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An educational video to increase clinical trials enrollment among breast cancer patients

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Abstract

Only 3% of women with breast cancer participate in cancer clinical trials nationwide. The lack of awareness about clinical trials is a significant barrier towards clinical trials participation. A study was conducted at a large urban Comprehensive Cancer Center to test (1) the effectiveness of an 18-min educational video on improving attitudes toward clinical trials and trials enrollment among new breast cancer patients seen at the Karmanos Cancer Institute, and (2) to assess racial differences in attitudes regarding clinical trials. Participants were randomized to either the educational intervention prior to their first oncology clinic appointment or to standard care. A baseline and 2-week post-intervention survey to assess attitudes toward clinical trials participation was completed by participants. Of 218 subjects recruited, 196 (55% white vs. 45% African American (AA)) eligible patients were included in the analysis. A small increase in therapeutic clinical trial enrollment was observed in the intervention arm but was not statistically significant (10.4% vs. 6.1%; $P = 0.277$). The intervention also did not result in a clear improvement in patients' attitudes toward clinical trials at posttest. However, a lower enrollment rate for the AA women was noted after adjusting for stage (OR = 0.282, $P = 0.049$). Significantly more negative scores were noted in 3 out of the 5 baseline attitudinal scales for AA women. The educational video did not significantly increase enrollment in breast cancer clinical trials. The findings that AA women had significantly more negative attitudes toward clinical trials than white women may partially explain the racial disparity in enrollment. An educational video remains a simple and cost-effective way to educate patients. Future studies should focus on designing a new educational video to specifically target cultural and attitudinal barriers in the AA population to more effectively change attitudes and increase trial enrollment.

Keywords

Clinical trials enrollment; Breast cancer; Educational video; Attitudes regarding clinical trials; Racial disparity

Introduction

Clinical trials offer cancer patients access to innovative therapeutic options frequently associated with better treatment outcomes [1–4]. However, despite the large number of available studies [5], only an estimated 3% of all breast cancer patients participate in clinical trials nationwide. The even lower participation rate among African Americans (AA) [6–9] limits the generalizability of study findings. To increase participation and diversity in clinical trials, new strategies are needed to have an impact on barriers experienced by a wide spectrum of the American population.

As with all determinants of behavior, the barriers contributing to low clinical trial enrollment are complex and multifaceted. Barriers to clinical trials participation can be classified into four categories: (1) physician-level factors, (2) patient-level factors, (3) trial design characteristics, and (4) cost issues [7, 10–14]. This study focused on examining patient-level barriers. Common patient-level barriers cited in the literature include lack of knowledge and awareness of clinical trials, fear and distrust of the medical establishment, fear of toxicities or side-effects, unwillingness to be randomized, loss of privacy, concern about the quality of the proposed research, work or family related time constraints, and/or lack of transportation. Common motivations for participating in clinical trials are to receive a potential health advantage, to contribute to scientific knowledge, to improve the health of others, or to receive monetary compensation [15]. Fears based on awareness of a history of abuses of the rights of human subjects in biomedical research, such as the Tuskegee syphilis experiment, are believed to be an important patient-level barrier particularly in the AA population [16–18].

In addition to misconceptions about clinical trials, most cancer patients simply do not have complete knowledge regarding clinical research. It was reported that lack of information and misconceptions were the most significant barrier to recruiting minority participants to cancer clinical trials [19]. The few studies testing new educational interventions as a tool to increase trials enrollment yielded mixed results [20–23]. One study evaluated the impact of an educational booklet on women's knowledge and willingness to participate in randomized breast cancer clinical trials (RCTs), and found that the booklet was ineffective in improving trial enrollment [20]. The second study randomly assigned member institutions of a large cancer cooperative group to standard information vs. an educational intervention which included standard information plus two seminars and educational materials directed at trial investigators through the internet, and no significant difference in enrollment between the study arms [22, 24] was found. A third study [23] of 126 lung cancer patients, randomized to receive an educational video (the same one used in current study) vs. standard care, found a higher enrollment rate in the intervention compared to standard care arm (17.5% vs. 11.1%; $P = 0.308$) although the differences were not statistically significant. The video, however, did appear to be effective in positively changing lung cancer patients' attitudes about their potential participation in clinical trials ($P < 0.010$).

