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Original Article

A Multicenter Investigation of Factors Influencing Women's Participation in Clinical Trials

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Abstract

Objective: To identify factors that influence women's participation in clinical research.
Methods: We administered a survey in outpatient and inpatient populations of Obstetrics and Gynecology facilities of six institutions located in four states. The survey included questions regarding any of the participant's past experiences in clinical research and the factors that would influence their participation in clinical research. Analyses included descriptive statistics and a Principal Component Analysis.
Results: The analysis included 3,773 respondents; 2,477 (68.1%) were pregnant. The majority of participants were Caucasian (1,453, 40.2%), followed by Hispanic (933, 25.8%), African American/black (744, 20.6%), other minorities (270, 7.5%), and multiracial (212, 5.9%). Ten potential motivating factors and 10 potential barriers were assessed. The greatest motivating factor was ''how well research is explained'' (mean = 2.87) while ''risk of unknown side effects'' was the greatest barrier (mean = 3.07) for women's participation in clinical trials. Among six helpful resources assessed, ''material in my own language'' was scored as the highest (mean = 2.8) in facilitating women's decision to participate. For ''risk to the fetus/future fertility'' as a barrier, pregnant women's score (mean = 3.25) was significantly higher than nonpregnant women's score (mean = 2.37).
Conclusions: Overall, the risk of unknown side effects discourages women in general, and the risk to the fetus/future fertility discourages pregnant women the most from participating in clinical trials. However, explaining a study well and providing written material in the patients' own language may increase their willingness to participate.

Keywords: women participation, clinical trials, gender disparity

Introduction

Although advances in medicine depend on successful clinical trials, recruitment of patients in clinical trials remains challenging. A recent analysis found that 19% of registered trials that closed or terminated in 2011 either failed to meet their enrollment goals (85% of expected enrollment) or terminated early due to insufficient enrollment.[1] While equity in clinical trials is important in ensuring the generalizability of data and the benefit to society, numerous reports show a large gender gap in all areas of clinical trials.[2–5]

Studies show that sex-based physiological and biochemical differences result in different pharmacokinetic responses to different drugs, and women are known to experience a higher incidence of adverse drug reactions.[6–8] It is recommended that routine pharmacokinetic analyses during

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early phase clinical trials (I and II) include women to help determine potential dosage recommendations and prevent adverse responses.[2]

Despite federal funding requisites mandating female enrollment in clinical trials[9,10] and the opinion that all women should be presumed eligible for clinical trials as well as the notion that the potential for pregnancy should not automatically exclude them,[11] women continue to be underrepresented in almost all nonsex-specific clinical trials.[2–5] Even in the area of obstetrics, where clinical studies are specifically designed to target female participation, not all eligible women participate.[12,13]

Thus, the following is a major question: why do nonsex-specific clinical trials designed to enroll participants of both genders recruit fewer women than men? Although a few reports have investigated the factors that may influence female participation in clinical trials,[3,14–19] the majority of these reports are based on retrospective review of clinical trials' data, hypothetical trials,[16,17] or small patient population surveys.[18,19] To overcome the limitations of these reports, a large-scale, multicenter, prospective survey study of women was conducted to identify those motivating factors, barriers, as well as helpful resources that may influence women's participation in clinical research.

Materials and Methods

The principal investigator had previously designed a survey to assess a variety of factors influencing a patient's decision to participate in clinical trials.[20] As reported by Kurt et al., the face validity of the survey was assessed through an expert opinion from statisticians and Lehigh Valley Health Network (LVHN) researchers and by piloting the survey among randomly picked 15 nonclinical and nonresearch staff at LVHN.[20] Without disclosing the purpose of the study, pilot participants were asked to determine what the survey questions were trying to address, how long it took them to take the survey, and if any questions were confusing to them. All the pilot participants accurately predicted that the purpose of the survey was to learn about the factors that influence the decision to participate in clinical research and that the survey took 7–8 minutes to complete. Furthermore, without disclosing that there would be an additional survey, the survey was redistributed among the same pilot participants at a 2-week interval to ensure consistent interpretation.[20]

Before utilizing the survey for this study, minor modifications were made to the demographic items pertinent to female patients only (such as pregnancy status), and expedited approval was obtained from the LVHN-Institutional Review Board (IRB). The survey was shared with participating organizations of Perinatal Research Consortium (PRC) for collaboration following IRB approval from all participating sites. Drexel University, Philadelphia, PA; Saint Peters University Hospital, New Brunswick, NJ; Columbia University, New York, NY; Christiana Care Health System, Newark, DE; and Virtua Health, Moorestown, NJ accepted to conduct the survey at their outpatient and inpatient facilities of the department of Obstetrics and Gynecology (OB/GYN). OB/GYN is defined as ''a branch of medicine that specializes in the care of women during pregnancy and childbirth and in the diagnosis and treatment of diseases of the female reproductive organs.''[21] The survey was conducted between February 2015 and December 2015.

The survey was anonymous and voluntary. The survey's coversheet explained to participants that the study was designed to ascertain their opinion about participating in clinical research, which was defined as, ''doctors test a new medication or device and collecting data to see whether the new medication or device is working.'' The survey was offered in English, Spanish, traditional Chinese, and simplified Chinese. Inclusion criteria required the participant to be at least 18 years of age, a patient at the time of the survey, and able to complete the survey on her own. Only those who reported that they were visiting the clinic as a patient were included in the data analysis. Participants were told not to retake the survey at any successive visit to eliminate duplication. Participants were asked to rate each factor as no (0), very little (1), some (2), significant (3), or most (4) influence. Participants were allowed to skip any questions that they did not want to answer and were given as much time as needed to complete the survey.

Data were entered by only trained research staff at each participating site for consistency. Every 10th–20th survey was audited by the lead coordinating site, LVHN, before merging databases for analyses.

Statistical analyses

Descriptive statistics (frequencies and percentages) were used to summarize study participants' responses to survey questions. Due to small sample sizes, responses to certain question categories were collapsed. For example, the question asking which family member played the most important role in deciding to participate in a clinical research study, responses of ''my mother,'' ''my sister,'' and ''my daughter'' were collapsed into the category ''female dominance.'' Responses of ''my father,'' ''my spouse or significant other,'' ''my brother,'' and ''my son'' were collapsed into the category ''male dominance.'' For the question pertaining to race, responses of ''Native Hawaiian or Other Pacific Islander,'' ''American Indian or Alaskan Native,'' and ''Asian'' were collapsed into the category ''Other Combined'' and a new category, called ''Multiracial,'' was created to account for participants who indicated ''Multiracial,'' ''Mixed,'' and ''Multiple Races.''

