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A population-based study of invitation to and participation in clinical trials among women with early-stage breast cancer

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Abstract

Purpose—Although many studies clearly demonstrate disparities in cancer clinical trial enrollment, there is a lack of consensus on potential causes. Furthermore, virtually nothing is known about associations between patients' decision-making style and their participation in clinical trials.

Methods—Women with newly diagnosed, stage 0-II breast cancer reported to the Georgia and Los Angeles County Surveillance, Epidemiology, and End Results (SEER) registries in 2013–14

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Conflicts of Interest

Dr. Patel declares that she has no conflict of interest.
Dr. Shah declares that she has no conflict of interest.
Mr. Abrahamse declares that he has no conflict of interest.
Dr. Katz declares that he has no conflict of interest.
Dr. Hawley declares that she has no conflict of interest.
Dr. Veenstra declares that she has no conflict of interest.

Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

were surveyed approximately seven months after diagnosis. We investigated two primary outcome variables: 1) invitation to participate in a clinical trial, 2) participation in a clinical trial. We evaluated bivariate associations using chi-squared tests and used multivariable logistic regression models to investigate associations between patient variables, including decision-making style, and the primary outcomes.

Results—2578 patients responded (71% response rate); 30% were > age 65, 18% were black, 18% were Latina, 29% had ≤ high school education. 10% of patients reported invitation to participate in a clinical trial; 5% reported participation in a clinical trial. After adjustment younger age, receipt of chemotherapy or radiation, disease stage, and a more rational (versus more intuitive) decision-making style were associated with a higher odds of invitation to participate. Being married was associated with a higher odds of participation; having an annual family income ≥ $40,000 was associated with a lower odds of participation.

Conclusions—10% of patients reported invitation to participate in a clinical trial, and half of these reported participation. Invitation to participate varied by age and decision-making style, and participation varied by marital status and income.

Keywords

Breast cancer; clinical trial; participation; enrollment; disparities

Introduction

Clinical trials are the cornerstone of high quality cancer care, since they provide objective evaluations of the safety and efficacy of new cancer treatments. Yet patient enrollment in cancer clinical trials is surprisingly low. In fact, recent studies show that <10% of adults with cancer in the United States enroll in clinical trials.[1,2] Moreover, there are concerns about disparities in clinical trial enrollment. In 1993 the National Institutes of Health passed the Revitalization Act, which was designed to address disparities in clinical trial enrollment.[3] Data on contemporary inequalities are mixed: many studies show that women, minority patients including Black patients, and patients ≥age 65 are still underrepresented in clinical trials[4–12], while some studies report adequate enrollment of women and Black patients.[5,7] These findings raise concerns about the potential clinical impact of disparities in trial enrollment as well as the generalizability of the findings generated from clinical trials.

Even when clinical trials are available and offered to patients, many patients choose not to enroll. The decision to participate is complex, and there are many barriers to clinical trial participation.[2] A 2008 systematic review of barriers to clinical trial participation found that multiple factors, including older age, lower socioeconomic status, minority race, and increased comorbidities were negatively associated with clinical trial participation.[13] A 2013 survey-based study of 5,499 patients with breast, colorectal, lung, or prostate cancer found that 40% reported having discussions about clinical trials with their providers, and approximately half (45%) of these patients reported being offered a trial. Of those who were offered a trial, approximately half (51%) reported participation in a clinical trial for an overall clinical trial participation rate of 9%.[7] Given that overall accrual to cancer clinical trials is low, that there is concern for disparities in clinical trial participation, and that there

are many potential barriers to enrollment, there is a need to better understand which patients are being invited to participate in clinical trials and, importantly, which patients choose to participate once invited. To help fill this gap in understanding, we used data from a large, population-based survey of women with early-stage breast cancer to investigate clinical and non-clinical factors associated with patients' report of 1) being invited to participate in a clinical trial, and 2) participation in a clinical trial. We also assessed associations between patients' decision-making style and these two outcomes.

Methods

Study Population

As previously reported,[14–17] the iCanCare Study is a large, population-based survey of women with newly diagnosed, early stage (0-II) breast cancer as reported to the Georgia and Los Angeles County (LA) Surveillance, Epidemiology, and End Results (SEER) registries in 2013 and 2014. We identified 3631 eligible women, age 20–79, who were sent a survey approximately six months after diagnosis. Exclusion criteria included stage III/IV disease, tumor size > 5cm, and inability to complete the survey in either English or Spanish.

