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Beyond Tuskegee: Qualitative Insights from Older African Americans on Clinical Trial Participation

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Abstract

Beyond Tuskegee: Qualitative Insights from Older African Americans on Clinical Trial Participation

By Heidi Gruhler

This study aimed to explore potential facilitators and barriers to clinical trial screening and enrollment participation among older African Americans. Despite efforts to increase enrollment in clinical trials in recent decades for a number of chronic and infectious diseases, clinical trial participation among elderly African Americans remains suboptimal. Therefore an intervention study was conducted entitled "Delivering a Dose of Hope" that sought to reach and influence clinical trial participatory outcomes in Atlanta area Black churches. This intervention also sought to uncover the influencing factors affecting study participation. This qualitative substudy was a component to the "Dose of Hope" program. Baseline (n=18) and Semi-structured in-depth interviews (n=12) were conducted with older African Americans who participated in an education intervention at their church in the metro Atlanta area. Interviews were transcribed verbatim, and coded for common thematic factors related to facilitators and barriers to clinical trial screening and participation. The analyses adopted a modified grounded theory qualitative approach for thematic elicitation. Three major themes were subsequently identified at baseline: Need for Education, Attitudes toward Clinical Trials, and Trust. Six major themes were also identified at follow-up: Lack of Awareness, Motivation to Participate in Clinical Trials, Psychosocial Barriers, Logistical Challenges, and Education Intervention. Lack of awareness was found to precede barriers and facilitators in the decision making process. Lack of awareness, although related to the need for education, emerged as a separate theme. This study successfully elicited a theoretical model that postulates relationships between thematic components how they influence willingness to screen and participate in clinical trials.

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INTRODUCTION

Problem Definition and Justification

It has been well established that the African American community is underrepresented in clinical trial research.[1-14] To address the underrepresentation in 1993 the NIH instituted a policy to increase minority participation in clinical trials, including African American and women.[15] Increasing participation of minorities and those underserved is important in order to create more effective treatments for diseases that disproportionately affect these communities.[5]

Background

The metro Atlanta area is comprised of 26 county regions and is the most populous metro region in Georgia.[16] According to the US Census Bureau, over 5.3 million people live in the metro Atlanta area. Over 1.5 million, 33% of the population is Black or African American.[16] Atlanta has a large number of African Americans. Health disparities disproportionately affect the African American community.[3] Health disparities are defined as differences in health that are closely linked with social, economic, or environmental disadvantage.[17] African Americans have faced a long history of discrimination and exclusion, and have systematically experienced greater health disparities.[17]

According to the 2013 Centers for Disease Control and Prevention (CDC) Health Disparities and Inequalities Report, data show that in 2009 African Americans had the largest death rates from heart disease and stroke compared to other racial and ethnic groups.[18] Hypertension had the largest prevalence among African American adults 65 years and older.[18] In addition, older African American women had higher prevalence of obesity

than white and Mexican American women.[18] According to the same study, prevalence of diabetes among African American adults was twice the prevalence as among white adults.[18]

Many of these health disparities lead to increased mortality among African Americans. According to a Nation Vital Statistics Report, in 2013 the top leading causes of death for African Americans were heart disease, cancer, stroke, diabetes and unintentional injuries.[19] Several of these chronic conditions are also leading causes of mortality among older adults.[20] Health disparities are tied to the economic, political, and environmental success of a society.[21] Therefore, in addition to the issues of social justice and equality, there are economic, political, and environmental reasons why health disparities should be eliminated.

Clinical trials help improve medicine by improving the standards of care and quality of life for people with chronic diseases.[22] In order to better develop treatments tailored to the African American community based on these health disparities, there has been a call to action to encourage more African Americans to participate in clinical trials and research studies. In order for clinical trials to most effectively improve medicine, studies need to be carried out within a representative sample population to ensure the external validity and generalizability of the study.[23]

There have been some studies that have looked at how clinical trials can be used to promote health education and community outreach, which may help overcome education and awareness inequality.[24] Increasing enrollment in clinical trials is therefore very important in order to address health disparities that affect African Americans. In 2013 the department of Health and Human Services published an Action Plan to Reduce Racial and Ethnic Health Disparities which included clinical trials as one strategy to reduce racial health disparities.[25] In this action plan, conducting research is one strategy to advance scientific

knowledge and innovation.[25] Despite the fact that African Americans share a greater burden of diseases and would benefit, they remain underrepresented in clinical trials.[9] Obstacles to African American recruitment and participation in clinical trials have been difficult to overcome.

There have been many studies that have looked at the recruitment and barriers to increasing African American enrollment and participation in research.[3, 5, 6, 23, 26, 27] Some of these barriers include fears and mistrust that stem from a legacy of historical abuse, a lack of awareness and education about clinical trials. Addressing fears and mistrust established in the African American community is difficult because there is a long history of abuse. Overcoming awareness and education can be difficult when fears and mistrust are present. Despite the research and identification of barriers in the last decade, African Americans, especially older African Americans are still underrepresented in clinical trial research. This is due in part to the challenges in overcoming the legacy of Tuskegee which have lead to fears and mistrust of the medical community, and the challenges of bringing in trustworthy education and awareness about clinical trials.

Community-Based Participatory Research

Community-based participatory research (CBPR) has emerged as an important research tool to address reducing health disparities by integrating education and social action into the research project.[28, 29] CBPR focuses on building relationships between community and academic partners. In another recent study, researchers found that one of the main successes of using CBPR was that it brought the research into the community to increase awareness and knowledge.[30] In 2012, Corbie-Smith et al. demonstrated that a more innovated and engaged approach, including research as part of the prevention and care can help foster improved health for minorities.[31]

Furthermore, recently researchers found evidence to support that utilizing CBPR reduces health disparities by using research itself as a force for social change as well as enhancing health by participating in the research process.[28] Some studies have demonstrated CBPR has been shown to be more effective in reaching the African American community by bringing research into a community with their consent and allowing a community to bring their own knowledge and insight into the research process.[32-35] The goals of CBPR are to improve health outcomes and reduce disparities through strengthening the intervention with community insight.[28] Therefore, using a CBPR approach may prove useful in overcoming many of the fears and mistrust toward clinical trials among African Americans.

Faith and Church

The church has been a centerpiece in African American life socially, politically, and spiritually. According to the Pew Research Center, 78% of African Americans are affiliated with evangelical or mainline protestant churches, and almost 80% of all African Americans cite religion as being a major influence in their life.[36] Bringing an intervention to a community via faith communities increases the exposure and chances that the intervention can reach the African American community and have a trustworthy impact.[32, 37, 38] In the past, African American churches have been supportive of health promotion initiatives.[39] Specifically in the south, the church is a trusted institution and a powerful community force for personal behavior change.[40-42]

There have been several successful faith-based interventions and studies conducted in church communities.[11, 30, 32, 35, 37, 38, 43, 44] Further studies support the idea that faith networks and religious behaviors can be associated with positive health outcomes.[45, 46] Most recently researchers found that churches with young and educated pastors were associated with congregant attitudes about research participation.[47] Another study also showed that a African

American church based pilot program was successful in increasing awareness about clinical trials among its' congregants.[30] These studies highlight the success of working with faith-based communities and demonstrate this as a possible way to reach the African American community with health interventions.

Barriers to Participation

There are several studies that have suggested a plethora of barriers to clinical trial participation for African Americans.[48-53] In a recent report, researchers discussed three main barriers that affect African Americans' participation in clinical research: historic barriers, societal barriers, and healthcare access barriers.[5] Historic barriers include the fear and mistrust that stem from historical abuses such as the Tuskegee study as well as the segregation and discrimination that dates back to slavery. Societal barriers relate to the fact that African Americans tend to live in close communities still separate from other groups. These societal barriers create a set of social norms related to research which include mistrust of doctors, scientists, and the government; concern about ethics; and believing that investigators would treat minorities unfairly.[5] Access to healthcare relates to socioeconomic factors including education, employment, and health insurance status, all of which limit African Americans' participation in clinical trials.[5] The same study also suggests that partnering with the African American community may help overcome many of these barriers.