A Principal Component Analysis (PCA) was performed to create a score for motivating factors and barriers. ''Money offered for my participation'' and ''risk to fetus/future fertility,'' were excluded from the PCA to measure their individual impact on decisions to participate. This variable-reduction analysis is appropriate when you have a number of variables and wish to develop a smaller number of artificial variables that account for most of the variance in the original variables.[22] A meaningful loading was defined as 0.40 or greater.[22] The assumptions of the PCA were assessed before analysis. All variables had at least one correlation coefficient greater than 0.3, the overall Kaiser–Meyer–Olkin (KMO) was 0.84, with all individual KMO measures greater than 0.7, and the Bartlett's test of sphericity was determined to be statistically significant ($p < 0.001$).

Scale scores for each component extracted from the PCA were calculated by adding participant responses for each question and then dividing by the total number of questions in that component. To assess for missing data patterns, sensitivity analyses were conducted. Three scores, complete case analysis (CCA) scores, personal mean imputation (PMI) scores, and item mean imputation (IMI) scores were calculated for each

participant. CCA scores required a participant to have a response for every item in each component, PMI scores used the personal mean for each component to fill in the missing questions, and IMI scores used the item mean to fill in the missing question. PMI and IMI scores were each calculated in two ways.

The first method included imputing the value for participants missing 25% of their responses on each component. The second method included imputing the value for participants missing 50% of their responses on each component. After inspecting the data for patterns in the missing data, it was determined that the CCA approach was appropriate. The variables were not weighted before creating scale scores as the questions were self-report Likert-type items, and items are theoretically on the same metric. Thus, an equal item variance can be assumed.[23]

Frequencies and percentages were used to describe the study population and means. Standard deviations were used to describe the potential motivating factors/potential barriers scale scores. Statistical analyses were completed through SAS Version 9.3 (SAS Institute, Cary, NC) and SPSS version 22 (IBM SPSS Statistics for Windows, Armonk, NY).

Results

Out of the 5,579 approached, the survey was offered to 5,550 patients (29 were <18 years old). 1,511 declined to participate. Out of the 4,039 (72.8%) participants, 266 were further excluded for various reasons (Fig. 1), leaving a total of 3,773 for analyses. Of that total, participants from women's health centers included 503 from Christiana Care, 477 from Columbia, 657 from Drexel, 1,344 from LVHN, 584 from St. Peter's, and 208 from Virtua women's health centers.

Principal Component Analysis

The PCA resulted in two Motivating and two Barrier Scales with the components of each scale reaching an acceptable level of agreement as measured by a Cronbach's alpha of >0.7 (Table 1).

The majority of the participants were Caucasian (1,453, 40.2%), 744 (20.6%) were African American, 933 (25.8%) were Hispanic, 212 (5.9%) were multiracial, and 270 (7.5%) were other minorities (of which 220 [81.5%] were Asian, 12 [4.4%] were Native Hawaiian or other Pacific Islander, 6 [2.2%] were American Indian or Alaska Native, and 32 [11.9%] were other unspecified minorities). Three hundred one (8.3%) had less than a high school diploma and 1,339 (37.1%) were college graduates or more. When asked who in the family makes medical decisions, most participants responded with male dominance (1,544, 44.9%); 993 (28.9%) reported female dominance; and 899 (26.2%) reported self (Table 2). Two hundred twenty-five (6%) of participants used translated surveys (222 in Spanish and 3 in Chinese).

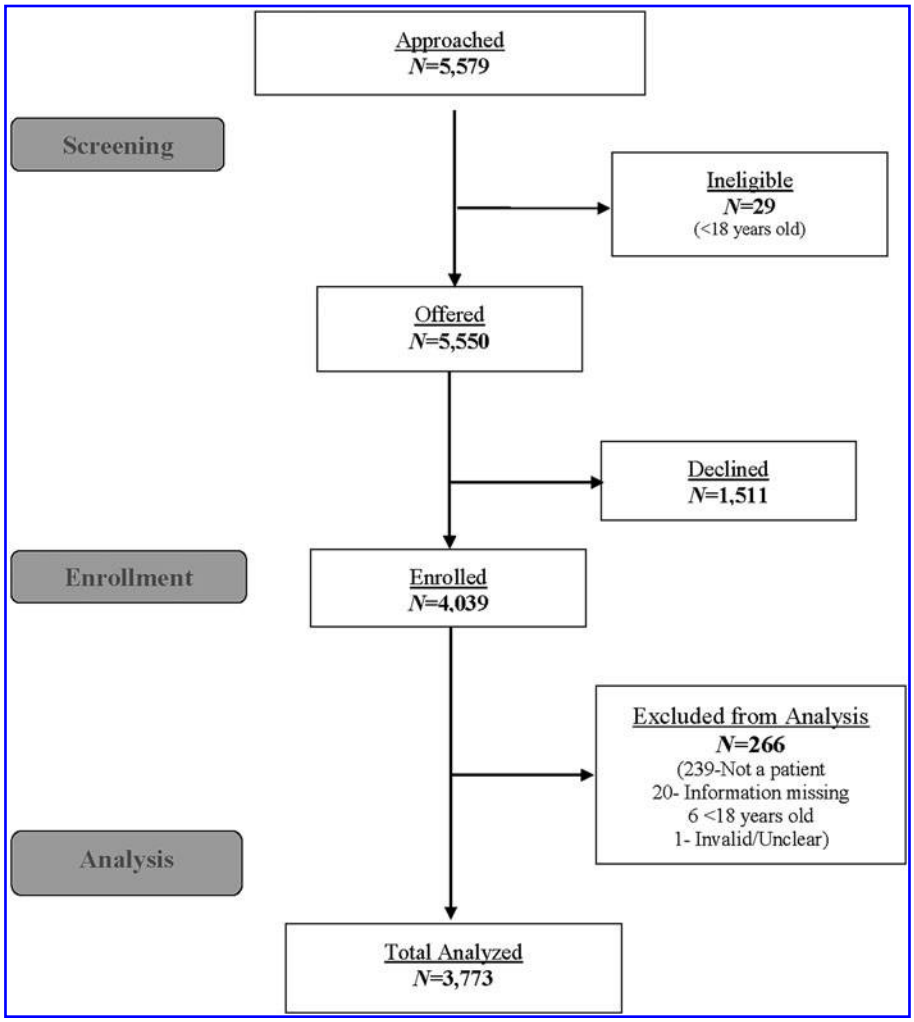

FIG. 1. CONSORT flow diagram—combined all sites.

