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Clinical trials-related knowledge, attitudes, and behaviors among Black and Latina women: A randomized controlled trial of the *Women United: Clinical Trials and the Fight Against Breast Cancer Program*

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Abstract
Black and Latino adult cancer patients are underrepresented in cancer clinical trials, which limits generalizability of findings and amplifies disparities in healthcare access and outcomes. Community-level education programs designed to address barriers to participation could improve representation in cancer clinical trials. Through a community–campus partner framework, this study evaluated the *Women United: Clinical Trials and the Fight Against Breast Cancer Program* in Spanish and English. Participants were 422 women (141 Black, 140 Latina Spanish preference, 141 Latina English preference) who were randomized to view either the intervention ($n = 215$) or a control ($n = 207$) program. Assessments of clinical trials knowledge and barriers to clinical trials participation were taken before and after viewing. Results suggested that clinical trials knowledge increased and perceived barriers to participation decreased for those who viewed the educational program. More specifically, those in the intervention condition perceived fewer barriers related to personal benefits, mistrust, and familiarity of clinical trials. As expected, there were no differences in perceived barriers related to community support for either condition. Participants in both conditions were equally likely to join a subsequent study or a clinical trials community ambassador program. There were no differences in any of the outcomes across ethnicity or language, suggesting the program works equivalently across groups. This program is easy to administer and can be recommended for use among Black and Latina women to address factors related to clinical trials participation.

Keywords Clinical trials · Cancer · Health disparities · Health education · Black · Latino

Cancer clinical trials are research studies aimed at testing methods to prevent, identify, diagnose, treat, and manage cancer and its consequences. Such studies are essential to improving cancer-related outcomes, although only approximately 8% of adult cancer patients participate in clinical trials [1]. Moreover, despite being disproportionately impacted by cancer, Black and Latino adult cancer patients are underrepresented in clinical trials participation, constituting only 3.1% and 6.1% (respectively) of clinical trial samples over the last decade [2]. Because there can be no assurances made that the advances developed through research will be of equal value to members of communities that were not represented in studies, such disparities will reduce confidence in the generalizability of findings. Indiscriminate use of methods that are not proven to work across the entire population can widen the gap in health disparities. As such, disparities in clinical trials participation uphold inequities in healthcare and undermine the basic tenets of evidence-based practice.

Numerous circumstances and barriers contribute to these lower participation rates among Black and Latino cancer patients. Financial [3], transportation, and other structural

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barriers (e.g., lack of access to institutions or physicians with resources to offer clinical trials) disproportionately affect these populations [4]. Individual-level factors also impact this disparity, including a lack of access to information about clinical trials [5, 6], negative attitudes and perceptions toward clinical trials such as fear [5] and researcher distrust [7, 8], family or cultural barriers [9], lack of minority physicians' involvement in clinical trials [10], and the logistics/burden of participation [5, 6].

Theories of health behavior change including cognitive-information processing theories and the *Health Belief Model* [11] provide a framework for understanding and addressing individual-level factors for low rates of clinical trials participation. These theories emphasize the importance of knowledge about a health issue and the extent to which one's sense of vulnerability and perceived barriers impact engagement in a health behavior (in this case, clinical trials participation). Cancer education programs designed specifically to address individual-level barriers to clinical trials participation through culturally appropriate strategies may increase enrollment in clinical trials [12]. Pre-post studies of Black and Latino [13, 14] and Chinese American [15] community participants have evaluated culturally tailored interventions about cancer clinical trials using small group education sessions [13, 15] and self-paced slide presentations [14], with some demonstrated improvements in both knowledge and attitudes about clinical trials at post-test. Studies that have evaluated clinical trials education programs using a gold-standard randomized controlled trial methodology are sparse, although one recent randomized controlled trial of ethnic minority (Black, Asian, Latino, Native American; 48.4% of sample) and White (51.6% of sample) oncology patients was conducted wherein respondents were allocated to either an intervention (in-office viewing of a cancer clinical trials education video and receiving an education booklet) or usual care (receiving the same materials to take home with no instructions) without specific cultural tailoring of the curriculum [16]. No differences in knowledge, attitudes, perceived barriers, or enrollment in a clinical trial within a year emerged between conditions [16]. To date, no studies have used randomized controlled trial methodology to test a cancer clinical trials education program on a community-based ethnic minority sample. As such, there is a clear need to develop and rigorously test clinical trials educational programs that have been tailored for groups who have been underrepresented in clinical trials for use in community-level, prevention-based contexts.

