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Eve Shapiro	Date

Relationships among functional ability, social interaction, and transportation that predict clinical research participation among church-going African American seniors

By

Eve Shapiro
MPH

Behavioral Sciences and Health Education

Paula Frew, PhD, MA, MPH
Committee Chair

Kimberly Parker, PhD, MA, MPH, CHES
Committee Member

Dick Levinson, PhD
Department Chair

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Eve Shapiro

Bachelor of Arts
University of Minnesota
2009

Thesis Committee Chair: Paula M. Frew, PhD

An abstract of
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Abstract

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By Eve Shapiro

Black/African American seniors experience disproportionately higher incidence of morbidity and mortality related to chronic diseases. They also have reduced access to health care and lower rates of early treatment. Clinical trials benefit black seniors by validating the efficacy of interventions for their population as well as provide individual-level advantages by acting as an alternative access point to health care. Currently, black seniors are significantly underrepresented in clinical research compared to white seniors. This study examined individual and interpersonal levels of the social ecological model, including sociodemographics, functional impairment, and social support to determine which factors influenced the likelihood of joining a clinical trial in the next six months among a sample of black church-going adults over the age of 50. Results from multiple logistic regression models demonstrated that higher degrees of three components of functional impairment, Basic Abilities, Errand Transportation, and Social Abilities were associated with lower likelihood of joining a clinical trial. An interaction between age and Crisis Support was also significant indicating that older adults with higher levels of crisis support were more likely to join clinical trials. Implications for these results indicate that clinical trials should consider the basic abilities and disabilities of their potential participants in recruitment and enrollment efforts and should utilize novel venues such as nursing homes, hospitals, and other senior communities to access this population. In addition, special attention should be paid to adults over 65 as they may require more intensive support from their peers in order to participate in trials.

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Introduction

Problem Definition and Justification

Black/African American adults are less likely to participate in clinical trials and medical research than their white peers [1, 2]. The disparity has been so great that the National Institutes of Health released guidelines in 1994 to address the issue of low enrollment among minorities and women [3]. Disparate rates of participation are problematic as it is difficult to substantiate which interventions or treatments are appropriate among specific demographic groups. The benefits of participating in clinical trials is documented and includes advantages ranging from access to health care and pre-market treatments as well as psychological improvement through feelings of altruism by volunteering for one's community [4, 5]. Black seniors, who experience increased morbidity and mortality due to chronic disease and a disproportionate burden of disability and functional impairment as they age, may be left behind in receiving benefits from these medical interventions compared to other racial and ethnic groups [6-9].

Research on barriers to clinical trial enrollment has focused on individual level factors like participant distrust of researchers and lack of familiarity with clinical studies [10-12]. It is important to examine multiple levels of factors that may act as barriers or facilitators to enrollment among black seniors. Identifying alternative ways for black seniors to receive community-based support and treatment through clinical trials is essential to reducing racial disparities in older adults. This is particularly critical for many older black adults with chronic medical conditions resulting in physical disabilities.

Theoretical Framework

The Social Ecological Model (SEM) may be considered as one framework through which researchers might understand the nature of health disparities related to clinical trial enrollment. SEM describes how various levels of environmental systems interact with each other and the individual to affect outcomes [13]. The utility of the SEM is demonstrated through the consideration of the multiple levels of determinants of clinical trial enrollment in black church-going seniors. While black populations experience a disproportionate burden of functional impairments, they also experience protective factors and health benefits through their strong social ties within a church-based context [14-17].

Within the SEM, individual-level factors that affect the health of black seniors might include age, income, partnership status and education. Each of these sociodemographics predicts the likelihood of joining clinical trials, primarily expressed through hindrances in tasks of daily living. These intrapersonal-level factors function both on their own and interact with multiple levels of influence to promote or deter black seniors from enrolling in clinical trials. Interpersonal factors, such as social support will affect research participation, as higher levels of social support and aid might encourage seniors to enroll in studies and facilitate their participation. Furthermore, social support that is specifically received in a church-based setting has been demonstrated to enhance the already positive effects of generalized social support. Therefore, it is predicted that elderly black church congregants who receive greater levels of social support and have fewer functional limitations will be more likely to enroll in clinical trials. The four levels of the SEM, seen in **Figure 1**, *Individual, Interpersonal, Cultural, and Societal,* will independently and intersectionally affect health outcomes of black seniors within the church.