Table 1. Results of Principal Component Analyses

Groups	*Component factors*	*Cronbach's alpha*
Motivation Scale 1	My relationship with my doctor	0.85
	Doctor's reputation in the community	
	How well the research study is explained to me	
	Knowledge learned from my participation will benefit someone in the future	
Motivation Scale 2	My desire to please the doctor	0.79
	The doctor conducting the research is the same gender (sex) as me	
	The doctor conducting the research is the same race/ethnicity as me	
	The doctor conducting the research speaks the same language as I do	
Barrier Scale 1	Time commitment	0.78
	Phone calls for follow-ups	
	Multiple follow-up visits related to the study	
	Risk of unknown side effects	
Barriers Scale 2	My distrust in doctors	0.72
	My family's concern	
	My religious beliefs	
	Clinical research studies are too hard to understand	

Motivating factors for participation

Based on the highest mean, the most important motivating factor was ''how well the research is explained to me'' (Fig. 2). The average score for Motivation Scale 1 was highest for Caucasians (2.71), those who were college graduates or more (2.72), those who reported excellent health (2.76), and those who reported an income of $75,001 or more (2.78; Table 2).

The average score for Motivation Scale 2 was highest for Hispanics (1.40), those who had less than a high school diploma (1.54), and those who reported an income of less than $30,000 (1.24; Table 2).

The independent motivator, ''money offered for my participation,'' average score was highest for multiracial women (1.84), those who reported female dominance when making medical decisions (1.80), those who were not pregnant (1.75), those with some college or a 2-year degree (1.78), those who were employed part-time (1.78), and those who reported an income of less than $30,000 (1.83; Table 2).

Barriers to participation

As determined by the highest mean, the most important barrier to participation was ''risk of unknown side effects'' (3.07; Fig. 3). The Barrier Scale 1 score was highest for other minorities (2.49), college graduates or more (2.49), those who reported male dominance when making medical decisions (2.42), those who did not have children (2.34), those who are employed full-time (2.39), and those who reported an income of $75,001 or more (2.61; Table 2).

The average Barrier Scale 2 score was highest for Hispanics (1.91), those with less than a high school diploma (1.87), those who reported female dominance when making medical decisions (1.81), those who have children (1.73), and those who were unemployed and not looking for work (1.87; Table 2).

The independent barrier, ''risk to fetus/future fertility,'' average score was highest for ''Other Minorities'' (3.15), those who reported male dominance when making medical decisions (3.19), those who were pregnant (3.25), those who did not have children (3.15), those who were college graduates or higher (3.23), those who were employed full-time (3.11), and those who reported an income of between $50,001 and $75,000 (3.3; Table 2).

Helpful factors for participation

As determined by having the highest mean, participants indicated the most helpful resource would be ''material in my own language'' (2.80; Fig. 4). It was the most important helpful resource to participation for the majority of demographic variable categories (Table 3). In those cases when it did not have the highest mean, the helpful factor ''written material explaining the research study'' had the highest mean, while ''having all material provided in my own language'' had the second highest mean. For those respondents who indicated that they ''cannot speak English,'' ''having all material provided in my own language'' were tied with ''having access to a medical interpreter throughout the study'' for the highest mean (2.90; Table 3).

Discussion

The study demonstrated equity in medical decision-making as almost half of respondents indicated that the medical decisions were made by a female member (including themselves) of the family. Although the sexual orientation of participants was not collected, any existence of lesbian, gay, bisexual, transgender, and questioning/queer (LGBTQ) participation would only result in higher reports of female dominance when making medical decisions.

The data demonstrate that only a small percentage of women were approached to participate in clinical trials, which may explain why a gender gap in clinical trials persists. Furthermore, this study demonstrates that the claim of women not being interested in clinical trials[18,24] needs further investigation because this study shows that a high number (77.7%) of those who were approached to participate had already participated in clinical research. This indicates that gender disparity in research is not because of women's unwillingness to participate in clinical trials, but perhaps they are not approached to participate in equal numbers by

TABLE 2. MOTIVATION AND BARRIER SCORES BY THE DEMOGRAPHICS OF RESPONDENTS

Variables (total respondents)	*Total* n *(%)*	*Motivation Scale 1 (mean ± SD)*	*Motivation Scale 2 (mean ± SD)*	*Monetary incentive (mean ± SD)*	*Barrier Scale 1 (mean ± SD)*	*Barrier Scale 2 (mean ± SD)*	*Risk to the fetus/future fertility (mean ± SD)*
Average scores	—	2.62 ± 1.08	1.10 ± 1.04	1.67 ± 1.40	2.29 ± 1.02	1.71 ± 1.05	2.97 ± 1.51
Missing	—	307	329	207	437	468	317
Self-reported health status (3,760)							
Excellent	679 (18.1)	2.76 ± 1.11	1.17 ± 1.17	1.70 ± 1.47	2.35 ± 1.06	1.75 ± 1.10	3.03 ± 1.52
Very good	1,467 (39.0)	2.61 ± 1.02	1.00 ± 0.96	1.63 ± 1.35	2.36 ± 0.95	1.68 ± 1.01	3.08 ± 1.44
Good	1,234 (32.8)	2.55 ± 1.11	1.13 ± 1.01	1.66 ± 1.40	2.22 ± 1.04	1.72 ± 1.06	2.94 ± 1.51
Fair	347 (9.2)	2.61 ± 1.13	1.25 ± 1.14	1.84 ± 1.45	2.12 ± 1.05	1.69 ± 1.07	2.53 ± 1.69
Poor	33 (0.9)	2.67 ± 1.23	1.29 ± 1.02	1.77 ± 1.50	2.16 ± 1.12	1.82 ± 0.96	2.89 ± 1.57
Missing	13	318	340	218	448	479	327
Approached to participate in clinical research study? (3,758)							
Yes	570 (15.2)	2.75 ± 0.89	1.15 ± 1.11	1.80 ± 1.38	2.32 ± 1.03	1.60 ± 1.04	3.03 ± 1.45
No	3,188 (84.8)	2.59 ± 1.11	1.09 ± 1.02	1.65 ± 1.40	2.29 ± 1.01	1.73 ± 1.04	2.96 ± 1.52
Missing	15	316	337	217	445	477	326
Ever participated in a clinical research study? (3,758)							
Yes	443 (11.8)	2.83 ± 0.86	1.14 ± 1.04	1.96 ± 1.36	2.30 ± 1.00	1.51 ± 1.08	3.03 ± 1.49
No	3,315 (88.2)	2.58 ± 1.10	1.09 ± 1.03	1.63 ± 1.40	2.29 ± 1.02	1.73 ± 1.04	2.96 ± 1.51
Missing	15	318	341	219	448	480	328
Family member role in medical decisions (3,436)							
Female dominance	993 (28.9)	2.68 ± 1.07	1.39 ± 1.14	1.80 ± 1.45	2.19 ± 1.05	1.81 ± 1.07	2.82 ± 1.57
Male dominance	1,544 (44.9)	2.66 ± 1.00	0.99 ± 0.94	1.70 ± 1.33	2.42 ± 0.95	1.71 ± 0.98	3.19 ± 1.36
Self	899 (26.2)	2.52 ± 1.16	0.95 ± 0.98	1.55 ± 1.43	2.20 ± 1.03	1.56 ± 1.09	2.83 ± 1.61
Missing	337	561	582	480	641	676	542
Currently pregnant (3,637)							
Yes	2,477 (68.1)	2.60 ± 1.08	1.07 ± 1.04	1.65 ± 1.39	2.32 ± 1.01	1.74 ± 1.05	3.25 ± 1.31
No	1,160 (31.9)	2.65 ± 1.07	1.15 ± 1.02	1.75 ± 1.40	2.25 ± 1.01	1.64 ± 1.03	2.37 ± 1.71
Missing	136	378	397	284	483	518	362
Has children (3,641)							
Yes	2,398 (65.9)	2.63 ± 1.08	1.12 ± 1.06	1.65 ± 1.41	2.27 ± 1.03	1.73 ± 1.05	2.88 ± 1.56
No	1,243 (34.1)	2.59 ± 1.08	1.06 ± 1.00	1.72 ± 1.37	2.34 ± 0.99	1.66 ± 1.03	3.15 ± 1.40
Missing	132	372	391	279	476	514	356
Highest education level (3,611)							
<High school diploma	301 (8.3)	2.34 ± 1.20	1.54 ± 1.21	1.36 ± 1.48	2.03 ± 1.16	1.87 ± 1.08	2.45 ± 1.64
High school graduate or GED	884 (24.5)	2.50 ± 1.20	1.40 ± 1.16	1.68 ± 1.49	2.12 ± 1.12	1.81 ± 1.09	2.62 ± 1.63
Some college or 2-year degree	1,087 (30.1)	2.64 ± 1.10	1.11 ± 1.04	1.78 ± 1.43	2.25 ± 1.00	1.80 ± 1.07	3.08 ± 1.46
College graduate or more	1,339 (37.1)	2.72 ± 0.92	0.79 ± 0.79	1.67 ± 1.28	2.49 ± 0.87	1.54 ± 0.95	3.23 ± 1.36
Missing	162	387	405	295	488	530	374