Patients were identified through rapid case ascertainment from surgical pathology reports. Patients were mailed surveys approximately two months after surgery with the median time from diagnosis to survey completion being seven months. A $20 cash incentive was provided, and a modified Dillman approach was used to encourage patient recruitment; this included postcard and telephone reminders with the option to complete the survey via phone interview in either English or Spanish.[18] For those with Spanish surnames, all materials were sent in both English and Spanish. Survey responses were merged with clinical data provided by the SEER registries. This study was approved by the University of Michigan Institutional Review Board and the state and institutional review boards of the SEER registries.

Measures

The content of the questionnaire was developed based on a conceptual framework derived from research on patients making decisions about, and dealing with, cancer.[19–21] Standard techniques were used to assess content validity, including expert reviews, cognitive pretesting, and pilot studies of measures in selected patient populations.

Primary Outcome Variables

There were two primary outcome variables: 1) invitation to participate in a clinical trial, and 2) participation in a clinical trial. These were assessed based on patients' response to the question, "Have you ever been invited to participate in a clinical trial for treatment of your cancer?" and the follow-up question, "Have you ever participated in a clinical trial for treatment of your cancer?" (yes/no/don't know).

Independent Variables

We considered both clinical and non-clinical independent variables. Patient-reported clinical variables included age in years (≤50, 51–65, >65), comorbid conditions (0, ≥1), and

information on treatments received, including surgical procedure (lumpectomy, mastectomy), receipt of chemotherapy (yes, no), and receipt of radiation therapy (yes, no). Patients' breast cancer stage was determined from SEER registry data.[17,22] Patient-reported non-clinical variables included race (White, Black, Latina, Asian, other/unknown/missing), acculturation (high, low), marital status (not married, married), education (≤high school, some college or technical school, ≥college graduate), annual family income (< $40,000, ≥$40,000), health insurance (none, Medicaid, other public, Medicare, private), geographic site (Georgia, LA), time from home to the nearest hospital (≤30 minutes, ≥31 minutes), employment status at time of the survey (employed, not employed), and of those who were employed, whether paid sick leave or a flexible work schedule were available through the employer (yes, no). $40,000 was chosen as the cutpoint for the family income variable because it represents the median income in the study sample. To account for provider-level variation, the breast cancer surgeon was identified for each patient.

Measures of patient's decision-making style

We assessed patients' decision-making style with the following question stem that assessed how rational versus intuitive their treatment decision-making process was: "Now we would like to understand how you decided what treatments to receive for your breast cancer." Patients' responses to five items were measured and a scale was created using the mean of the component responses. The scale was then dichotomized using the median to create high and low categories. A higher score indicates a more rational decision-making style, while a lower score indicates a more intuitive decision-making style. The five items were: 1) Did you spend more time thinking about your instincts and feelings or weighing the pros and cons, 2) Were you more intuitive or more rational in your thinking, 3) Did you really think things through or did you go with your first instinct, 4) Did you spend a lot of time reviewing the details or did you make decisions quickly, 5) Did you do what seemed most logical or did you just follow your heart (4-item response scale from more intuitive to more rational for each).

Additional Methods to Assess Regional Availability of Clinical Trials

To augment data available from the patient surveys and the SEER registries, and to ascertain the regional availability of cancer clinical trials for the patients included in our study, we analyzed data available in ClinicalTrials.gov as of February 14, 2020. We specifically reviewed information on ClinicalTrials.gov regarding clinical trial availability for patients with stage 0-II breast cancer in Georgia and within a 200-mile radius of LA. As these patients were diagnosed primarily between October 2012 to August 2014, we queried ClinicalTrials.gov for clinical trials with a start date on or before August 31, 2014. The following "Advanced" search parameters were used: "stage 0 breast cancer", "stage I breast cancer", or "stage II breast cancer"; study type: "All studies"; Country: "United States"; State: "Georgia" or "California"; City: "Los Angeles" for California only; Distance: "200 miles" for Los Angeles only; Study Start: "To: 08/31/2014".

Statistical Analyses

Using chi-square tests, we evaluated bivariate associations between each outcome (invited to participate in a clinical trial; enrolled in a clinical trial) and independent patient variables.

We also used multivariable logistic regression models to evaluate our outcomes. To account for clustering at the provider level, we included the surgeon identifier as a random effect. Although nonresponse was low (<5%) for most covariates, we multiply imputed all missing items using sequential multiple imputation techniques.[23] The multiply imputed data were used only in the multivariable models. All statistical tests were two-sided. P values <0.05 were considered significant. Analyses were conducted with SAS 9.4 (Cary, North Carolina).