There is also evidence that even with direct access to research studies in the community, African Americans and minorities are underrepresented in HIV/AIDS research.[1] The study found that there were several factors that influence participation in HIV/AIDS clinical trials, including trials having a reputation for not being friendly to other

African Americans, a lack of knowledge and understanding about clinical trials, as well as fears of being a guinea pig.[1]

Past historical abuses of African Americans has lead to mistrust and fear of the medical community, especially research.[49, 52, 53] One of these main fears and mistrust of the biomedical community is being used as a guinea pig for research in the past. Researchers have found that the issue of trust was a common theme influencing participation in research among minorities.[54, 55] Several recent studies have found that issues of trust might factor into the low levels of minority clinical trial participation.[8] Tuskegee is the most cognizant abuse in the resent past and therefore is often used to describe these fears.[48] However, a recent study has found that knowledge of Tuskegee doesn't impact the willingness to participate to the extent other studies have shown, but instead contributed to overall distrust of medical research.[55]

Education and a lack of awareness have also been identified as barriers that influence willingness to participate in clinical trials.[23, 51, 54, 56-59] Several studies have found that general attitudes toward research participation and medicine impact willingness to participate in clinical trials. Clinical trial awareness and knowledge have also influence willingness to participate.[2, 5, 27, 44, 54, 56, 58, 60, 61] In a study looking at what factors were associated with clinical trial awareness, researchers found that among African Americans, education, trust and mistrust of health information were correlated with being less likely to have heard of a clinical trial than white participants.[56] In this same study, researchers argued that awareness was the most important factor because it precedes other factors and was in part, an explanation for lower African American participation in trials.[56]

Theoretical Framework

Previous studies have utilized both quantitative and qualitative methods. However, few of these studies have also situated their findings within a behavioral theory or framework. The socioecological model (SEM) has been used to understand societal, community, relationship, and individual influences on health behavior and promotion.[62] In 2011, the (SEM) was introduced as a possible framework to understand socioecological influences on community involvement in HIV vaccine research.[63]

Another previously used theory is Fishbein and Ajzen's Theory of Reasoned Action (TRA) which integrates individual behavioral attitudes and social subjective norms as predictors of behavioral outcomes.[64, 65] Two previous studies have specifically looked at willingness to participate in clinical trials using the TRA.[66, 67] This study found that willingness to participate was not fully explained using TRA. Recent studies have tested an extended model of reasoned action to understand factors that influence African Americans' participation in HIV vaccine research.[68] This study found that there are other factors organizational and social factors that influence intention in addition to behavior attitudes and subjective norms.[68] These and other studies emphasize the importance of attitudes and beliefs as being important predictors of behavior and show how valuable it is to situate a study within a behavioral framework.

Another relevant model that may help provide a framework is the Precaution Adoption Process model (PAPM). This stage theory was developed by Weinstein in the 1980s and further developed into a model with colleagues in 2008.[69] PAPM asserts that behavior change is explained through sequencing through different stages.[69] In the decision making process, sequencing through different stages, researchers postulates that individuals move through each stage in order, beginning with awareness.[69] In a recent study, researchers

used the PAPM to work with older adults to reduce the risks of falling.[70] This study shows that the precaution adoption model can be applied in older populations to address health behaviors.

Study Purpose

There has been extensive research into interventions and barriers to African American and minority participation in clinical trials. However, in addition to identifying barriers, it is also necessary to understand how barriers interact with other factors including education and awareness, to influence willingness to participate in clinical trial research. More research is needed to understand what other factors are influencing willingness to participate in clinical trials, and how these factors interact with barriers and facilitators. A more complete understanding of what drives African Americans' willingness to participate in clinical trials is important in order to create more effective and impactful interventions to increase clinical trial participation and ultimately eliminate racial and ethnic health disparities. A qualitative study is necessary to explore in detail and understand the nuanced relationship between these factors. Although many barriers and facilitators have been identified, a better understanding of the relationship between these factors and willingness to participate in clinical trials will be more useful for future interventions to be more effective.

Research Questions

The purpose of this study is to understand facilitators and barriers to clinical trial participation. This study also sought to understand how the educational intervention entitled "Delivering a Dose of Hope" influenced clinical trial participation among older African Americans in the metro Atlanta community who were regular church congregants.

LITERATURE REVIEW

Racial Health Disparities

Health disparities exist when social, economic, or environmental disadvantage influence differences in health.[17] It has been well established that minorities, including African Americans are more burdened by health disparities for diseases like diabetes, cardiovascular disease and HIV resulting in health disparities.[6, 9, 11, 12, 14, 27, 71] Racial health disparities are even more prominent among seniors.[72-74] Older populations often have comorbidies, such as hypertension, diabetes, and cardiovascular disease, which poses an extra challenge in clinical trial participation.[75, 76] There are several factors leading to underrepresentation of the older in clinical trials including comorbidies, greater fear and mistrust of the medical establishment due to past historical abuses, and transportation challenges.[77] In focus groups, Owens et al.2013 found that older African American's are less likely to participate in clinical trial research than younger African Americans because they grew up and heard more about historical abuses.[77] Health disparities lead to greater morbidity and mortality among African Americans.[78, 79]Increasing participating in clinical trials may be one avenue to reduce health disparities among African Americans.

Representative participation in clinical trials is important so that the results of clinical trials can be generalized to the population. These disparities in clinical trial participation pose barriers to development and delivery of appropriate medical therapies for African Americans. Increasing African American participation in clinical trials is an important step forward toward eliminating health disparities.[23, 25, 40]

Although clinical trials may be useful in reducing racial health disparities, there is still low willingness to participate in clinical trials among African Americans.[80, 81] Barriers such as

fears, mistrust, a lack of education, and access to healthcare have all been noted as factors that influence African American willingness to participate in clinical research trials.

Willingness to Participate in Clinical Trials

Willingness to participate in clinical trials is an important factor in being able to recruit African Americans in clinical trials. Owens et al. 2013 showed that willingness to participate in clinical trials hinged on several factors including motivators like money (e.g., compensation for participation), specific knowledge of the study procedures, free healthcare, and barriers like mistrust, transportation, and a complicated informed consent procedure.[77] The study also found that assurance of safety and general clinical trial awareness and education were important factors influencing willingness to participate in research.[77]

Understanding the decision making process that arrives at willingness to participate is important to consider when understanding why so many African Americans are not willing to participate in clinical trials and medical research. Shavers et al. 2002 detailed the relationship between race and willingness to participate in medical research as an issue of trust toward medicine.[55] However, in this study they found that knowledge of Tuskegee didn't impact the willingness to participate, but instead contributed to overall distrust of medical research.[55] In another study, Corbie-Smith et al. 1999 conducted a focus group with African American outpatients at an urban public hospital in Atlanta and found trusting research and medicine was a common theme.[54] These studies show that there may be other factors beyond historic abuses such as Tuskegee which influence African Americans' trust of research and medicine.

Barriers to Clinical Trial participation

Studies have suggested a plethora of barriers to clinical trial participation for African Americans. In a 2014 systematic review George et al. found that mistrust and lack of access to information as the most cited barriers to clinical trial participation among minorities including African Americans.[82] The study points out that fears and mistrust often have their root in the Tuskegee Syphilis study, however fears and mistrust can also be associated with not believing that the research will benefit the community, and a mistrust of researchers themselves.[82] Fisher and Kalbaugh found that issues of trust might factor into the low levels of minority clinical trial participation.[8]

There are several barriers that influence African American participation in clinical research, including historic barriers, societal barriers, and healthcare access barriers.[5] Because of the memory of historical abuses like the Tuskegee experiments in the 1930s, African Americans are hesitant and more cautious about participating in research. Although many of the historical abuses are less likely to occur today because of ethical review boards, community advisory boards, and federal oversight, the knowledge of historic research abuses is still a deterrent. Societal barriers include reading level and the education of participants as well as living in segregated or tight-knit communities which can create societal mores related to research.[5]

Healthcare access barriers included factors related to education, employment and health insurance as hindrances to participating in clinical research.[5] Access to healthcare is often discussed alongside health disparities, so it makes sense that it would also influence willingness to participate in clinical trials.

In another study, Owens et. al.2013 conducted focus groups with African American men and women in the south.[77] Researchers found that the most often discussed barriers

were fear related to mistrust of clinical research, the uncertainty of research, a lack of knowledge, and physical discomfort of participating as well as time constraints.[77] In this same study, participants also noted the time commitment/schedule as a barrier to participating as well as transportation problems.[77] These studies have identified many barriers to clinical trial participation.

Therapeutic Misconception

There have been a few published studies detailing therapeutic misconception, or the idea of getting free healthcare, or primary healthcare by participating in clinical trials. Understanding what motivates people to participate in clinical trials is important for recruiting efforts among African Americans.

Much of the research into the ethics of therapeutic misconception has been related to participation in cancer trials. In a 2014 study, Burke examined cancer clinical trial recruitment in the US safety net hospital, and how therapeutic misconception plays a large role in the recruitment process.[83] Burke study found that there is often confusion between the concepts of participating in research and getting medical treatment. For one of the interviewed participants, details about why the research was being conducted was just as important as what is being done.[83] Owens et al. study also found that although mentioned least often as a motivator, getting free healthcare was still emerged as a factor in clinical trial participation.[77] Lack of access to healthcare has been noted as a barrier to clinical trial participation, but also a large factor influencing health disparities that exist between African Americans and other ethnic and racial groups.[77]

In a 2014 systematic review of barriers and facilitators to minority research participation among African Americans, George et al. found that one of the benefits to clinical trial participation was free healthcare. The authors raised some concerns with

receiving healthcare primarily through participating in clinical trials as a motivator to participate in trials.[82] Although receiving healthcare is important, participants should not feel obligated to participate in a trial in order to receive healthcare. Unethically recruiting participants based on their need for healthcare is not ethical and should be avoided when recruiting African Americans into clinical trials.