(*continued*)

TABLE 2. (CONTINUED)

Variables (total respondents)	*Total* n *(%)*	*Motivation Scale 1 (mean ± SD)*	*Motivation Scale 2 (mean ± SD)*	*Monetary incentive (mean ± SD)*	*Barrier Scale 1 (mean ± SD)*	*Barrier Scale 2 (mean ± SD)*	*Risk to the fetus/future fertility (mean ± SD)*
Race (3,612)							
Caucasian	1,453 (40.2)	2.71 ± 0.95	0.88 ± 0.85	1.73 ± 1.30	2.38 ± 0.88	1.52 ± 0.93	3.11 ± 1.44
African American	744 (20.6)	2.54 ± 1.15	1.23 ± 1.13	1.81 ± 1.51	2.18 ± 1.10	1.80 ± 1.12	2.83 ± 1.56
Hispanic	933 (25.8)	2.55 ± 1.18	1.40 ± 1.17	1.55 ± 1.46	2.21 ± 1.11	1.91 ± 1.09	2.81 ± 1.58
Multiracial	212 (5.9)	2.58 ± 1.09	0.98 ± 1.01	1.84 ± 1.42	2.17 ± 0.98	1.66 ± 1.03	3.09 ± 1.49
Other minorities	270 (7.5)	2.52 ± 1.15	1.03 ± 1.00	1.34 ± 1.29	2.49 ± 1.08	1.85 ± 1.07	3.15 ± 1.38
Missing	161	393	414	303	495	537	377
Speak and understand English? (3,583)							
Very well	3,102 (86.6)	2.65 ± 1.04	1.04 ± 0.99	1.74 ± 1.39	2.31 ± 0.99	1.67 ± 1.03	3.02 ± 1.49
Pretty good	187 (5.2)	2.50 ± 1.16	1.55 ± 1.20	1.35 ± 1.34	2.42 ± 1.14	2.04 ± 1.13	2.69 ± 1.56
Can understand, but have a hard time speaking it	210 (5.9)	2.23 ± 1.35	1.42 ± 1.25	1.08 ± 1.34	2.03 ± 1.21	1.85 ± 1.13	2.58 ± 1.61
Cannot speak English	84 (2.3)	2.12 ± 1.33	1.43 ± 1.19	0.88 ± 1.35	1.92 ± 1.24	2.02 ± 1.14	2.66 ± 1.62
Missing	190	419	437	330	491	528	373
Employment (3,578)							
Full-time	1,759 (49.2)	2.63 ± 1.04	0.94 ± 0.94	1.68 ± 1.35	2.39 ± 0.96	1.62 ± 1.02	3.11 ± 1.43
Part-time	588 (16.4)	2.60 ± 1.10	1.22 ± 1.10	1.78 ± 1.42	2.28 ± 1.04	1.77 ± 1.03	2.95 ± 1.52
Unemployed looking for work	416 (11.6)	2.57 ± 1.10	1.45 ± 1.19	1.65 ± 1.50	2.11 ± 1.06	1.83 ± 1.04	2.71 ± 1.56
Unemployed not looking for work	482 (13.5)	2.62 ± 1.07	1.16 ± 1.04	1.60 ± 1.39	2.27 ± 1.04	1.87 ± 1.09	3.10 ± 1.45
Student	164 (4.6)	2.43 ± 1.20	1.02 ± 1.05	1.62 ± 1.40	2.13 ± 1.02	1.63 ± 1.04	2.92 ± 1.54
Other	169 (4.7)	2.70 ± 1.19	1.14 ± 1.01	1.57 ± 1.49	1.97 ± 1.14	1.59 ± 1.16	1.96 ± 1.89
Missing	195	418	436	332	516	560	403
Income (3,399)							
<$30,000	1,315 (38.7)	2.63 ± 1.12	1.24 ± 1.10	1.83 ± 1.45	2.16 ± 1.04	1.76 ± 1.05	2.87 ± 1.57
$30,001–$50,000	584 (17.2)	2.71 ± 1.01	1.05 ± 0.97	1.74 ± 1.34	2.37 ± 0.94	1.72 ± 1.00	3.15 ± 1.39
$50,001–$75,000	410 (12.1)	2.73 ± 0.90	0.80 ± 0.79	1.80 ± 1.24	2.46 ± 0.85	1.53 ± 0.96	3.31 ± 1.26
>$75,000	336 (9.9)	2.78 ± 0.87	0.67 ± 0.75	1.48 ± 1.24	2.61 ± 0.82	1.45 ± 0.96	3.23 ± 1.36
I'd rather not answer	754 (22.2)	2.38 ± 1.18	1.20 ± 1.11	1.44 ± 1.44	2.20 ± 1.13	1.77 ± 1.10	2.71 ± 1.63
Missing	374	555	575	479	651	688	542

Missing values are shown in numbers.
SD, standard deviation.