Results

Study Cohort

Of 3631 eligible patients surveyed, 2578 completed the survey (71% response rate); 106 patients did not respond to the question regarding invitation to participate in a clinical trial and were excluded from these analyses, resulting in a final study sample of 2472 patients. The study flow diagram is shown in Figure 1.

Availability of Clinical Trials

The number of clinical trials potentially available to these patients, as listed in ClinicalTrials.gov, ranged from 15 trials for patients with Stage 0 breast cancer in Georgia to 227 trials for patients with Stage II breast cancer in LA. These include trials of surgical approaches, hormonal therapy, systemic chemotherapy, and radiation therapy. More trials were available in and around LA than in Georgia. The number of available trials increased as stage increased (Table 1).

Characteristics of the Study Sample

As shown in Table 2, 30% of patients were >age 65, 18% were black, 17% were Latina, 38% were unmarried, 29% had ≤high school education, 37% had annual family income < $40,000, and 14% had Medicaid. 54% had Stage I disease, 40% underwent mastectomy (including unilateral and bilateral mastectomy), 34% received chemotherapy, and 48% received radiation. Fewer than half of the patients (39%) were employed at the time of the survey; of those, 35% reported that paid sick leave was not available through their employer, and 50% reported that a flexible work schedule was not available through their employer.

Factors Associated with Invitation to Participate in Clinical Trials

Among all 2472 patients, 253 (10%) reported having been invited to participate in a clinical trial. In bivariate analyses of invitation to participate (Table 3), patients more likely to be invited were <age 65, Latina or Asian, had lower levels of acculturation, were married, were a college graduate, had Medicaid or private insurance, were accrued from the LA SEER registry, were employed at the time of survey, had no comorbid conditions, had stage II disease, and received chemotherapy (all $P \leq 0.05$). Among those who were employed at the time of survey, those with a flexible work schedule were more likely to report invitation to participate (P=0.02).

After adjustment for all clinical and non-clinical covariates included in the bivariate analyses, receiving chemotherapy (odds ratio (OR) 2.32; 95% CI 1.61–3.33; $P<0.01$) and receiving radiation therapy (OR 1.53; 95% CI 1.03–2.27; $P<0.01$) were associated with a

higher odds of invitation to participate. Patients ≥age 65 (OR 0.43, 95% CI 0.24–0.78; P=0.02), and patients accrued from the Georgia SEER registry (OR 0.54, 95% CI 0.34–0.85; $P < 0.01$) had a lower odds of invitation to participate (Table 4).

Factors Associated with Participation in Clinical Trials

The overall clinical trial participation rate for patients in this study was 5%. Of those who reported invitation to participate in a clinical trial (N=253), 118 (47%) reported participation in a trial. In bivariate analyses of patient participation in a clinical trial, patients more likely to participate were those who had annual family income <$40,000 ($P < 0.01$). There were no statistically significant differences by age, race, marital status, or any other clinical or non-clinical covariate (Figure 2).

After adjustment for all clinical and non-clinical covariates included in the bivariate analyses, being married was associated with a higher odds of participation in a clinical trial (OR 2.56; 95% CI 1.40–4.71; $P<0.01$). Having an annual family income ≥ $40,000 was associated with a lower odds of participation in a clinical trial (OR 0.21; 95% CI 0.10–0.47; $P < 0.01$) (Table 5). We tested alternative cutpoints of income levels and found evidence of a dose-response pattern, with decreasing odds of participation associated with increasing income.

Decision-making style and clinical trial invitation and participation

Approximately half of patients (49%) reported a more rational decision-making style. In bivariate analyses, patients with a more rational decision-making style were more likely to report invitation to participate in a clinical trial ($P = 0.03$); this remained significant after adjustment for clinical and non-clinical covariates (OR 1.59; 95% CI 1.13–2.24; $P = 0.01$). A rational decision-making style was not significantly associated with participation in a clinical trial in bivariate or multivariable analyses.

Discussion

In this population-based study of a diverse sample of women with early-stage breast cancer, we found that only 10% of patients reported invitation to participate in a clinical trial. Moreover, only half of those patients (5% of the total sample) reported that they did participate in a clinical trial. We found that non-clinical factors—marital status and income—were associated with participation in a clinical trial.

Previous studies have suggested that approximately 30% of Americans would be willing to participate in a cancer clinical trial if offered, although actual rates of trial enrollment among patients with cancer are far lower than this.[24] Similar to our findings, a rigorous observational coding study examining patient and physician interactions related to clinical trial invitation and enrollment found an invitation rate of only 15%. In contrast to our findings, however, 77% of invited patients in that study did participate in a clinical trial.[25] Among patients in our study who reported invitation to participate, we found that unmarried patients were less likely than their married counterparts to participate in clinical trials. Spouses/partners have been shown to support patients through cancer diagnosis and treatment in a number of ways, including in decision-making around treatment options.