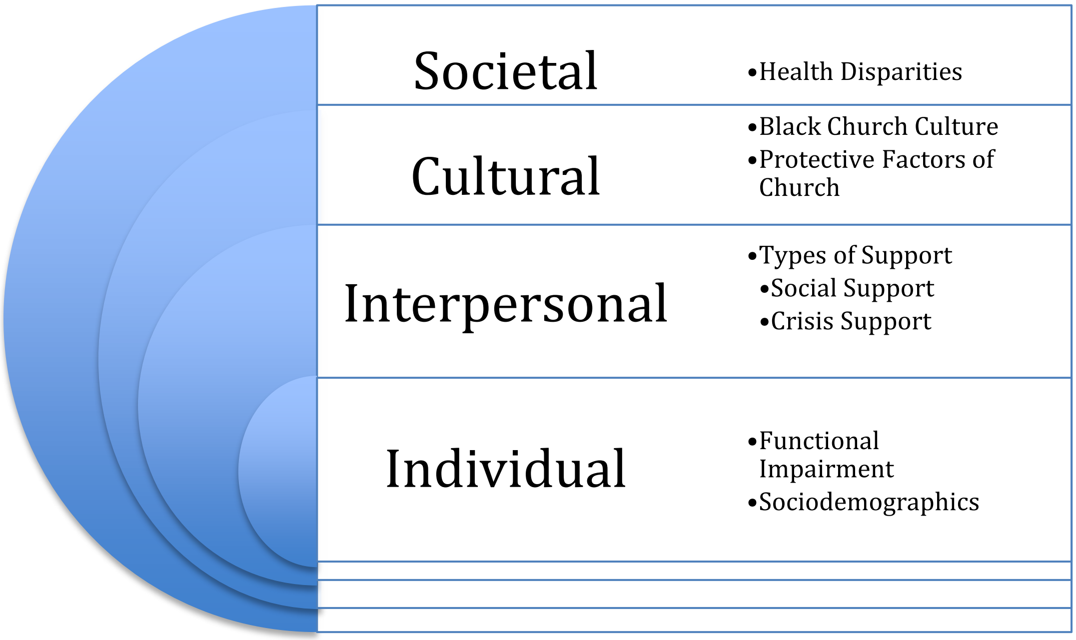

Figure 1: Socialecological Model

The SEM has been used in previous studies to establish and validate the interaction of multiple levels of factors that influence health outcomes and clinical trial enrollment among seniors and African Americans. A study of post-stroke activities among stroke survivors indicated that individual, interpersonal, and institutional factors facilitated and hindered activities. These factors ranged from individual perceptions and attitudes, friends and family who facilitated access to programs, institutional links to health care, and governmental funding of income support, demonstrating how participation with the health care system interacts with different layers of the model [18]. Another study testing the effects of a chronic disease self-management course found that individual and interpersonal levels of the SEM, including coping capacity, social engagement, collective identity, and exchange relationships, were related to course outcomes in participants [19].

Among black/African Americans specifically, utilization of the SEM has been foundational in developing comprehensive interventions. A cancer survivorship study of risk and protective factors among black women found that influences existed and interacted at all levels of the SEM to impact survivorship, including individual attitudes, social support, and spirituality [20]. While there is strong support through previous research of the utility of the SEM in framing health outcomes among black populations there are few studies that utilize this model to consider the determinants of clinical trial enrollment. Research in this area is foundational to understanding which components of the model have the most impact on enrollment practices.

Research Question

The purpose of this study is to understand how likelihood of joining a clinical trial is affected by social support, functional impairment, and sociodemographics among black seniors in a church-based setting.

Primary Study Objective: Utilizing the social ecological model as a framework for examining the interaction between individual level factors (sociodemographics, basic abilities, strength and mobility, social abilities, errand transportation, and other independent assessments of functional abilities), interpersonal level factors (social support and crisis support), and community level factors (church membership), this study aims to evaluate the associations between the degree of social support received, level of functional impairment and socio-demographic factors on the likelihood to join a clinical research study in the next six months among a sample of 208 African Americans over the age of 50 across six Atlanta churches. Measures were gathered through a quantitative survey that included items related to sociodemographics as well as validated instruments that assess social support and level of functional disability.

