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Perceptions of Women that Prevent Participation in Clinical Trials in the Affluent Versus Impoverished Communities of Miami, Florida

Article by Lois Collie Acasio
Texila American University, USA
E-mail: aud2010@gmail.com

Abstract

A gender gap exists in biomedical research because more Caucasian men take part than women. As a result, recommended dosages are based on the male physiology with the risks to women unknown. The symptoms, severity, prevalence and age of onset of many diseases may be different in men. Warning signs, and adverse effects may also be different in women and the number of women who have Adverse Events from taking male based recommended dosages is unknown. The gender gap may contribute to medication errors which cause an increasingly large amount of deaths each year. Although women participants are needed and mandated, they may be underrepresented because of child-bearing age and its fluctuating hormones. The possible long-term effect of study drugs on women's gonads is unknown. Women may have a knowledge gap that needs to be bridged as they may not be aware of biomedical medicine research, are unfamiliar with the terms being used to describe the topic, and when faced with multiple therapeutic options, may worry about making informed decisions. Shareholders and women benefit when the gender gap is decreased, safety and efficacy is increased and the result of research become more generalizable. This study investigated perception barriers to participation in Clinical Trials of the women of Liberty City who were 94% African-American, were contrasted with the women of Coral Gables who were 90% Latin-American. This study has never been done before and investigates the barriers that prevent women who are ambulatory patients, from participating in clinical studies.

Keywords: *Gender gap, Women's health research, Barriers to participation.*

Introducing the topic of research

The crisis in clinical trials may not be limited to constrictions in the drug pipeline and the decreasing number of new molecular entities (Drennan, 2002). The crisis may also be due to the decreasing number of available participants due to the recruitment and enrollment process (Getz, 2008). The recruitment process is expensive and forms a critical bottleneck in the research and development of treatments. Studies have indicated that, approximately 80% of 50,000 clinical investigations done in the United States each year fail to start on time because of recruitment problems (Davis, 2003). Trials are delayed or postponed when there are not enough participants (Peters, 2013). Delays increase the time it takes for much-needed medication to reach patients. Inadequate recruiting may affect the start of oncology trials (Wright, 2006). Attrition problems may also cause trials to terminate early at a great financial loss (Bill-Axelson et al., 2008). For example, a recent trial on the prevention of the hardening of the arteries in subjects that had lupus had to be closed because of low participation (Costenbader, et al., 2007). The delay of the arrival of a drug to the market may cost sponsors a loss of $8 million per day (CISCRP, 2012), and investors consider patient recruitment to be the weakest link in the clinical trial process (Aliyar, 2004). The Government mandates that women and children of ethnic minorities must be included in clinical trials regardless of costs (NIH, 2012). Many diseases are gender-based and affect women disproportionately more than men, but women may still be underrepresented in clinical trials (FDA, 2018). It is pivotal for the clinical research industry to achieve recruitment targets (Lui, K., et al., 2016). This paper is based on a survey that examines the perceptions and barriers that prevent women living in affluent versus impoverished communities in Miami, Florida, from taking part in clinical trials.

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Conceptual definitions

Participant: This is another word for a subject who takes part in a clinical study.

Patient: This is a person, who receives medical care, may be an inpatient or an outpatient.

Respondent: This is a person who participates in a written or oral survey questionnaire.

Subject: This is another word for a participant who takes part in a clinical study. Patients became subjects or participants the moment they agreed to be respondents in this survey questionnaire.

The theoretical framework of gender gap research

Besides physiological differences, other variables contribute to the difference between the male and female participant in clinical trials. For example, there are lifestyle differences, environmental differences, behavioral differences, and biological differences at the cellular and molecular level. For example, the fact that unlike men, women may have estrogen related hormonal changes and mood-swings may affect a woman's response to certain medications such as antidepressants. Underlying variables need to be better understood because they contribute to the variations in clinical outcomes, and also to the differences between the health outcomes seen in women and men. Since 2001, The Institute of Medicine and the Committee on Understanding the Biology of Sex and Gender Differences both recognize sex (male or female) as an important variable in clinical research. This new branch of science is called sex-based biology and differentiates sex from gender. Sex refers to chromosomal differentiates between men and women. Gender refers to the cultural and social views of sex. Various diseases manifest differently in one sex over the other terms of diagnosis, prevalence, severity, and outcomes.

Diseases that affect women disproportionally over men include

1. Migraine Headaches	7. Sexually Transmitted Infections
2. Multiple Sclerosis	8. Breast Cancer
3. Lupus and Autoimmune Disorders	9. Urinary Incontinence
4. Chronic Fatigue Syndrome	10. Lung cancer*
5. Anxiety and Depression	11. Eating disorders due to fat shaming
6. Celiac Disease	12. Irritable bowel syndrome**

*Female heavy smokers are 70% more likely to get lung cancer male heavy smokers. **65% of the people affected by irritable bowel disease are women (NIH, 2018).

The symptoms of a disease may be different in a woman than in a man. For example:

1. Cardiovascular disease, the symptoms are different in women and their susceptibility increases with the postmenopausal decrease of estrogen.
2. Venereal diseases have different symptoms and long-term complications in women than in men.
3. Fractures from osteoporosis are twice as common in women than in men.

According to the National Osteoporosis Foundation, approximately 80% of Americans living with osteoporosis are women.

