Abstract

Background: Clinical trials are a critical resource for the discovery of new prevention, diagnostic, and treatment methods for cancer. The most effective prevention and treatment modalities are based on previous clinical trial results. However, participation in clinical trials is underrepresented by racial/ethnic minority populations, Asian Americans in particular. Asian Americans are the least represented of any ethnic groups in clinical trials. The purpose of this study is to develop and evaluate a culturally and linguistically appropriate community-based educational intervention to increase knowledge of and intent to participate in cancer clinical trials among underrepresented Chinese Americans.

Methods: Community-Based Participatory Research approach was used to guide the development, cultural tailoring, implementation, and evaluation of clinical trial intervention. First, 22 Asian community representatives were recruited as community health educators (CHE) who received 12-hour training on clinical trial education. Second, 262 members were recruited from 11 Chinese community organizations. Of those recruited, a total of 247 eligible Chinese enrolled and participated in the clinical trial education delivered by trained CHEs. Participants completed pretest before and posttest after the intervention.

Results: Fifteen of 21 measures of clinical trial knowledge showed significant changes post the intervention ($P < 0.05$). Education remained the sole demographic factor increasing clinical trial knowledge in multivariate analysis.

Conclusion: Clinical trial education should emphasize both benefits to science and the larger Asian community. This community-based clinical trial intervention demonstrated promising results and has potential to enhance recruitment and participation in clinical trial research among the underrepresented Asian Americans.

Impact: Improving clinical trial participation in the fast-growing Asian American population is key to dissemination of health innovations targeted to diminish health disparities.

See all articles in this CEBP Focus section, “Community Network Program Centers.”

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Introduction

Clinical trials are a critical resource for the discovery of new prevention, diagnostic, and treatment methods for cancer. Many of today’s most effective prevention and treatment modalities are based on previous cancer clinical trial results. Clinical trials are an important part of improving quality of health care. However, the impact of clinical trial research may be limited by low participation in cancer clinical trials by underrepresented racial/ethnic minority populations, Asian Americans in particular. Asian Americans are the least represented of any U.S. ethnic groups in clinical trials.

Studies of patients enrolled in cancer treatment trials sponsored by the National Cancer Institute (NCI) recognize that the following populations are underrepresented in terms of their participation in cancer treatment trials: the elderly, those of low socioeconomic status, those living in rural areas and Latino/Hispanic, Asian/Pacific Islander and American Indian/Alaska native men and women, as well as African American men (1, 2).

Underrepresentation of minorities goes beyond cancer research. In a review of NIH-funded community-based clinical trials, only half of the studies reported minority inclusion (3). Of the 21 identified studies, Asian Americans only made up 1.1% of the recruited participants. In the Prostate, Lung, Colorectal and Ovarian (PLCO) screening trials, only 3.6% of Asians were recruited in areas where they made up 5.4% of the population. In a larger review of 240 randomized controlled trials (RCT), only half of the studies included minorities and 1.6% of these were Asian Americans (4). Such low rates of
Clinical Trial Educational Intervention for Chinese Americans

participation preclude reporting trial outcomes for ethnic subgroups (4, 5). Clinical trials that do not include an adequately diverse population will not ensure broad generalizability of results.

Although the NIH mandates inclusion of minorities in federally funded clinical trials, their guidelines do not set benchmarks for minority accrual (6). Researchers have used a number of approaches to better understand enrollment. The NCI funded the CanCORS study to identify rates of participation to provide an evidence base for possible benchmarks (7). In this large, population-based study, only 5.3% of patients with colorectal and lung cancer enrolled into trials over the course of the study. Another participation estimate comes from a health organization-based study. This intervention study sought to improve institutional minority participation. Their estimated minority participation improved from 12% to 14% over a 5-year period (8). The institution researchers estimated that the “rolling” average of minority cancer incidence at the institution increased 17.5% over the same time period so that increases in enrollment lagged behind cancer incidence (9). Asian American-specific clinical trial accrual rates that could be used as benchmarks are unknown.