Attitudes, Awareness, and Education

Attitudes toward research and medicine, perceptions of clinical trials, and education and awareness of research are factors that impact willingness to participate in clinical trials.[2, 5, 27, 44, 54, 56, 58, 60, 61] Past studies have showed a negative attitude toward clinical trials and research among African Americans.[54] These negative attitudes toward clinical trials were attributed to fears and mistrust stemming from knowledge of the Tuskegee study.[50] Recently however, studies have consistently showed a change in attitudes.[30, 82] In 2012, Colo-Otero et. al. piloted a program to increase awareness of the importance of cancer research and participation in research studies among African Americans.[30] This study found that African American have generally positive attitudes towards clinical trials and research, and were willing and interested in participating in cancer research.[30] Although attitudes and willingness to participate were evident, this pilot program demonstrated that a lack of awareness about the importance of cancer research and a need for education programs focused on the African American community.[30] However, despite generally positive attitudes toward clinical trials and research, African American participation in clinical trials is still low.

In 2013, Brown et al. recruited cancer patients who had been approached by a clinical to consider participating in a cancer clinical trial in the last 3 months to complete survey's and interviews with the goal of better understand reasons African Americans

refused to participate in the cancer trials. [84] This study found that 41% of study participants had no prior knowledge or opinions about clinical trials and that the majority of participants expressed the need for information.[84] The same study also found that participants felt they had the ability to understand and participate in care.[84] Although this study focused on participant knowledge, it didn't address the lack of knowledge of the clinical trial process and issues of therapeutic misconception. In the study, many of the refusers cited they were concerned the randomization of treatment and wanted to know they would be getting before agreeing to participate.[84]

Langford et al. 2010 conducted a study using the National Cancer Institute's 2007 Health Information National Trends Survey data to examine the association of race/ethnicity on clinical trial awareness.[56] They found that African Americans were significantly less likely than whites to have heard of a clinical trial.[56] This same study found several other factors that correlated with of clinical trial awareness including education, trust and mistrust of health information.[56] In this study, awareness was the most important factor because it was in part, an explanation for lower African American participation in trials.[56] In another study Lara et al. looked at factors affecting awareness of and willingness to participate in cancer clinical trials.[58] This study found a similar relationship demonstrating awareness of clinical trials was associated with willingness to participate.[58] This same study also found that lower levels of clinical trial awareness among African Americans.

These studies have showed that a lack of awareness and a lack of knowledge about trials, and research lead to decreased interest or willingness to participating. Awareness and education are important factors in the decision making process and more research is needed to understand the relationships between awareness and education and willingness to participate in clinical trials. Many of these studies grouped awareness and education

together, yet they are separate issues and involve different intervention strategies. To increase education, an education intervention is needed, whereas to increase awareness a targeted communication campaign may be enough to overcome a lack of awareness about clinical trials. Understanding how these two factors overlap and in what ways they are similar may help when developing targeted education and communication strategies. It is also not clear how other factors may influence willingness to participate and differences between lack of awareness, and the need for education in the overall decision-making process. There may be other important factors underlying or driving the need for knowledge and lack of awareness that need to be identified and addressed through separate interventions as well as addressed together.

Previous Interventions

There has been a need for more innovative interventions to increase clinical trial enrollment among racial and ethnic minorities. To increase diverse enrollment in clinical trials, researchers have used CBPR, and Patient Navigator programs to improve enrollment outcomes.[85] Ghebre et al. reviewed how Patient Navigation was used as a strategy to increase minority enrollment in clinical trials.[85] Although they found that many programs utilizing patient navigators were aimed at increasing awareness and access to clinical trials, they also found low support and trust in the community for these programs. The researchers stressed there is more evidence needed on the effectiveness of patient navigator systems for increasing minority enrollment in clinical trials.[85]

Although these interventions have all been focused on different health topics, a common theme has been trying to break through and engage at the community and individual level. Corbie-Smith and colleagues argue that a more innovated and engaged approach, including research as part of the prevention and care can help foster improved

health for minorities.[31] However this engaged research as part of medical care poses other ethical issues surrounding therapeutic misconception.

In a pilot program Colon-Otero et al. collaborated with African American Churches to test an education intervention designed to increase awareness of the importance of cancer research and participation in cancer research among African Americans.[30] Researchers found that the pilot program successfully increased awareness of cancer research trials among African Americans.[30] They also found that most participants had little knowledge or education on the importance of cancer research, despite being interested and willing to participate. One of the main successes of this pilot program was that it brought the research into the community to increase awareness and knowledge.[30]

Theory and justification for qualitative study

Unfortunately, there are many factors that limit clinical trial participation among older African Americans that are not well understood within a theoretical framework. Studies keep pointing to the same topics of fear and mistrust, lack of awareness and education as key factors for engaging the African American community in research studies. However, there is the need for further exploration to understand the relationship between these factors. Thus exploratory research is needed to better understand how the process of engaging these communities is affecting willingness to participate in clinical trials.

Despite several studies identifying many barriers, there is still a need to understand how those barriers fit into the decision making process and how those barriers influence willingness to participate in a clinical trial. A more thorough understanding of the decision making process and attitudinal pathway will give insight to better focus interventions to increase African American clinical trial participation. In-depth understanding of an individuals' attitudes and perceptions is best suited to qualitative in-depth interviews. As

part of a randomized intervention study, we will conduct follow up interviews in order to explore the perspectives of individuals on attitudes toward clinical trials.

Utilizing a grounded theory qualitative approach, this study will explore potential facilitators and barriers to clinical trial screening and participation. There has been extensive research into interventions and barriers to African American and minority participation in clinical trials. In addition to understanding barriers, it is also necessary to understand the process African Americans experience when making decisions regarding clinical trial participation. More research is needed to understand what other factors are influencing the decision making balance between barriers and facilitators. A qualitative study is warranted to further explore and understand factors that may influence African American clinical trial participation. Although many barriers and facilitators have been identified, a better understanding of how these factors influence willingness to participate in clinical trials will be useful for future interventions. Specifically, differentiating between awareness and education as influencing factors may help innovative interventions be more effective. Exploring these relationships and factors can be done using a modified grounded theory approach.

METHODS

This research project is a qualitative substudy of the primary Dose of Hope (DOH) intervention. The DOH intervention is a faith-based intervention which intended to positively influence older (age greater than or equal to 50 Years) African American adults' attitudes towards research and medical clinical trials. The intervention aimed to increase enrollment of intervention participants in ongoing clinical trials. Qualitative interviews will add context and a deeper understanding of potential barriers and facilitators for clinical trial participation among older African American. These interviews will also explore how attitudes and knowledge may have changed from participating in the DOH intervention. The interviews will also explore any potential barriers and facilitators to participating in clinical research trials.

Participants

Participants for baseline and in-depth interviews were recruited from all the volunteers who had already participated in either the intervention or control groups of the initial DOH program. Participants for the baseline interviews were asked after one of the DOH sessions to answer a few questions. To have been eligible for the program and the follow-up interviews, participants must have been over the age of 50, been a standing member of one of the participating churches, a resident of the metro Atlanta area, and self identified as black/African American. Exclusion criteria for the program included moving within the year of the DOH program, previous participation in a clinical trial or faith-based intervention, or not being able to attend all three sessions of the program.

Potential participants for in-depth interviews included those who screened to participate in clinical trials but did not enroll by October 2014 (n=11), those who screened and enrolled in a trial by October 2014 (n=6), those who did not screen or enroll in a clinical

trial by October 2014, (n=177) and those who refused participation in a clinical trial (n=19). Participants were recruited from the program for 1 month from November to December 2014. Interviews took place at the participants' church, their home, or at the DOH clinic to accommodate participant preference. The locations were convenient, familiar, and comfortable for the participants.

Study design

DOH qualitative data collection points had two time points. The first time point was during the intervention and control group information sessions. Participants from each group were asked quick qualitative interview questions after participating in a session at either three or six month time points. The goal of the informal interviews was to understand participant perceptions of the DOH study, perceptions of health concerns, barriers to health education and clinical trials within the community, as well as understanding what information they learned from the sessions. Each interview participant received a $20 gift card incentive. In between sessions, both groups were sent information by phone and through email, and invited to participate in ongoing health-related studies. After the program, participants screening, enrolling, and refusing participation in clinical trials was tracked.

Follow-up in-depth interviews were collected after the six month time point and before the end of the one year follow-up period. The follow-up in depth interviews were designed to capture attitudes toward the DOH program, knowledge and attitudes toward clinical research, participant intention to participate in clinical research after either the intervention or control session, and understand what barriers exist to participating in clinical research after participating in the DOH program. Each participant received a $20 gift card incentive for the interview.

Study Procedures

The DOH program involved an intervention group and a control group. The intervention group had three workshops, one at baseline, one at three months, and one at 6 months. Each session lasted approximately 1.5 to 3 hours. The intervention sessions were given information on health disparities, clinical research, and health risks. These sessions were given by DOH staff, physicians, external health practitioners, health ministers, and church staff. The sessions were composed of didactic instruction, group discussions, as well as interactive games. The control group sessions included basic health information that would be relevant to seniors and older adults.

Investigators utilized a community randomized sampling method to create the study sampling frame for churches. Churches were comprised of greater than or equal to 60% African American congregants. Six churches were randomly selected of three different denominations (Baptist, Seventh-Day Adventist, and African Methodist Episcopal) and then paired matching on denomination and size. All six churches were randomly assigned 'intervention' or 'control' status. Pastors and other faith leaders at each of the selected churches reached out to their respective congregations inviting those for those who fit the inclusion criteria to participate in the program.