The outcomes and responses to treatment may differ in men than in women. For example: Metabolic rates may be higher in men than in women, and these differences may affect patient outcomes and responses to medication. Sexual differences such as the endogenous hormones of estradiol and testosterone may affect the PK and or PD of specific drugs and negatively impact their safety and efficacy when prescribed to a man versus a woman. Sex-related physiological differences such as muscle mass, body fat, body weight, metabolic enzymes, and plasma proteins also affect the PK parameters of drugs. A woman's body composition body weight and size are usually lower than a man. Lipophilic drugs are more widely distributed in a woman's body because females usually have more body fat than men. Other variations

between men and women include biotransformation, protein binding, and enzyme levels and receptor sites that relate to the ADME process. Certain drugs show fatal pharmacodynamic differences between men and women. For example, drugs that prolong the QT interval are likely to cause the potentially fatal arrhythmia of torsades de pointes in women. Also, more women experience liver failure from certain drugs than men. The dosages of many drugs are still administered in fixed doses rather than based on BSA and body weight. For example, the same dose of Zolpidem given to men and women results in women having double the blood levels of the drug. As a result, Zolpidem is the only drug that is dosed based on gender. Men and women have different health disparities based on biological, economic, social and cultural factors. These differences need to be studied at all life stages, in both sexes with the goal of reaching health equity. Sex and Gender should be examined as separate variables. Women should be included and evaluated in all the phases of clinical trials, especially since the disease burdens are often higher in women than in men.

Review of literature

Perceptions of subjects in general

Subjects attitudes towards clinical trials may need to be improved if the Clinical Research industry is to ease the bottleneck of recruitment. In 2006, a self-report survey was done to assess the subject's attitude about participating in clinical trials. According to Sood, the findings were: 28% had taken part in clinical trials before, 82% were satisfied with their knowledge of clinical research, yet 82% did not know that they could access clinical trials information online; 58% wait for their doctors to inform them about available studies, 76% were willing to participate in conventional trials and 44% were willing to participate in complementary intervention trials; 91% wanted to know the results of trials and 68% would not be interested unless they would be informed about the results. Findings from the survey indicated that the main barrier to participation was the need for information. The recommendation was made that future studies involve a more diverse group of subjects so as to generate more definitive results (Sood, et al., 2009). In 2008, the Society for Women's Health Research shared the viewpoints of clinicians on how to make clinical trials more diversified and inclusive to women and minorities. They recommend the use of new technologies and better ethical oversight of clinical trials without imposing more regulatory actions (SWHR, 2008). However, the community effort method of recruiting may not be applicable in every clinical trial.

Review of related studies to coral gables and liberty city in miami, florida

Liberty City is the most impoverished community within Miami. In 2008, The Liberty City Community Advisory Board was formed. It collaborates with the University of Miami Health System and recognizes the need to develop intervention partnerships in order to reduce the health disparities that are apparent in this under-served community. There is a scarcity of surveys that address the perceptions of Liberty City and Coral Gables women regarding potential barriers to participation in research. There is no available literature of any related study that compares the perceptions of women of childbearing age with the perceptions of older women. A summary of market research reports and literature surveys was done in 2004 by the National Cancer Institute (NCI) on the attitudes, barriers and motivating factors to participation in oncology clinical trials. The findings indicate that more studies are needed on the recruitment of minorities such as Hispanic/Latin-Americans and African-Americans. (NCI, 2004) There is not enough published data on the actual clinical trial recruitment process for participants and others from highly selected groups such as women and minorities. (Williams, S, 2004). This is the only study of Liberty City and Coral Gables women's perceptual barriers to participation in research.

Rationale & need for the study

Although women participants are needed and mandated, they may be underrepresented because of child-bearing age and their fluctuating hormones. The possible long-term effect of teratogenic study drugs on a women's gonads is unknown. A gender gap exists in biomedical research because more Caucasian men take

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part than women. As a result, recommended dosages are based on the male physiology with the risks to women unknown. The symptoms, severity, prevalence and age of onset of many diseases may be different in men. Warning signs, and adverse effects may also be different in women and the number of women who have Adverse Events from taking male based recommended dosages is unknown. Thus, the gender gap may contribute to medication errors that cause an increasingly large amount of deaths each year, exceeded only by cancer and heart disease. Women may have a knowledge gap that needs to be bridged as they may not be aware of biomedical medicine research, are unfamiliar with the terms being used to describe the topic, and when faced with multiple therapeutic options, may worry about making informed decisions. Shareholders and women benefit when the gender gap decreases, safety and efficacy increase and the result of research become more generalizable. This study has never been done before and investigated the perception barriers that prevent women who are ambulatory patients in Miami, Florida, from participating in clinical studies. 94% of the Liberty City arm were African-Americans. 90% of the Coral Gables arm were Latin-Americans. The study may have produced unusual findings about prospective female participants and may be of value in contingency planning and in the strategizing of direct-to-patient outreach campaigns by recruiters.

Research questions

What are the perceptions of low-income women versus more affluent women in Miami, Florida towards clinical research, and the barriers that may prevent their participation?

The study seeks the opinions and viewpoints of women in order to identify some reasons why willing women participants may be difficult to find.

Objectives

- To identify the perceptions of women in Miami, Florida towards clinical research.
- Evaluate potential barriers that may prevent women in Miami, Florida from enrolling in clinical trials.

