Racial and Ethnic Minority Population Knowledge, Perception, and Facilitator to Participation in Clinical Trial Research

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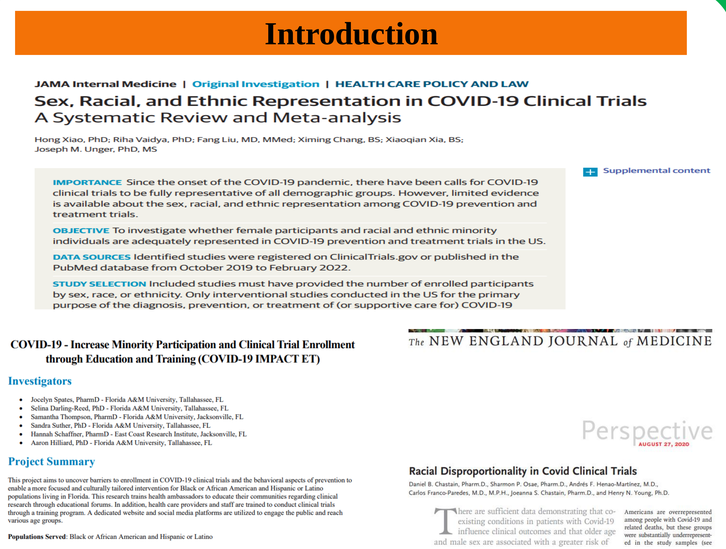
Introduction



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Sex, Racial, and Ethnic Representation in COVID-19 Clinical Trials
A Systematic Review and Meta-analysis

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Supplemental content

IMPORTANCE Since the onset of the COVID-19 pandemic, there have been calls for COVID-19 clinical trials to be fully representative of all demographic groups. However, limited evidence is available about the sex, racial, and ethnic representation among COVID-19 prevention and treatment trials.

OBJECTIVE To investigate whether female participants and racial and ethnic minority individuals are adequately represented in COVID-19 prevention and treatment trials in the US.

DATA SOURCES Identified studies were registered on ClinicalTrials.gov or published in the PubMed database from October 2019 to February 2022.

STUDY SELECTION Included studies must have provided the number of enrolled participants by sex, race, or ethnicity. Only interventional studies conducted in the US for the primary purpose of the diagnosis, prevention, or treatment of (or supportive care for) COVID-19

COVID-19 - Increase Minority Participation and Clinical Trial Enrollment through Education and Training (COVID-19 IMPACT ET)

Investigators

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Project Summary

This project aims to uncover barriers to enrollment in COVID-19 clinical trials and the behavioral aspects of prevention to enable a more focused and culturally tailored intervention for Black or African American and Hispanic or Latino populations living in Florida. This research trains health ambassadors to educate their communities regarding clinical research through educational forums. In addition, health care providers and staff are trained to conduct clinical trials through a training program. A dedicated website and social media platforms are utilized to engage the public and reach various age groups.

Populations Served: Black or African American and Hispanic or Latino

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Perspective
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Racial Disproportionality in Covid Clinical Trials

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There are sufficient data demonstrating that co-existing conditions in patients with Covid-19 influence clinical outcomes and that older age and male sex are associated with a greater risk of

Americans are overrepresented among people with Covid-19 and related deaths, but these groups were substantially underrepresented in the study samples (see

Objective

The purpose of the focus groups was to hear the opinions of the community about how to encourage racial and ethnic minority populations to participate in clinical trials.

Methods

Data Sources and Study Population

Between November 2022 and March 2023, six focus groups were conducted with 66 lay community members reside in three Florida Counties - Duval County in Jacksonville, Leon County in Tallahassee, and Hillsboro County in Tampa.

Data Extraction

Data from the focus groups were transcribed verbatim. The transcripts were organized, coded, and analyzed utilizing NVivo qualitative software©. Two reviewers identified key themes using the a priori objectives from the focus group guide. A general code list was developed based on the review of the transcripts. The code list of themes was further refined after the reviewers' initial coding pass.

Table 1. List of Code Descriptions

Code	Description
Clinical Trial Information	Where would you go for information regarding clinical trials?
Community Description	How would you describe your community?
Community Information Needs	What would your community need to know about clinical trials?
Knowledge of Clinical Trials	What do you know about clinical trials?
Most helpful information	What is the most important information you need to know about clinical trials?
Most Trusted Source of Information	Most trusted source to get information regarding clinical trials.
Most unhelpful information	What is the most unhelpful information to receive about clinical trials?
Motivation to Participate	What would make you decide to participate in a clinical trial?
Cons to Participate	Why a person would not participate in clinical trials
Pros of Participation	Why a person would participate in clinical trials
Often Receive Information	How often do you receive or see information about clinical trials?
Participate in clinical trial	Has ever participated in a clinical trial.