The primary outcome is of this study is to examine the likelihood of joining a clinical research study in the next six months, which is measured using one question item with a scale of 0 (definitely not) to ten (definitely). Based on previous studies highlighted in the literature review, it is predicted that lower levels of all four functional impairment factors and higher levels of social support will be associated with higher likelihood of joining a clinical research study.

Secondary Objectives: Additional questions aim to understand: which sociodemographic factors are predictive of higher likelihood of joining a clinical research study? In addition, are there differences in the likelihood of joining a clinical research study between sampled churches?

Literature Review

Racial Health Disparities

Health disparities have been a great concern in the field of public health. Healthy People 2020 describes health disparities as inequalities that may include dimensions such as race, ethnicity, gender, sexual orientation, age, socioeconomic status, disability and many other factors [21]. However, disparities among racial and ethnic groups are of especially high concern due to the large differences in health outcomes that are identified, especially between black and white populations [2]. Substantial health disparities between black and white adults have been found among many diseases and illnesses, including: heart disease, cancer, diabetes, and perinatal conditions, with black populations experiencing a disproportionate burden of disease [9, 22]. These factors will compound as individuals and populations age, leading to a significantly lower lifespan for black men and women compared to white populations [9]. The overall life expectancy at birth for all women in the United States is 81.0, while white women experience a life expectancy of 81.3 years compared to 78.0 years among black women [9]. Disparities in mortality between black and white men are even more dramatic. The overall life expectancy from birth of all men is 76.2 year, among black men it is 71.8 years while among white men it grows to 76.5 years [9].

The causes of these great disparities are varied and occur at multiple levels of health; while individual behaviors like diet or exercise play a role, much of the difference can be attributed to community and social factors including insurance status, access to healthy foods, and neighborhood infrastructure [2]. At an economic level, black U.S.

residents are more likely to live in poverty, with a rate of 25.8% in contrast to 11.6% of white and 14.3% of all residents [23].

Although there is evidence that these factors contribute to differential health outcomes, other sources identify that differences still exist between racial groups even when these social factors are controlled [2, 24]. Internal determinants, such as racism or minority stress may also contribute to negative health outcomes. In one study, disparities were examined through assessment of allostatic load, the "cumulative wear and tear" a person experiences throughout their life, as operationalized by algorithms of primary mediators (norepinephrine, epinephrine, cortisol, and DHEA-S) and secondary effects (increased blood pressure, cholesterol levels, hemoglobin levels, and waist-to-hip measurements). The mean allostatic load score for black participants at various ages was similar to that of white participants aged ten years older [25]. Those allostatic load differences unrelated to poverty may indicate worse health outcomes are due to stress caused by racism and discrimination, potentially at multiple levels (individual, institutional, or societal). Therefore, even when other inequalities may be alleviated, health disparities related to racial discrimination may persist in minority populations and must be addressed on an individual and institutional level.

Racial Disparities in Morbidity and Disability among Seniors

Health disparities in morbidity are intertwined with disability and that overlap is demonstrated through the construct of *functional impairments*. As people age and their diseases persist, the severity of their symptoms often increases leading to reduced functioning at tasks of daily living (also called *functional impairment*). Furthermore, the later stages of many diseases have consequences such as amputation, memory loss, or macular degeneration, which may result in increased functional impairments [22]. Health disparities can present themselves across the lifespan and tend to compound as individuals age. Although most seniors will experience some form of disability as they age, black adults have one and a half to two times the chance of disability across their lifespan; this is especially demonstrated in functional limitations, activities of daily living, and memory/learning problems [6, 7].

According to a study of self-reported disability status between black and white individuals, racial differences in the incidence of disability varied across the lifespan, however, the greatest distinction emerged at 50-69 years [7, 8]. Another study found that among a population where racial differences were minimal at baseline the disparities had increased significantly for blacks after 6-years at follow-up. Some differences were reduced when income was controlled, but disparities still remained, more so among women [26]. However, other studies have shown that of the disability disparity between black and white adults, 90% of the variance for men and 75% of the variance for women is explained by income and educational differences [27].

There is conflicting evidence about the contributing factors related to functional impairment disparities. In one study, functional impairment was closely linked with socioeconomic status, with a linear negative relationship between level of impairment and income, even up to 700% of the Federal Poverty Limit [28]. While other studies have corroborated that black adults have a higher level of disability across their lifespan compared to whites, there is evidence that this disparity does not increase nor decrease across age category when controlled for economic resources, social integration, and other health indicators [29].