[15,17] Married patients are more likely to complete curative-intent chemotherapy and have improved cancer-related and overall survival compared to unmarried patients.[26,27] Spouses/partners may value treatment more than patients themselves do, and may urge patients to consider options beyond standard therapy.[28] It is possible that unmarried patients are less likely to participate in clinical trials in part because they lack the social, emotional, and tangible support provided by a spouse/partner. Clinical trials often require more time and appointments than standard treatment, and spouses/partners may help provide transportation and offset the opportunity cost of patients who take time away from work and home responsibilities to participate in a trial. Patients without a spouse/partner may benefit from additional resources, such as regular visits with social workers and patient navigators and referral for financial and transportation assistance, in order to more easily participate in clinical trials.

We also found that patients in our study with an annual family income ≥$40,000 were less likely to participate in clinical trials than those with an annual family income <$40,000. This is an interesting finding and is in contrast to some previous studies, which have found lower income to be a barrier to clinical trial enrollment.[7,29,30] However, our finding is supported by other studies that have reported similar associations between lower income and increased participation in clinical trials, especially among Black patients.[10] Potential reasons for this might be that lower income patients enroll in clinical trials as a way to attain healthcare they cannot otherwise access, or that lower income patients may also have limited health literacy and an incomplete understanding of the potential risks and benefits of clinical trial participation.[31] These findings suggest that further study of the complex associations between socioeconomic status and clinical trial participation is warranted.

Patients in our study ≥age 65 were less likely to report invitation to participate in a clinical trial, even after adjusting for clinical factors such as comorbid conditions. Once invited, age was not a factor in whether or not patients reported participation. Many prior studies, some dating back more than 20 years, have found age disparities in cancer clinical trial enrollment.[32,5] A more recent study found that age disparities in enrollment persist and are growing.[33] Our findings suggest that the disparity in enrollment may stem from age-based gaps in invitations for patients to participate in clinical trials. While eligibility criteria that exclude older patients based on an upper age cutoff may play a role, this was not found to be the case in a recent study of enrollment disparities in industry-funded trials.[33] Other restrictions in eligibility criteria, such as organ dysfunction or history of prior malignancy, may disproportionately impact older patients.[34]

Multiple prior studies have demonstrated that women, patients who are Latinx or Black, and elderly patients are underrepresented in cancer clinical trials.[5,8,33,35] Unfortunately, these disparities in enrollment persist decades after the 1993 Revitalization Act.[6] In fact, two recent studies demonstrated persistent racial disparities in enrollment to both industry-funded and cooperative group cancer clinical trials.[12,36] The reasons for these disparities are unclear but may be related to systemic inequities in access to care, health literacy, transportation, lodging, and employment.[4,29,1] We did not find independent disparities in patient-reported invitation or participation by race or ethnicity in our study sample. This may be partially explained by the fact that our study was limited to women with early stage breast

cancer who may be healthier overall, may have access to more resources, and may be more motivated to pursue participation in clinical trials than patients with advanced disease and/or other cancer types.

A unique strength of our study is our investigation of associations between decision-making style and clinical trial invitation and participation. Our finding that a more rational decision-making style was associated with invitation, but not participation, suggests that clinicians' perceptions of patients' decision-making style may influence their likelihood of inviting patients to participate in a clinical trial. It is possible that this reflects bias on the part of clinicians as to who is (1) more likely to "know their own mind" and (2) more likely to understand the concept of a clinical trial. Clinicians may be inappropriately conflating decisiveness with receptivity to trial invitation, when in fact, it is possible that a multiplicity of decision-making styles may be associated with a willingness to engage with the equipoise inherent to most clinical trial construction. It is also possible that patients with a more rational decision-making style are more likely to initiate conversations about the availability of clinical trials with their clinicians, or to recall having been invited to participate in a clinical trial.

Our study has limitations inherent to observational research. Recall bias is possible, and some patients may not remember whether they were invited to participate in a trial. It is possible that patients do not understand the nature of discussions about clinical trials with their clinicians. Prior research found that some patients who were explicitly offered trials did not think there was a trial option for them, and other patients who had discussed the possibility of a trial with their oncologist actually believed that they were offered enrollment to a trial.[25] Likewise, it is possible that some patients were actually enrolled in a clinical trial, but did not know that it was called that and thus reported that they did not participate in a trial. Geography is a known limitation as our population was limited to LA and Georgia and may not be representative of the entire United States population. However, this is mitigated by the fact that both urban and rural areas are represented given the urban nature of LA as well as the urban and rural nature of parts of Georgia. In addition, we could not determine the specific trials that were available for individual patients in the study. Thus, we performed our query of ClinicalTrials.gov to demonstrate that a broad range of trials were potentially available to the patients in this study. Unmeasured heterogeneity in the indication for clinical trial may have biased our results. However, we did control for clinical and treatment factors that to some extent addresses this analytic threat.