The primary aim of this study was to examine the effect of an 18-min educational video on the attitudes of breast cancer patients' regarding cancer clinical trials, and thereby potentially increasing their clinical trial enrollment rates. The secondary aim was to examine

racial differences in the attitudes of breast cancer patients' regarding cancer clinical trials and racial differences in clinical trials participation.

Methods

Study design

New breast cancer patients who were scheduled to be seen for the first time at the Comprehensive Breast Clinic (CBC) at the Karmanos Cancer Institute (KCI) between September 2003 and April 2005, and who agreed to participate, were randomized either to view either an 18-min educational video about cancer clinical trials prior to their first clinic appointment or to standard care. Randomization was stratified by race (AA or White). A survey assessing participants' attitudes toward clinical trials participation was administered at baseline immediately before their medical appointment and again two weeks later. All aspects of the study were approved by the Wayne State University Human Investigations Committee.

Inclusion criteria

Study participants included women scheduled for treatment evaluation by a medical oncology specialist at the KCI breast clinic. The KCI is one of 55 NCI designated comprehensive cancer centers in the U.S.A. Patients aged 21–80 years were eligible for this study if they were a new female patient at the CBC, had a diagnosis of histologically confirmed invasive breast cancer, and were self-identified as either AA or white. AA women comprised approximately 45% of the total breast cancer population seen at the CBC from 2003 to 2005. Patients of other races represent < 1% of the patient population and therefore were not included in this study. Other inclusion criteria included: (a) the ability to read and understand English at least at the 6th grade level, (b) the capability to make their own treatment decisions, (c) not having previously participated in a cancer clinical trial, and (d) performance status (PS) ≥ 2 (Southwest Oncology Group (SWOG) scale).

Study procedures

Patients were contacted by telephone regarding their potential participation in this study by the Study Coordinator prior to their first CBC appointment. Consenting participants met with the Study Coordinator one hour prior to their scheduled oncology appointment in order to provide written informed consent, baseline demographic information, and to complete a questionnaire measuring their personal attitudes about clinical trials (pre-test). Upon completion of the baseline survey, study participants were stratified by race and then randomized to either the intervention or control arm. Participants assigned to the intervention arm proceeded to view the educational video, while those in the control arm returned to the waiting room for their clinic appointment. Two weeks after the initial appointment, the same survey was mailed to all participants to reassess their attitudes about clinical trials (post-test). A nurse or physician assistant completed a treatment notification form after the patient's clinic visit to provide basic clinical information and their subsequent trial enrollment status.

Video intervention

The 18-min video (*Cancer Clinical Trials: An Introduction for Patients and their Families*) used in our study is the second version of a similar video that was developed by the NCI to promote cancer patients' knowledge and awareness about clinical trials (*Patient to Patient: Cancer Clinical Trials and You*). The video presents an overview of Phase I, II and III clinical trials and the importance of cancer clinical research to society. The video addresses common concerns regarding clinical trials and cancer treatment from the patient's

perspective such as side effects, expected risks and benefits, eligibility criteria, the enrollment process, and treatment costs. Patients are informed how the randomization process works and that they would receive nothing less than the best available standard therapy if they decide to participate in a clinical trial. The video also emphasizes that placebo treatments are rarely used in therapeutic cancer clinical trials, and that patients are always provided all of the facts about the study treatment through a process called “informed consent” prior to enrollment. Patients are told in the video that they can withdraw from a trial at any time, and that clinical trials are monitored and reviewed routinely by an Institutional Review Board (IRB) and a Data and Safety Monitoring Committee if it is a phase III trial. More information about the video can be found on the NCI educational website (<http://www.cancer.gov/clinicaltrials/learning/clinical-trials-education-series>).