Health Outcomes of Seniors with Disabilities

The effects of functional impairment can range from mild to severe, lead to significant decreases in activity and independence, and oftentimes worsen with age. Of the top ten disabling conditions among adults with self-reported disabilities, seven were associated with aging: arthritis (19.0%), back or spine problems (16.8%), heart trouble (6.6%), respiratory problem (4.9%), diabetes (4.5%), vision problem (3.2%), and stroke (2.4%) [30]. In the U.S., 17.3% of all people reported difficulty with functional activities such as walking three blocks or reading a newspaper, 47.5% among those over 65 years [30]. Of all people assessed, 3.9% reported difficulty with activities of daily living such as getting around the home, bathing, or eating, 12.5% for those over 65 [31]. In addition, 6.2% reported difficulty with instrumental activities of daily living including getting around outside of the home, preparing meals, or doing light housework, 19.1% over 65 [31].

Black adults experienced higher rates of disability across their lifetime as well as worse limitations [7, 8]. According to one study, higher odds of disability among older African Americans were related to lower-income and no post-secondary education, however, after controlling for joint effect, only education was a significant factor demonstrating that there are other influences that may not yet have been assessed [8]. Having a disability may lead to other health consequences, also compounding health disparities. Overall, 25.6% of disabled adults versus 12.8% of non-disabled adults identified as being inactive during the last week [32]. Considering race as a factor, black adults with disabilities are even less likely to be physically active than white adults with disabilities [33].

Often physical limitations are a consequence of impairments, which may lead to additional negative outcomes. One study found that mobility limitations were significantly associated with medical conditions and major depressive symptoms while functional disability was found to be a significantly higher risk factor for depressive symptoms in black adults [15, 34]. Considering the health outcomes of physical limitations and reduced activity, it is unsurprising that adults with lifelong disabilities are more likely to have coronary heart disease (aOR=2.92), cancer (aOR=1.61), diabetes (aOR=2.57), obesity (aOR=1.81), and hypertension (aOR=2.18) [35]. The Centers for Disease Control and Prevention (CDC) declared in 2013 that improving the wellbeing of individuals with disabilities is a public health concern [36]. This followed a call to action from the Surgeon General in 2005 to improve life for individuals with disabilities [37]. This has mandated our directive to give more attention to the health needs of those with functional and other impairments.

The Role of Clinical Trials

One possible way to bridge the gap of health disparities and provide care for seniors is through clinical trials. The benefits of clinical trial participation among seniors are numerous and include access to free medical care, availability of novel treatments, and a sense of volunteerism and altruism [4, 5]. However, minorities are less likely to participate in medical research and consequently less likely to experience these benefits [1]. The National Institutes of Health established guidelines in 1994 to increase enrollment of women and minorities in clinical trials to alleviate the effects of this disparity [3].

Major barriers to enrollment experienced by black participants are a lack of familiarity with clinical trials, mistrust of research related to historical abuses, like Tuskegee, negative physician attitudes towards patient enrollment, and unexpected costs [10, 12]. Yet, another mixed-methods study found that black participants were unlikely to participate in future trials because of perceived treatment-related burden, randomization to an undesirable treatment arm, and possible negative effects of treatments [11]. Others have shown that black participants desire more racially diverse research staff and increased efforts to regain trust of the black community through building lasting relationships [1, 38].

Additionally, seniors and especially black seniors are less likely to participate in clinical research compared to younger, white individuals. This has been demonstrated in reviews of participant recruitment and enrollment in cancer (black compared to white OR= 0.71, $p < .001$; black over 75 compared to black under 64 OR= 0.24, $p < 0.001$; black 65-74 compared to black under 64 OR= 0.53, $p < 0.001$), heart failure, surgical oncology (black compared to white OR= 0.67, $p < 0.001$; patients 65-74 years old compared to patients 20-44 years OR= 0.20, $p = 0.001$), and lung injury trials (men >75 years compared to men <35 years OR= 0.59, $p < 0.001$, women >75 years compared to men <35 years OR= 0.45, $p < 0.001$) [39-42]. It is important to uncover the logistical barriers that especially prevent black seniors from participating in clinical research and which mechanisms may facilitate enrollment.