Hypotheses

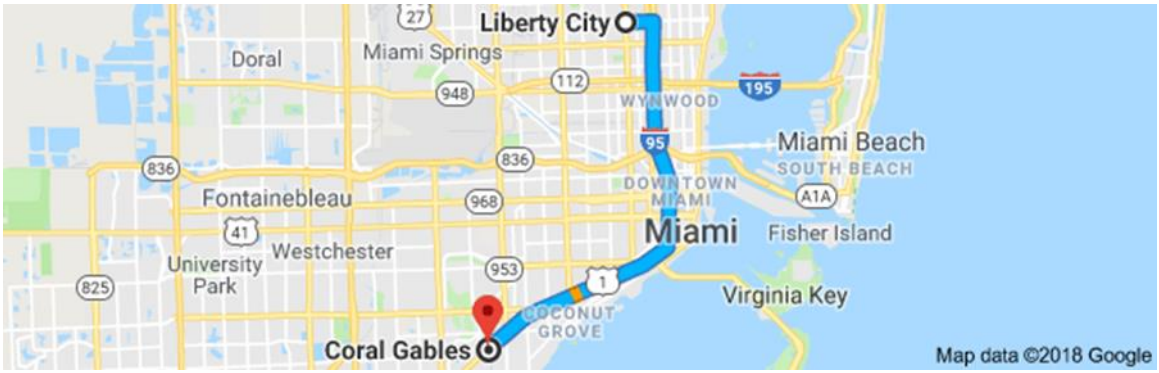
To identify the perceptions of women in Miami, Florida towards clinical research, and the barriers that may prevent their participation.

Methodology

Statement of the problem

The root cause of recruiting problems is uncertainty and that uncertainty is centered on finding large numbers of human subjects that meet the inclusion criteria in a timely manner. As the need for more subjects has increased, the number of recruited participants has decreased. The testing of interventions on the naive subjects of developing countries is no longer an easy option, because the countries have become warier of unethical trials and the risk of exploitation. The mandate that women must be included in all clinical trials have also compounded the difficulty, because many women may have perception barriers to participation. This study was never done before and investigated the gender gap problem by contrasting the opinions of women from Coral Gables, an affluent area of Miami, with those of Liberty City, the economically depressed and impoverished area that is located 20 minutes away, on the other side of the track. **Liberty City:** The US Census (2010) provided demographic information about Liberty City. It is the poorest inner-city in Miami-Florida, with 47% of the residents living below the Federal Poverty limit, and the median income per household is $19,847 per annum. **Coral Gables:** The affluent and historic city of Coral Gables is known as “the city beautiful.” It is famous for its upscale neighborhood with authentic castles in Mediterranean architecture style such as the Villa Vizcaya. The University of Miami Hospital and Healthcare system serves the Coral Gables area. Coral Gables has 228 physicians per 1000,000 populations which are higher than the national average of 210 per 1000,000 (US Census, 2013). The US Census (2013)

provides demographic information about Coral Gables. It is possibly the richest city in Miami, Florida with a median income per household of $93,590 per annum.



Map 1. Affluent Coral Gables is 20 minutes away from impoverished Liberty City

Source: Google maps

Research design

A descriptive, cross-sectional survey was conducted on female subjects who fill their prescriptions at a community pharmacy in, Miami, Florida. The pharmacy is well established in the inner-city community of Liberty City. The descriptive, cross-sectional survey was also conducted on female subjects who randomly attended three well established walk-in clinics in Coral Gables, Miami Florida.

Independent variables

Age, gender and socio-economic variables

Coral Gables Women aged 18-39 years
Coral Gables Women aged 40-65 years
Liberty City Women aged 18-39 years
Liberty City Women aged 40-65 years

Dependent variables

The five domains of questions in the survey questionnaire

1.Willingness & Experience	Items: 1, 2, 3, 4, 5, 23, 31, 35
2.Perception of Benefits	Items: 5, 6, 11, 16, 21, 34, 35, 36
3.Subject needs information	Items: 7, 12, 14, 17, 22, 24, 26, 27
4.Barriers to Participation	Items: 8, 13, 18, 19, 20, 30, 32, 34
5.Subjects'safety concerns	Items: 9, 10, 15, 20, 25, 28, 29, 33

The sample

The target sample size was found by multiplying the 36 questions in the questionnaire by three to ten due to factor analytical procedures (Jenkinson et al., 2005). The ideal number of respondents would be 360, but no less than 108. 150 copies of the Survey instruments were provided. The Liberty City arm completed 51 of 75 copies, while the Coral Gables arm completed 75 of 75 copies for a total of 126.

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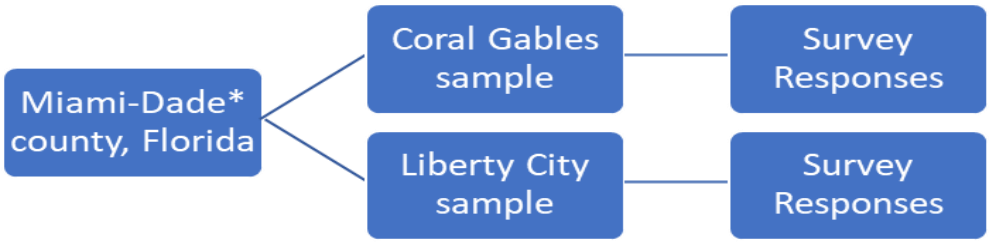

Figure 1. Diagram of the arms of the study

*Miami-Dade County is the most populous county in Florida, with 2,751,796 people, or 13.4% of the states' entire population in 2017. Miami-Dade is the seventh most populous county in the United States.