Data collection

A one-page self-administered questionnaire was used to measure the participant’s attitudes about clinical trials participation. This questionnaire consisted of one question assessing the likelihood that the participant would enroll in a clinical trial, as well as 23 questions that constituted five subscales assessing their attitudes regarding participation, including trust in doctors, altruism, perceived personal benefits (e.g., wanting best treatment, having access to new drugs, closer monitoring and management of side-effects, etc), and perceived negative aspects (e.g., possible toxicity, fear of randomization or receiving a placebo, additional tests required, feeling like a guinea pig, trial not covered by insurance), as well as inconvenience factors (e.g., demand of personal or family members time, transportation, child care issues, etc). The 23 items were taken from a survey developed by Michigan State University (MSU) researchers, Drs. Barbara and Charles Givens, with some modifications (see Appendix A). Each of these survey questions were scored on a 5-point scale, and each of the five subscales was standardized into scores of 0–100. In addition, a single item assessing participants’ global attitudes about clinical trials participation was included. The item asked: “At this moment, how likely do you think you are to agree to participate in a clinical trial if one was offered to you?” with response choices of: 1—Extremely unlikely, 2—Unlikely, 3—don’t know, 4—Likely, 5—Extremely likely. This questionnaire was reviewed by behavioral scientists for content validity, and pilot-tested in a sample of 10 cancer patients for clarity and level of understanding.

Finally, a “notification of treatment decision form,” completed by the nurses or physician assistants, recorded participants’ stage of disease, cancer histology, SWOG performance status, co-morbidities, and whether or not the participant enrolled onto a clinical trial. Participants’ clinical trial enrollment status was also verified with the KCI Clinical Trials office’s database. Co-morbid conditions evaluated included diabetes, heart disease, chronic lung disease, liver disease, and renal disease.

Baseline demographic information collected included participants’ race, age, marital status and socioeconomic status (SES) at the time of the enrollment. The SES variable utilized Hollingshead’s 4-factor scoring system [25] incorporating both participant and spouse education and occupation (single patients used only their own information) to categorize participants as low, medium or high SES.

Statistical methods

The study endpoints are participants’ enrollment status as well as the 6 attitudinal scales. Two-sample *t*, Wilcoxon’s Rank Sum, and chi-square and Fisher’s exact tests were used to assess differences in patient characteristics and study endpoints between patient subgroups. Linear and logistic regression analyses were used to assess differences in outcomes between study groups while controlling for co-variates. Backward model selection method was used

to determine the final multivariable models. The α -level for significance was set at 0.05, and all reported *P*-values were based on 2-sided tests.

Results

A total of 218 patients were accrued to this study, completed the baseline assessment, and were randomized to receive either an educational intervention or standard care. After their initial clinic visit, 22 patients were determined to be ineligible and dropped from the study leaving 196 eligible patients for the analysis. Of the remaining 196 eligible patients, 193 completed and returned the follow up questionnaire. The three eligible patients that did not complete the follow-up survey were included in the analysis because their trial enrollment status was available. Among the 22 ineligible patients, 4 had poor performance status (PS > 2), 1 had advanced age (>80), and 17 had a non-invasive breast cancer diagnosis.

Patient baseline characteristics by study arm

Table 1 lists the demographic and clinical characteristics of the study cohort stratified by study arm. Among the 196 eligible patients, 45% were AA, 50% were married, and 41%, 31%, and 28% were classified in the low, medium, and high SES status group. The mean and median age of the study participants were 53.9 years and 53.7 years. The distribution of stage I–IV disease was 25%, 30%, 18%, and 23%. Lastly, 23% of the participants had at least one or more comorbid conditions, and 68% had a performance status score equal to 0. Overall, women in the two study arms had similar demographic and clinical characteristics except that control participants were more likely to have a diagnosis of diabetes ($P=0.006$) and were slightly more likely to be categorized in a lower SES group, although this difference did not reach statistical significance.

Effect of the video intervention

Table 2 shows the statistics on clinical trials enrollment and attitudes towards clinical trials participation among the study cohorts. Enrollment in therapeutic trials was higher in the intervention compared to the control arm although this difference was not statistically significant (10% vs. 6%; $P=0.277$). There was no difference in the participant's stated likelihood to enroll onto a clinical trial either at baseline or follow-up. Furthermore, in regards to participant attitudes towards the clinical trials process, there was no control versus intervention arm differences in the 5 measured attitudinal scales that were measured either at baseline or at the time of follow-up. Multivariable analyses of clinical trials enrollment and patient attitudinal scores adjusting for various demographic and clinical characteristics did not reveal any significant impact of the intervention on the enrollment rates for the participants or on their attitudes towards clinical trials participation (data not shown).

