

# Evaluating Effective Communication and Thorough Explanation in Promoting Participation in Clinical Research

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## Abstract

The historic gender disparity in participation in clinical research has resulted in many difficulties in generalizing research study results. The purposes of this pilot were to investigate experience, attitudes and barriers for women's participation in clinical research and find the strategies to enhance recruitment as well as supportive resources to facilitate their participation. Eligible female patients at LVHN Center for Women's Medicine (CWM) were approached and invited to take the survey, which was translated into four different languages. Outcomes indicate that women from all backgrounds are open to supportive resources to help them better understand the research study and to facilitate their participation. Effective communication with the doctors and researchers can also reduce mistrust and overcome this barrier which would potentially prevent women from participating in clinical research.

## Keywords

Participation in clinical research, women and minority, communication and explanation, language barrier

## Introduction

Historically, there has always been a significant gender disparity in participation in clinical research – a majority of clinical trials are found to have inadequate inclusion of women. This under-representation is attributable, in large part, to a 1977 regulation issued by the Food and Drug Administration (FDA), which excluded women of childbearing potential from Phase I drug trials (Rodger et al., 2003). Sadly, even after the FDA explicitly reversed its 1977 policy of exclusion and after federal funding organizations started emphasizing women's inclusion in studies, women of all ages are still under-represented in trials in all phases of development. A report published in 2009 found that the average enrollment of women in Phase III to IV randomized cardiovascular trials from 1997 to 2006 was only 27% (Kim & Menon, 2009). Reports also indicate that rates of participation in clinical trials are especially low among the socially disadvantaged and racial/ethnic minority groups, deepening the disparities even further (Giuliano et al., 2000).

The inadequate women and minority enrollment in clinical trials remains one of the greatest challenges for both research and public health reasons as it reduces the ability to generalize study results. Therefore, a few

studies have been done in recent years to investigate the factors that potentially influence the successful recruitment of both groups into clinical research trials. Many of them have identified the overall lack of trust in healthcare systems and researchers as one of the most significant barriers (Smith, 2007). Further, it is reported that this kind of suspicion and mistrust is increased when language becomes a barrier (Giarell, 2011). All participants, not just minorities, want to feel that they are valued and appreciated, which may only be achieved when researchers thoroughly explain the trial, including its benefits and potential side effects. Therefore, at an FDA conference held in 2011, a number of speakers from the clinical research field stressed the need for transparent communication to overcome the history of distrust (Coakley, 2012). At this stage, a large scale, prospective investigation is needed in order to produce generalizable data and draw authoritative conclusions.

This diversity study is a part of the first multi-center study, which investigates experience, attitudes and barriers for women's participation in clinical research. Through this study, we hope to find the strategies to enhance recruitment as well as supportive resources to boost women and minorities' comfort level with clinical research (Kurt, 2015). We hypothesize that a thorough

and factual explanation of the research study can be a strong motivation for women who consider "distrust in doctors" as a barrier. In addition, women from all backgrounds are open to supportive resources to facilitate their participation, especially those that ensure effective communication with the doctors/researchers. It is also hypothesized that better communication and explanation is especially important to non-English speaking women.

## Methods

This descriptive pilot explores perceived barriers and motivators to women's participation in clinical research. We aim to find preferred resources to overcome barriers and facilitate their participation. We analyzed data collected through surveys to answer the following research questions:

- 1) Is there a correlation between "how well the research study is explained to me" as a motivating factor and women's distrust in doctors as a barrier to their participation?
- 2) Are women and minorities open to supportive resources to boost their determination and comfort level with clinical research?
- 3) Do non-English speaking women consider more effective communication and thorough explanation more important than English speaking women?

### Participants

The study targeted female patients who were at least 18 years of age. Patient must be both mentally and physically competent to take the survey on her own. A woman was not eligible if she was not there to be seen by a medical staff on the day the survey was conducted. Approval for human subject research was obtained from the Institutional Review Board (IRB) at Lehigh Valley Health Network (LVHN).

### Recruitment

Female patients were recruited, during regular clinic hours, in the waiting area of LVHN Center for Women's Medicine (CWM) in Allentown, Pennsylvania. This center primarily serves urban areas, providing comprehensive health care for women, and approximately 40% of patients are minorities. Recruiters were LVHN Research Scholars, who were trained specifically for this clinical research recruitment.