Explaining disparities in clinical trial participation is complex for Asian Americans. Our large community-based study among Asian Americans found only 21% of Asian Americans understood the meaning of a clinical trial and 14% stated that they would like to participate in a clinical trial (10). Another study showed that more Asians (34%) than Whites (20%) had never heard the term “clinical trial” (11). Chinese American communities have low knowledge of and negative attitudes toward clinical trials. In this study of Chinese cancer patients, 62% reported no knowledge of clinical trials (12). Similarly, in a study of patients with cancer and care providers, Asian Americans were less likely than other groups to have heard the term “clinical trials,” to know someone who had participated in a RCT and to be willing to participate in a RCT (11).

Disparities of participation in cancer clinical trial research may be attributable to cultural beliefs and attitudes toward or lack of knowledge about the importance of clinical or biomedical research to the health of the community (13, 14). Respondents in the study of Asian American cancer patients and care providers were more likely to think of RCTs as experiments and be concerned about insurance coverage and costs of care (11). In addition, the complex consent forms and procedures prevent Asian Americans, especially those who have low literacy levels and limited English proficiency from participating in clinical trials (13, 14). Other barriers to participation in cancer clinical trials include mistrust of researchers, language issues, lack of financial and social support, and cultural differences from the mainstream (12, 15).

Facilitators of participation in cancer prevention and treatment clinical trials have been linked to recommendations by trusted health care providers, language-specific materials, a supportive family, good doctor–patient communication that was sensitive to culture, anticipation of a personal benefit to participants, financial incentives, culturally appropriate advertisements, and convenience to participants (12, 15).

Unfortunately, little intervention research has been done to date to address such barriers and facilitators of clinical trial participation in communities. Our literature review found no reports of evidence-based interventions to increase community knowledge about and participation in cancer clinical trials among Asian ethnic groups.

The primary purpose of this study is to develop and evaluate a culturally and linguistically appropriate community-based educational intervention to increase knowledge of and intent to participate in cancer clinical trials among underrepresented Chinese Americans. This community-based clinical trial education program is part of the Community Core of the National Asian Community Cancer Health Disparity Center (ACCHDC), one of the Community Networks Program Centers (CNPC) funded by the National Cancer Institute’s Center to Reduce Cancer Health Disparities.

As such, this study represents a first step toward increasing representation of all racial and ethnic groups in cancer research so that personalized prevention and treatment options will be available and, hopefully, gains made in addressing health disparities.

Materials and Methods

Study sites and participants

The Asian Community Health Coalition (ACHC) partnered with the Center for Asian Health (CAH), Temple University to recruit Chinese community-based organizations (CBO) located in greater Philadelphia area that could identify 2 community members willing to be trained as Community Health Workers and implement the intervention according to protocol. The ACHS includes more than 300 organizations serving Asian populations of which approximately 100 serve Chinese populations in Philadelphia. The eleven recruited CBOs are social, religious, and human services agencies predominantly serving low-income, uninsured, and underrepresented Asian American populations. CBO staff members were trained as described below and recruited a total of 262 eligible Chinese. Of those recruited, 247 (94.3%) enrolled, participated in the clinical trial education program, and completed pre- and post-tests. Participants eligible for this pilot intervention were: (i) self-identified as Chinese ethnicity; (ii) active members of the community organizations; (iii) aged 18 and above; and (iv) have not previously participated in any cancer clinical trial education programs.

Development of the clinical trial education intervention

In 2011, CAH collaborated with Education Network to Advance Cancer Clinical Trials (ENACCT) to
implement a cancer Clinical Trials Train-Of-the-Trainer program (CT-TOT) for Asian Community Health Educators (CHE). Key to the development of the training content was ENACCT’s use of a “Learning and Feedback” approach with to inform cultural adaptations to key messages about cancer clinical trials awareness and participation. CAH/ENACCT first conducted one 4-hour Learning and Feedback session with 22 recruited volunteer Asian community representatives (as future CHEs). At the session, a core community education module was demonstrated by CAH/ENACCT team to generate real-time community input on the changes needed to adapt and create messages about cancer clinical trials participation to improve Asian American accessibility and cultural relevance in the CAH service area. Specifically, qualitative feedback and a quantitative ranking questionnaire were used to reach agreement on the most desired changes. CAH/ENACCT applied the gathered community feedback to revise the module text and visual content. Follow-up phone meetings and written comments captured after the session were also used for final module refinement.