Differences in patient characteristics by race

Table 3 summarizes patients' demographic and clinical characteristics by race. AA participants were more likely to be in the lowest SES group than the white participants (64% vs. 22%; $P<0.001$), less likely to be married (21% vs. 74%; $P<0.001$), and more likely to have had a diagnosis of hypertension (20% vs. 7%; $P=0.004$) or COPD (11% vs. 3%; $P=0.018$) at enrollment. There were no statistically significant differences by race for age at diagnosis, stage, other co-morbid conditions, and performance status.

The effect of race on enrollment in therapeutic trials

The correlation between various patient characteristics such as race and other factors including age, marital status, SES status, stage, PS, comorbidities, and study arm assignment with clinical trials enrollment were examined (see Table 4). Advanced stage (stage 3 or 4)

was the only patient characteristic that was found to be correlated ($P = 0.036$) with trial enrollment with advanced stage patients being more likely to enroll in a clinical trial (OR = 3.151; 95% CI: 1.031–9.629) in univariate analyses. Overall, 11.2% of white participants enrolled in a clinical trial compared with 4.5% of AA participants (see Table 5), but the difference did not quite reach statistical significance ($P = 0.087$). After adjusting for stage in a multivariable logistic regression analysis, race became significantly correlated with trial enrollment ($P = 0.049$). The final multivariable logistic regression model shows that being AA had a lower odds ratio of enrolling in clinical trials (OR = 0.282; 95% CI: 0.076–0.981), while a diagnosis of a stage 3 or 4 breast cancer was associated with a higher odds ratio of enrolling in clinical trials (OR = 3.15; 95% CI: 1.018–9.729).

The effect of race on patients' attitudes

Similarly, we performed an analysis to examine the relationship between patient characteristics and their attitudes toward clinical trials. In univariate analyses, only race was found to be correlated with patient attitudes. In a subsequent analysis, we examined the effect of race on patients' attitudes (see Table 5). There were no significant differences by race in the stated likelihood to enroll score at baseline or at follow-up, although white participants were more likely than AA participants to indicate that they were "extremely likely" to enroll onto a clinical trial (23% vs. 12%, $P = 0.050$). This difference in response by race was also present at the time of follow-up (22% vs. 15%), but was no longer statistically significant ($P = 0.194$). At baseline, AA scored significantly lower than white participants on 3 of the 5 composite attitudinal scales regarding clinical trials including "trust in doctors" ($P = 0.019$), "negative aspects" (<0.001) and "inconvenience" (0.035). At the time of follow-up AA women continued to score lower on these same three scales, although the difference in the "inconvenience" scale was no longer statistically different ($P = 0.119$). There were no racial differences in the scores on the other two attitudinal scales (altruism and personal benefits). These differences in the attitudinal scales remained significant in multivariable analyses adjusting for the stage effect.

In a separate subset analysis, we compared the change in attitude from baseline to follow-up among the study participants who were randomized to the video arm. No statistically significant racial differences in their change in attitude were found in any of the 6 attitudinal scales (5 composite and one single-item).

Discussion

Cancer clinical trials are an important mechanism in which to test new therapies and to improve the overall standard of care for breast cancer patients [1–3, 8]. A major road block to achieving successful completion of clinical trials is the overall low level of participation among eligible breast cancer patients [5]. In addition to administrative barriers inherent in health care system, major barrier exist among eligible women who either lack the knowledge about the purpose and importance of clinical trials, or have serious misconceptions about the trial process [19, 26–28]. Lack of information and misconceptions were the most significant barrier to recruiting minority participants [19]. Educational efforts to improve knowledge about clinical trials have the potential to improve trial participation, and if carried out in a manner sensitive to the needs of women from different racial groups, might lessen disparities in clinical trials participation.