All of them were bilingual in English and in either Spanish or Chinese.

Recruiters approached female patients who they determined met eligible criteria and explained the study, including its purpose and required action from the individual to participate. Patients were informed of their right not to participate and right to stop at any time. Those who agreed to participate were presented the language-appropriate survey for completion.

### Data Collection and Entry

Data were collected through surveys. The survey was piloted among 15 non-research and non-clinical staff at LVHN for their review prior to its distribution in clinics. To target a diverse population, this survey was professionally translated into Spanish, Traditional Chinese and Simplified Chinese. All were approved by the IRB at LVHN.

The survey asked a combination of multiple-choice questions and rating questions regarding the individual's knowledge, experiences, perceptions and attitudes regarding clinical research. It sought out basic demographic information, but no identifiers or Protected Health Information (PHI) was collected.

A patient participation log was maintained to indicate how many patients were approached for the survey and how many agreed to participate. All responses were entered into a password-protected database by the Research Coordinator.

### Data Analysis

Data Analysis was completed by the author using Microsoft Excel. Descriptive statistics included means and standard deviations for continuous variables and tables for categorical variables (Kurt, 2015). Chi-square test was also used to assess whether the differences were statistically significant.

## Results

### Sample Characteristics

Over a period of 5 weeks, we got our preliminary data from a total of 400 female patients who agreed to participate and completed the survey. Among them, 21% identified themselves as White or Caucasian and 74.3%

as minorities which included Black or African American, Asian, Hispanic/Latin, and other. Despite their race, 45.5% of participants indicated that they only spoke English at home, and the remainder either only spoke one foreign language (23.5%) or spoke both English and another language (27.0%). The majority (74.0%, N=296) reported speaking and understanding English very well, but there was still a noticeable number of participants who cannot speak English at all (N=15). For additional characteristics, see Table 1.

**Table 1. Characteristics of the Study Sample**

Characteristics (N=400)	Range	Mean, SD
Age (years)	18 – 88	29.9, 10.4
	N	Total %*
Past research participation		
Never participated	369	92.3
Participated once	24	6.0
Participated more than once	4	1.0
Race		
White or Caucasian	84	21.0
Black or African American	35	8.75
Asian	8	2.0
Hispanic/Latina/Mexican/Puerto Rican/Dominican/Colombian/Spanish	214	53.5
Other	40	10.0
Spoken language		
English only	182	45.5
Other language only	94	23.5
English + another language	108	27.0
English proficiency		
Very well	296	74.0
Pretty good	23	5.8
Understand English, but hard to speak	50	12.5
Cannot speak English	15	3.8
Education		
< High school	62	15.5
High school graduate/GED	143	35.8
Some college/2 year degree	135	33.8
4 year college graduate	24	6.0
> 4 year college degree	18	4.5
Annual income		
< \$30,000	221	55.3
≥ \$30,000	137	34.3

\*Percentages are based on valid cases. Total percent may not always equal 100% because of incompleteness.

### Overall Ratings on Attitudinal Statements

Attitudinal statements regarding clinical research were evaluated in a 0 – 4 Likert scale, where 0 meant "no motivation" and 4 represented "most motivation". The group of 400 female participants gave an overall rate of 2.95 to "how well the research study was explained to me" as a motivating factor. The majority of participants indicated that their distrust in doctors created "some barrier" preventing them from participation in clinical research (Mean=2.09). On average, women rated the proposed supportive resources at 2.62, indicating that those resources could bring "some" to "significant help". The highest average rating of 2.89 was given to "having all material provided in my language" (See Table 2).

**Table 2. Average Ratings on Attitudinal Statements**

Variable	Mean, Md, SD
Potential barriers	
My distrust in doctors	2.09, 2.00, 1.46
Motivating factors	
How well the research study is explained to me	2.95, 3.00, 1.28
The doctor conducting the research speaks the same language	1.83, 2.00, 1.55
Helpful Resources	
Written explanation provided	2.72, 3.00, 1.28
DVDs or electronic material explaining the study	2.60, 3.00, 1.34
Having opportunity to speak to patient who has participated	2.69, 3.00, 1.32
Having access to a support group of patients who have participated	2.46, 3.00, 1.33
Having all material provided in my language	2.89, 3.00, 1.33
Having access to a medical interpreter throughout the study	2.33, 3.00, 1.50

### Effectiveness of Explanation and Language Tools

Stratified by English proficiency and the language spoken at home, the correlation between the distrust in doctors and quality of explanation was illustrated in Figure 1 and 2.