Second, the 22 Asian CHEs completed an 8-hour TOT program using the revised education module. Upon completion of the program, all trained Asian CHEs delivered a practice session of the clinical trial education before conducting sessions in the community. In the practice session, CHEs successfully presented: (i) the purpose of cancer clinical trials and how they work; (ii) names for the various types and steps of clinical trials; (iii) a description of the purpose of randomization in clinical trial protocols; (iv) potential costs associated with participation in clinical trials and how insurance and other programs may cover all or part of costs; (v) the process by which people are referred to cancer clinical trials; (vi) current methods of participant protection that are implemented throughout the research process; and (vii) appropriate use of adult learning theory as it relates to training health care professionals. A role play was also incorporated in the practice sessions. Using scenario-based designs, CHEs had opportunities to rehearse how to address questions and concerns related to clinical trial topics.

Study design and data collection procedures
The Community-Based Participatory Research (CBPR) framework guided the study process. Fundamental CBPR principles of participation, relevance, empowerment, community competence, and issue selection were incorporated into the intervention study (16, 17).

CAH implemented the clinical trial educational intervention study at 11 CBO sites. Community leaders serving Chinese populations were involved in the development and pilot testing of program content and procedures. CHEs trained in the development phase provided clinical trial education to all eligible participants. The clinical trial education sessions were delivered in small groups of approximately 35 participants. The clinical trial education curriculum included basic discussions of: (i) cancer clinical trials; (ii) stages and types of cancer clinical trials; (iii) benefits of participating in cancer clinical trials; (iv) reasons that people have for not participating in cancer clinical trials; and (v) processes for self-protection when participating in cancer clinical trials.

In addition to CHEs, CBO community volunteers also provided assistance in clarifying information for participants, such as reading the evaluation questions aloud to participants or interpreting the direct meaning of the specific question(s) if someone with low literacy level had difficulty in understanding them. To increase self-efficacy, the Chinese CHEs used activities such as “share your story” and linguistically appropriate printed materials to model and reinforce positive attitudes towards clinical trials. Chinese language handouts on clinical trials and some types of cancer (colorectal cancer, breast cancer, and cervical cancer) were also provided. Participants (N = 247) completed pre-tests before and post-tests after the clinical trial education.

Measures
Study assessment tools (pre- and post-test questionnaires) were partly developed by Dr. Ma and her team and partly adapted from the ENACCT knowledge assessment. The assessments were translated from English into Chinese and other Asian languages and back translation was conducted. The Chinese questionnaire was then pretested for acceptability, comprehension, and cultural appropriateness as well as face validity. All necessary modifications were made. Final study measures included: (i) demographic and acculturation variables (e.g., age, marital status, education, country of birth, and English language fluency); (ii) health care access (e.g., health insurance, having a regular health provider); (iii) knowledge and beliefs about clinical trials (e.g. What are clinical trials?, clinical trial disparities, procedures of randomization and informed consent, participant rights and benefits of clinical trials); (iv) trust toward researchers and motivations of clinical trial participation. Participants choose “true” or “false” as responses to knowledge items. The average time for questionnaire completion was 30 minutes.

Statistical analysis
Pre- and post-clinical trials knowledge item responses were coded as “correct” (1) and “incorrect” (0). SPSS (V20) was used to estimate differences between pre- and post-tests knowledge item scores (χ² and McNemar tests). A summary knowledge score variable was created from the 22 knowledge items (range = 1–18, mean = 11.6, SD = 4.0) and was used as the dependent variable in subsequent analyses. The Tukey test of additivity was significant at \( P = 0.000 \) (Friedman’s \( \chi^2 = 125.0 \)) indicating strong scale reliability (18). Knowledge scale mean differences for demographic categories were calculated using a Student t test. Multiple regression modeling was conducted to
identify important demographic predictors of knowledge scores.