Our randomized study of an educational video to improve clinical trials participation among breast cancer patients appeared to have little or no effect on therapeutic clinical trial enrollment. In addition, the video intervention did not appear to improve patient's attitudes related to clinical trials or have an impact on their willingness to participate in clinical trials

as demonstrated by the lack of a change in their stated likelihood to enroll at follow-up when compared to baseline.

Other studies have evaluated educational instruments in an attempt to improve clinical trials participation [20–23]. In an evaluation of the same 18 min educational video among a cohort of lung cancer patients at the same comprehensive cancer center, enrollment in therapeutic clinical trials was improved in the intervention arm, although this difference was not statistically significant [23]. In our lung study, a significant increase in patients' stated likelihood to enroll in clinical trials was observed, although similar findings were not seen in current study. It is possible that the educational video had more of an impact on the attitudes of lung cancer patients because of the relative lack of effective chemotherapy regimens for lung cancer and the feeling on the part of patients that clinical trials were their only potential for hope.

In order to better understand other sociodemographic barriers to clinical trials participation, we also looked at the effect of race on trials enrollment. Our data show that AA were less likely than white participants to enroll in clinical trials (OR = 0.282; $P = 0.049$) which is consistent with other studies [7, 8, 29]. Our data also show that AA had more negative attitudes toward clinical trials participation as shown by their significantly lower scores on 4 out of the 6 attitudinal measures. Specifically, AA demonstrated more distrust towards their oncologists and the medical establishment, and were more concerned in regards to clinical trials about the need for additional laboratory tests and X-rays, being treated like a guinea pig, lack of insurance coverage, complex paperwork, and the additional time requirements. It is conceivable that the racial difference in enrollment rate may in part be explained by the racial differences in perceptions of clinical trials. The data from this study could serve as a guide to help researchers design more effective educational interventions that target specific barriers pertinent to the AA population.

Barriers contributing to low clinical trial enrollment are multifaceted [7, 10–14]. This study focused on examining patient-level barriers related to lack of knowledge and misconceptions about clinical trials. It is not surprising that an 18-min educational video had little or no impact on improving breast patients' trial enrollment. Stringent eligibility criteria and the lack of therapeutic trials to accommodate breast cancer patients of all stages are other potential barriers contributing to low enrollment. Efforts toward removing non-patient-level barriers are needed in order to achieve significant increases in clinical trial enrollment.

A major weakness of this study is its relatively small sample size. A pilot study of this size does not have sufficient statistical power to detect a difference in enrollment rate that is less than 20%. Another limitation is that the status of participants' eligibility for any open therapeutic trial could not be known at time of randomization. It would have been ideal if study inclusion criteria allowed only patients who were eligible for at least one open trial at time of study registration. However, the design of our study required that patients be surveyed and administered the intervention before meeting a medical oncologist. Lastly, because only breast cancer patients were included in this study, generalization of the results to other types of cancer should be done with caution.

In summary, while our data indicate that clinical trials enrollment rates were not significantly affected by exposure to the educational video in our patient population, an increase in enrollment by even 4.3% ($P = 0.277$), if proven real, could potentially have a clinical impact due to the low cost and ease of implementation of the video intervention. Since patient education is an important aspect of clinical practice and because this format of intervention is easy and cost-efficient to integrate into clinical practice, it is worthwhile to design and test new educational videos to target the cultural and attitudinal barriers

experienced in the AA population to more effectively impact on racial differences in attitudes and enrollment in breast cancer clinical trials.

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Appendix A: Attitudes about clinical trials

How much would each of the following reasons affect your decision whether or not to participate in a clinical trial?

	<i>Very Greatly</i>	<i>Greatly</i>	<i>Some</i>	<i>Little/No</i>	<i>Don't know</i>
1. Trust in the doctor who offers me the trial	—	—	—	—	—
2. The reputation of the treatment center	—	—	—	—	—
3. The reputation of the cancer doctors	—	—	—	—	—
4. Wanting to help future cancer patients	—	—	—	—	—
5. Wanting to make a contribution to cancer research	—	—	—	—	—
6. Obtaining medical benefits for me personally	—	—	—	—	—
7. Wanting the best possible treatment	—	—	—	—	—
8. Having access to new drugs or treatments	—	—	—	—	—
9. Getting closer monitoring of my health care	—	—	—	—	—
10. Better management of my treatment side effects	—	—	—	—	—

How much would each of the following reasons affect your decision whether or not to participate in a clinical trial?