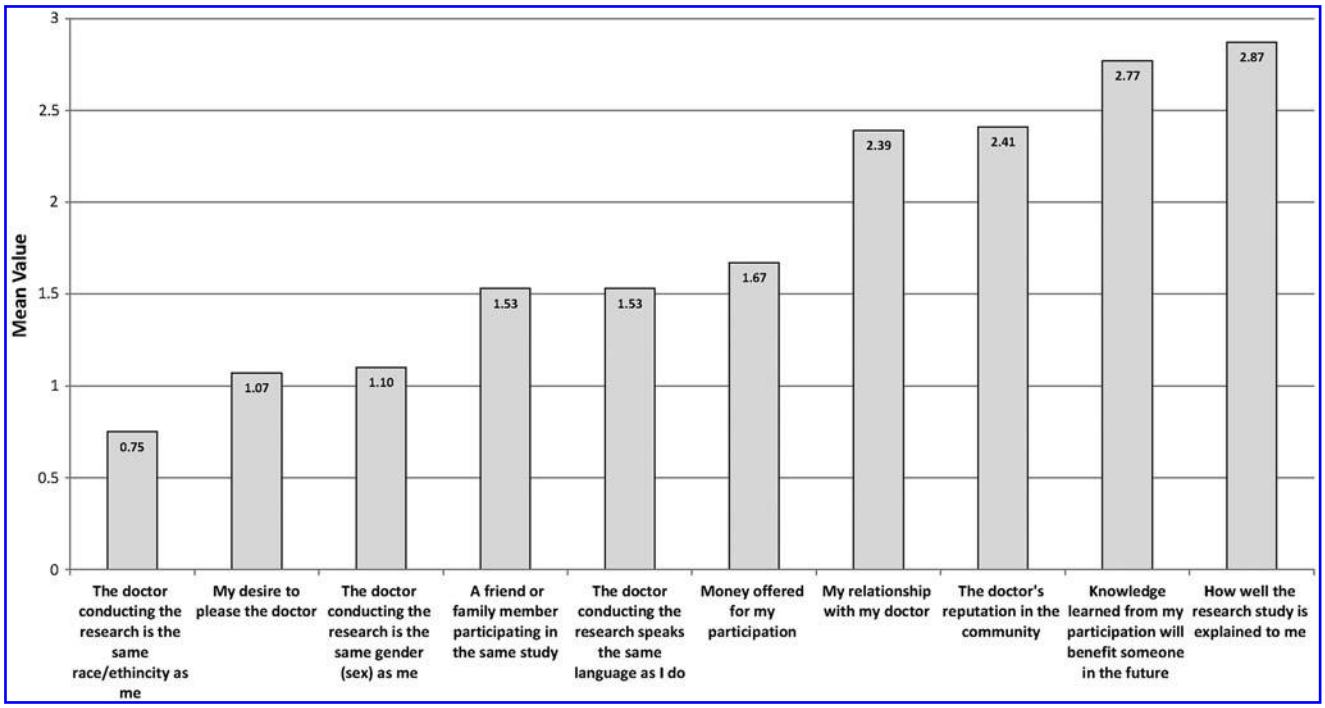

FIG. 2. Response to each motivational factor.

investigators. A previously reported gender bias at clinicians' level[25–27] may be a contributing factor to the gender gap in clinical trials.

Furthermore, the current study shows that despite the existence of barriers, the top two motivating factors for participation were as follows: if the study was explained well and if the knowledge learned would benefit others in the future. Our findings are in concordance with other reports, which indicate the influence of effective communication on patient's decision-making on participation in clinical trials[13,15,20,28,29] and with those who show altruism as a driving force to participate.[30]

In addition to assessing 10 potential motivating factors for their influence on women's decision to participate, the current study aggregated four factors (''how well the research study is explained to me,'' ''my relationship with my doctor,'' ''knowledge learned from my participation will benefit someone in the future,'' and ''doctor's reputation in the community'') in Motivation Scale 1, highlighting mainly altruistic reasons for participating along with general motivators. The

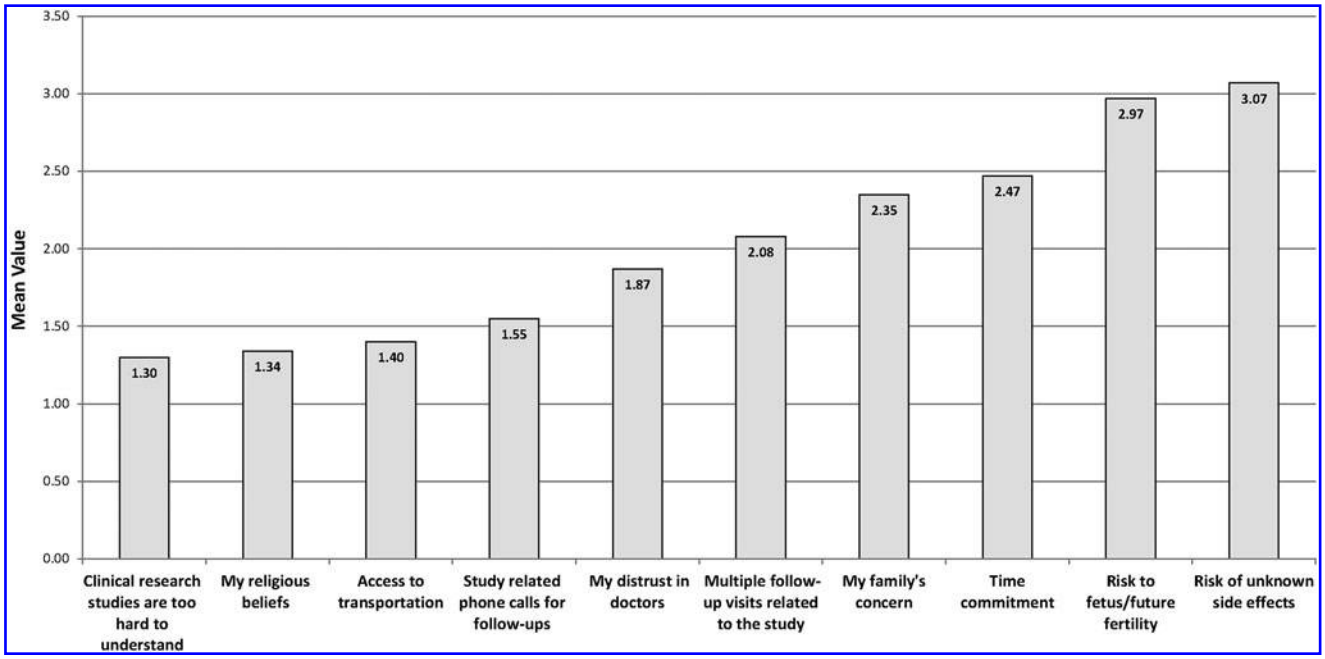

FIG. 3. Response to each barrier.