Taken together, our findings have multiple clinical implications. Interventions to educate patients about the existence and purpose of clinical trials could help patients initiate discussions about trials with their clinicians.[37] Clinicians may also require education about patients' desires for clinical trial involvement, and about how to best discuss trials with patients in a way that is easy to understand.[25] Better understanding of a patient's decision-making style may also help clinicians tailor their discussions about trials. Patients without partners may require additional supports, such as those provided by lay navigators, to help facilitate their participation in trials. Given that clinician involvement requires additional time and effort,[24] clinicians may also need additional resources and support to help them identify and discuss available clinical trials with patients.

Conclusions

We found that 10% of patients in our study reported clinical trial invitation, and only half of these patients reported participation in a clinical trial. Our results have important clinical implications as they identify that a key barrier to clinical trial accrual may be invitation to participate, and therefore emphasize the role played by clinicians in discussing clinical trials with patients. In addition, patients without a spouse or partner and those of all incomes should be provided with resources to help them participate in clinical trials. Further investigation is required to understand the drivers and limitations of clinicians inviting patients to participate in clinical trials and of patients ultimately participating in clinical trials. Clinical trials are the cornerstone of high quality cancer care. Interventions are needed to support clinician discussions about, and patient participation in, clinical trials in order to ensure the equitable inclusion of all patients.

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Compliance with Ethical Standards

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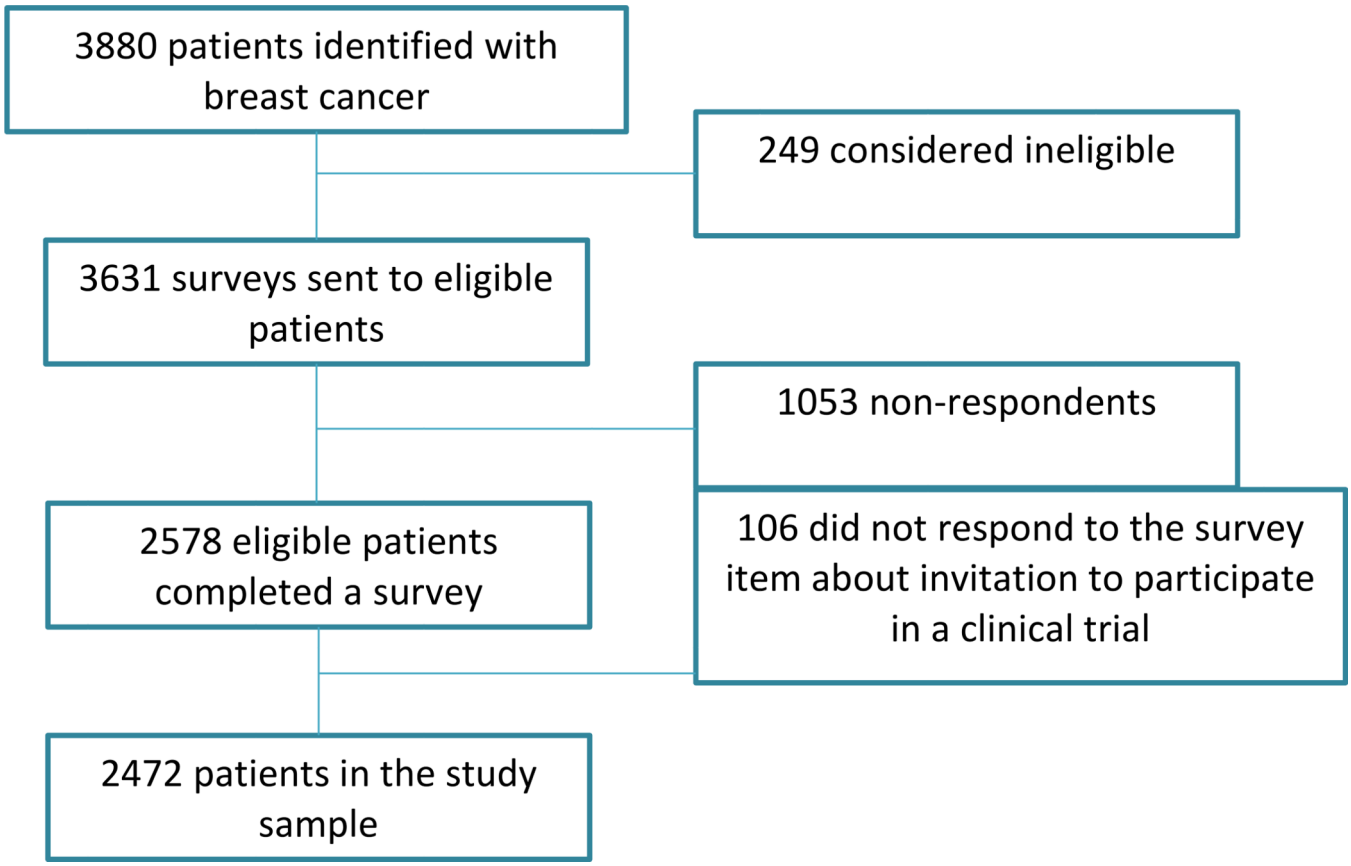