Current Study

Thus, the overall goal of the current study was to evaluate the effectiveness of a simple, easy-to-administer educational program about breast cancer clinical trials for Black and Latina women. The program, titled *Women United: Clinical Trials and the Fight Against Breast Cancer*, was initially adapted from the National Cancer Institute's (NCI) *Clinical Trials Education Series*. The development and refinement of the program via a community–campus partnership that included a community advisory committee and over 40 Black and Latina women who participated in a series of focus groups is detailed elsewhere [17]. Such community–campus partnerships have been shown to play an important role in achieving culturally competent interventions focused on improving clinical trials participation [18]. The partnership originally anticipated that only minor cultural modifications to the NCI's existing *Clinical Trials Education Series* would be needed. However, serious concerns arose about the NCI program because 1) it had not been evaluated for effectiveness, 2) the Spanish and English versions were of very different content and length, and 3) the community advisory committee and focus group participants raised significant concerns about its content, relevance, engagement, and literacy levels. For those reasons, the partnership ultimately made major modifications to the program, streamlining content and enhancing cultural and linguistic alignment based on the suggestions of community advisors and focus group participants.

The final *Women United Program* is available in Spanish and English and consists of a series of self-paced slides with embedded commentary and video clips. The estimated completion time is 20 min. Content of the program includes the general principles of how clinical trials are conducted, types of clinical trials, protection of human subjects, impact and benefits of clinical trials, barriers to participation in clinical trials, how clinical trials contribute to the advancement of medical science, why sample diversity is important to generalizable findings, and how participation in clinical trials could benefit the Black and Latino communities. The program features a "sisterhood" theme that focuses on women uniting to fight breast cancer.

The study aims were achieved via a randomized control trial implemented through the community–campus partnership. The first aim was to evaluate whether the program would increase clinical trials-related knowledge. It was hypothesized that participants who viewed the educational program would have increased knowledge, compared to a control condition. The second aim was to evaluate whether the program would decrease perceived barriers to participating in clinical trials. It was hypothesized that participants who viewed the educational program would perceive fewer barriers to participating in clinical trials, compared to a control condition. The third aim was to evaluate two behavioral outcomes related to clinical trials participation, specifically, agreement to participate in (1) an additional study that requires providing a biological sample and (2) a community-based clinical trials advocacy program. It was hypothesized

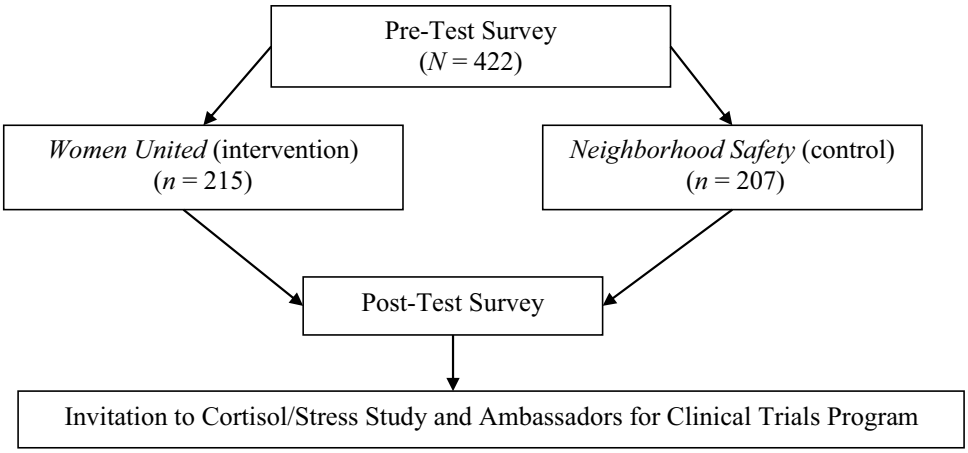

Fig. 1 Flowchart of the randomized controlled trial

that participants who viewed the educational program would be more likely to participate in these activities, compared to a control condition. As a final component of each primary study aim, ethnic/language group differences (Black, Latina Spanish preference, Latina English preference) for the results were also explored. It was hypothesized there would not be group differences in any of the findings from aims 1–3; that is, the educational program would have equivalent effects for all groups.