Results

Demographics

Frequencies for demographic variables are presented in Table 1. More than half (57.7%) of participants were aged 66 to 79 years and 17.9% were 80 or older, a primarily elderly group. More females (68.4%) participated in the study than males (31.6%). Most participants (97.15%) were born outside the United States and more than half (67.9%) lived in the United States less than 15 years. Most participants had incomes less than $10,000 (80.2%), education at the high school level or below (64.1%) and health insurance (72.1%). Mean scores and significant differences on the clinical trials knowledge scale are shown for demographic variables. Participants with higher education and aged 66 to 79 had higher scores on the Cancer Clinical Trials Knowledge scale.

Outcomes of clinical trials knowledge

Table 2 displays pre- and post-test percentages and mean differences for Clinical Trial Knowledge scores. Fifteen of the 22 questions were significantly improved after the clinical trial education intervention. Examples include significant percentage differences for the variables understanding reasons for cancer clinical trials blinding procedures (17.8%–38.9%), understanding that patients can withdrawal during clinical trials at any time (68.0%–88.7%) and knowing that people treated for cancer are now living longer because of the progress of clinical trials (75.3%–83.8%). Seven items did not show significance differences including three of the four measures of trust in researchers, the two measures of motivation for participation and the item measuring knowing that the new approach is not necessarily better than the one currently being used with other patients. The dependent variable in multivariate analyses was calculated from these items into the scale referred to in tables as "Clinical Trials Knowledge."

Outcomes of post clinical trial factors

The results of the generalized linear model assessing the associations between demographics and post-intervention knowledge of clinical trials are displayed in Table 3. The overall model was not significant (F = 1.689, df = 7, P = 0.119) which is not surprising given...
Table 2. Pre- and postclinical trial knowledge items, correct percentages (t scores, P values)