Figure 1.
Flow of patients, starting with the initial patient sample, into the study.

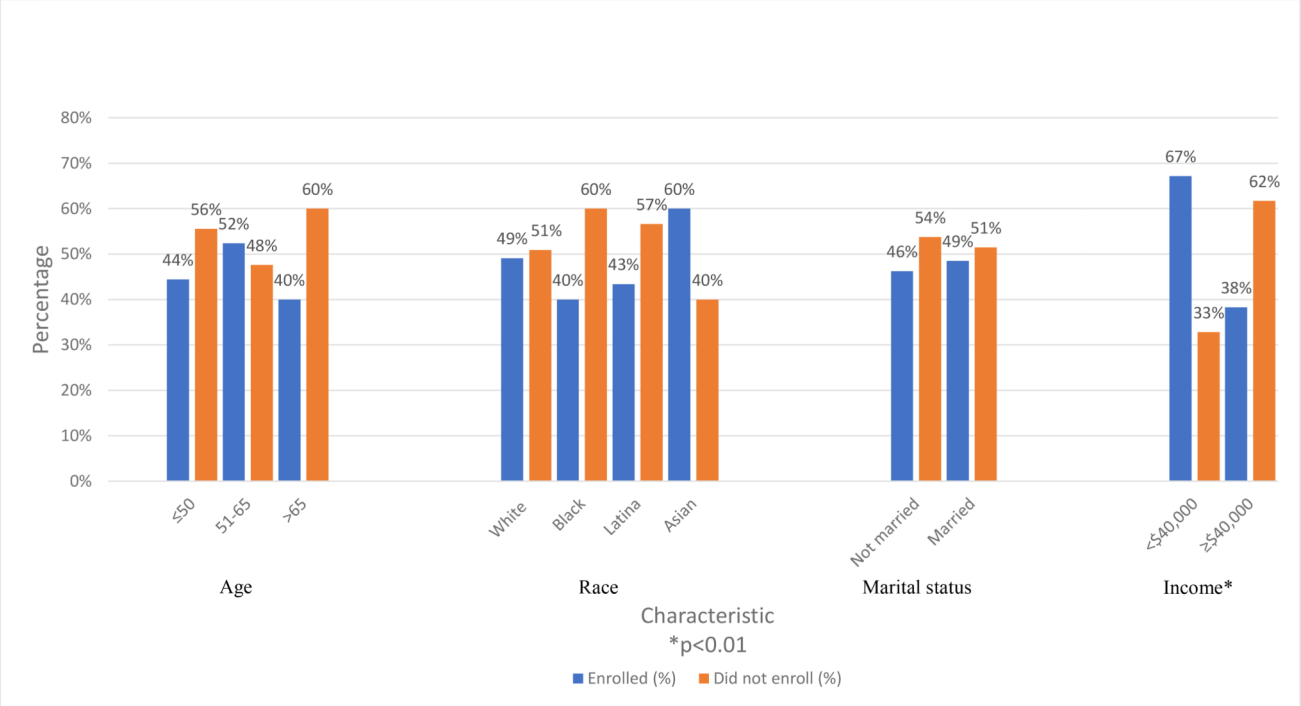

Figure 2.
Participation in a clinical trial, among patients who were invited to participate (N=253)

Table 1.

