

Connection Between Education and Relationship with Doctor in Female Clinical Research Participation
A Multi-Center Study Investigating the Factors that Influence Female Participation in Clinical Research
Lauren Crawford; Anita Kurt PhD, RN

Abstract

Women, particularly those in racial and ethnic minorities, have long been underrepresented in clinical research. There are many barriers that prevent women from participating. This study aims to determine some of the less recognized factors and barriers faced in women's decisions, specifically trust of and relationship with doctors. It is hypothesized that trust of doctors varies by level of education and that female participants in research believe these factors to be more important than those who do not participate. The study conducted was an anonymous, IRB-approved survey in which women ranked influencing factors on a scale of 0 to 4. Preliminary data do not support either hypothesis, suggesting that factors other than education influence trust and that importance of relationship with the doctor does not vary across women who have and have not participated in clinical research. Study results provide insight into how best to increase female participation in clinical research to allow for more comprehensive studies with wider applications.

Background

Historically, there has been seen a discrepancy between genders in participation in clinical research. The discrepancy widens across people with a lower level of education. More barriers seem to exist preventing women, particularly those with little education, from participating in clinical studies and trials. Rothenberg (1996) suggests that gender roles and ignorance about women's health issues have prevented outreach to women for clinical studies. Additionally, previous FDA regulations on women with the potential to become pregnant limited the participation of many women; although these regulations have changed, continuing misunderstanding has created and continues to create further barriers to participation.

A lack of participation by women in clinical research limits the span of application of this research. This study aims to determine some of the lesser-recognized barriers that prevent women from participating in research. Correction or adjustment of these barriers could allow for further application of clinical research, particularly early phase trials in which women are most underrepresented.

One potential barrier studied in this trial is relationship with and trust (or distrust) of doctors. Good doctor-patient relationships and improved trust in doctors improves health outcomes for patients (McKinstry, Ashcroft, Car, Freeman, and Sheikh 2006). Trust is also likely to be influential in a patient's decision to participate in clinical research. Improving relationships and trust between doctors and patients could help increase female participation in clinical research.

It is hypothesized that women who do participate in clinical research will rank their relationship with or trust of their doctors as more important than those who do not, and that differing education levels will cause changes in the importance of these values. It is

predicted that this trend will be reflected in higher survey self-scores of “my relationship with my doctor” or “my distrust of doctors” for women with lower levels of education. Research by Corbie-Smith, Thomas, and St. George (2002) determined that African American patients are less likely than their white counterparts to trust their doctors. This study corrected for social markers such as socioeconomic class. These markers, specifically education level, are likely also influential in a woman’s trust of her doctor. A lack of trust translates to less participation in clinical research and studies (Shavers, Lynch, and Burmeister 2002). Determining factors that influence women’s trust in their doctors could provide a path to more participation by women in clinical research.

Methods

A Lehigh Valley Health Network IRB-approved survey was conducted at the Center for Women’s Medicine at LVHN’s 17th Street site. Surveys included questions regarding demographics, participation in clinical research, and motivating factors or barriers to participation in clinical research. No identifying information was collected.

The research team approached patients to briefly explain the study and confirm meeting eligibility requirements (female, age 18 or older, a patient of the site, and able to fully understand the survey and give informed consent in one of four available languages).

Consent was confirmed verbally with research team members; patients were then presented surveys in English, Spanish, Traditional Chinese, or Simplified Chinese, and provided an informed consent information sheet in their language of choice. A screening log was maintained to record each patient’s gender, language of survey and consent, and age eligibility. Surveys were also presented at other LVHN sites and outside of LVHN; however, these surveys were not analyzed in this report.

Data from 400 collected surveys were entered into a password-protected Microsoft Excel database by research associates. Data analysis was performed with Excel by the author.

Results

Factors analyzed were “Did you ever participate in a clinical research study?” “What is the highest grade or level of school you completed?” “What factors would motivate you to participate in a clinical research study? : My relationship with my doctor,” and “What factors would prevent you from participating in a clinical research study? : My distrust in doctors.”

Education levels were ranked as shown in Table 1.

Table 1. Education levels and numerical values.

Numerical Value	Descriptive education level
1	8th grade or less
2	Some high school, but did not graduate
3	High school graduate or GED
4	Some college or 2 year degree
5	4-year college graduate
6	More than a 4-year college degree
7	Masters degree (for example, MA, MS, MSN, MEng, Med, MBA)
8	Professional degree (for example, RN, MSW, MD, DDS, DVN, LLB, JD)

9	Doctoral Degree (for example, Ph.D, EdD, DSW, DNP)
---	--

Participants were asked to choose their highest level of education. No participants analyzed selected 9 (Doctoral Degree).

Other factors were ranked numerically on a 0 to 4 scale from least to most impact. 356 surveys were analyzed. Mean education level was 3.476 (between high school graduate/ GED and some college/two year degree). Median education level was 3 and mode education level was 3. Mean ranking for importance of “my relationship with my doctor” across all education levels was 2.466. Mean ranking for “my distrust in doctors” was 2.087. Average values of other factors surveyed ranged from 0.905 to 2.946.

Table 2. Average score for importance of relationship and distrust by level of education.

Ed. Level	n	Relationship	Distrust
1	5	2.200	0.600
2	53	2.491	2.019
3	132	2.538	2.114
4	130	2.346	2.154
5	21	2.667	2.476
6	5	3.400	1.400
7	6	2.667	2.333
8	4	3.000	2.250

Headings represent average survey scores for “my relationship with my doctor” (heading title: relationship) and “my distrust of my doctor” (heading title: distrust). Sample size represented by n. Education level 9 (Doctoral degree) was excluded as no patients analyzed chose this option.