Methods

This study was approved by the Institutional Review Boards of the University of California San Diego and San Diego State University. Participants were recruited from San Diego County through flyers, face-to-face meetings at community sites, and word-of-mouth. Staff provided recruitment presentations in both Spanish and English. Eligibility criteria included self-identifying as a Black or Latina woman, being at least 21 years old, residing in San Diego County, and being able to read and understand either Spanish or English.

Procedure

See Fig. 1 for a flowchart of the procedure for the trial. Participants were scheduled for individual study visits at the Vista Community Clinic or San Diego State University. All communication and study materials were provided in the participants' language of preference (Spanish or English). After providing written, informed consent, participants completed a pre-test survey containing a demographics questionnaire and pre-test measures of clinical trials-related knowledge and perceived barriers to clinical trials participation. Following the pre-test survey, staff opened an envelope containing the randomization assignment of a participant to view either the *Women United Program* (i.e., intervention condition) or a control condition where they viewed a *Neighborhood Safety Education Program*. Randomization was determined using a computer-generated randomization table with two sets of randomized assignments (one each for Spanish and English). Paired randomization assignments were generated to increase the odds of equal numbers in the intervention and control conditions.

Prior to viewing their assigned program, participants were provided with a standardized, low-literacy introduction to their program and told there would be no discussion of the content so as to evaluate the program in a way that resembles how it would be delivered in a physician's office or online. Participants were instructed on the operation of the laptop to view their program at a comfortable pace, allowing for adequate time to view embedded video clips and to review previous slides as needed. For participants who were uncomfortable using a laptop, staff assisted the participant, but did not discuss content with the participant. After finishing their assigned program, participants completed a post-test survey containing the same measures of clinical trials-related knowledge and perceived barriers to clinical trials participation. After the post-test, two behavioral outcomes related to clinical trials participation were assessed to determine willingness to participate in cancer clinical trials-related research and/or advocacy. First, participants were invited to participate in a research study on breast cancer-related stress, involving completing an additional survey and providing a saliva sample to assess respondents' cortisol levels. Second, participants were invited to join the *Clinical Trials Ambassadors Program* at the UC San Diego Moores Cancer Center. All participants received $50 as a thank you for their participation.

Intervention and Control Condition Activities

Women United: Clinical Trials and the Fight Against Breast Cancer Program Participants randomized to the intervention

condition viewed the *Women United Program*, described above.

Neighborhood Safety Education Program The community–campus partnership's members agreed that the control program should have the potential to be equally beneficial to the control participants and their communities. Given the concerns and limitations previously mentioned about the NCI's *Clinical Trials Education Series* and the fact that its effectiveness had not been evaluated, the partnership opted to find an alternative program available in Spanish and English with a similar format, length, and community focus. Thus, participants randomized to the control condition viewed a slide-based, self-paced *Neighborhood Safety Education Program* with embedded commentary and video clips from the California Neighborhood Watch Program. This program is used by law enforcement officials to encourage community members to become involved in promoting safety in their neighborhoods. The program was viewed on a laptop with an approximate watch time of 20 min.

Pre- and Post-Test Measures

Clinical Trials Knowledge Ten true/false questions based on content from the video were used. An example item is: "In a clinical trial, the new treatment being tested is known to be at least as good as treatments already being used." The number of correct items was summed to create a total knowledge score ranging from 0–10, with higher scores indicating greater knowledge about clinical trials.

Barriers to Clinical Trials Participation Scale [19, 20] The 19-item BCTP evaluates perceived barriers towards participating in clinical trials and contains four subscales: *Lack of Personal Benefits* (4 items; example item: "There's nothing in clinical trials for me"), *Lack of Community Support* (3 items; example item: "People in my community don't think it's a good idea to get involved in clinical trials"), *Mistrust* (6 items; example item: "I worry that they are not telling me everything I need to know"), and *Lack of Familiarity* (6 items; example item: "I don't know enough about clinical trials to decide"). The response scale ranges from 1 (strongly disagree) to 5 (strongly agree). Higher scores reflect greater perceived barriers. The instrument was initially developed and validated in English via a community sample of Black and Latino women and men. The Spanish version was forward- and back-translated with reconciliation. The BCTP has demonstrated a 4-factor structure with high intercorrelations among factors, supporting use of the total score as an outcome measure, while using factor scores to aid in interpretation. The total score was calculated by averaging the 4 subscale scores. Internal consistencies for the subscales ($\alpha = 0.63$—0.74) and total score ($\alpha = 0.88$) were adequate.