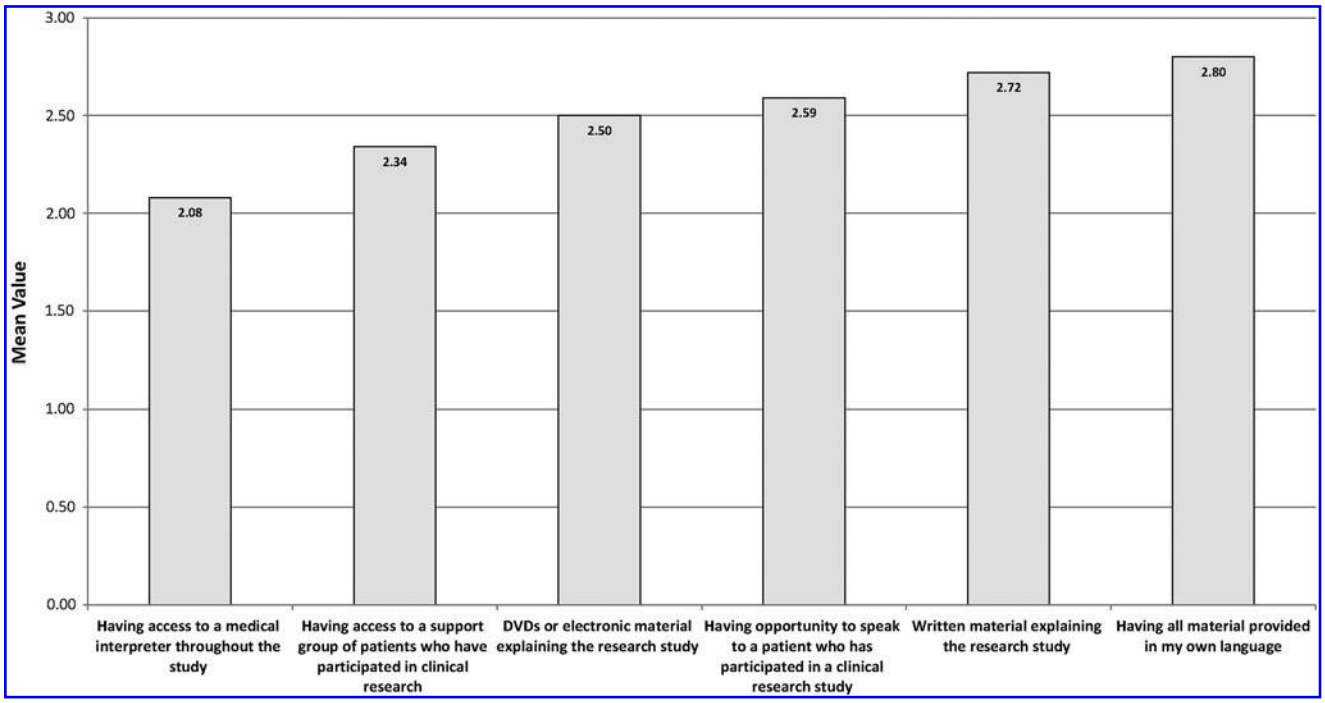

FIG. 4. Response to each helpful resource.

four other motivating factors (''The doctor conducting the research is the same race/ethnicity as me,'' ''the doctor conducting the research is the same gender (sex) as me,'' ''my desire to please the doctor,'' and ''the doctor conducting the research speaks the same language as I do'') were aggregated in Motivation Scale 2 and highlight reasons that are based on shared identity.

The current study shows that scores for Motivation Scale 1 were always higher than the scores for Motivation Scale 2, which indicates that how well a study is explained, altruism, the doctor's reputation, and patient–doctor relationship matter more to potential participants of all demographics than a doctors' race, gender, or language being the same. This finding is in agreement with other reports[13,15,20,30] and emphasizes that the time taken to explain a study well, address all questions/concerns in great details, and establish a rapport with the patients increases the possibility of participation in clinical trials.

Compared with Caucasian women, women from minorities are reported to participate in lesser numbers in clinical trials.[3,15,18] This study shows that compared with other demographics, women who were Caucasian who had a higher education, a higher income, and spoke English well were more motivated by factors of Motivation Scale 1. Interestingly, compared with these populations, Motivation Scale 2 scores were a little higher for those women who belonged to minorities, had lower income, less education, and did not speak English very well. It is logical that patients who do not speak English well would prefer a doctor who speaks the same language as them. Also, a doctor or research staff who speaks the same language as potential participants is important for the understanding of medical conversations that usually are complex, particularly when discussing the details of a clinical trial. The preference to have a doctor of the same race and/or the same gender indicates the trust that comes with shared identity. Previous reports have shown that this shared identity is important and enables trust between physicians and patients.[20,30,31] This additionally signifies the importance of recruiting and promoting minority and bilingual physicians to conduct research.[30,32] This also signifies the need to promote female investigators during clinical research recruitment. Reports show that gender disparity not only exists at the participants' level but also at the investigator level.[32–34]

The current study shows that compared with other groups, ''money offered for my participation'' was not a strong incentive for participation from those who were pregnant, earned a high income, spoke English very well, and had not participated in research. These results indicate that monetary incentives may be more effective in recruiting those who are not pregnant and belong to low-income groups.

In comparison to a prior study where 40% of eligible women refused to participate in clinical intervention studies,[12] the refusal of only 27.2% eligible to participate in this survey study is in concordance with a recent report showing that women are more willing to participate in an interview study in comparison to participating in a clinical trial.[18] Our finding that the risk of unknown side effects was the top-most barrier for women participation is in agreement with other reports that indicate that women perceive probability of harm by participation in clinical trials.[18,35] However, this perception directly conflicts Nijjar et al. who reported that women participating in a clinical trial were found to experience a better health outcome compared with those not enrolled in a clinical trial.[36] Since suggesting to potential participants that they may experience better outcomes than nonparticipants may be considered coercive, good clinical practice is to provide all facts to the potential participants and let them decide whether to participate.