<table>
<thead>
<tr>
<th>Knowledge Category</th>
<th>Pre-test correct percent</th>
<th>Post-test correct percent</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical trials knowledge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Understand what are cancer clinical trials</td>
<td>63.2</td>
<td>88.3</td>
<td>0.000b</td>
</tr>
<tr>
<td>2. Know that the new approach is not necessarily better than the one currently being used with other patients</td>
<td>59.9</td>
<td>65.2</td>
<td>0.177</td>
</tr>
<tr>
<td>Clinical trial disparities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Know participation rates in clinical trials are low for minority groups</td>
<td>33.6</td>
<td>53.8</td>
<td>0.000b</td>
</tr>
<tr>
<td>Randomization procedure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Understand cancer patients are not told about the option of getting their care through a clinical trial</td>
<td>17.8</td>
<td>38.9</td>
<td>0.000b</td>
</tr>
<tr>
<td>5. Know that a percentage of patients may get a placebo</td>
<td>19</td>
<td>20.2</td>
<td>0.648</td>
</tr>
<tr>
<td>6. Know that treatment to patients is chosen randomly, doctors cannot pick the best treatment to give the patient</td>
<td>67.2</td>
<td>82.6</td>
<td>0.000b</td>
</tr>
<tr>
<td>7. Understand that the treatment you get is decided by chance in a clinical trial</td>
<td>39.7</td>
<td>51.8</td>
<td>0.001b</td>
</tr>
<tr>
<td>Informed consent procedure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Know that the law requires doctors and nurses explain all risks and benefits before someone agrees to join</td>
<td>74.9</td>
<td>87.4</td>
<td>0.000b</td>
</tr>
<tr>
<td>9. Know that patients must sign the informed consent before entry</td>
<td>65.6</td>
<td>81.8</td>
<td>0.000b</td>
</tr>
<tr>
<td>Participant rights</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Know participants have the right to withdraw from a clinical trial at any time</td>
<td>68.0</td>
<td>88.7</td>
<td>0.000b</td>
</tr>
<tr>
<td>11. Know that joining a clinical trial is entirely voluntary</td>
<td>82.2</td>
<td>89.9</td>
<td>0.007b</td>
</tr>
<tr>
<td>12. Understand a patient cannot be required to have additional tests if he/she enters a trial</td>
<td>20.6</td>
<td>25.5</td>
<td>0.019b</td>
</tr>
<tr>
<td>13. Understand that patients will not get the other treatment offered in the trial if they don’t get the treatment they wanted</td>
<td>46.6</td>
<td>61.5</td>
<td>0.000b</td>
</tr>
<tr>
<td>14. Understand that joining in clinical trial does not mean free of charge for all cares received</td>
<td>5.3</td>
<td>15.4</td>
<td>0.000b</td>
</tr>
<tr>
<td>15. Understand that the risk of participating in clinical trials does not always outweigh the benefits</td>
<td>28.3</td>
<td>36.4</td>
<td>0.015b</td>
</tr>
<tr>
<td>Benefits of clinical trials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Know that people treated for cancer are now living longer because of progress of clinical trials</td>
<td>75.3</td>
<td>83.8</td>
<td>0.008b</td>
</tr>
<tr>
<td>Fear/mistrust to researchers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Believe that patients may be placed into a clinical trial without knowing it</td>
<td>55.1</td>
<td>55.9</td>
<td>0.906</td>
</tr>
<tr>
<td>18. Believe that the medical records and names of patients in clinical trials will not be published</td>
<td>55.5</td>
<td>54.3</td>
<td>0.822</td>
</tr>
<tr>
<td>19. Do not believe that participant almost never gets a placebo in a clinical trial</td>
<td>85.2</td>
<td>77.3</td>
<td>0.033b</td>
</tr>
<tr>
<td>20. Do not believe doctors cannot require patients to join a clinical trial even if it asks a very important question</td>
<td>86.6</td>
<td>85.0</td>
<td>0.618</td>
</tr>
<tr>
<td>Barriers of participation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21. Do not believe that patients only join a treatment clinical trial when no other treatments have worked</td>
<td>70.0</td>
<td>67.2</td>
<td>0.419</td>
</tr>
<tr>
<td>22. Do not believe that the mistrust of medical care system is the only major barrier for participating in a cancer clinical trial</td>
<td>89.5</td>
<td>87.4</td>
<td>0.511</td>
</tr>
</tbody>
</table>

*aMcNemar test was used to identify significant differences between pre- and post-test knowledge items.  
*bIndicates significant differences between pre- and post-test scores.
that only one variable, education \((t = 3.214, P = 0.002)\), was significant. Because of the homogeneity of the sample on most demographics as in Table 1 and that the sample size of the multivariate analysis was lower because of missing data, few demographics were expected to be significant. That education was more significant in the multivariate analyses than in the mean differences (Table 1) indicates suppression from the other variables in the model.

**Discussion**

Asian Americans are one of the fastest growing populations in the United States. From 2000 to 2010, the Asian alone or in combination U.S. population increased more than four times faster than the total U.S. population to reach 17.4 million persons (19). Asian Americans and Pacific Islanders (API) will continue to be the fastest growing population in the United States and it is projected that APIs will reach 41 million or 10% of the total U.S. population by 2050 (20). Chinese Americans are the largest subgroup of Asian Americans and Pacific Islanders. With the fast population growth, CBPR intervention projects in diverse ethnic communities like the one described in this study should be a priority.

Cancer is the leading cause of death among Asian Americans and Pacific Islanders in the United States (21). Asian Americans suffer disproportionately from certain types of cancer, such as Hepatitis B-related liver cancer, cervical cancer, stomach cancer, and colorectal cancer. Despite these cancer health disparities, the recruitment of Asian Americans into cancer clinical trials for these cancers continues to be low (10, 11, 22, 23). The health needs of these ethnic subgroups are still largely unknown (24–27), partly because of a scarcity of research on these populations and partly because of the diversity of different racial and ethnic groups that makes this research complex.