Post-Test Behavioral Outcomes

Stress/Cortisol Study Participants were asked if they would be willing to participate in a research study on breast cancer and stress where they would fill out a short survey and provide a biological sample (saliva) to measure cortisol, but that additional compensation would not be offered for their participation. Those who agreed gave written informed consent, filled out the Perceived Stress Scale [21] and provided a saliva sample via "salivette" devices composed of cotton swabs in a plastic holder fitted inside a centrifuge tube. Participants were provided with detailed instructions for producing their sample. Time to completion for the stress/cortisol study was approximately 10 min.

UC San Diego Moores Cancer Center's Clinical Trials Ambassadors Program Participants were asked if they would be willing to join a community-based advocacy program for clinical trials. This involves receiving mailings of recruitment flyers for research studies and clinical trials to consider joining themselves, disseminating these flyers among others in their community, and periodically completing surveys that are used to assess the utility of the program. Those who agreed provided contact information for receiving the mailings.

Analytic Plan

Data analyses were conducted in SPSS 26. Descriptive statistics were calculated for the sample and each condition (intervention, control). Independent samples *t*-tests and chi-square tests for independence were evaluated to examine potential pre-test differences across demographic characteristics.

For aims 1 and 2, two-factor mixed ANOVA was used to examine mean differences in the pre- and post-test measures across experimental condition. The within-subjects factor was time (i.e., pre- and post-test); the between-subjects factor was condition (i.e., intervention, control). For aim 3, two binary logistic regression models were evaluated to examine differences (intervention vs. control) in willingness to participate in either of the post-test behavioral outcomes.

A final set of analyses was performed, to determine whether there were ethnic/language group differences in the findings from aims 1–3. For aims 1 and 2, a three-factor mixed ANOVA was used; this incorporated an additional between-subjects factor for the 3 ethnic/language groups (Black, Latina Spanish preference, and Latina English preference) to the previous models. For aim 3, the ethnic/language group variable and the interaction between experimental condition and ethnic/language group were added as predictors to the logistic regression model.

Results

Sample

Table 1 presents the sample characteristics. Participants were 422 women who self-identified as Black ($n = 141$) or Latina (Spanish preference $n = 141$, English preference $n = 140$). Ages ranged from 21 to 82 ($M = 42.01$). Approximately half of the overall sample had at least some college ($n = 227$), had an annual household income less than $35,000 ($n = 296$), and were not currently working ($n = 239$). There were no baseline group differences between the intervention and control conditions across demographic characteristics ($ps > 0.05$).

Aim 1: Clinical Trials Knowledge

The pre- and post-test results for clinical trials knowledge are presented in Table 2. There was a significant condition X time interaction, F (1, 409) = 28.54, $p < 0.001$, partial $\eta^2 = 0.07$. Clinical trials knowledge increased for the intervention condition (pre-test = 3.12, post-test = 3.98) but not the control condition (pre-test = 3.13, post-test = 3.13). When the ethnic/language groups were considered, the condition X time X ethnic/language group interaction was not significant, suggesting that the intervention's effect on clinical trials knowledge did not differ across Black, Latina Spanish preference, and Latina English preference women ($p > 0.05$).[1]

Aim 2: Barriers to Clinical Trials Participation

The pre- and post-test results for the BCTP total score and subscales are presented in Table 2. For the BCTP total score, there was a significant condition X time interaction, F (1, 420) = 24.16, $p < 0.001$, partial $\eta^2 = 0.05$. Respondents in the intervention condition (pre-test = 11.06, post-test = 9.32) reported a greater reduction in overall perceived barriers to clinical trials participation compared to the control condition (pre-test = 11.38, post-test = 10.72).