All study administrators were CITI certified in Social and Behavioral Research. The study was approved by the Emory IRB. Before participating in the DOH program, all participants were given consent forms which were read individually by participants as well as read aloud by study staff. Staff answered all questions and participants signed consent forms before beginning interventions or participation in any part of the DOH study, including the qualitative interviews. At follow-up, study administrators reviewed consent verbally before beginning in-depth interviews. Interviews were double recorded with digital voice recorders

and immediately transferred onto the secure Emory drive. All data was transcribed verbatim, de-identified, and stored on the secure Emory drive. Data was analyzed in MaxQDA software, version 11. Recordings were destroyed after transfer to Emory drive and analysis was complete.

Interview Format

Informal baseline interviews were conducted after the first DOH session and three month sessions for both intervention and control groups. Questions included:

What motivated you to participate in this study?

Could you tell me about your thoughts on clinical trials and medical research?

Could you please describe a little bit about your community?

What does it mean to you to be part of the black community?

How does the black community feel about clinical research?

How do you think we can address the fears and myths surrounding clinical research?

How do you think we can get the black community involved in clinical research?

How can researchers find out about the concerns that exist in the black community?

Where do people in your congregation get their health information?

In-depth interviews were conducted after the six-month session and before the one year tracking period ended. Field guide development was guided by the results from informal baseline interviews conducted during the DOH program sessions. All interviews were conducted by a study investigator in-person. Each interview last between 15 and 70 minutes. Interview questions asked about attitudes and impressions of the Dose of Hope program, why or why not they chose to enroll in a clinical trial, and any barriers that stopped a participant from enrolling in a clinical trial. Sample questions included:

For those who enrolled in a clinical trial:

A1: What was your impression of the Dose of Hope Program? What did you like or dislike? Why did you join?

A2: Why did you to contact the research team about joining the clinical trial [insert trial name here]?

A3: Why did you enroll?

A4: What do you think about clinical trials now that you have participated in one?

A5: Do you think you would enroll in another clinical trial? Would you (or have you) recommend(ed) clinical trial participation to others?

For those who screened for a clinical trial but did not enroll:

B1: What was your impression of the Dose of Hope Program? What did you like or dislike? Why did you join?

B2: Why did you to contact the research team about joining the clinical trial [insert trial name here]?

B3: Why didn't you enroll? Were there transportation issues, medical exclusions, scheduling issues, or something else? Do you feel like you had enough information to make a decision to enroll?

B4: Would you ever try enrolling in another clinical trial? Why or why not?

For those who neither screened nor enrolled in a clinical trial:

C1: What was your impression of the Dose of Hope Program? What did you like or dislike? Why did you join?

C2: Why didn't you enroll in a clinical trial? Were there transportation issues, medical exclusions, scheduling issues, or something else? Do you feel like you had enough information to make a decision to enroll?

C3: Would you ever try enrolling in a clinical trial? Why or why not? What type of clinical trial might you be interested in?

Analysis

After transcription, a four part systematic analysis was conducted. The coding framework was developed using a modified grounded theory approach. Grounded theory was developed as an analytic method by Glazer and Strauss in the 1960s to develop theory through qualitative analysis of data.[86, 87] This approach uses constant comparison of transcripts, analyzing cases that deviated from others, and identifying emergent and anticipated themes.[87]

Part 1: Open coding

Preliminary/exploratory analysis

Part 2: Axial Coding

Hierarchical Coding (reduction and clustering)

Part 3: Selective and discrete coding

Validation of codes

Restructure into final coding scheme

Part 4: Advanced analysis (content, domain analysis)

Theoretical Modeling and Theory Development

In part 1, all transcripts for both preliminary interviews and in-depth interviews were coded using MaxQDA 11. Initial open coding was done based on invivo codes that emerged from the transcripts. These codes were further refined in part 2 with axial and hierarchical coding. The codebook from initial interviews was developed based on identifying text associated with particular questions. Both inductive and deductive codes

(from the baseline interviews) were used to code in-depth interviews. In part 3, selective and discrete coding was done along with double coding to ensure intercoder reliability validate the code structure. The codebook was further refined and restructured based on intercoder agreement exercises into a final coding scheme. Part 4 of the analysis consisted of advanced content and domain analysis as well as theoretical modeling. After fitting the codes into a concept map, the main themes and concepts were modeled into an established theoretical framework.

Intercoder reliability Assessment

The transcripts for both informal and for in-depth interviews were double coded by two members of the research team. The intercoder agreement of structural coding was assessed by independently coding 20% of the transcripts (4 Baseline and 3 In-depth). They were compared using MaxQDA 11. The intercoder reliability kappa coefficient measures the agreement between two independent coders to rigorously quantify the intercoder agreement to increase the reliability of the data. The aggregate average Kappa coefficient was >.80 for the in-depth interviews after discussing discordance in the coding.

RESULTS

Qualitative Sample Characteristics

There were 18 baseline interviews, and 12 in-depth interviews conducted. Participant characteristics and demographic information was not collected for baseline interviews. The median age of the in-depth interview participants was 63.70 years old. In this sample, 12 of the 12 in-depth interviewees were women. Two of the participants had refused screening and enrolling in clinical trials saying they were 'not interested.' Two participants had screened but not enrolled in a study after the educational intervention. Two participants had both screened and enrolled. Six participants had not indicated or been contacted asking if they were interested in a study. Participants were from all 6 of the study churches, both intervention and control groups.

Overview of Qualitative Findings

As described, coding and analysis was conducted in 4 parts, resulting in 504 codes. A codebook was developed in a MaxQDA database. Saturation was achieved with the 30 interviews. The final average intercoder reliability rating was a combined average Kappa score of .98.

Baseline Interviews

Baseline interviews had 3 main themes that emerged, Attitudes, Education, and Trust. These themes provided deductive codes for the in-depth interviews. The questions aimed to get a very quick baseline sense of what motivated participation in the educational intervention, to get a sense of what the African American community meant to them, as well as to see what they learned after the first or second sessions. Attitudes were describing how

participants felt about clinical research in general, and asking how they thought the Black community felt about clinical trials.

Education theme emerged in response to talking about fears and mistrust and how to overcome some of these fears and mistrust in the Black community as well as when talking about what they learned from the intervention. Trust emerged as a theme when discussing fears and mistrust. Participants generally felt that clinical trials were good, but that they needed more education and information in order to trust studies. Trust also had mixed responses from participants, a few citing Tuskegee as a source of fear and mistrust, others stating that they didn't know of any fears or mistrust in their community regarding clinical trials or research. One participant replied,

> "There was a time when Black community didn't trust clinical research because we were forced upon to be used as research guinea pigs. And for now this time has passed and now the community is backing the community research because we find that it will help the community out."

Table 1. Baseline Themes (n= 18)

Theme	**Quote**
Attitudes toward Clinical Trials	"I think they're [clinical trials are] great because they help people to find out what cures are out there and also to find out the diseases that families have generations ago " "My thoughts right now [about clinical trials] are a little um concerning based on history. Um, based on how um African Americans have been treated previously as it relates to clinical studies. So I'm a little concerned and a little...um a little...I'll just say a little concerned." "Oh I think it's [clinical trials are] super." "In my opinion, enough has not been done to educate the black community on clinical research. I think that those who have been educated about it are more likely to participate and those who have just heard the horror stories

	will not gravitate at all." "Oh I think it's [clinical trials are] very good. We need that.
Need for Education	"And when I say gaining trust it's by giving people the true message about what research is all about. Giving them the inner works of that research letting them know what the research is all about other than just giving them the topical review of that research. Give them the inner message, give them what they need to know and the true meat of what research is all about. As I said, once by gaining the trust and if you give them the truth then everything will be all right." "Knowledge is very important. To know what's going on with your body, and that's one of the main things that you all brought out to us is things that we probably don't even think about or realize. Is just doing these studies….what things can be brought out for our understanding… for us to realize it's very important to take care of your body. so ya'll brought out some things that we need. By doing certain things you can prevent other things, so that's one of the main things that y'all brought out to us and even that we need to do some of these studies."
Trust	What fears, mistrust, and stigma related to clinical research exist in the black community? "Tuskegee. Tuskegee." "Do I know about any. No." "Um, there was a time when Black community didn't trust clinical research because we were forced upon to be used as research guinea pigs. And uh, for now during this time has passed and now community is uh backing the community research because we find that it will help the community out"

In Depth Interview Main Themes

Five major themes emerged from the in depth interviews. These main themes were: Lack of Awareness, Motivation for Clinical Trial Participation, Psychosocial Barriers, Logistical Challenges, and Education Intervention (see Table 2). These five main themes show the relationship between attitudes and the barriers older African American church-

goers may experience when it comes to participating in clinical trials and scientific research studies. Awareness serves as the main driver of for motivation to participate in clinical trials and also influences their perception of barriers. Barriers and Motivation both influence willingness to participate in clinical trials. There is an important flux between barriers and motivation because an increase in the perception of barriers can influence motivation to participate in clinical trials, and if the motivations to participate are higher than the barriers, they are more likely to be willing to participate in clinical trials.