Table 3. Helpful Resources Scores by the Demographics of Respondents

Variables (total responses)	*Written material explaining the study (mean ± SD)*	*DVDs or electronic material explaining the study (mean ± SD)*	*Opportunity to speak with a previous clinical research patient (mean ± SD)*	*Access to a support group of previous clinical research patients (mean ± SD)*	*Material provided in native language (mean ± SD)*	*Access to medical interpreter throughout the study (mean ± SD)*
Self-reported health status (3,760)						
Excellent	2.82 ± 1.28	2.52 ± 1.37	2.62 ± 1.39	2.42 ± 1.45	2.82 ± 1.48	2.14 ± 1.62
Very good	2.75 ± 1.18	2.50 ± 1.28	2.57 ± 1.31	2.29 ± 1.33	2.83 ± 1.35	2.01 ± 1.49
Good	2.68 ± 1.26	2.49 ± 1.27	2.59 ± 1.29	2.33 ± 1.34	2.77 ± 1.37	2.11 ± 1.50
Fair	2.61 ± 1.30	2.50 ± 1.30	2.61 ± 1.41	2.39 ± 1.36	2.75 ± 1.42	2.08 ± 1.58
Poor	2.40 ± 1.35	2.30 ± 1.39	2.37 ± 1.35	2.23 ± 1.33	2.87 ± 1.17	2.40 ± 1.33
Missing	284	312	288	326	295	327
Approached to participate in clinical research study (3,758)						
Yes	2.86 ± 1.04	2.43 ± 1.19	2.41 ± 1.28	2.20 ± 1.33	2.89 ± 1.31	1.94 ± 1.52
No	2.70 ± 1.27	2.51 ± 1.31	2.62 ± 1.34	2.36 ± 1.36	2.79 ± 1.40	2.10 ± 1.53
Missing	283	311	286	325	294	325
Ever participated in a clinical research study (3,758)						
Yes	2.97 ± 1.00	2.46 ± 1.23	2.41 ± 1.31	2.19 ± 1.37	3.05 ± 1.22	2.03 ± 1.52
No	2.69 ± 1.27	2.50 ± 1.30	2.61 ± 1.33	2.36 ± 1.35	2.77 ± 1.40	2.08 ± 1.53
Missing	285	313	288	327	295	327
Family member role in medical decisions (3,436)						
Female dominance	2.69 ± 1.30	2.54 ± 1.30	2.69 ± 1.32	2.45 ± 1.36	2.85 ± 1.35	2.24 ± 1.52
Male dominance	2.78 ± 1.12	2.51 ± 1.22	2.58 ± 1.26	2.30 ± 1.29	2.80 ± 1.34	2.03 ± 1.48
Myself, me, none, N/A	2.67 ± 1.34	2.41 ± 1.37	2.47 ± 1.42	2.24 ± 1.42	2.77 ± 1.46	1.95 ± 1.58
Missing	503	526	504	542	512	538
Currently pregnant (3,637)						
Yes	2.71 ± 1.24	2.48 ± 1.29	2.56 ± 1.33	2.31 ± 1.35	2.78 ± 1.39	2.07 ± 1.50
No	2.76 ± 1.25	2.54 ± 1.29	2.63 ± 1.33	2.38 ± 1.37	2.85 ± 1.38	2.08 ± 1.58
Missing	312	337	313	350	317	347
Has children (3,641)						
Yes	2.72 ± 1.26	2.51 ± 1.31	2.54 ± 1.35	2.33 ± 1.37	2.80 ± 1.40	2.07 ± 1.55
No	2.73 ± 1.20	2.47 ± 1.25	2.68 ± 1.28	2.34 ± 1.32	2.81 ± 1.35	2.08 ± 1.47
Missing	307	332	307	344	311	341
Highest education level (3,611)						
<High school diploma	2.30 ± 1.46	2.29 ± 1.43	2.46 ± 1.47	2.29 ± 1.50	2.68 ± 1.47	2.36 ± 1.56
High school graduate or GED	2.54 ± 1.38	2.44 ± 1.38	2.54 ± 1.40	2.33 ± 1.42	2.68 ± 1.47	2.14 ± 1.55
Some college or 2-year degree	2.79 ± 1.25	2.61 ± 1.30	2.65 ± 1.35	2.46 ± 1.36	2.89 ± 1.36	2.22 ± 1.54
College graduate or more	2.89 ± 1.02	2.49 ± 1.17	2.59 ± 1.22	2.25 ± 1.27	2.85 ± 1.31	1.86 ± 1.46
Missing	324	349	324	360	329	358

(*continued*)

TABLE 3. (CONTINUED)

Variables (total responses)	*Written material explaining the study (mean ± SD)*	*DVDs or electronic material explaining the study (mean ± SD)*	*Opportunity to speak with a previous clinical research patient (mean ± SD)*	*Access to a support group of previous clinical research patients (mean ± SD)*	*Material provided in native language (mean ± SD)*	*Access to medical interpreter throughout the study (mean ± SD)*
Race (3,612)						
Caucasian	2.83 ± 1.08	2.46 ± 1.17	2.60 ± 1.23	2.24 ± 1.27	3.02 ± 1.24	1.95 ± 1.48
African American	2.66 ± 1.36	2.54 ± 1.40	2.64 ± 1.38	2.44 ± 1.43	2.76 ± 1.44	2.15 ± 1.59
Hispanic	2.60 ± 1.38	2.49 ± 1.39	2.53 ± 1.43	2.39 ± 1.44	2.70 ± 1.45	2.28 ± 1.55
Multiracial	2.82 ± 1.20	2.55 ± 1.32	2.61 ± 1.37	2.33 ± 1.34	2.77 ± 1.40	1.96 ± 1.53
Other minorities	2.70 ± 1.17	2.57 ± 1.23	2.52 ± 1.31	2.38 ± 1.30	2.12 ± 1.46	2.00 ± 1.41
Missing	330	355	331	366	334	364
Speak and understand English (3,583)						
Very well	2.77 ± 1.20	2.51 ± 1.27	2.61 ± 1.31	2.34 ± 1.34	2.82 ± 1.37	2.00 ± 1.52
Pretty good	2.50 ± 1.31	2.50 ± 1.35	2.50 ± 1.38	2.41 ± 1.34	2.65 ± 1.37	2.47 ± 1.39
Can understand, but have a hard time speaking it	2.31 ± 1.54	2.32 ± 1.50	2.38 ± 1.53	2.31 ± 1.56	2.67 ± 1.55	2.58 ± 1.55
Cannot speak English	2.19 ± 1.59	2.28 ± 1.67	2.34 ± 1.55	2.36 ± 1.51	2.90 ± 1.41	2.90 ± 1.50
Missing	327	350	327	362	329	361
Employment (3,578)						
Full-time	2.77 ± 1.16	2.48 ± 1.25	2.60 ± 1.28	2.33 ± 1.32	2.82 ± 1.36	1.95 ± 1.51
Part-time	2.72 ± 1.27	2.50 ± 1.32	2.60 ± 1.35	2.29 ± 1.39	2.84 ± 1.39	2.13 ± 1.55
Unemployed, looking for work	2.65 ± 1.32	2.62 ± 1.31	2.64 ± 1.35	2.47 ± 1.35	2.75 ± 1.38	2.38 ± 1.50
Unemployed, not looking for work	2.70 ± 1.29	2.53 ± 1.33	2.58 ± 1.34	2.33 ± 1.36	2.81 ± 1.40	2.20 ± 1.51
Student	2.56 ± 1.39	2.30 ± 1.35	2.49 ± 1.39	2.25 ± 1.42	2.62 ± 1.46	1.94 ± 1.55
Other	2.66 ± 1.37	2.47 ± 1.37	2.38 ± 1.51	2.30 ± 1.47	2.81 ± 1.49	2.12 ± 1.60
Missing	358	379	359	394	363	392
Income (3,399)						
<$30,000	2.72 ± 1.29	2.57 ± 1.33	2.68 ± 1.34	2.44 ± 1.38	2.84 ± 1.39	2.24 ± 1.52
$30,001–$50,000	2.87 ± 1.10	2.60 ± 1.22	2.71 ± 1.25	2.50 ± 1.30	2.93 ± 1.29	2.19 ± 1.48
$50,001–$75,000	2.88 ± 1.00	2.45 ± 1.16	2.52 ± 1.20	2.16 ± 1.25	2.92 ± 1.25	1.61 ± 1.42
>$75,000	2.96 ± 0.96	2.46 ± 1.18	2.50 ± 1.25	2.19 ± 1.27	2.78 ± 1.40	1.74 ± 1.50
I'd rather not answer	2.44 ± 1.40	2.31 ± 1.38	2.41 ± 1.43	2.18 ± 1.41	2.60 ± 1.48	2.02 ± 1.54
Missing	500	522	502	533	507	530