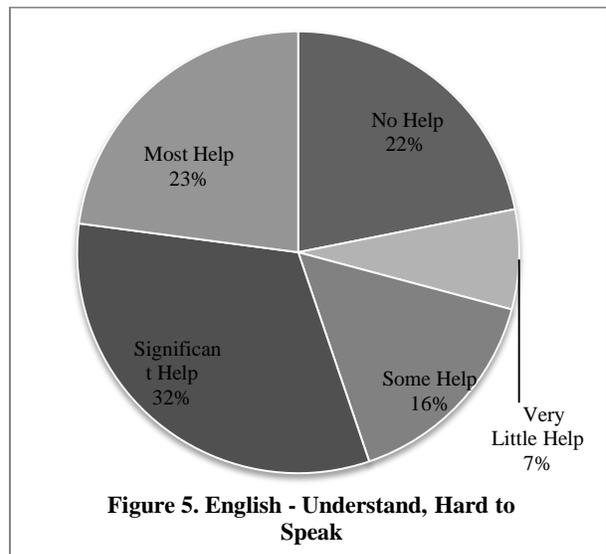
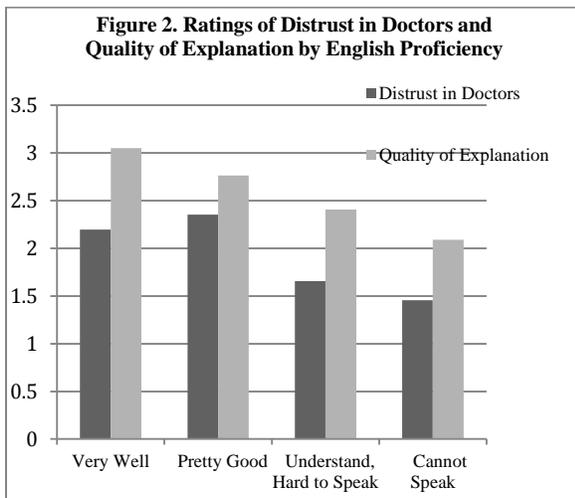
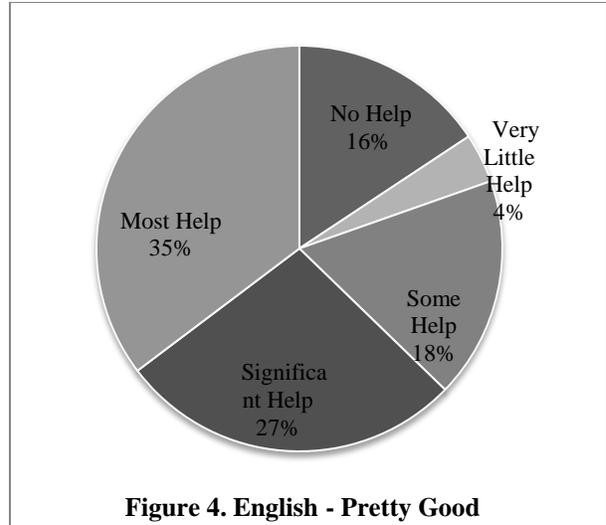
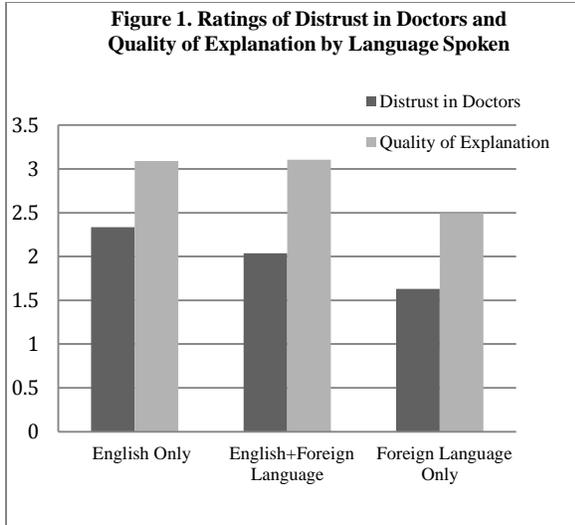
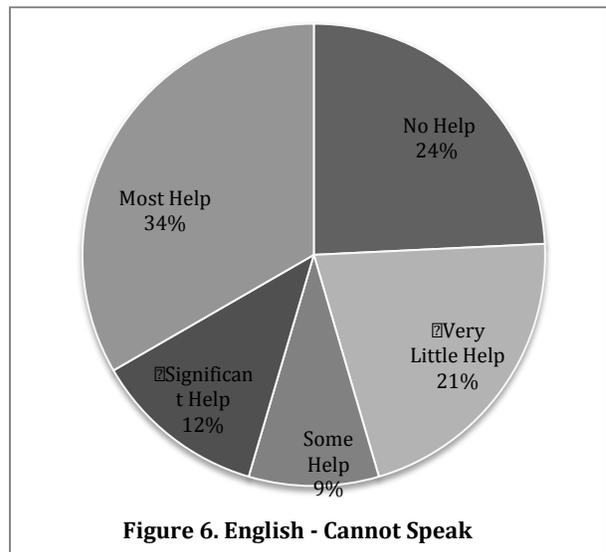
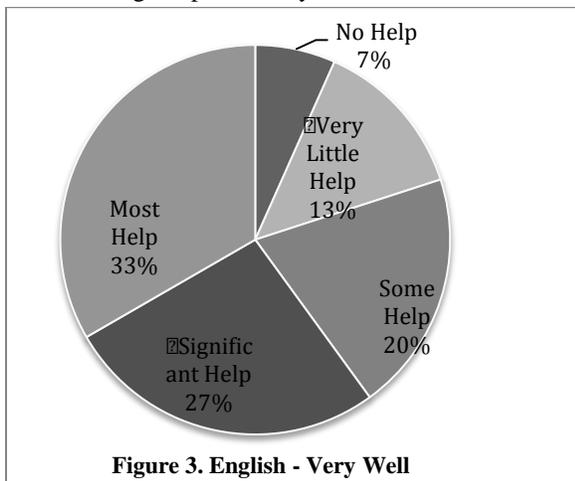