Table 2. In-Depth Interview Themes (n=13)

Theme	**Quote**
Awareness (lack of)	"I: so, before they came to your church, were you aware of clinical trials at all? P: no. no, I: no, never hear anything about them? P: no."
\Need for Knowledge	"I: Why did you decide to join (educational) program? P:cause it's something that you need, and you might need to learn something from, you know what I'm saying?, you might not know some things that, that people know more of, so, it was a learning thing for me. Um, teaching me something that maybe I might want to call someone that has these issues…."
Motivation to Participate in a Clinical Trial	"Well, I don't know that I have been…particularly interested. Like the first one kinda so to speak fell in my lap, and I didn't mind doing it at all. And I also thought well that wasn't so bad, and so I did the second one, and I hadn't thought about it anymore except when the flu came on my internet. The flu one, I considered that one, that's about all. For those, those, and I don't know if I'll do another one or not. I guess it, probably depends on how much time and everything it entails, and also, um, I already have a lung problem so trying to be very careful about what kind of shots I take something like that, yeah. "
\Trust	"That's all I'm saying. I don't think that there's a distrust, I think there's a lack of information."
\\Peer Influence	"Well, I have to admit, I , I have a little bit more [trust] in people that I already know or that I'm associated with, or have built up a quote track record with, um, with others

	I'm probably a little less sure, and that's where the bedside manner comes in. to make me feel comfortable about what they're doing."
\\Medical Center	"Oh I defiantly feel that (a medical center) is trustworthy. Oh yeah, I don't have a problem with that. They've got a really good name. The students that come out of there are, are highly trained, as far as I can tell it has a track record of being very influential …. But their track record is good and they seem to know what they're doing."
\Relevant Health Topics	"My health is would be more what I would be interested in. you know. Um, oh…I don't know. That's about it. I guess, you know. I have, well I do have, high blood pressure, and um, I take cholesterol medicine. So anything in my area, you know, I would be interested in."
\Therapeutic Misconception	"I wouldn't want to be in the group with a placebo…I don't know for some reason in my mind, I don't see getting the placebo as helping me."
\Curiosity	"I: So why did you end up joining (educational intervention) program? P: uh, originally I did it just because I was curious."
Psychosocial Barriers	"I: okay, so what made you decide to um, participate in the studies? P: um, cause I think the questions that they were asking in and it was nothing invasive, and um, pretty easy for me to do."
\Knowledge of Historical Abuses	"As…blacks or African Americans, we have a real fear when it comes to studies. uh, most of the community I feel like, um, we, we feel like we're gonna be treated as guinea pigs. so, we back as far away as possible from that. okay, so that fear has just always been there. um, even I can go back as far as when I was 8, I guess 10 or 12 maybe, when my grandmother used to go to a doctor that had colored and white waiting rooms. so that fear goes way back, even to then when they thought that the blacks were being treated one way and the whites were being treated one way. so that they always felt, I know my grandmosther did, always felt that you know, she really wasn't getting the best of care, but it was the best that she could get at the time. "
\Study Demands	"It's the strangest thing. I just, I have always been, um…shy of uh needles and I'm a medical technologist and I used to draw blood at the first part of the day years ago, for just working in a lab. I'm just, just would rather not with needles."
\\Untested Product	"I might be slightly hesitant on on some medications that um, have not truly been tried out for side effects, so I would not, I'd be a little leery at that. um, but maybe in

	the final stages of some some drugs um, that are proven to um, to work, I would probably be yeah, interested in doing those."
Logistical Challenges	"Might be because of time, and now that I'm working and stuff, cause I think to come for some of those programs on site, and it might be um, might have been too far out of the way. Or time interference."
\Transportation Challenges	"I don't want to drive for so far…"
\Study Procedures	"She said that they were drawing blood, like three times, and I have sunken veins, and I told her no."
\\Study Design	"I: yeah, like given a lot of information, is there anything else that might make you hesitate. P: naw, the only thing's knowing what , what they're given me."
\\Cormorbidities as Exclusion	"She said that they were drawing blood, like three times, and I have sunken veins, and I told her no.. So she said she understood, and I told her I would be interested in something else, you know…and uh, she thanked me..."
Education Intervention	
\Community-developed program	"I: What about the program impressed you? P: Well, they included me."
\Church-Research Partnership	"I thought it was a great because if it hadn't of come to my church I probably wouldn't have done it." "Well, really I guess the first thing that um, most favorite thing was definitely getting the congregation involved."
\\Convenience	"It was really, really really nice, and then it's convenient cause it was at the church and I knew where I was going."
\Trustworthy Source of Information	"P: in everyone that came out, everyone was so honest and open and they even from their own personal experience would tell you how it was and so, the info, the literature they gave was very revealing of everything that would be involved in a study. And the paperwork that we signed, the study that they did here which didn't involve anything medical, everything that they signed it was it was always honest and upfront and you know, so. I know it's better then it used to be."
\\Persuasive Approach	"I: okay. and why did you decide to join the dose of hope program? P: because my pastor, uh, announced one Sunday that um, (a medical center) wanted to do a study with the seniors. so he asked us uh, the seniors, would we participate. so that's how I found out about it, and I did. and It was three different three different events, or what did you call it, it's scheduled us three different times"

\\Knowledgeable Speakers	"They [the presenters] seemed knowledgeable; they had facts to back up everything that they were speaking on. They were really engaging, they just appeared knowledgeable. They weren't just telling you tell you something. They whatever they were talking speaking on, they had data, they had facts, they had information right in front of you regarding it."
\Relevant Content	"They gave information say for instance for women, African American groups. When they would talk about the diabetes, they would center it around the African Americans, what would be important for me to know. So, the information that they gave was tailored just for me and my ethnicity. So that's what made it good."
\Reliable Source for Continuous Information	"Then when they get around and they give you the books and the papers and such to back up their claim, you know. You're going through that and you're reading the books and going through it. You know, it gives you a better insight you being able to understand what it's about."
\Supportive Environment	"I thought all the speakers were very good. Very informative. They knew their topic, they were friendly, they made people feel at ease, you know, and that helped." "It [the intervention] kinda met people where they were. So I felt that was good."
\Gift Card Incentive	"I did like the idea of getting a gift card."

Lack of Awareness

The theme of Lack of Awareness (lack of) was driven by the facet of knowledge, or the need to gain knowledge about clinical trials. Having a thorough knowledge of clinical was an important facet of the participants being aware of clinical trials and the need for participating in clinical trials. When asked why they decided to join the educational program, participants answered,

> "Cause it's something that you need, and you might need to learn something from, you know what I'm saying?, you might not know some things that, that people know more of, so, it was a learning thing for me. Um, teaching

> me something that maybe I might want to call someone that has these issues…."

Participants said that they needed to know more about what was going on in a particular study. A lack of knowledge on what the study entailed was part of the lack of awareness.

> "I just think it's just, it's just for me, a good idea to have some knowledge of what's going on and what better knowledge than to know what's going on with you personally."

Participants' lack of awareness about clinical trials was an important theme that was often talked about as an important preceding factor in the motivation to participate in clinical trials. When asked about if they would consider participating in clinical trials, the most common response centered on not being aware of what trials were out there. A lack of awareness on what trials were available was one facet for this theme. In order to be willing to participate in a trial, one would first need to know the opportunity existed.

> " I haven't ever been places where things like [clinical trials] are really talked about. So I can't give you a reasonable answer. I guess if I knew exactly what was going on, you know, I would want to be a part of it. But I can't tell you because I don't really know."

When asked if they had heard of clinical trials before the educational intervention came to their church, many of the participants said they had never heard of clinical trials before.

> "I: so, before they came to your church, were you aware of clinical trials at all?
>
> P: no. no,

I: no, never hear anything about them?

P: no."

Motivation to participate in Clinical Trials

The major theme of motivation to participate in clinical trials is influenced by awareness, as well as the psychosocial barriers and logistical challenges to participate in trials. The motivation theme has two main subthemes including Trust and Relevant Health Topics. The trust theme is comprised of Peer Influence and Medical Center Influence. Relevant Health Topics has further subthemes of Therapeutic Misconception and Curiosity. The two main aspects of trust were the influence of peers, and the medical center influence. Motivation to participate is an intermediate concept between being aware of a clinical trial, and being willing to participate in clinical trials. Participants described trust as an important aspect in their motivation to participate in trials. Their perception of trusting the medical center and trusting the influence of their friends and family leads to a greater trust of the study. For example, participants who really trusted a medical center were more likely to trust a study being conducted with that same medical center.

"Oh I defiantly feel that (a medical center) is trustworthy. Oh yeah, I don't have a problem with that. They've got a really good name. The students that come out of there are, are highly trained, as far as I can tell it has a track record of being very influential …. But their track record is good and they seem to know what they're doing."

Another example was that when family and friends spoke of their experience in trials, the participant was more likely to feel trusting toward the clinical trial experience.

> "Well, I have to admit, I have a little bit more [trust] in people that I already know or that I'm associated with, or have built up a quote track record with, um, with others I'm probably a little less sure, and that's where the bedside manner comes in. To make me feel comfortable about what they're doing."

The other main factor in participants' motivation to participate in clinical trials was relevant health topics. Every participant commented that they would be interested in participating in a study if it were pertinent to their health, or on a topic that was of interest to them.

> "My health is would be more what I would be interested in. you know. Um, oh…I don't know. That's about it. I guess, you know. I have, well I do have, high blood pressure, and um, I take cholesterol medicine. So anything in my area, you know, I would be interested in."