Inclusion criteria

Female between the ages of 18 and 65 years
Willingness to take part in an anonymous survey
Able to read and write English and/or Spanish

Exclusion criteria

Male

The cognitively impaired

Measures/Tools used for data collection

The questionnaire for the survey was a compilation of questions, all of which were re-worded by the student researcher so as not to plagiarize and to specifically meet the needs of the research question. The majority of the questions were adapted from and supported by a validated survey designed by researchers from the University of Oxford and which had been used to assess the attitudes of asthma and cancer subjects towards clinical trials. Cronbach's alpha was used to measure the reliability and validity of the model questionnaire (Jenkinson et al., 2005). The design and wording of the questionnaire were critically reviewed by instructors, advisors, and peers to ensure that the meanings were clear and within the parameters of the inclusion criteria. There were 36 questions plus a section that collected socio-economic data such as age, ethnicity and employment status. The mean survey completion time was 15 minutes. The questionnaire assessed the women's perceptions about participating in clinical trials on the survey instrument through a 5-point Likert scale with five levels of responses and viewpoints.

Table 1. Item levels

Scale Value of Positive Item	Point Level	Scale Value of Negative Item	Reverse Score for Negative Statements
5	Definitely	1	5
4	Probably	2	4
3	Not sure	3	3
2	Probably not	4	2
1	Definitely not	5	1

Reverse Scoring was used for negative statements (Furr, 2007). Data were analyzed using Excel and descriptive statistics to determine

1. the mean,
2. standard deviation, and

3. percentage as applicable.

Procedure

A descriptive, cross-sectional survey was conducted on female subjects who randomly fill their prescriptions at a community pharmacy in, Miami, Florida. The pharmacy is well-established in the inner-city community of Liberty City. The descriptive, cross-sectional survey was also conducted on female subjects who randomly attended three well established walk-in clinics in Coral Gables, Miami Florida. The introduction and consent page of the survey was handed out by the pharmacy manager or clinic manager before the survey is conducted. The Pharmacy Manager and the Clinic Managers agreed to participate and were trained to invite ambulatory patients to volunteer. This page extracted a general consent from the individuals without the collection of personal information and identified those that satisfy the inclusion criteria. The survey was conducted with a convenience sample of women that attending a community pharmacy located in Liberty City, Miami, Florida and also 3 walk-in clinics in Coral Gables. A copy of the introduction and consent page for the survey is available with the thesis.

Ethical considerations

Women who attend the clinics and pharmacy and agreed to fill out the survey were provided with a participant information sheet explaining the study before answering the questionnaire and confidentiality regarding their identification will be ensured. No identifying information was collected. The informed consent or assent feature to the survey was the statement: “The return of this questionnaire is your consent to participate in the survey AND completes your participation in this research project.” At the end of the survey period the raw data was collected, reviewed and analyzed in order to find trends and the results were compiled.

Data analyses and technique

Data were analyzed using Excel and descriptive statistics to determine the mean, standard deviation, and percentage as applicable. Data from the questionnaire was collected regarding age categories (18-39 versus 40-65 years of age) and tabulated to show the characteristics of the sample in terms of:

1. Socio-demographic data,
2. The percentage of respondents that had taken part in a clinical trial before,
3. Respondents who are willing to take part in a clinical trial and,
4. Respondents that had been asked to take part in a clinical trial. Frequency summaries regarding categories of response to the question: “Would you be willing to take part in a clinical research?” were presented and the general attitudes of participants towards clinical trials were assessed based on five levels of response that range from “definitely” to “definitely not”.

Results and interpretation

Objective 1: To find answers to the Research Questions.

Hypothesis 1: Women may have knowledge gaps that need to be bridged as they may not be aware of biomedical medicine research, are unfamiliar with the terms being used to describe the topic, and when faced with multiple therapeutic options, may worry about making informed decisions. Knowledge gaps may contribute to the gender gap in biomedical research.

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Table 2. Experience and willingness to take part in clinical trials in liberty city

Items 1-3 of Questionnaire:	**Age Group**	**% (N) of Subjects:**		
		Yes	**No**	**Not sure**
Q1. Have you ever taken part in a clinical research?	18- 39: 40-65:	0% (0) 14.7% (5)	100% (17) 85.3% (29)	0% 0%
Q2. Were you ever asked to take part in a clinical research?	18- 39: 40-65:	17.6% (3) 23.53% (8)	82.35% (14) 76.47% (26)	0% 0%
Q3. Would you be willing to take part in a clinical research?	18- 39: 40-65: Total:	29.4% (5) 47.05 % (16) 41.17% (21)	52.94% (9) 34.29 % (12) 41.17% (21)	17.64% (3) 17.64% (6) 17.64% (9)

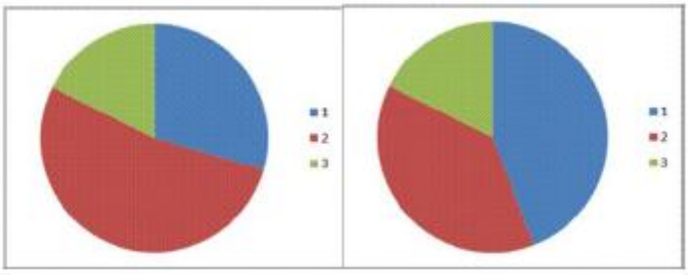

Figure 2. Responses to question 3 of younger women vs. older women of liberty city color code of responses: Blue: Yes. Red: No, Green: Not Sure