	<i>Very Greatly</i>	<i>Greatly</i>	<i>Some</i>	<i>Little/No</i>	<i>Don't know</i>
11. Taking the risk of side effects (possible toxicity) involved with the treatment	—	—	—	—	—
12. The possibility of receiving a “placebo” or no treatment	—	—	—	—	—
13. Additional laboratory and/or x-ray tests required initially for eligibility	—	—	—	—	—
14. Additional testing or procedures required throughout treatment	—	—	—	—	—
15. The possibility of being randomized or assigned to a treatment by chance (like flipping a coin)	—	—	—	—	—
16. Feeling like I would be treated as a guinea pig	—	—	—	—	—
17. Concerns that the instructions for participation will be too complex	—	—	—	—	—
18. Concerns about insurance coverage	—	—	—	—	—
19. Demands too much of my personal time	—	—	—	—	—
20. Demands too much from my family members	—	—	—	—	—
21. Concerns about travel distance or transportation	—	—	—	—	—
22. Concerns about child care issues	—	—	—	—	—
23. Difficulty taking time off from work	—	—	—	—	—

Now please answer the following question.

24. At this moment, how likely do you think you are to agree to participate in a clinical trial if it was offered?

Extremely unlikely___ Unlikely___ Likely___ Extremely likely___ Don't know___

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Table 1

Demographic and clinical characteristics stratified by study arm

Characteristics (%)	Control (n = 98)	Intervention (n = 98)	P-value (2-sided)
Age (median/mean)	53.8/54.1	53.4/53.6	0.719
AA/White	46%/54%	44%/56%	0.761
SES Ranking ^a			0.076
Low	48%	32%	
Medium	29%	34%	
High	23%	33%	
Married (Y/N)	45%	56%	0.114
Stage ^b			0.821
Stage I	25%	24%	
Stage II	36%	33%	
Stage III	15%	20%	
Stage IV	23%	23%	
Comorbidities			
Hypertension	15%	10%	0.310
Diabetes	10%	1%	0.006
COPD	7%	5%	0.576
Renal Disease	2%	2%	0.983
Liver Disease	0%	1%	0.311
Performance Status = 1 or 2 vs. 0	32%	32%	0.991

^aThe SES ranking utilized Hollingshead's 4-factor scoring system^bStage was based on the American Joint Committee on Cancer staging criteria^cSouth West Oncology Group (SWOG) performance status ranking

* P-value 0.05;

** P-value 0.01

Table 2

Enrollment and attitudes toward clinical trials participation

Characteristics (%)	Control (n = 98)	Intervention (n = 98)	P-value (2-sided)
%Enrollment in Therapeutic Trials	6.1%	10.4%	0.277
Baseline Survey ^a			
Likelihood to Enroll Score ^b	3.5 ± 1.1	3.2 ± 1.1	0.085
Trust in Doctors ^c	81.1 ± 23.5	81.8 ± 24.8	0.846
Altruism ^c	76.5 ± 25.1	74.8 ± 28.1	0.667
Personal Benefits ^c	80.4 ± 21.0	84.8 ± 18.9	0.124
Negative Aspects ^c	58.4 ± 27.3	65.0 ± 26.7	0.094
Inconvenience ^c	38.1 ± 30.4	43.4 ± 29.9	0.222
Follow-up Survey ^a			
Likelihood to Enroll Score ^b	3.2 ± 1.3	3.2 ± 1.4	0.897
Trust in Doctors ^c	81.5 ± 24.7	81.3 ± 26.1	0.962
Altruism ^c	71.9 ± 28.7	69.1 ± 30.2	0.517
Personal Benefits ^c	78.9 ± 21.9	81.0 ± 20.2	0.492
Negative Aspects ^c	62.1 ± 25.0	66.9 ± 24.5	0.187
Inconvenience ^c	41.6 ± 31.2	43.2 ± 26.3	0.712
Change in Likelihood Score from Baseline to Follow-Up	-0.3 ± 1.2	0 ± 1.4	0.227