When asked if they would be interested in participating in a clinical trial, participants mentioned they would be interested if the content was interesting. Some of the topics that were of interested were Alzheimer disease, the ageing process, cardiovascular and heart disease, hypertension and diabetes, and mental health. Relevant topics were important because motivation to participate in clinical trials is driven in part by interest in the topic. Another aspect of motivation to participate in clinical trials was the misconception that clinical trials are for treating, and getting medical treatment for a disease/illness/ health concern. The code for therapeutic misconception emerged as an important motivator.

> "I wouldn't want to be in the group with a placebo…I don't know for some reason in my mind, I don't see getting the placebo as helping me."

> "Yes I had [heard of clinical trials]. actually, there was one that was done on diabetes some years ago that (a medical center) did and I had talked to some of the people in the church into going and getting their blood work and all that stuff done... this is the first one that um, I've actually, the one that, that that I sent people to were people who I knew were borderline diabetic and so, I wanted to make sure, you know, kinda get them in the door."

Psychosocial Barriers

The major theme of psychosocial barriers has two main facets including Knowledge of Historical Abuses and Study Demands. Psychosocial Barriers are the barriers that prevent participants from feeling motivated or willing to participate in a clinical trial. The study demands theme has a further subtheme of Untested Product.

> "Probably ones that there're not gonna be drawing blood. [laughing] um, ones where um, if it's a medication um, I might be slightly hesitant on on some medications that um, have not truly been tried out for side effects, so I would not, I'd be a little leery at that. um, but maybe in the final stages of some some drugs um, that are proven to um, to work, I would probably be yeah, interested in doing those."

Knowledge of Historical Abuses encompasses the fears and mistrust that African American's may experience when dealing with the medical and research community.

> " If you know about the past clinical trials where um, uh, African American's were taken advantage of, and then that makes them non trusting, um, clinical trials, and even and even to go get healthcare. Then to have um, a program

> to come here and speak especially to African Americans makes me feel like, you know, that that wee matter. um, and you know, as a group, and um it just helps me uh as far as my family goes, like I said, I'm always lookin for better ways to do it, so that lets me know that there is a system that that's still you know, that cares about what knowledge we receive so that we can can do better. Knowledge is power, so um, …yeah."

Another psychosocial barrier African Americans experience are study demands. Study demands are

> "It's the strangest thing. I just, I have always been, um…shy of uh needles and I'm a medical technologist and I used to draw blood at the first part of the day years ago, for just working in a lab. I'm just, just would rather not with needles."

Logistical Challenges

The theme of Logistical Challenges has two subthemes including Transportation challenges and study procedures. Transportation Challenges are barriers related to how easy it is to get to a clinical trial including issues with transportation as well as distance being a problem. When asked why they did not enroll in a clinical trial, one participant answered,

> "Might be because of time, and now that I'm working and stuff, cause I think to come for some of those programs on site, and it might be um, might have been too far out of the way. Or time interference."

The Study Procedures subtheme includes two subthemes of study design and comorbidities as exclusions. Study procedures are physical barriers to participating in a study such as time, or how often they are required to meet per week.

> "Yeah, and one of his reasons too is that probably a lot of other people, why he may not do a trail, study they'll say, well I'm already taking a lot of medicine, why do I need to go to a trial study"

Study design is how often or how many times a week they study design calls for participation including the length of time in months or years follow-up.

> "I: yeah, like given a lot of information, is there anything else that might make you hesitate.
> P: naw, the only thing's knowing what , what they're given me."

Cormorbidies as exclusion are physical factors and cormorbidies that exclude participants from participating in a clinical trial. For example one participant said,

> "I don't want to drive for so far, and then, after I called her back, she said that they were drawing blood, like three times, and I have sunken veins, and I told her.. So she said she understood, and uh, I told her I would be interested in something else, you know…and uh, she thanked me, yeah yeah."

Education Intervention

There was a theme of Education Intervention that emerged and included four subthemes. Those subthemes were community developed program, church-Research Partnership, Trustworthy Source of Information, and Supportive Environment. The

subtheme of Community Developed Program has one subthemes of convenience. Participants generally were impressed with the education intervention, the program. They were impressed that doctors came to them, came to their community and met them where they were and simply included them in the research process.

> "I: What about the program impressed you?
>
> P: Well, they included me."

By coming into the community, participants felt that the information was important and needed in their community. The idea of the church-research partnership as part of a community developed program was successful in reaching the community.

> "I: and why do you feel that the community collaboration is key?
>
> P: um, because we reach more people. and even in our little individual pockets, we're more familiar with what, what is needed in that community."

The Church-Research Partnership had subthemes of Persuasive approach. Many of the participants would not have known, or would have been less inclined to participate in the program if it had not been brought to them through their church.

> "I: how did you feel about it coming to your church?
>
> P: I thought it was a great because if it hadn't of come to my church I probably wouldn't have done it."

> "I: can you tell me more about what your experiences was like doing it through your church?

> P: … But yeah, they were really, really really nice, and um, and then it's convenient cause it was at the church you know, and uh, I knew where I was going. [chuckling] and I think some other people…I forget whether it was all from our church or not at the time, cause some other people might have to come from another place to our church you know, but, it was really convenient and everybody was really nice, no pressure and that's what I liked, you know. Um, so um, like I said, I was pleased with it. And uh, I'd do it again if if it needed that."

Three facets of the Trustworthy Source of Information theme include Knowledgeable Speakers, Relevant Content, and Reliable Source for Continuous Information. One of the main reasons the education intervention was seen as successful was how organized, open, honest, and trustworthy the speakers were.

> "Everyone was so honest and open and they [the speakers] even from their own personal experience would tell you how it was and so, the info, the literature they gave was very revealing of everything that would be involved in a study. And the in the paperwork that we signed the study that they did here which didn't involve anything medical, everything that they signed it was it was always honest and upfront and you know. I know it's better then it used to be."

> "I really liked how organized it was—how everything was presented. They [the speakers] seemed knowledgeable. They had facts to back up everything that they were speaking on. They were really engaging—they just appeared knowledgeable. They weren't just telling you tell you something. They whatever they were talking speaking on, they had data, they had facts, they had information right in front of you regarding it."

The speakers were not only knowledgeable, but they spoke on topics of interested to the community, and gave handouts as a reliable source of information.

> "…Then when they get around and they give you books and the papers and such to back up their claim. You're going through that and you're reading the books and going through it. You know, it gives you a better insight, you being able to understand what it's about."

The last main theme of Supportive Environment had no subthemes. The program was designed to be in a supportive environment, and the participants enjoyed the atmosphere the programs had. The participant were generally engaged with the topics, and all wanted to know more information, and being put at ease and feeling comfortable makes it easier to ask questions.

> "I thought all the speakers were very good, very informative. They knew their topic, they were friendly, they made people feel at ease, and that helped. They got to be around professional people, doctors, this is what they do, and yet they felt comfortable enough to walk up to them and talk and ask questions. So I think the atmosphere, having it at the church made it more relaxed. I really think so. It kind of met people where they were, so I felt that was good."

The themes that emerged from the follow-up interviews came together to show that there are relationships between all 6 of the main themes. The education intervention is a key factor that influences willingness to participate. From the baseline interviews we can see a change in understanding their community has a need for education, and then after the intervention, there was a need for increased awareness around the issue of clinical trials.

From the baseline interviews we also see how important trust is when implementing a community based education intervention.

DISCUSSION

Findings

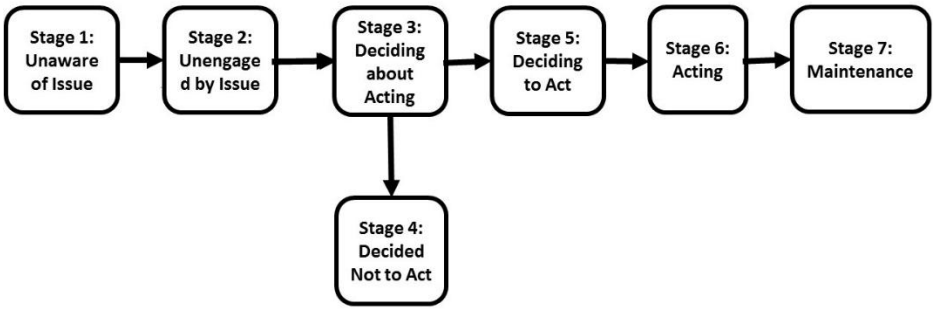
Understanding the decision making process, and how motivations and barriers influence willingness to participate is an import step to increasing minority enrollment in clinical trials. The results show how the main theme of awareness precedes barriers and motivations for clinical trial participation. Motivations and barriers can influence each other like tipping a scale from being willing to participate to being unwilling to participate. An education intervention influences participants' willingness to participate in research by increasing awareness as well as increasing motivations and decreasing barriers. We found that even with few barriers and willingness to participate, without being aware of clinical trials that are being conducted, participants did not participate in trials. This shows another facet of education interventions that are necessary to increase clinical trial participation—increasing awareness of specific clinical trials available in the community. The education intervention was key in increasing knowledge about clinical trials and the benefits of research for the African American community, as well as addressing the lack of awareness surrounding clinical trials by increasing education and sending out information about the current available clinical trials.