Table 3. Experience and Willingness to take Part in a Clinical Trial (Coral Gables)

Items 1-3 of Questionnaire:	**Age Group**	**% (N) of Subjects:**		
		Yes	**No**	**Not sure**
Q1. Have you ever taken part in a clinical research?	18- 39: 40-65:	33.56% (14) 25% (8)	58.81% (24) 68.7% (22)	11.63%(5) 6.25%(2)
Q2. Were you ever asked to take part in a clinical research?	18- 39: 40-65:	33.56% (14) 25% (8)	32.88% (15) 46.87% (15)	32.56% (14) 28.12% (9)
Q3. Would you be willing to take part in a clinical research?	18- 39: 40-65: Total:	34.88% (15) 31.25% (10) 33.3% (25)	30.23% (13) 40.6% (13) 34.6% (26)	34.88% (15) 28.12% (9) 32% (24)

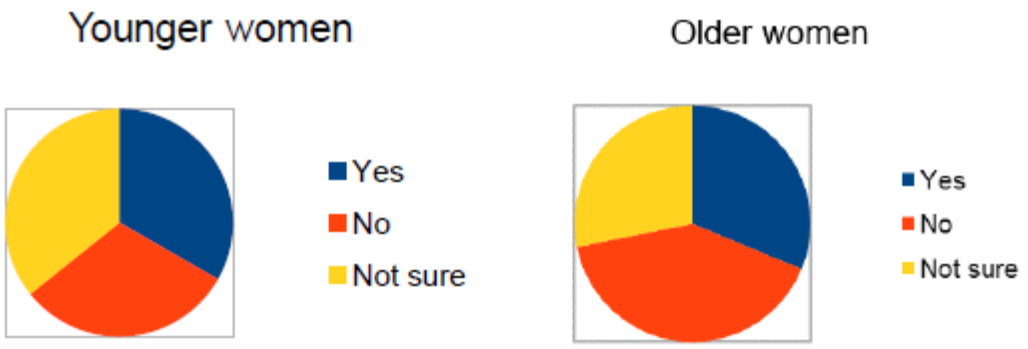

Figure 3. Responses to question 3 of younger women vs. older women of coral gables, color code of responses: blue: yes. red: no, yellow: not sure

Graph: Coral Gables vs. Liberty Group Mean (SD) or Mean ± SEM

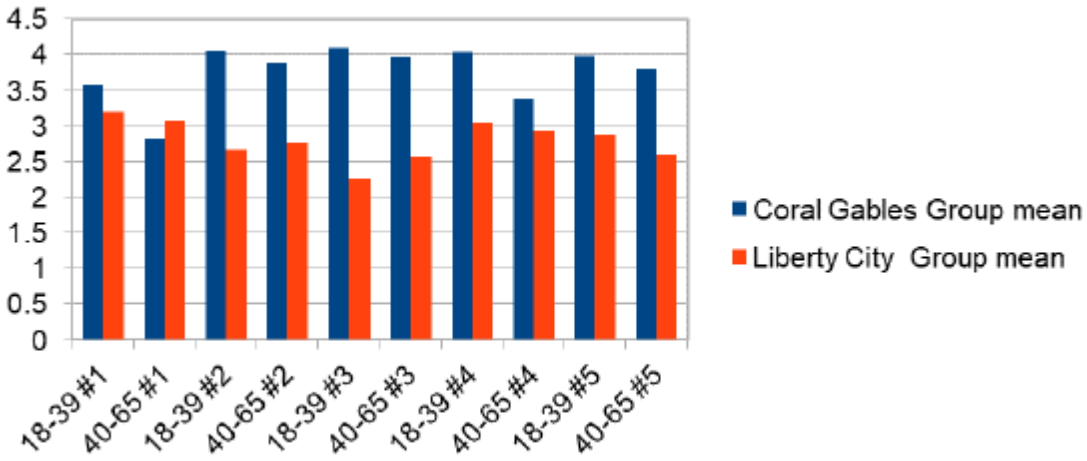

Figure 4. Liberty city and coral gables responses compared

Discussion

Domain 1: Willingness and Experience, Coral Gables Figure 4, columns 1 represent the Mean and Standard Deviation of Domain 1 which concerns Willingness and Experience (Items: 1, 2, 3, 4, 5, 23, 31, 35) and compared younger women with older women respectively. The results: 3.57848 ±0.96467 and 2.81640 ±1.26735 respectively showed that the mean and the standard deviation are slightly higher among the older women. This study finds that 31.25% of the older women (aged 40-65) and 34.88% of the younger women (aged 18-39) and were definitely willing to take part in clinical studies. The majority of the participants in Coral Gables were Hispanic-Latino Americans, and the most common disorder was migraine headaches which affected 28 of the 75 subjects. Migraine headaches were prevalent in the 30-39 age group which is a woman's most productive years. Migraine headaches affect women disproportionately and are three times more common in women than in men. Migraine headaches may be chronic and debilitating, and presently there is no known cause, treatment, or cure. The Society of Women Health Research stated that in order to reduce the health and economic burden of migraine headaches on society, more research is needed on gender differences as they relate to migraine disease (Schroeder, R.et al., 2018). Clinical research that explores gender differences in migraine headaches has been limited.16 More research is needed in diseases that disproportionately affect women.