Results

Table 2. Community Participant Demographics

Patient Characteristics	Number of Study Participants (N= 66)	Patient Characteristics	Number of Study Participants (N= 66)
Race		**Age Group**	
American Indian or Alaska Native	1	18-24 years old	8
Asian	5	25 - 34 years old	32
Black or African American	41	35 - 44 years old	13
Native Hawaiian or Other Pacific Islander	2	45 -54 years old	3
White	11	55 to 64 years old	1
Prefer not to answer	2	65 years or older	4
Unknown	4	Unknown	5
Ethnicity		**Geographic locations- Florida County**	
Hispanic	12	Duval	13
Non-Hispanic	48	Leon	20
Prefer not to say	2	Hillsboro	33
Unknown	4		
Gender/Sexual Identity			
Male	39		
Female	21		
Another identity	1		
Prefer not to answer	1		
Unknown	4		

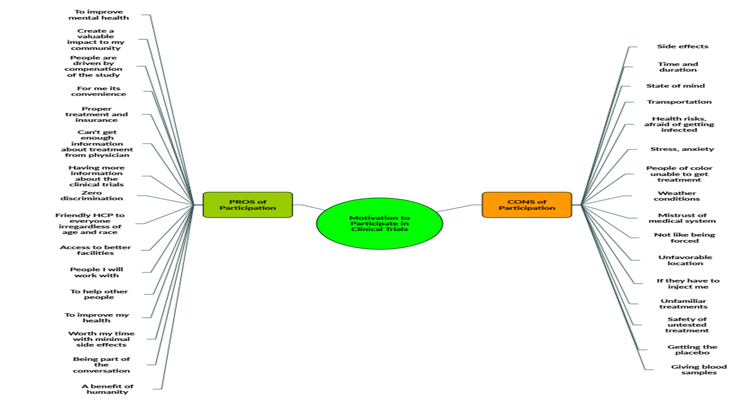

Figure 1. Motivation to Participate in Clinical Trials – Pros and Cons

Although the most trusted resource for information about clinical trials was physicians or health care providers, most participants had little knowledge and never received information about clinical trials. Updated and more informative education regarding clinical trials should be made available in medical practices and community clinics to encourage racial and ethnic minority populations to participate in clinical trials.

Results

Table 3. Focus Group Participants' Response

Discussion point	Participants response
What do you know about clinical trials?	One participant stated, "My knowledge about clinical trials is just simple …the basic knowledge I see online or in books." Others told what they perceived to be the purpose of clinical trials. Nine participants stated that clinical trials were research studies to test a new medical device, treatment, or drug. As explained by these A few of the participants or someone in their family had participated in a clinical trial. The trials mentioned were ADHD and multiple myeloma
How often do you receive information about clinical trials?	Five spoke up to say "rarely" or "not often." One stated, "I have never received clinical trial invitations for accessible studies." Two had received information 1-2 times per year. If participants wanted information regarding clinical trials, they looked in numerous places. Healthcare providers, social media, and the internet were the most mentioned.
Who would you most trust as a source of information about clinical trials?	Twenty-five concurred that they trusted information from their healthcare providers. At least 13 trusted social media or the internet for clinical trial information. As one stated, "I would actually go to the website, use keywords and be specific if I wanted to find something out…clinical trials on African Americans with high blood pressure, heart disease, or obesity." Other trusted sources included Webinars, clinical trial websites, friends, family members, community members, community schools, and others.
What is the most important information you need to know about clinical trials?	The most helpful information for the participants were getting the "facts and figures" instead of "excessive things" that didn't relate to the benefits of participating. Remarks included: "It's helpful if I'm being educated on the outcome…People need to know what they are about to participate in and it's not going to harm them. I don't want to hear about having side effects." "It should also be encouraging that people know by participating in a clinical trial they are going to be indirectly solving problems of others."
What would make you decide to participate in a clinical trial?	The participants revealed many pros and cons of participation in clinical trials (Figure 1). The top pro of participating was to help people and compensation for participating. Many mentioned the fear of side effects as a con of participating in clinical trials.
How do you describe your community?	Most said their community was predominately Black or African American residents. There were three that said their community consisted of Black Muslims. Others were mixed or diverse communities. As stated by these participants: "We have a mixture, but mostly we have white people in my community." "I would say that my community is both urban and suburban as well as city. I think there's a pretty good blend…depending on what area you live in." "It's mainly pretty diverse. There's a combination of Whites and Blacks and Hispanics, and they're not all in the same exact section. But at the same time, if I look at my block, I could say that I'm the only person of color that lives on my block."
Regarding clinical trial, What kind of information the community need and what type of messaging would be best to communicate this information?	Knowing about the health benefit as well as possible risks and side effects was top of their list. Knowing all the facts and what types of clinical trials that are available was also important information for the community and what compensation will be provided. "My community needs to understand that it is important for our population to participate in clinical trials. Most of us take high blood pressure pills. Well, the study that was done at the Framingham study, was just done on people that don't look like us. If we are not part of these studies, they will never know how we be affected." "I think it should focus more about the type of clinical trial it is, maybe for what type of disease. Also the information should assure them of safe health. We should prepare the community for understanding what clinical research is and why we do it. You want to dispel of the myths and urban messages about research and replace that with more positive messages." "I think an explanation of how the information in the clinical trial is going to be used and how your information is going to be secured and kept confidential would probably be something to include in a message about trials."

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