We saw a change in expressing a need for more education in the baseline interviews to a need for more awareness in the follow-up interviews. This change suggests that the intervention brought an increase in knowledge, and some increase in the general awareness of what clinical trials are and what they can do for the African American community. This change shows that the education intervention was an effective tool for increasing education of participants. It also shows that simply participating in a study was an effective way to increase general awareness on clinical trials. All of the participants interviewed expressed a

desire to know more about trials and that they would pay more attention to clinical trials in the future. A majority of the participants overcame some of the barriers and increased expressed their willingness to participate in clinical trials, as long as they were given information honestly and upfront, and the trials were relevant to their interest and non-invasive.

The descriptive research yielded themes that described a similar attitudinal pathway as the PAPM suggests. The PAPM has 7 stages shown in Figure 2: 1) being aware, 2) aware, but not personally engaged, 3) engaged and deciding about acting, 4) deciding not to act, 5) deciding to act, but not yet acting, 6) acting, 7) maintaining the new health behavior .[69] We examined conceptual structures that may align with the PAPM. We mapped the 5 main themes from the in-depth interviews to the PAPM stages.

Figure 1. Precaution Adoption Model



Awareness is stage 1 of the PAPM and the main driver in African Americans' decision making process relating to willingness to participate in clinical trials. In order to begin the decision making process, participants need to be aware of the issue. For study participants, in order to be willing to participate in clinical trials, they first need to be aware

of what clinical trials are available. Motivation to participate in clinical trials encompasses Stage 2 of being engaged with the issue. The factors that impact participants motivation to participate and where participants may decide about participating in trials if the motivations outweigh the barriers. Psychosocial and logistical barriers are Stage 4 of the PAPM. Barriers can often lead to deciding not to act, in the case of these participants, many of the barriers lead to deciding not to participate in clinical trials. If these barriers are overcome, they move on to Stage 3, willingness to participate in clinical trials. Education Intervention intervenes at stage 1 by increasing clinical trial awareness. The intervention also intervenes at stage 2 by bring the study to the community and engaging them in the research process educating them about the needs and benefits of clinical trial and study participation.

According to the PAPM, decisions progress starting at stage 1, and follow though all the stages. Understanding this model, an individual cannot be willing to participate in clinical trial research unless he is first aware of the opportunity to participate in clinical trials. The same process is true for implementing interventions. If there is a lack of awareness about clinical trials, interventions aimed at decreasing barriers and increasing motivators may be effected in those stages of the process, but ultimately ineffective because the intervention doesn't address the first stage of being awareness of clinical trials.

Comorbidities was an important barrier that emerged during analysis. Adams-Campbell et al. found that there is a disproportionate burden of comorbidities among the African American population.[3] Participants were aware that comorbidities might influence their ability to participate in clinical research and often did not even look into a trial if they thought it might influence or interact with one or more of their comorbidities. Understanding how comorbidities affect eligibility for clinical trial participation is important

when recruiting among African American who experience a greater number of comorbidities.

Different from Castillo-Mancilla and colleagues study which found that white participants were more worried about getting a placebo, we found that African Americans are also concerned about getting a placebo as a barrier to clinical trial participation.[1] This concerned exposed an underlying therapeutic misconception as either a motivator or a barrier to clinical trial participation. Brown et al. reported similar participant concerns surrounding the process of randomization and placebo/treatment groups.[84] Participants in the Brown et al. study looking at therapeutic cancer trial refuses showed that participants preferred to get the treatment compared to the placebo.[84] This study also showed that most participants wanted a guarantee that they would not get the placebo and would get the experimental treatment. This important finding suggests that greater care is needed when recruiting participants to minimize participation from participants who are seeking a source of free healthcare. It is also important for more time to be spent on increasing education about clinical trial designs and the treatment options in clinical research. These findings show that it is not clear how therapeutic misconception is influencing clinical trial enrollment among African Americans. Burke discusses how it is not clear how the ethical principal of therapeutic misconception has shaped enrollment of minorities including African Americans' in clinical trials.[83] This finding warrants further research into understanding how and why therapeutic misconception may work as a barrier or facilitator to clinical trial participation.

Health related factors were more important than psychosocial perceptions in influencing decision to participate in research. Gadegbeku et al found similar results in their study on factors associated with African American clinical trial enrollment. This study showed that African American have positive views on medical research integrity and also see

the benefits to society that medical research offers.[60] Situating trust within interventions and recruitment efforts

There is a growing body of literature supporting strategies that target communication of the health benefits of the research for participants. Langford et al. discussed how tailored campaigns to increase awareness of clinical trials would be successful among minorities, when also accounting for cultural and structural factors other than socioeconomic factors.[56] The authors mentioned social media and faith organizations as a few ways to increase clinical trial awareness among African Americans.

Conclusions

This study successful explores the relationships between awareness of clinical trials and willingness to participate in clinical trials. The depth of data gathered provides a useful conceptual framework which can be utilized when developing innovative programs and strategies to increase African American enrollment in clinical trials. Situating barriers and motivators as mediators between awareness and willingness to participate in research shows an important area to target.

One barrier not discussed was the potential bias of large research hospitals and research dollars being focused in high income areas, and not in more economically stratified areas. Understanding how lack of access to healthcare intersects with willingness to participate may be an important barrier to clinical trial participation.

Strengths

True to the purpose of exploratory qualitative research, this study showed the attitudinal decision process African Americans' experience when approached with the idea of participating in a clinical trial. This study also filled gaps in the previous body of literature

surrounding a more in-depth understanding of awareness. This study has many strengths including using rigorous qualitative methodology to ensure reliability of the coding structure as well as providing the perspective of a hard to reach population. In addition, this study also provided a theoretical advancement utilizing the PAPM with African American willingness to participate in clinical trials.

Limitations

As a qualitative, inductive study, the research is limited to recounting the experiences of individuals in a specific context and therefore not generalizable. Recruiting from those who were already part of a study means that the participants may have already been more likely to participate in research further limiting my results.

Racial differences between the participants and the interviewer may also have lead to less detailed and specific data as compared to interviews conducted by someone of the same race as the participants, although this was not apparent during the interview process. Another potential limitation was the overrepresentation of women in the sample. Two participants, a husband and wife, interviewed together which may have influenced how each individual responded to questions.

Implications and Recommendations

The process of increasing awareness and improving the education of African Americans may help foster a more positive willingness to participate in clinical trials research, which may help o boost enrollment in clinical trials. It is important to further distinguish between awareness and education and separate but related factors that precede barriers and motivators to clinical trial participation. Many participants reported the extent to which an education intervention can be used to address this problem of increasing

knowledge among their community and the success of using a community based intervention in a trusted faith setting. However, they also continually reported a lack of awareness as a precedent to the need for knowledge.

Future research is needed to understand the differences between an increase in knowledge, and an increase in awareness and understand how awareness and education affect behavior change—increasing enrollment in clinical trials. There needs to be a better understanding of how awareness and education break down barriers, and increase motivation to participate in order to focus strategies and interventions to increase enrollment. It is also important to focus intervention efforts away from tendencies of therapeutic misconception. Therapeutic misconception emerged as an important factor. Minimizing therapeutic as a motivation to enroll in trials is important for future interventions. Enrolling participants for the wrong reason is not ethical and a misrepresentation of motivation for participating. Therapeutic misconception as a motivation to participate, or a barrier for participating may be overcome with better education and awareness surrounding clinical trials.

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FIGURES

Baseline Interview Guide

1. What motivated you to participate in this study?
2. Could you tell me about your thoughts on clinical trials and medical research?
3. Could you please describe a little bit about your community?
4. What does it mean to you to be part of the black community?
5. How does the black community feel about clinical research?
6. How do you think we can address the fears and myths surrounding clinical research?
7. How do you think we can get the black community involved in clinical research?
8. How can researchers find out about the concerns that exist in the black community?
9. Where do people in your congregation get their health information?

In-Depth Interview Guides

For those who enrolled in a clinical trial:

A1: What was your impression of the Dose of Hope Program? What did you like or dislike? Why did you join?

A2: Why did you to contact the research team about joining the clinical trial [insert trial name here]?

A3: Why did you enroll?

A4: What do you think about clinical trials now that you have participated in one?

A5: Do you think you would enroll in another clinical trial? Would you (or have you) recommend(ed) clinical trial participation to others?

For those who screened for a clinical trial but did not enroll:

B1: What was your impression of the Dose of Hope Program? What did you like or dislike? Why did you join?

B2: Why did you to contact the research team about joining the clinical trial [insert trial name here]?

B3: Why didn't you enroll? Were there transportation issues, medical exclusions, scheduling issues, or something else? Do you feel like you had enough information to make a decision to enroll?

B4: Would you ever try enrolling in another clinical trial? Why or why not?