^aMean ± standard deviation^bValues scored on (1–5) scale^cSubscales were standardized into scores of 0–100

*P-value 0.05;

**P-value 0.01

Table 3

Demographic and clinical characteristics of study cohort stratified by race

Characteristics (%)	AA (n = 89)	White (n = 107)	P-value (2-sided)
Age (median/mean)	54.3/53.8	53.3/54	0.890
SES Group ^a			<.001 **
Low	64%	22%	
Medium	25%	36%	
High	11%	42%	
Married (Y/N)	21%	74%	<.001 **
Stage ^b			0.537
Stage I	22%	27%	
Stage II	39%	30%	
Stage III	19%	17%	
Stage IV	20%	26%	
Comorbidities			
Hypertension	20%	7%	0.004 **
Diabetes	8%	5%	0.353
COPD	11%	3%	0.018 *
Renal Disease	3%	1%	0.408
Liver Disease	1%	0%	0.361
Performance Status = 1 or 2 vs. 0	40%	26%	0.065

^aThe SES ranking utilized Hollingshead's 4-factor scoring system^bStage was based on the American Joint Committee on Cancer staging criteria^cSouth West Oncology Group (SWOG) performance status ranking

* P-value 0.05;

** P-value 0.01

Table 4

Predictors of enrollment in therapeutic breast cancer clinical trials

Characteristics	Univariate ^a <i>P</i> -value	Logistic Regression ^b <i>P</i> -value
Race (Black vs. White)	0.087	0.049 [*]
Age (≥ 65 years vs. <65 years)	0.831	–
Married vs. Not Married	0.602	–
High/Medium SES Status vs. Low	0.778	–
Stage (Stage 3 or 4 vs. 1 or 2)	0.036 [*]	0.046 [*]
Performance Status (1 or 2 vs. 0)	0.296	–
Co-morbidity (any vs. none)	0.090	–
Intervention vs. Control	0.277	–

^a Univariate analysis results were obtained using chi-square or Fisher's exact tests.^b Backward model selection method was used to determine the final model^{*} *P*-value 0.05

Table 5

Study Outcomes Stratified by Race

Endpoints	AA (n = 89)	White (n = 107)	P-value (2-sided)
% Enrollment in Therapeutic Trials	4.5%	11.2%	0.087
Baseline Survey ^a			
Likelihood to Enroll Score ^b	3.2 ± 1.1	3.5 ± 1.2	0.173
% Responded "Extremely likely to enroll"	12%	23%	0.050 *
Trust in Doctors ^c	77.1 ± 26.9	85.4 ± 20.7	0.019 *
Altruism ^c	75.6 ± 28.0	76.0 ± 25.3	0.907
Personal Benefits ^c	84.1 ± 19.9	81.6 ± 20.1	0.374
Negative Aspects ^c	69.7 ± 25.5	55.1 ± 26.8	< 0.001 **
Inconvenience ^c	45.4 ± 31.9	36.3 ± 28.2	0.035 *
Follow-Up Survey ^a			
Likelihood to Enroll Score ^b	3.1 ± 1.3	3.2 ± 1.4	0.636
% Responded "Extremely likely to enroll"	15%	22%	0.194
Trust in Doctors ^c	77.0 ± 27.5	85.3 ± 22.7	0.025 *
Altruism ^c	72.9 ± 28.2	69.1 ± 30.5	0.372
Personal Benefits ^c	80.5 ± 20.7	79.5 ± 21.2	0.740
Negative Aspects ^c	71.8 ± 23.9	58.4 ± 24.1	<0.001 **
Inconvenience ^c	45.7 ± 29.9	39.2 ± 27.5	0.119

^aMean ± standard deviation^bValues scored on (1–5) scale^cSubscales were standardized into scores of 0–100

* P-value 0.05;

** P-value 0.01