This article reported the process of developing a community-based culturally and linguistically appropriate clinical trial educational intervention in the Chinese community as well as results generated from this exploratory study showed an overall significant improvement on essential knowledge about clinical trials in comparison of pre and post-test scores for the education intervention. The study suggested that the CHE-led culturally tailored educational intervention can effectively increase community members’ understanding of clinical trials, knowledge about clinical trial randomization procedures, informed consent, participants’ rights, and benefits of clinical trials. The findings also suggested that the improvement in clinical trials knowledge was significantly associated with education in the multivariate regression models. This finding underlines the importance of health literacy in cancer communication including providing sufficient information to patients with cancer so that they can know about and make decisions in regards to clinical trial participation (28).

The term, “clinical trial” is unfamiliar to lay Asian community members (10). The effective diffusion of clinical trial messages in the Chinese community may be attributed to the comprehensive strategies and processes of culturally tailoring the educational intervention for the targeted community, including the use of CBPR, Learning and Feedback, and TOT approaches. Many communities either do not know about clinical trials or have misunderstandings about how clinical trials work which serves as a significant barrier to clinical trial participation (15, 29). The participants in this community study made great gains in knowledge of clinical trials, yet, because this study recruited community members who may not have much experience with cancer, their improvements in knowledge may not be directly linked to increased participation in clinical trials. The value of community interventions like this is that participants may discuss the information gained in the community which may in turn break down stigma and reduce misinformation. Participants may also introduce the idea of asking a health care provider about participating in clinical trials for friends and family who may experience cancer. Further research.

**Table 3. Multiple regression model between demographics and summed score of postintervention clinical trial knowledge items \((n = 114)\)**

<table>
<thead>
<tr>
<th>Variable</th>
<th>(\beta)</th>
<th>(T)</th>
<th>(P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female gender</td>
<td>0.100</td>
<td>1.003</td>
<td>0.318</td>
</tr>
<tr>
<td>Born in United States</td>
<td>0.034</td>
<td>0.359</td>
<td>0.720</td>
</tr>
<tr>
<td>Have health insurance</td>
<td>0.045</td>
<td>0.350</td>
<td>0.727</td>
</tr>
<tr>
<td>Annual income</td>
<td>−0.078</td>
<td>−0.734</td>
<td>0.465</td>
</tr>
<tr>
<td>Age</td>
<td>−0.111</td>
<td>−0.832</td>
<td>0.407</td>
</tr>
<tr>
<td>Years in United States</td>
<td>0.083</td>
<td>0.756</td>
<td>0.451</td>
</tr>
<tr>
<td>Education</td>
<td>0.347</td>
<td>3.214</td>
<td>0.002</td>
</tr>
<tr>
<td>Intercept</td>
<td>9.855</td>
<td>2.535</td>
<td>0.013</td>
</tr>
</tbody>
</table>

Test for model \(R^2, F, df, P\)

\[ R = 0.099, F = 1.689, df = 7, P = 0.119 \]
Barriers to clinical trial recruitment have been well documented (14, 27). Common structural obstacles/barriers included lack of accessible and affordable research trials and patient’s inability to qualify for or comply with specified research protocols, especially those who are medically underserved and have limited English proficiency. Patient fears and mistrust of the research community are essential cultural barriers (11, 14, 22, 27, 30, 31). Our study results further supported the literature that fear and mistrust of medical care system is one of the major barriers for participating in a cancer clinical trial. For the assessment about “Trust to Researchers/doctors”, the intervention did not make significant changes in participants’ beliefs about “use placebo” and “patient confidentiality”. The findings suggest that future clinical trial education should focus on strategies that address patient fears and mistrust and solutions for overcoming structural barriers to increase clinical trial participation and enrollment, especially among underrepresented ethnic communities.