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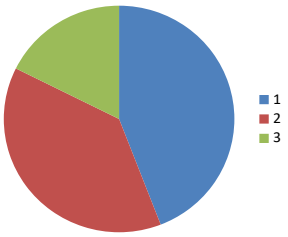
Domain 1: Willingness and Experience, Liberty City. Figure 5, columns 1 represents the Mean and Standard Deviation of Domain 1 which concerns Willingness and Experience (Items: 1, 2, 3, 4, 5, 23, 31, 35) and compared younger women with older women respectively. The results: 3.18821 ±1.28164 and 3.07141 ±1.40696 respectively showed that the mean and the standard deviation are higher among the older women. This study finds that 47.05 % of respondents aged 40-65 are more likely to be willing to take part in a clinical trial compared to 29.4% of those aged 18-39 years. This is a reversal of the findings of a national survey by the Society for Women's Health Research (2008) and shows that the national survey questionnaire may not fully apply to the respondents from Liberty City.

Figure, Blue represents the findings of a survey done by the Society for Women's Health Research (2008) and shows that 49.3% of younger women aged 18-34 responded with yes or probably and were more likely to participate than other age groups combined**.** (SWHR, 2008)

Responses of younger women in a comparative SWHR study



Source: Society for women's health research

The unusual finding that older women are more receptive to taking part in clinical trials may have been due to fact that more of the older women attend pharmacies to fill their prescriptions. The most common disorder in Liberty City was high blood pressure which affected 16 of the 51 subjects or 31.37% of the respondents. There is a disproportionate stroke morbidity and mortality among African Americans. (Worrall, B., 2009). Many are at risk for heart disease and stroke, which are leading causes of death in the United States15 and a leading cause of death among women.

Domain 2: Subjects' Perception of Benefit, Coral Gables. Figure 6 Domain 2, Columns 2 represents the Mean and Standard Deviation of Items: 5, 6, 11, 16, 21, 34, 35, 36 which assessed the Subjects' Perception of Benefit. The Means to Standard Deviation ratio respectively was 4.05232 ± 0.65404 and 3.80078 ± 0.91469 and shows perception of benefits as a motivating force is strong in both groups. Perceived benefits to participation include: a. improvement to the lives of others, b. advancement of medical knowledge, c. improvement to their condition and d. earning extra money from the stipend. Although stipends are like petty cash, 81.40% of the subjects ages 18-39 years and 59.38% of the subjects aged 40-65 years, Coral Gables were motivated by financial benefit to take part. Coral Gables has a higher percentage of financially-motivated respondents than Liberty City where 47.05% of the younger subjects and 50% of the older subjects were interested in financial benefit.

Domain 2: Subjects' Perception of Benefit, Liberty City, Figure 5, columns 2 represents the Mean and Standard Deviation of Domain 2 (Items: 5, 6, 11, 16, 21, 34, 35, 36) or the Subjects' Perception of Benefit. The Means to Standard Deviation ratio respectively was 2.65909 ±1.43028 and 2.74985±1.40696 respectively which shows the perception of benefits as a motivating force is close to even in both groups. Liberty City is the most impoverished inner city in Miami, Florida, and unemployment is higher than the national average. The unemployment rate among the subjects was 37.2%. This is higher than the national average which is currently slightly below 8%. Fifty percent of older women and 24% of the younger women were willing to take part in order to get free laboratory tests. Although stipends are not large enough to be incentives and may only reimburse costs, 50% of older women and 47% of the younger women would take part in a clinical trial in the hope of getting a stipend as may be the case in low-wage countries.

Domain 3: Subjects Needs Information, Coral Gables. Figure 6 columns 3 represents the Means and Standard Deviation of Domain 3. (Items: 7, 12, 14, 17, 22, 24, 26, 27) or the Subjects Need for Information.

The Means to Standard Deviation ratio was 4.10359 ± 0.62332 and 3.95312 ± 0.69871 respectively. The responses showed that both groups believed that their level of information about clinical trials was inadequate and would like to be introduced to suitable clinical trials by their pharmacists or doctors. However, if the study is blinded the information that the patient may want may not be available. The majority of the respondents from both groups would only take part if the doctor was not blinded as was shown by their responses. Access to clinical trials online may counteract the cultural latency of information which normally affects specifics populations. The negative responses show that a few of the respondents did not know that the clinical study information was available online.

Domain 3: Subjects Needs Information, Liberty City Domain 3: Subjects Needs Information, Liberty City. Figure 5, columns 3 represents the Mean and Standard Deviation of Domain 3 (Items: 7, 12, 14, 17, 22, 24, 26, 27) or the Subjects Need for Information. The Means to Standard Deviation ratio was 2.25426 ±1.15641 and 2.57191 ±1.34703 respectively. The responses showed that both groups believed that their level of information about clinical trials was inadequate and may like to be introduced to suitable clinical trials by their pharmacists or doctors. This would counteract the cultural latency of information which normally affects specifics populations. Results showed that 88.23% of younger women needed written information in comparison to 70.58% of older women in order to participate in clinical trials. Responses to questions 7 and 14 show that the subjects considered being informed about the results of the clinical trial to be a greater incentive for participation than being informed about the treatment they would be given.