Number of clinical trials available for patients with a start date on or before August 31, 2014, per ClinicalTrials.gov

Breast Cancer Stage	Georgia	Los Angeles area
0	15	36
I	52	96
II	148	227

Table 2:

Characteristics of the Entire Patient Sample, N=2472

Characteristic	N (%)
Age	
≤50	601 (24)
51–65	1127(46)
>65	744 (30)
Race (67 missing)	
White	1342 (56)
Black	436 (18)
Latina	422 (18)
Asian	205 (9)
Acculturation	
High	2110 (85)
Low	362 (15)
Marital status	
Not Married	930 (38)
Married	1542 (62)
Education (27 missing)	
High school or less	708(29)
Some college or technical school	787 (32)
College graduate or higher	950 (39)
Annual family income (428 missing)	
<$40,000	749 (37)
≥$40,000	1295 (63)
Insurance (97 missing)	
None	12 (1)
Medicaid	329 (14)
Medicare	696 (29)
Other public	32 (1)
Private	1306 (55)
Geographic site	
Georgia	1305 (53)
Los Angeles County	1167 (47)
Time to nearest hospital (186 missing)	
30 minutes or less	1664 (73)
31 minutes or more	622 (27)

Characteristic	N (%)
Employment status at time of survey (37 missing)	
Not employed	1494 (61)
Employed	941 (39)
Of those who were employed, paid sick leave available through employer	
No	331 (35)
Yes	610 (65)
Of those who were employed, flexible work schedule available through employer	
No	470 (50)
Yes	471 (50)
Comorbid conditions	
0	1752 (71)
1 or more	720 (29)
Disease stage (107 missing)	
0	477 (20)
I	1283 (54)
II	605 (26)
Surgical procedure	
Lumpectomy	1481 (60)
Mastectomy	991 (40)
Receipt of chemotherapy (11 missing)	
No	1624 (66)
Yes	837 (34)
Receipt of radiation therapy (22 missing)	
No	1269 (52)
Yes	1181 (48)

Table 3:

Bivariate Analyses of Invitation to Participate in a Clinical Trial, Among All Patients, N=2472

Characteristic	Invited to Participate, N(%)	Not Invited to Participate, N(%)	P
Age			
≤50	84 (33)	517 (23)	<0.01
51–65	129(51)	998 (45)	
>65	40 (16)	704 (32)	
Race			
White	113 (45)	1229 (55)	0.01
Black	47 (18)	389 (18)	
Latina	56 (22)	366 (16)	
Asian	30 (12)	175 (8)	
Acculturation			
High	204(81)	1906 (86)	0.02
Low	49 (19)	313 (14)	
Marital status			
Not Married	81 (32)	849 (38)	0.05
Married	172 (68)	1370 (62)	
Education			
High school or less	57 (23)	651 (30)	<0.01
Some college or technical school	72 (28)	715 (32)	
College graduate or higher	123 (49)	827 (38)	
Annual family income			
<$40,000	65 (31)	684 (37)	0.09
≥$40,000	143(69)	1152 (63)	
Insurance			
None	2 (1)	10 (1)	
Medicaid	44 (18)	285 (13)	<0.01
Medicare	43 (17)	653 (31)	
Other public	2 (1)	30 (1)	
Private	155(63)	1151 (54)	
Geographic site			
Georgia	96 (38)	1209 (54)	<0.01
Los Angeles County	157(62)	1010 (46)	
Time to nearest hospital			
30 minutes or less	174 (72)	1490 (73)	0.83
31 minutes or more	67 (28)	555(27)	

Characteristic	Invited to Participate, N(%)	Not Invited to Participate, N(%)	P
Employment status at time of survey			
Not employed	137 (55)	1357 (62)	0.03
Employed	112 (45)	829 (38)	
Of those who were employed, paid sick leave available through employer			
No	40 (36)	291 (35)	0.94
Yes	72 (64)	538 (65)	
Of those who were employed, flexible work schedule available through employer			0.02
No	43 (38)	427 (52)	
Yes	69 (62)	402 (48)	
Comorbid conditions			
0	197 (78)	1555 (70)	0.01
1 or more	56 (22)	664 (30)	
Disease stage			
0	51(21)	426 (20)	<0.01
I	95 (40)	1188 (56)	
II	94 (39)	511(24)	
Surgical procedure			
Lumpectomy	152 (60)	1329 (60)	0.95
Mastectomy	101 (40)	890 (40)	
Receipt of chemotherapy			
No	124 (49)	1500 (68)	<0.01
Yes	128(51)	709 (32)	
Receipt of radiation therapy			
No	119 (48)	1150 (52)	0.18
Yes	130 (52)	1051 (48)	

Table 4:

