Annual income less than $50,000**: 129 (68)

<table>
<thead>
<tr>
<th>Education</th>
<th>Mean ± SD or No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than college</td>
<td>66 (33)</td>
</tr>
<tr>
<td>College or more</td>
<td>136 (67)</td>
</tr>
<tr>
<td>Annual income less than $50,000</td>
<td>129 (68)</td>
</tr>
</tbody>
</table>

**Baseline interview in English**: 116 (57)

**Consider self**: More Filipino than American (56), Equally Filipino and American (39), More American than Filipino (5)

<table>
<thead>
<tr>
<th>Language used with friends</th>
<th>Mean ± SD or No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mainly Filipino</td>
<td>38 (19)</td>
</tr>
<tr>
<td>Half Filipino, half English</td>
<td>153 (76)</td>
</tr>
<tr>
<td>Mainly English</td>
<td>11 (5)</td>
</tr>
</tbody>
</table>

**Has any health problem**: 161 (80)

**Has family history of cancer**: 70 (35)

**Has health insurance**: 138 (68)

**Has regular doctor**: 162 (80)

**Colorectal cancer screening**

- **Doctor recommended any CRC screening**: 88 (44)
- **Ever had any CRC screening but not within guidelines**: 60 (30)
- **Doctor recommended FOBT**: 59 (29)
- **Ever had FOBT but not within last 12 mo**: 48 (24)
- **How likely to get FOBT in 6 mo**: Not likely (16), Somewhat likely (19), Very likely (47), Depends on doctor recommendation (18)
- **Doctor recommended endoscopy**: 64 (32)
- **Ever had endoscopy but not within guidelines**: 19 (9)
- **How likely to get endoscopy in 6 mo**: Not likely (41), Somewhat likely (26), Likely (33)

**Note**: FOBT = fecal occult blood test. Endoscopy was either by sigmoidoscopy or colonoscopy.

\(^{a}\)Some rows do not total 548 because of missing values.

\(^{b}\)P values based on the \( \chi^2 \) test.

\(^{c}\)Not a response option, but many respondents volunteered this answer.
and liaisons of several community organizations endorsed the study and the need for CRC screening, enforcing social norms in support of screening. Filipino American health professionals (nurses) led the sessions in English or in Filipino, ending the sessions with a strong recommendation to get screened, and all materials were provided in English and Filipino using large type. The fact that more than 90% of participants attended a group session demonstrates the reach, acceptability, and feasibility of this intervention component.

At follow-up, we achieved a large effect (odds ratios of 4.9 and 3.7) when comparing self-reported CRC screening in the intervention groups versus the control group. Other studies that have implemented screening interventions among baseline nonadherent community samples have found similar screening rates. The large proportion of participants who did not get screened (70%–75% in the intervention groups) may be attributed to 2 primary factors: many participants had never been screened at baseline and may have been resistant to adopt a new screening behavior, and participants had to take the initiative either to complete the FOBT kits at home and return them to their provider or to request a screening test from their provider. Providing participants with additional assistance, such as reminders to complete the FOBT kits or explanations regarding bowel preparation before the sigmoidoscopy or colonoscopy, may further increase screening rates.

The intervention consisted of multiple components, and we did not assess the effectiveness of each individual component. However, a comparison of the 2 intervention arms shows that distribution of free FOBT kits increased CRC screening rates (any test) only moderately (about 5 percentage points over and above the intervention without FOBT distribution). This effect size is within the range found in previous community setting studies in which FOBT kits were mailed to residents of Wright County, Minnesota, or to patients of practice groups who all had health insurance. In addition, of the participants who got screened, about 90% in both intervention arms received an FOBT, either with or without endoscopy. When interpreting this finding, it is important to note that almost 80% of Filipino Americans in our sample had a regular doctor and 70% had health insurance, reflecting the relatively high level of health insurance in this community. Distribution of free FOBT kits may lead to larger effects among populations with lower access to health care. In addition, our study encouraged participants to ask their providers for a CRC screening test, and many providers were informed about the study by mail and urged to recommend CRC screening to their patients. Both of these components may have prompted a discussion of CRC screening with the provider. Distribution of free FOBT kits may lead to larger effects in studies that do not include these intervention components or similar components.

**Limitations**

As in many other surveys and intervention studies, our outcome was based on self-reported screening, which could be biased. However, intervention effects held up after adjusting for the sensitivity and specificity of self-report. In addition, our sample did not constitute a population-based sample of Filipino Americans, which may limit the generalizability of our findings. However, our sample is representative of foreign-born Filipino Americans who are served by many religious and community-based organizations, which could potentially implement similar interventions to increase CRC screening in the future. Because members of the same community organization who were assigned to different study arms may have interacted, there is a potential for contamination. However, this contamination would bias our results against finding differences, making the results more conservative.

**Conclusions**

Our results suggest that an educational group session in a community setting, followed by a reminder letter to participants and a letter to providers, can lead to a significant increase in CRC screening, even without providing free FOBT kits. This finding is important for future attempts to implement similar programs more widely through Filipino American community organizations, especially for organizations that may not have the resources to distribute FOBT kits.

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**TABLE 3—Effectiveness of the Intervention by Intent-to-Treat Analysis: Filipino Health Study, Los Angeles, CA, 2004–2009**

<table>
<thead>
<tr>
<th>Follow-Up Period</th>
<th>Screened During (Self-Report), No. (%)</th>
<th>OR (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention with FOBT kit (n = 202)</td>
<td>61 (30)</td>
<td>4.9 (2.4, 9.9)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Intervention without FOBT kit (n = 183)</td>
<td>45 (25)</td>
<td>3.7 (1.8, 7.5)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Control (Ref) (n = 163)</td>
<td>14 (9)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note. CI = confidence interval; FOBT = fecal occult blood test; OR = odds ratio. Analyses were conducted by using mixed effects logistic regression with random intercepts for organization and session within organization and adjustment for language of baseline interview.

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**About the Authors**

At the time of the study, Annette E. Maxwell, Roshan Bastani, Leda L. Danao, Cynthia Antonio, Gabriel M. Garcia, and Catherine M. Crespi were with the School of Public Health and Jonsson Comprehensive Cancer Center, University of California, Los Angeles. Correspondence should be sent to Annette E. Maxwell, 650 Charles Young South, Room A2-125 CHS, Los Angeles, CA 90095-6900 (e-mail: amaxwell@ucla.edu). Reprints can be ordered at http://www.ajph.org by clicking the Reprints/Eprints link.

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**Contributors**

A.E. Maxwell and R. Bastani designed and supervised the study and developed the article. A.E. Maxwell led the writing. L.L. Danao, C. Antonio, and G.M. Garcia implemented the study and contributed to the analyses and the writing. C.M. Crespi conducted the analyses and contributed to the writing.

**Acknowledgments**

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**Human Participant Protection**

This study was approved by the University of California, Los Angeles, institutional review board and all participants provided informed consent. The trial was registered at ClinicalTrials.gov (NCT000742729).
References