The highest number of positive responses were in Domain 3 which questions the need for more information. These questions received the highest number of positive responses, and revealed what was most important to the young women. For example, 93.02 % of the Coral Gables young women had a positive response to "I expect my doctor or pharmacist to inform me about suitable trials," and 88.23% of Liberty City young women had a positive response to "I need written information about a clinical research before participating." This may show that women are open to receive more information about clinical trials

Domain 4: Barriers to Participation, Coral Gables. Figure 6 columns 4 represents the Mean and Standard Deviation of Domain 4 (Items: 8, 13, 18, 19, 20, 30, 32, 34) or Barriers to Participation responses. Columns 4 (younger group) and column 4 (older group) with 4.04069 ± 0.73333 and 3.83883 ± 0.85211, are shown respectively and reveal the difference between both groups. In addition, the subjects' response to question 25 shows that the risk of pregnancy as a barrier to participation for subjects of child-bearing age was not a concern for 76.47% of the younger women from both arms of the study: Liberty City and Coral Gables. Question 13 shows that the majority of women from Coral Gables would not take part because the clinic hours would be disruptive of their daily routine.

Domain 4: Barriers to Participation, Liberty City Figure 5 columns 4 represents the Mean and Standard Deviation of Domain 4 (Items: 8, 13, 18, 19, 20, 30, 32, 34), or the Barriers to Participation responses. Columns 4 (younger group) and column 4 (older group) with 3.05185 ±1.32242 and 2.91916 ±1.41167, are shown respectively. A comparison of the columns shows that there is not much difference between both groups. In addition, the subjects' response to question 25 shows that the risk of pregnancy as a barrier to participation for subjects of child-bearing age was not a concern for 76.47% of the younger women. Researches have learned from the tragedy of thalidomide and steps are taken to protect the unborn during drug studies.

Domain 5: Subjects' Safety Concerns, Coral Gables. Figure 6 columns 5 represents the Mean and Standard Deviation of Domain 5 (Items: 9, 10, 15, 20, 25, 28, 29, 33) or the Subjects' Safety concerns. Columns 5 (younger group) and column 5 (older group) with 3.98837 ± 0.73517 and 3.78906 ± 0.83319, respectively. A comparison of the columns shows that younger women perceive more barriers to participation than the older women. Knowledge of unethical trials that were done in several Latin American countries impact the perception of participants because many people are from immigrants' families. For example, the ethically impossible syphilis research in Guatemala from 1946 to 1948 and gynecological research in the US territory of Puerto Rico a few years later. South Florida has an influx of middle-upper

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class Puerto Ricans many of which reside in Coral Gables. Many Puerto Rican Latin Americans are aware and wary of the participating in clinical trials. Puerto Rican women were used as guinea pigs in the testing of contraceptive pills in the 1950s. This large-scale unethical research was done on the destitute Puerto Rican women who lived in the Rio Piedras housing projects. The pill was a form of population control. In 1937, the passage of Law 136 by the Government of the United States, legally sanctioned sterilization of Puerto Rican women for eugenics, population control and to reduce poverty (Briggs, L., 2002). Responses to Question 33 show that 81.40% of the younger women from Coral Gables were wary of unknown side effects from the study drug. In response to Question 19, 76.74% of the younger women from Coral Gables preferred their current drug over the study drug and their preference was a barrier to participation. Question 25 shows that 76.47% of the younger women both from Coral Gables and Liberty City share the identical negative response about not participating in clinical studies as they may be pregnant. However, question 35 shows that younger women from Coral Gables were more altruistic than those from Liberty City and did not mind taking part in during their child bearing years to find new medicines for women.

Domain 5: Subjects' Safety Concerns, Liberty City, Figure 5, columns 5 represents the Mean and Standard Deviation of Domain 5 (Items: 9, 10, 15, 20, 25, 28, 29, 33) is about Subjects' Safety Concerns. The Mean and Standard Deviation of younger versus older women are compared in columns 5 with 2.86648 ±1.48753 and 2.6104 ±1.58544, respectively. This data shows that younger women perceive more barriers to participation than the older women. Both groups of women were equally concerned about the amount of blood that may be drawn in a clinical trial. A correlation between patients' safety concerns and patient's needs for information had on patients' willingness to participate in clinical trials was suggested. The majority of the respondents believed that they were healthy enough to participate and that their health was not a barrier to participation. In response to question 28, 35 of the 51 respondents were not willing to take part in clinical trials if they would be treated like a guinea pig or given placebos. Fear of being used as a guinea pig is a very real psychological barrier against participation in clinical studies by African Americans, due to the common knowledge about several unethical studies, the worst of which was the racist non-therapeutic Tuskegee Syphilis Study which took place for 40 years, from 1932 to 1972. The Tuskegee Syphilis study was medical experimentation that involved nearly 400 impoverished and poorly educated African-American men diagnosed with latent syphilis. The men showed no symptoms of the disease, and for 40 years they were not told that they were infected, but that they had "bad blood," The subjects were not treated even though Salvarsan for syphilis was discovered in 1909, and penicillin was the standard cure for syphilis since 1947 (CDC, 2018), while the progress of the disease was observed. The majority of the Liberty City respondents were African American and may have been negatively impacted by the well-known tragic history of the Tuskegee Syphilis Study. Of the 51 respondents, 64.70% of younger women and 70.58% of older women said that they did not want to be made a guinea pig. Nevertheless, 70.58% of the 51 respondents were willing to take part in clinical research for altruistic reasons.