Both aspects were analyzed for correlation with education level. Correlation values between variables were determined with Excel. The correlation of education and relationship had values $R^2=0.00172$ and $r=0.0415$. The correlation of education and distrust had values $R^2=0.00441$ and $r=0.0664$.

Mean values of factors were compared using Students’ t-tests. Means were calculated for education levels 1-3 (up to and including high school education or GED) and 4-8 (some college/ 2 year degree through advanced degrees). Mean values for education levels 1-3 were 2.516 and 2.047 for relationship and distrust. For education levels 4-8, means were 2.446 (relationship) and 2.181 (distrust). Student t-tests performed to compare rankings between education tiers gave t value for relationship 0.604 and p value 0.547. T value for distrust was 0.392 and p value was 0.696.

Factors were also analyzed by participation (or lack of participation) in clinical research. Comparison of means between survey participants who had versus had not previously participated in clinical research gave t-test values of 0.278, 0.306, and 0.246 for education level, relationship with doctor, and distrust of doctor, respectively. P values were 0.785, 0.764, and 0.809 for these same factors.

Table 3. Comparison of factors by participation.

	Education	Relationship	Distrust
Yes	2.167	1.833	3.889

No	2.492	2.131	3.450
t value	0.278	0.306	0.246
p value	0.785	0.764	0.809

“Yes” indicates survey participant has previously participated in clinical research. “No” indicates participant has not. “Relationship” corresponds to “my relationship with my doctor” and “distrust” corresponds to “my distrust of my doctor.”

Conclusion

The p values for “my relationship with my doctor” and “my distrust of my doctor” between education levels 1-3 and 4-8 were 0.547 and 0.696, respectively. These values indicate that there was not a statistically significant difference in mean rankings of trust between participants of different education levels. Correlation coefficients $r=0.0415$ and $r=0.0664$ indicate that the overall correlation between education and relationship with doctor and between education and distrust of doctors is very weak. These values suggest that education level does not largely impact the importance of relationship and trust of doctors. Although it was hypothesized that education would, like race, influence trust of medical professionals, there seems to be little relationship between these factors. It is likely that other factors have more influence on trust of doctors than does education. Other factors that may be influential in the importance of trust include race, which has been studied extensively (Murthy, Krumholz, and Gross 2004), religion, age, and childbearing potential. These factors and others will be analyzed in the future of this study. Future studies could investigate other influences, such as history of health issues or time constraints.

Additionally, it is likely that even though education is not a motivating factor in trust and relationship with doctors, it affects other aspects of the decision to participate in clinical research. This study considers deciding factors such as gender or race of participants’ doctors, provision of educational materials, and future benefit of the research. Going forward, these aspects could be analyzed with regard to education levels to determine what aspects are most affected by education level.

The differences in rankings for “my relationship with my doctor” and “my distrust of my doctor” were not statistically significant between women who had and had not previously participated in clinical research, with p values 0.764 and 0.809. This indicates that women who participate in clinical research are not relying any more or less on their relationship with their doctors than their non-participating counterparts. As there is no statistically significant difference in rankings between participants and non-participants, it is likely that trust is not a major barrier preventing women from participating in clinical research.

The range of average rankings for the factors studied was 0.905 to 2.946. Both “my relationship with my doctor” and “distrust of my doctor” had rankings in the top half of values, suggesting that both factors were more important than other factors studied (such as doctor’s gender or race, or whether money is offered for participation) but less important than factor III (how well the research was explained). This information provides a framework for LVHN to increase women’s participation in clinical research. Initial data collected in this study has determined that women most value how well a study is explained to them in deciding whether or not to participate in clinical research. Given this information, LVHN and partner sites could work to improve the information

that is provided about clinical studies to ensure that women (and all participants) sufficiently understand the studies. Additionally, fostering trust of doctors and improving doctor-patient relationships may help to increase participation.

As this study was completed by self-reported surveys, data may be skewed due to self-report biases. Response rate for surveys at the Center for Women's Health is about 66%, so there may exist nonresponse bias in the data. Because several members of the research team gave surveys, some participants may have completed more than one survey. If survey participants took surveys in a language with which they were less comfortable, responses could be altered. These shortcomings of the survey may have slightly altered results.

Data analyzed in this paper were preliminary data of 400 surveys gathered at one site. The study will continue at this site (Center for Women's Medicine) and at other sites. Completed study results may not reflect these findings. Preliminary results and conclusions may not apply to complete study results at the conclusion of the study. The continuation of this study will provide additional insight into the lesser-known factors that influence women's decisions to participate (or to choose not to participate) in clinical studies and trials. Addressing these issues will provide prospects for improvement in creating future research opportunities and ensuring representative participation across all genders, races, and more.

References

- Corbie-Smith, G., Thomas, S.B., St. George, D.M.M. (2002). Distrust, Race, and Research. *Arch Intern Med* 162(21):2458-2463.
- McKinstry, B., Ashcroft, R., Car, J., Freeman, G.K., Sheikh, A. (2006). Interventions for improving patients' trust in doctors and groups of doctors. *Cochrane Database of Systematic Reviews* (3).
- Murthy, V.H., Krumholz, H.M., Gross, C.P. (2004). Participation in Cancer Clinical Trials: Race-, Sex-, and Age-Based Disparities. *Journal of the American Medical Association* 291(22):2720-2726.
- Rothenberg, K.H. (1996). Gender Matters: Implications for Clinical Research and Women's Health Care. *Houston Law Review* 32:1201-1272.
- Shavers, V.L., Lynch, C.F., Burmeister, L.F. (2002). Racial Differences in Factors that Influence the Willingness to Participate in Medical Research Studies. *Annals of Epidemiology* 12(4):248-256.