Multivariable Analysis of Invitation to Participate in a Clinical Trial, Among All Patients, N=2472

Characteristic	Odds Ratio (95% CI)	P
Age		
≤50	Ref	0.02
51–65	0.77 (0.55–1.07)	
>65	0.43 (0.24–0.78)	
Race		
White	Ref	
Black	1.26 (0.75–2.12)	0.76
Latina	1.12 (0.73–1.74)	
Asian	1.35 (0.75–2.46)	
Acculturation		
Low	Ref	0.82
High	1.06 (0.62–1.82)	
Marital status		
Not married	Ref	0.19
Married	1.02 (0.70–1.48)	
Education		
High school or less	Ref	0.44
Some college or technical school	1.23 (0.61–2.47)	
College graduate or higher	1.50 (0.89–1.82)	
Annual family income		
<$40,000	Ref	0.23
≥$40,000	1.31 (0.85–2.03)	
Insurance		
Private	Ref	
Medicare	0.91 (0.54–1.53)	0.83
Medicaid	1.13 (0.64–2.00)	
Geographic site		
Los Angeles County	Ref	<0.01
Georgia	0.54 (0.34–0.85)	
Time to nearest hospital		
30 minutes or less	Ref	0.74
31 minutes or more	0.93 (0.62–1.40)	
Employment status at time of survey		
Not employed	Ref	

Characteristic	Odds Ratio (95% CI)	P
Employed without benefits (paid sick leave and a flexible work schedule)	1.33 (0.91–1.95)	0.35
Employed with benefits (paid sick leave and/or a flexible work schedule)	1.21 (0.77–1.89)	
Comorbid conditions		
0	Ref	0.21
1 or more	0.79 (0.55–1.14)	
Disease stage		
0	1.80 (1.16–2.79)	
I	Ref	<0.01
II	1.84 (1.23–2.80)	
Surgical procedure		
Mastectomy	Ref	0.81
Lumpectomy	0.95 (0.64–1.42)	
Receipt of chemotherapy		
No	Ref	<0.01
Yes	2.32 (1.61–3.33)	
Receipt of radiation therapy		
No	Ref	<0.01
Yes	1.53 (1.03–2.27)	
Decision-making style		
Intuitive	Ref	0.04
Rational	1.37 (1.02–1.84)	

Table 5:

Multivariable Analysis of Participation in a Clinical Trial, Among Patients who were Invited to Participate in a Clinical Trial, N=253

Characteristic	Odds Ratio (95% Cl)	P
Age		
≤50	Ref	0.17
51–65	1.39 (0.74–2.65)	
>65	0.61 (0.20–1.84)	
Race		
White	Ref	
Black	0.44 (0.17–1.19)	0.05
Latina	0.23 (0.08–0.64)	
Asian	0.86 (0.30–2.46)	
Acculturation		
Low	Ref	0.69
High	0.83 (0.34–2.06)	
Marital status		
Not married	Ref	<0.01
Married	2.56 (1.40–4.71)	
Education		
High school or less	Ref	0.28
Some college or technical school	1.26 (0.22–7.25)	
College graduate or higher	0.65 (0.14–2.94)	
Annual family income		
<$40,000	Ref	<0.01
≥$40,000	0.21 (0.10–0.47)	
Insurance		
Private	Ref	
Medicare	1.39 (0.43–4.51)	0./5
Medicaid	1.39 (0.52–3.72)	
Geographic site		
Los Angeles County	Ref	0.12
Georgia	0.57 (0.28–1.16)	
Time to nearest hospital		0.66
30 minutes or less	Ref	
31 minutes or more	1.16 (0.59–2.3)	
Employment status at time of survey		

Characteristic	Odds Ratio (95% CI)	P
Not employed	Ref	
Employed without benefits (paid sick leave and a flexible work schedule)	1.06 (0.48–2.36)	0.47
Employed with benefits (paid sick leave and/or a flexible work schedule)	0.69 (0.28–1.67)	
Comorbid conditions		
0	Ref	0.15
1 or more	0.54 (0.23–1.26)	
Disease stage		
0	0.73 (0.32–1.68)	
I	Ref	0.50
II	0.66 (0.30–1.48)	
Surgical procedure		
Mastectomy	Ref	0.06
Lumpectomy	0.46 (0.2–1.04)	
Receipt of chemotherapy		
No	Ref	0.55
Yes	1.28 (0.56–2.89)	
Receipt of radiation therapy		
No	Ref	0.26
Yes	1.64 (0.69–3.92)	
Decision-making style		
Intuitive	Ref	0.66
Rational	1.18 (0.57–2.42)	