Summary and conclusion

The efficiency challenges of recruiting women have created roadblocks and reduced profitability and the availability of new medicines for women. This study examined the perceptional barriers of women from the richest and poorest areas of Miami, Florida, towards their participation in clinical research. The purpose of this study is to add to the available knowledge concerning the conditions that may affect the willingness of this specific population of women to participate in clinical trials. In regard to question 18, over 80% of women of all ages in the Coral Gables group were not concerned about the amount of blood that may be drawn in a clinical trial than the Liberty City Group. This was not the case in Liberty City where 64.70% of both younger and older women gave negative responses to blood being drawn. The negative responses from Liberty City were unfounded because there is a maximum allowable amount of blood that can be drawn from participants in clinical studies. Negative responses may signify that the respondents need more information about phlebotomy. Domains 1, 2 and 5 are intertwined when the women's concern for their current medication were addressed in questions 23, 33and 19 respectively. Responses to Question 23

concern willingness to participate and show the 88.37% of the younger women in the Coral Gables group were still willing to participate even though the treatment with the study drugs may end when the study is completed. Question 34 addresses the role of the family in permitting participants to take part in clinical studies. The head of a household who is in charge of making decisions for the family varies among cultures, such as paternal tribes where the chief is the decision-maker, and in families where the father is missing, and the household is run by a woman. The female breadwinner in a household may be too busy to fit clinical studies in their schedule. In Liberty City more households are run by single or unmarried women than in Coral Gables. However, the percentage of women who would take part if the family agrees was higher in Coral Gables than in Liberty City. The US government now recognizes a patient's "right to try" option. 82.35% of the young people from Liberty City, 74.42% of the young people from Coral Gables, 64.70% of the older women from Liberty City and 71.875% of the older women from Coral Gables all were willing to take the "right-to-try" option and take part in an Investigative New Drug study. The results for Question 27 show that 67.44 % of Coral Gables young respondents and 68.75% of the older respondents need written information, which is the mandated informed consent process. Question 7 is about women who would take part only if the results were made known to them. More respondents from Liberty City expressed the need more information than the respondents from Coral Gables. In response to Question 22, most respondents from both Liberty City and from Coral Gables said that they would only take part if they understood the clinical trial. In response to Question 14 most respondents from both Liberty City and from Coral Gables said that they would only take part if they knew which study drug they were going to receive.

Research outcomes

The study assessed the perceptions of patients concerning clinical trials, and examined the reasons they give for participating or not participating in clinical trials. This research may provide insight into barriers that may prevent the recruitment of women into clinical trials. It is hoped that this survey will add to the body of knowledge on the perceptions of women towards clinical trials and barriers that may prevent recruitment from both affluent and poor neighborhoods of Miami, Florida.

Limitations of the study

In the Liberty City group, the fact that older adults are more likely to fill many prescriptions than younger adults may have disproportionally impacted the number of respondents available for participation in the survey. Twice as many older patients than younger patients that visited the community pharmacy agreed to take part while the survey questionnaire was being run. Therefore, the overall rate from women of childbearing age was lower than expected. The recommended minimum sample size was 108 respondents, and the goal was to get 75 participants per arm. However, only 51 patients from Liberty City consented to enroll and 75 from Coral Gables with a total of 126 participants. This sample size made it easy to compare survey results. In Liberty City there were unequal numbers of 18-39 years-old (17) versus 40-65 (34), participating in the survey. This ratio of 1:2 may cause the sample to have some inherent selection bias. Although a 1:1 ratio produces the most power, a ratio of 1:2 does not significantly reduce power, with a reduction from 80% to 75% (Wittes, 2002). Recommendations are that the survey be run at other participating locations within the economically depressed community of Liberty City. The Coral Gables Group also had an unequal number of 18-39 years-old (43) versus 40-65 years-old (32), participating in the survey. This 4:3 ratios may also cause the sample to have some inherent selection bias but did not significantly reduce power. In spite of the lower power, some correlations were found between the responses to the survey and the findings from the review of the relevant literature concerning patients' perceptions of clinical trials and their willingness to participate.

Implications of the study

The general public needs to be more informed about clinical studies. However, media coverage of unethical clinical studies may negatively impact the perceptions of potential participants. There were 8 questions in Domain 3. Question 4 asked if the respondents believed that their knowledge of clinical

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research was satisfactory. Both age groups of the Coral Gables arm were positive that their knowledge of clinical research was satisfactory, with 74.41% of younger women from Coral Gables and 68.75% of older women from Coral Gables giving a positive response. In comparison, 52.94% of younger women from Liberty City and 55.88% of older women from Liberty City were positive that their knowledge of clinical research was satisfactory. It is not known how the groups get informed, and media coverage are not always positive. There are many reasons why women responders may have safety concerns and be apprehensive of participating in Clinical Trials. 53.12% of the young women of Coral Gables believed that research is too frightening. 82.35% of the young women of Liberty City said that the study may be too risky. A "not sure" response may become a positive response depending on the benefits perceived. This information may be of value in contingency planning and in the strategizing of direct-to-patient outreach campaigns by recruiters. Recruiters may highlight the informational gap that the responses revealed and emphasize patient-centered research studies. Female patients may want to be informed about improvements that make participation in studies less burdensome to patients and which allow patients to benefit from participating in cutting-edge research.

Directions for future research

Re: people-centered research: 51% of the general population are women (HRSA., 2013). It is not known if women who are not patients have the same perception barriers to participation as women who are patients. A future telephone survey questionnaire may be administered to women aged 18-65 years in the general population who are not patients, because participants in Phases I and II are volunteers, not patients. To remove the gender gap which limits the generalizability of research results, more informed female participants, both patients and non-patients, are needed.

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