The intervention had no documented significant change in scale items that measured trust toward health care professionals. Health care providers play a pivotal role in recruiting and retaining eligible clinical trial participants. Providing cancer clinical trial training to health care providers in the cultural context can help increase clinical trial participation rates (7, 9). Recently, we at Center for Asian Health launched an online Culturally Appropriate National Cancer Clinical Trial Education program for physicians who serve a large number of Asian American patients. Future research will need to test health care provider interventions for increasing clinical trial participation by Asian Americans. Also, enrollment into clinical trials is a complex process involving a timely match between eligibility criteria and patient characteristics and assumes interest in and resources to fully participate in the trial. Interventions to improve Asian American representation in clinical trials will need to address access to health care, community norms, and values, and, most importantly, knowledge of clinical trials.

The study has two limitations. First, results of this study in the Chinese community may not be generalizable to all Asian ethnic groups. Furthermore, the results may underestimate the role of socioeconomic factors beyond education. This sample reflects a convenience factor where study participation is influenced by the availability of older Chinese Americans who have the flexible time to come to the education sessions. Although this may introduce some sample bias, older people are most at risk for some cancers and are likely to be eligible for Medicare and/or Medicaid in addition to some private insurance, making this sample a relevant population. Second, this study used a one group pre- and post-test study design that did not include a control or comparison group. Hence, the results may not reflect the full range of knowledge and attitude changes in the population.

Nonetheless, this study represents a first step towards evidence-based interventions to increase knowledge of and participation in cancer clinical trials among Asian Americans specifically and underrepresented populations in general. Although published studies like those described in the introduction for NCI and NIH (1, 2) note minority participation rates, few have gone to the next step to test interventions to improve community understandings of clinical trials. Future research needs to build on this study to: (i) expand the scope of clinical trial intervention research to capture the diversity both within and between U.S. Asian and other ethnic groups; (ii) conduct longitudinal studies to track subsequent participation in prevention and treatment trials; and (iii) consider including or adapting education modules for different kinds of cancer and/or other health conditions.

The investigators also observed changes in those recruited and trained CHEs who offered education intervention to the lay community. Future research should include CHEs to identify both changes in CHE attitudes and behaviors and best practices in conducting clinical trial education. The latter would further inform those developing, tailoring and implementing such interventions and contribute to a better understanding of measuring and achieving model fidelity.

In summary, culturally appropriate CHE-led community-based educational intervention can effectively deliver clinical trial messages and potentially improve the participation in clinical trials among underserved Chinese and other Asian communities.

Best practices for improving recruitment and retention of underrepresented populations to clinical trials is an important topic for public health professionals, especially for those interested in addressing cancer health disparities. New efforts are in the making. For example, in 2011, the international Cochrane Collaboration (31) for evidence based practice held the first meeting for those studying clinical trial methodology and approximately 450 delegates attended. The second conference is planned for 2013 and this meeting now includes a track for recruitment and retention of special populations (33). With forums such as this, research like that reported here has potential to be disseminated widely offering new options to clinical trials looking to improve minority representation.

U.S. national initiatives like the one released by the White House to address Hepatitis screening and treatment among Asian Americans would also benefit from improved recruitment of Asian Americans. NIH and independent organizations like the Institute of Medicine have also called for increased participation of minorities in clinical trials research for a wide range of health risks and conditions. Such diversity is critical.
to verify the generalizability of clinical trial study findings for all U.S. populations.

Disclosure of Potential Conflicts of Interest
N.C. Blakeney is employed (other than primary affiliation; e.g., consulting) as an independent contractor in ENACCT. No potential conflicts of interest were disclosed by the other authors.

Authors' Contributions
Conception and design: G.X. Ma, Y. Tan
Development of methodology: G.X. Ma, Y. Tan, X.S. Ma
Acquisition of data (provided animals, acquired and managed patients, provided facilities, etc.): S. Zhai
Analysis and interpretation of data (e.g., statistical analysis, biostatistics, computational analysis): G.X. Ma, Y. Tan, B.F. Seals, Y. Tai
Writing, review, and/or revision of the manuscript: G.X. Ma, Y. Tan, N.C. Blakeney, B.F. Seals, M. Michaels
Study supervision: G.X. Ma, Y. Tan, A. Liu

References

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The Impact of a Community-Based Clinical Trial Educational Intervention among Underrepresented Chinese Americans

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