For the BCTP *Lack of Personal Benefits* subscale score, there was a significant condition X time interaction, F (1, 399) = 15.13, $p < 0.001$, partial $\eta^2 = 0.04$. Respondents in the intervention condition (pre-test = 8.89, post-test = 7.31) reported a greater reduction in barriers related to lack of personal benefits, compared to the control condition (pre-test = 9.13, post-test = 8.49). For the BCTP *Lack of Community Support* subscale score, the condition X time interaction was not significant, suggesting there were no differences across condition between pre- and post-test, F (1, 417) = 0.37, $p = 0.546$, partial $\eta^2 = 0.00$. For the BCTP *Mistrust* subscale score, there was a significant condition X time interaction, F (1, 404) = 20.50, $p < 0.001$, partial $\eta^2 = 0.05$. Respondents in the intervention condition (pre-test = 15.00, post-test = 12.27) reported a greater reduction in barriers related to mistrust, compared to the control

Table 1 Sample Characteristics

	Full sample ($N = 422$)	Intervention ($n = 215$)	Control ($n = 207$)
Age [a]	42.01 (13.92)	41.89 (13.91)	42.13 (13.95)
Ethnicity [b]			
Black	141 (33.4%)	74 (34.4%	67 (32.4%)
Latina—Spanish preference	141 (33.4%)	70 (32.6%)	71 (34.3%)
Latina—English preference	140 (33.2%)	71 (33.0%)	69 (33.3%)
Marital status [b]			
Married/living w/ partner	169 (40.0%)	90 (41.9%)	79 (38.2%)
Never married	101 (23.9%)	45 (20.9%)	56 (27.1%)
Widowed/divorced/ separated	150 (35.5%)	80 (37.2%)	70 (33.8%)
Education [b]			
Middle school or less	71 (16.8%)	36 (16.7%)	35 (16.9%)
Some high school	44 (10.4%)	22 (10.2%)	22 (10.6%)
High school diploma/ GED	77 (18.2%)	44 (20.5%)	33 (15.9%)
Some college	146 (34.6%)	72 (33.5%)	74 (35.7%)
College or vocational degree	63 (14.9%)	29 (13.5%)	34 (16.4%)
Beyond college	18 (4.3%)	11 (5.1%)	7 (3.4%)
Income [b]			
Less than $10,000	96 (22.7%)	44 (20.5%)	52 (25.1%)
$10,000—$19,999	115 (27.3%)	60 (27.9%)	55 (26.6%)
$20,000—$34,999	85 (20.1%)	42 (19.5%)	43 (20.8%)
$35,000—$49,999	44 (10.4%)	24 (11.2%)	20 (9.7%)
$50,000—$74,999	27 (6.4%)	11 (5.1%)	16 (7.7%)
$75,000 or more	16 (3.8%)	13 (6.0%)	3 (1.4%)
Employment [b]			
Employed for wages	175 (41.5%)	87 (40.5%)	88 (42.5%)
Out of work	90 (21.3%)	50 (23.3%)	40 (19.3%)
Homemaker	58 (13.7%)	26 (12.1%)	32 (15.5%)
Student	38 (9.0%)	14 (6.5%)	24 (11.6%)
Retired	20 (4.7%)	9 (4.2%)	11 (5.3%)
Unable to work/disability	33 (7.8%)	25 (11.6%)	8 (3.9%)

[a] *M*(*SD*);[b] *n* (%); Intervention=viewed the*Women United: Clinical Trials and the Fight Against Breast Cancer Program*;Control=viewed the *Neighborhood Safety Education Program*

[1] A descriptive table containing the pre- and post-test results for clinical trials knowledge, barriers, and behavioral outcomes for the intervention and control conditions by ethnicity/language is available from the authors on request.

Table 2 Pre- and post-test results

	Pre-test	Post-test
Clinical Trials Knowledge [a]		
Intervention	3.12 (1.66)	3.98 (1.48)
Control	3.13 (1.74)	3.13 (1.68)
BCTP—Total Score [a]		
Intervention	11.06 (2.89)	9.32 (2.90)
Control	11.38 (2.92)	10.72 (3.17)
BCTP—Lack of Personal Benefits [a]		
Intervention	8.89 (2.80)	7.31 (2.86)
Control	9.13 (3.05)	8.49 (3.12)
BCTP – Lack of Community Support [a]		
Intervention	6.21 (2.41)	5.99 (2.35)
Control	6.25 (2.32)	6.16 (2.43)
BCTP—Mistrust [a]		
Intervention	15.00 (4.41)	12.27 (4.46)
Control	15.69 (4.62)	14.64 (4.99)
BCTP—Lack of Familiarity [a]		
Intervention	14.25 (4.28)	11.53 (3.98)
Control	14.49 (4.37)	13.69 (4.35)
Stress/Cortisol Study [b]		
Intervention		187 (87.0%)
Control		169 (81.6%)
Clinical Trials Ambassadors Program [b]		
Intervention		180 (83.7%)
Control		174 (84.1%)