Missing values are shown in numbers.

In addition to assessing 10 potential barriers for the overall influence on women's decision to participate, the current study has aggregated four factors (''multiple follow-up visits related to the study,'' ''time commitment,'' ''study-related phone calls for follow-ups,'' and ''risk of unknown side effects'') as Barrier Scale 1 representing inherent features of clinical trials—those things which one cannot control. These barriers exist regardless of patient's trust in the investigator or the patient's level of understanding a study. While Barrier Scale 1 was focused on measuring the fear of the unknown and uncontrollable, Barrier Scale 2 (''my religious beliefs,'' ''my distrust in doctors,'' ''my family's concern,'' and ''clinical research studies are too hard to understand'') represented barriers that are extrinsic and are related to one's own beliefs and circumstances.

This study demonstrates that those who reported higher scores for Barrier Scale 1 had a higher education, were employed full-time, and had a higher income. This is logical given that this population is employed full-time and would not like to commit to multiple follow-up visits and phone calls. These results are in concordance with other reports that indicate that study-related follow-up visits and phone calls discourage women from participation.[2,29] Those who reported higher scores for Barrier Scale 2 had not participated in research, belonged to minorities, had a lower education, did not speak English well, and had a lower income. It is logical that this demographic of participants scored Barrier Scale 2 higher than their counterparts. While a lower education may hinder the ability to understand the complicated process of clinical trials, an inability to speak English well also diminishes the possibility of participation because fluency in English is increasingly included within the eligibility criteria of clinical trials.[37]

Although the current study demonstrates that the scores for independent barrier ''risk to the fetus/future fertility'' were always higher for all demographics than the scores for Motivation scales, monetary incentives, and Barrier scales, the difference was strongest between pregnant and nonpregnant women. This may help explain the difficulty researchers experience while enrolling pregnant women for obstetrics studies.[38–40] According to Frew et al., recruitment methods that make a broader use of patient providers and general practitioners may boost the recruitment of pregnant women.[13] Interpersonal communication facilitated between staff and potential participants may also help to overcome psychosocial obstacles and positively influence women's willingness and ability to participate.[13]

Overall, women who had previously participated in clinical research scored Motivation Scale 1 and ''money offered for my participation'' higher and Barrier Scale 2 lower than those who had never participated in research. Further analyses are underway to investigate the difference between the demographics of those who participated in clinical research versus those who were approached and did not participate.

Despite knowledge of gender disparity in clinical research, no prospective studies have been conducted involving a larger female population to investigate what helpful resources could be deployed to facilitate their participation. The fact that providing all material in participant's own language was found to be the most helpful resource in making a decision, and further, for those respondents who indicated that they ''cannot speak English,'' ''having all material provided in my own language'' were tied with ''having access to a medical interpreter throughout the study'' for being the greatest help, indicate that to promote equity in clinical trials, linguistic barriers must be addressed.

Linguistic barriers could be ameliorated through translated written material provided at a level which is more easily understood. In addition, written material can be shared with family and friends when considering participation. Furthermore, while a verbal explanation of any study has the risk of the research team forgetting to explain all aspects of the study, another risk is the potential participant not remembering the details of the study. Translated material and bilingual research staff are reported to be effective in enrolling minority women into a randomized trial.[14] The high response rate (72.8%) for our study was partly due to the survey being offered in multiple languages by a bilingual staff. In agreement with previous reports, we recommend that sponsors provide sufficient funds to cover these costs before initiating a trial.[20,30,36,41]

Strengths and limitations

To our knowledge, this is the largest prospective multicenter study investigating the factors that may influence female participation in clinical trials. It was conducted by six institutions located in four states. Participants included outpatient as well as inpatient female patients. Availability of translated surveys in Spanish and, at some sites, in simplified Chinese and traditional Chinese promoted participation from a highly diverse population. While the majority of participants were Caucasian, the combined percentage of non-Caucasian races and ethnicities comprised 59.8% of participants. The data generated by this study are more generalizable than any other study published so far.

We acknowledge that a selection bias could have been introduced to the study due to the convenience sampling. Using a random sampling might be a better approach for future survey studies. Also, we acknowledge that patients who accepted to participate in this survey may already have a greater interest to participate in research than those who declined to take the survey. While the nonrespondents are a better source to learn about the barriers, the reasons for nonparticipation were not collected, and IRB restrictions did not permit collecting demographics on nonparticipants. Therefore, the difference between the characteristics/demographics of those who participated versus those who declined could not be tested. Another limitation is that we did not ask about the sexual orientation of the participants and were unable to identify factors that preclude LGBTQ community members from participating in clinical trials. Finally, the decision to participate in a clinical trial depends on a variety of factors, and it is possible that the survey inadvertently missed other potential motivators and barriers. We highly recommend expanding on additional motivators and barriers for future research.

Conclusions

Overall, the risk of unknown side effects discourages women in general and the risk to the fetus/future fertility discourages pregnant women the most from participating in clinical trials. However, explaining a study well and providing written material in patients' own language may increase their willingness to participate.

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