Figure 3-6 illustrates patients' attitudes towards the effectiveness of thorough explanation and language tools in promoting participation among women with different English proficiency.



## Discussion

Ranging from 18 to 88 years of age, coming from all ethnicity background including 21% White or Caucasian and 74.3% self-identified minorities, these 400 female patients well represented a diverse population.

Similar to the previous findings (Smith, 2007), "distrust in doctors" remained to be one of the common barriers that potentially would prevent women from enrolling in clinical research ( $p=0.018$ ). Among the 400 participants, "how well the research study was explained to me" was very highly rated as an important motivating factor ( $p=0.0017$ ). When we examined this motivating factor with the distrust in doctors as a potential barrier, we found a close relationship – a positive correlation – between the two elements. The more the patients considered distrust as a barrier, the more likely that they would like to receive better explanation of the research study. The progression was especially clear among women who were less fluent in English (Figure 1,2). Therefore, it was reasonable for us to think of language barrier as a source of mistrust, and trust could be built through better communication, such as a transparent and comprehensive explanation of the research study.

Overall, the majority of women considered supportive resources to be somewhat helpful or even significantly helpful (Table 2). More women, regardless of their English proficiency and language background, rated same language explanation and communication as "Most Help" (Figure 3-6). Adrian Paskey, a 2014 LVHN Research Scholar, investigated the rating of helpfulness of explanation as well as the rating of support tools stratified by education and income (Paskey, 2014). Both this study result and her result confirmed that women from all backgrounds are open to supportive resources to facilitate their participation, especially those that ensure effective communication with the doctors/researchers. However, because of the insufficient number of participants who could not speak English (only 5.8%), the p-value of their ratings of the better explanation and supportive resource were 0.0823 and 0.0310 correspondingly. With these p-values, we were not confident that the data was statistically significant; therefore, whether non-English speaking women consider effective communication and

explanation more important than English speaking women, remained unanswered.

Although the surveys were translated into several languages, the recruiter of this study still initiated the process in English and, depending on the response of the individual, transitioned to speaking in the same language as the individual. This process might have already created tension for non-English speaking women and forestalled their further participation. Because of the particular demographic of the area, there was a dearth of participation from non-English speakers. Therefore, more diverse population in different settings would bring more desirable results for this study.

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