[a]*M*(*SD*);[b]*n* (%); Intervention=viewed the *Women United: Clinical Trials and the Fight Against Breast Cancer Program*; Control=viewed the *Neighborhood Safety Education Program*; BCTPBarriers to Clinical Trials Participation Scale

condition (pre-test = 15.69, post-test = 14.64). For the BCTP *Lack of Familiarity* subscale score, there was a significant condition X time interaction, F (1, 400) = 33.85, $p < 0.001$, partial $\eta^2 = 0.08$. Respondents in the intervention condition (pre-test = 14.25, post-test = 11.53) reported a greater reduction in barriers related to lack of familiarity of clinical trials, compared to the control condition (pre-test = 14.49, post-test = 13.69). When the ethnic/language groups were considered in the three-factor mixed model ANOVAs, no significant differences emerged for the condition X time X ethnic/language group interactions, suggesting that the intervention worked equivalently for across Black, Latina Spanish preference, and Latina English preference women ($ps > 0.05$).

Aim 3: Behavioral Outcomes

A description of the behavioral outcomes (Stress/Cortisol Study, Clinical Trials Ambassador Program) by condition is available in Table 2. There were no differences in agreement to participate in the *Stress/Cortisol Study* between the intervention (87.0% agreed) and control (81.6% agreed) conditions, χ^2 (1) = 2.28, $p = 0.131$. There were also no differences in agreement to participate in the *Moores UCSD Cancer Center's Clinical Trials Ambassadors Program* between the intervention (83.7% agreed) and control (84.1% agreed) conditions, χ^2 (1) = 0.01, $p = 0.925$. When the models were evaluated with the inclusion of the ethnic/language variable, there were no significant effects for the agreement X ethnic/language group interactions, suggesting that the observed null effects were not different across Black, Latina Spanish preference, and Latina English preference women ($ps > 0.05$).

Discussion

This study aimed to evaluate the effectiveness of a "sisterhood" themed *Women United: Clinical Trials and the Fight Against Breast Cancer Program* [17]among Black and Latina (Spanish- and English-preference) women. In support of the hypothesis for aim 1, clinical trials knowledge increased from pre- to post-test for those who viewed the program, whereas knowledge remained stable for those in the control condition. While this increase was statistically significant, it is worth noting that this was a small practical change (approximately 1 additional item answered correctly). This finding parallels several pre-post designed studies of cancer clinical trial educational interventions that have also reported minor improvements for total knowledge [13, 14] and individual questions [15] among ethnic minority community respondents. Moreover, the prior samples of Black and Latino respondents demonstrated identical knowledge improvements across ethnicity [13, 14], as in the current study. It is notable that the one other randomized controlled trial of a cancer clinical trials education program did not yield any improvement in knowledge [16]. Differences across that trial and the current one may offer potential explanations for these contrasting findings. For example, the previous randomized controlled trial focused on both ethnic minority and White oncology patients, had limited statistical power due to a small sample size ($N = 63$), did not culturally tailor the intervention, and the key distinction between conditions was whether the video was viewed in the office or provided to take home without instructions [16].