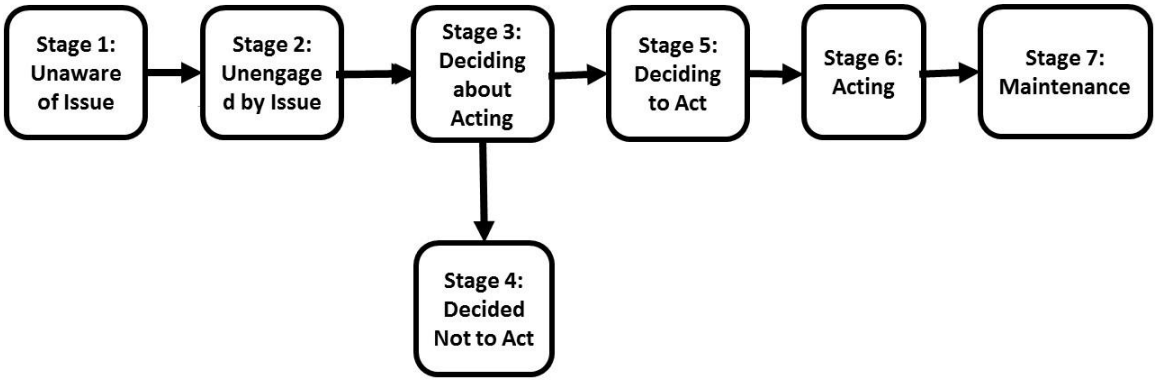
For those who neither screened nor enrolled in a clinical trial:

C1: What was your impression of the Dose of Hope Program? What did you like or dislike? Why did you join?

C2: Why didn't you enroll in a clinical trial? Were there transportation issues, medical exclusions, scheduling issues, or something else? Do you feel like you had enough information to make a decision to enroll?

C3: Would you ever try enrolling in a clinical trial? Why or why not? What type of clinical trial might you be interested in?

Precaution Adoption Model



TABLES

Table 1. Baseline Themes

Theme	Quote
Attitudes	"I think they're [clinical trials are] great because they help people to find out what cures are out there and also to find out the diseases that families have generations ago " "My thoughts right now [about clinical trials] are a little um concerning based on history. Um, based on how um African Americans have been treated previously as it relates to clinical studies. So I'm a little concerned and a little...um a little...I'll just say a little concerned." "Oh I think it's [clinical trials are] super." "In my opinion, enough has not been done to educate the black community on clinical research. I think that those who have been educated about it are more likely to participate and those who have just heard the horror stories will not gravitate at all." "Oh I think it's [clinical trials are] very good. We need that.
Education	"And when I say gaining trust it's by giving people the true message about what research is all about. Giving them the inner works of that research letting them know what the research is all about other than just giving them the topical review of that research. Give them the inner message, give them what they need to know and the true meat of what research is all about. As I said, once by gaining the trust and if you give them the truth then everything will be all right." "Knowledge is very important. To know what's going on with your body, and that's one of the main things that you all brought out to us is things that we probably don't even think about or realize. Is just doing these studies….what things can be brought out for our understanding… for us to realize it's very important to take care of your body. so ya'll brought out some things that we need. By doing certain things you can prevent other things, so that's one of the main things that y'all brought out to us and even that we need to do some of these studies."
Trust	What fears, mistrust, and stigma related to clinical research exist in the black community? "Tuskegee. Tuskegee." "Do I know about any. No." "Um, there was a time when Black community didn't trust

	clinical research because we were forced upon to be used as research guinea pigs. And uh, for now during this time has past and now community is uh backing the community research because we find that it will help the community out"

Table 2. In-Depth Interview Themes

Theme	**Quote**
Awareness (lack of)	"I: so, before they came to your church, were you aware of clinical trials at all? P: no. no, I: no, never hear anything about them? P: no."
\Need for Knowledge	"I: Why did you decide to join (educational) program? P:cause it's something that you need, and you might need to learn something from, you know what I'm saying?, you might not know some things that, that people know more of, so, it was a learning thing for me. Um, teaching me something that maybe I might want to call someone that has these issues…."
Motivation to Participate in a Clinical Trial	"Well, I don't know that I have been…particularly interested. Like the first one kinda so to speak fell in my lap, and I didn't mind doing it at all. And I also thought well that wasn't so bad, and so I did the second one, and I hadn't thought about it anymore except when the flu came on my internet. The flu one, I considered that one, that's about all. For those, those, and I don't know if I'll do another one or not. I guess it, probably depends on how much time and everything it entails, and also, um, I already have a lung problem so trying to be very careful about what kind of shots I take something like that, yeah. "
\Trust	"That's all I'm saying. I don't think that there's a distrust, I think there's a lack of information."
\\Peer Influence	"Well, I have to admit, I , I have a little bit more [trust] in people that I already know or that I'm associated with, or have built up a quote track record with, um, with others I'm probably a little less sure, and that's where the bedside manner comes in. to make me feel comfortable about what they're doing."
\\Medical Center	"Oh I defiantly feel that (a medical center) is trustworthy. Oh yeah, I don't have a problem with that. They've got a really good name. The students that come out of there are, are highly trained, as far as I can tell it has a track record of being very influential …. But their track record is good and they seem to know what they're doing."
\Relevant Health Topics	"My health is would be more what I would be interested in. you know. Um, oh…I don't know. That's about it. I guess, you know. I have, well I do have, high blood pressure, and um, I take cholesterol medicine. So anything in my area, you know, I would be interested in."

\Therapeutic Misconception	"I wouldn't want to be in the group with a placebo…I don't know for some reason in my mind, I don't see getting the placebo as helping me."
\Curiosity	"I: So why did you end up joining (educational intervention) program? P: uh, originally I did it just because I was curious."
Psychosocial Barriers	"I: okay, so what made you decide to um, participate in the studies? P: um, cause I think the questions that they were asking in and it was nothing invasive, and um, pretty easy for me to do."
\Knowledge of Historical Abuses	"As…blacks or African Americans, we have a real fear when it comes to studies. uh, most of the community I feel like, um, we, we feel like we're gonna be treated as guinea pigs. so, we back as far away as possible from that. okay, so that fear has just always been there. um, even I can go back as far as when I was 8, I guess 10 or 12 maybe, when my grandmother used to go to a doctor that had colored and white waiting rooms. so that fear goes way back, even to then when they thought that the blacks were being treated one way and the whites were being treated one way. so that they always felt, I know my grandmosther did, always felt that you know, she really wasn't getting the best of care, but it was the best that she could get at the time. "
\Study Demands	"It's the strangest thing. I just, I have always been, um…shy of uh needles and I'm a medical technologist and I used to draw blood at the first part of the day years ago, for just working in a lab. I'm just, just would rather not with needles."
\\Untested Product	"I might be slightly hesitant on on some medications that um, have not truly been tried out for side effects, so I would not, I'd be a little leery at that. um, but maybe in the final stages of some some drugs um, that are proven to um, to work, I would probably be yeah, interested in doing those."
Logistical Challenges	"Might be because of time, and now that I'm working and stuff, cause I think to come for some of those programs on site, and it might be um, might have been too far out of the way. Or time interference."
\Transportation Challenges	"I don't want to drive for so far…"
\Study Procedures	"She said that they were drawing blood, like three times, and I have sunken veins, and I told her no."
\\Study Design	"I: yeah, like given a lot of information, is there anything else that might make you hesitate. P: naw, the only thing's knowing what , what they're given me."
\\Cormorbidities as Exclusion	"She said that they were drawing blood, like three times, and I have sunken veins, and I told her no.. So she said she understood, and I told her I would be interested in something else, you know…and uh, she thanked me..."

Education Intervention	
\Community-developed program	"I: What about the program impressed you? P: Well, they included me."
\Church-Research Partnership	"I thought it was a great because if it hadn't of come to my church I probably wouldn't have done it." "Well, really I guess the first thing that um, most favorite thing was definitely getting the congregation involved."
\\Convenience	"It was really, really really nice, and then it's convenient cause it was at the church and I knew where I was going."
\Trustworthy Source of Information	"P: in everyone that came out, everyone was so honest and open and they even from their own personal experience would tell you how it was and so, the info, the literature they gave was very revealing of everything that would be involved in a study. And the paperwork that we signed, the study that they did here which didn't involve anything medical, everything that they signed it was it was always honest and upfront and you know, so. I know it's better then it used to be."
\\Persuasive Approach	"I: okay. and why did you decide to join the dose of hope program? P: because my pastor, uh, announced one Sunday that um, (a medical center) wanted to do a study with the seniors. so he asked us uh, the seniors, would we participate. so that's how I found out about it, and I did. and It was three different three different events, or what did you call it, it's scheduled us three different times"
\\Knowledgeable Speakers	"They [the presenters] seemed knowledgeable; they had facts to back up everything that they were speaking on. They were really engaging, they just appeared knowledgeable. They weren't just telling you tell you something. They whatever they were talking speaking on, they had data, they had facts, they had information right in front of you regarding it."
\Relevant Content	"They gave information say for instance for women, African American groups. When they would talk about the diabetes, they would center it around the African Americans, what would be important for me to know. So, the information that they gave was tailored just for me and my ethnicity. So that's what made it good."
\Reliable Source for Continuous Information	"Then when they get around and they give you the books and the papers and such to back up their claim, you know. You're going through that and you're reading the books and going through it. You know, it gives you a better insight you being able to understand what it's about."
\Supportive Environment	"I thought all the speakers were very good. Very informative. They knew their topic, they were friendly, they made people feel at ease, you know, and that helped." "It [the intervention] kinda met people where they were. So I

	felt that was good."
\Gift Card Incentive	"I did like the idea of getting a gift card."