The hypothesis for aim 2 was also supported; total perceived barriers towards participating clinical trials significantly decreased for those who viewed the education program, whereas total perceived barriers remained stable for those in the control condition. Inspection of the individual types of perceived barriers (i.e., the subscale scores from the BCTP) suggested that participants who viewed the program perceived fewer barriers in terms of the personal benefits they might receive by participating

in clinical trials, less mistrust of clinical trials participation, and more familiarity with clinical trials. However, there were no changes in perceived community support for clinical trials, which is not surprising given that the program addressed individual barriers to participation, and would not be expected to change perceptions of community attitudes about clinical trials. Similarly, other studies have noted small improvements in attitudes towards clinical trials including: trust in medical researchers and willingness to participate in clinical trials for Black (but not Latino) respondents [13], and perceived benefits and barriers of clinical trials participation for both Black and Latino respondents [14]; the one previous randomized controlled trial did not yield any change in perceived barriers [16]. The one discrepant effect for trust in medical researchers among Black and Latino groups is notable, especially in contrast to the current results which did not uncover any ethnic group differences in attitudes. This may have been attributable to higher baseline levels of trust among Latinos [13], although another explanation could be due to different types of attitudes being evaluated across the studies, and/or differences across the interventions applied (e.g., group education sessions vs. slide presentation; features of the cultural tailoring).

The hypothesis for aim 3 was not supported; there were no differences in agreement to participate in an additional study involving giving a biological sample, or joining a community-based clinical trials advocacy program. This is similar to the previous randomized controlled trial [16], which found no improvement in actual clinical trial enrollment. Interestingly, agreement for both programs in the current study was quite high across conditions, whereas enrollment in clinical trials was low for both conditions in the previous study [16]. That is, while patterns of agreement were quite different across the two studies, neither yielded significant differences in the behavioral outcomes due to equivalently high or low response rates across condition. In the current study, it is possible that, having already agreed to participate in educational research, participants from both conditions were already more receptive to such invitations. Also, trust had been established with the project staff, and participants may have been favorably disposed to participate based on a positive experience in the initial study. Structural barriers to participation were also reduced, given that the respondents were already present when the offer to participate was made, and no additional steps needed to be taken to participate, whereas these factors likely inhibited real-world clinical trial participation in the other randomized controlled trial [16].

Finally, in support of the final hypothesis, the observed findings for knowledge, attitudes, and behavioral outcomes were equivalent across Black, Latina Spanish preference, and Latina English preference respondents.

Limitations

The first limitation of the current study is generalizability of the sample. Most Latinos in the San Diego area are of Mexican descent and do not represent other areas of Central and South America. Before applying the current findings to such groups, cultural and linguistic differences in the intervention and study materials should be evaluated, as evidenced by modifications made successfully to employ the program in New York City among Latinos of different heritage groups [14]. Moreover, the sample was comprised of women who had the time and resources to participate in the study. Because this was a community sample, it is unclear whether the program would be similarly effective among women diagnosed with breast cancer. A second limitation is that the behavioral outcomes of the study were simpler and less burdensome than a true clinical trial, and thus may not have accurately captured true willingness to participate. Finally, having only post-test data collected immediately after program completion precludes determining whether the knowledge and attitudinal changes are maintained over time.

Future Research

These limitations should be addressed in future studies by: increasing representation in the sample across geography, ethnicity, and cancer diagnostic status; including behavioral outcomes that better represent the burden of clinical trial participation; and measuring long-term effects of the program. Additionally, although the trial was conducted in a way to approximate the intended delivery modalities (i.e., in a doctor's office or via the Internet), efficacy of the program in these specific environments should also be tested.

Conclusion

In sum, the *Women United: Clinical Trials and the Fight Against Breast Cancer Program* increased knowledge and reduced barriers to clinical trials participation among Black and Latina women in the study. Although the changes were modest, this should be considered within the context of the low time requirement (i.e., 20 min), ease, and low cost of administration of the program. Moreover, the effects were similar to interventions with an in-person component [13, 15], suggesting that improvements in knowledge can be attained with very low burden, which is crucial for real-world implementation. Importantly, there were not ethnic/language differences in the outcomes, suggesting that the program was equally effective for all women who participated. The final program can be recommended for use

among Black and Latina women and in both Spanish and English. It is available upon request to the corresponding author in its present form. The program can be branded for use in specific institutions or adapted by other clinical or research organizations.

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Data Availability The data that support the findings of this study are available from the corresponding author upon reasonable request.

Code Availability The SPSS code that support the findings of this study are available from the corresponding author upon reasonable request.

Declarations

Ethics Approval Ethics approval was obtained through the local institutional review boards at [redacted for blind review].

Consent to Participate All participants provided written informed consent.

Consent for Publication Not applicable. Data are de-identified and presented in pooled form.

Conflicts of Interest/Competing Interest None declared.

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