Benefits of Social Support

There are also other protective factors that communities and individuals maintain such as social support that can alleviate the disparities related to aging and impairments and facilitate enrollment in clinical trials. Since so many seniors experience conditions leading to functional impairments, it is imperative that we place a focus on the needs of seniors, especially those with limitations [30]. While immediate steps in public health may involve policy-level actions such as extending the scope of Medicare benefits for those with disabilities or increasing employment opportunities for those with functional impairments, more comprehensive efforts are needed to ensure that seniors with disabilities are able to participate in society to the greatest extent possible [36]. Beyond the scope of managing negative health outcomes and concerns related to disability and functional impairments among seniors, formal and informal social support plays a major role in mitigating harms [43].

Social support may come in many forms, from having a network of health care to something as simple as a talking with neighbors and/or friends. The benefits of social support are widespread and extend to many facets of well-being. Social support has been found to improve mental health, counteracting disability's effect of increasing depressive symptoms [44]. Patients experiencing chronic disease are more likely to adhere to treatment regimens with the aid of social support networks [43]. Caregiving networks are especially essential in allowing those with functional disabilities to live as independently as possible and remain in their own homes longer. It is important therefore that we address the potential role that daily living challenges may pose for those with functional impairments who wish to volunteer in medical research. This is especially true for at-risk populations, such as black seniors, who experience higher incidence of disability and more severe outcomes.

Social Support in the Black Church

Black populations have experienced reduced access to care within the traditional medical system. This is expressed through a higher likelihood of being uninsured among those under 65 (13% white uninsured and 21% black uninsured), a lower likelihood of seeing a primary care provider in the past year (70.4% blacks and 78.1% whites), and delayed treatment and management of chronic illnesses [45, 46]. Therefore, informal systems of care have come forward to fill many of the gaps of the medical system. Within the black community, the church has been a cornerstone of neighborhoods and broader societies. Many churches have multiple community-based ministries stemming from traditional religious teachings and may offer job training, voter registration, issue-based activism, economic support, health programs, and even health clinics [47]. When church is utilized as a form of community in addition to a spiritual venue, congregants often experience improved health outcomes [48]. For example, church attendance is associated with reduced odds of having a lifetime mood disorder [49]. Concurrently, low religiosity in African American women with functional limitations has been associated with greater depressive symptoms [15].

In addition, among church congregants with functional limitations, church attendance was associated with increased cognitive functioning [16]. While many benefits may be tied to traditional social networks, the advantages for churchgoers are extended through church-specific ties. In one nutrition intervention, social support was associated with fruit and vegetable consumption however, specifically religious social support was associated with additional vegetable consumption [50]. The benefits of church participation clearly extend beyond the scope of religious education.

Despite similar rates of church attendance between blacks and whites, black congregants may have deeper experiences and may gain more significant benefits from church attendance compared to other racial and ethnic groups [16]. Black congregants had better-developed relationships with other congregants and with clergy compared to whites and Hispanic-origin Mexican-Americans [51]. Among black adults, the social support that is provided in churches uniquely mediates improved mental health and life satisfaction [17]. Furthermore, black church members are significantly more engaged in supportive relationships in the church than other racial/ethnic groups [14].

The benefit of church attendance in black populations may be especially salient for seniors. Among senior congregants, one study found that emotional support increased between church members while tangible support decreased; despite the decreases in tangible support, participant satisfaction with both emotional and tangible support also increased over time [14]. Another study found that there were associations between church-based support and healthy lifestyles among black senior congregants but not among white seniors; these relationships were especially strong among congregants who closely identified with their church [52]. However, despite the numerous benefits of church attendance, black adults with one or more functional limitations were less likely to attend church services than white adults with similar levels of impairment, thus highlighting the importance of maintaining social networks that can aid with church attendance and the transportation needs that may disproportionately affect black adults with limitations [16].

Considering the church as an agent of change may be helpful in improving health outcomes. One church-based health intervention that focused on increasing physical activity and fruit and vegetable intake by augmenting institutional practices, such as serving healthier foods at church events and programming that included physical activity, demonstrated that community-level changes positively influenced parishioners' own health behaviors [53]. However, while an abundance of research exists to quantify the physical benefits of church attendance, there are fewer studies that detail the effects of church-based interventions [54]. The black church may be a key player in encouraging congregants to enroll in clinical trials, especially if interventions are based within the church itself. Through church-based programs, black seniors may be more likely to join clinical trials, thus improving intervention outcomes among this population and promoting interaction between individuals and the health care system, thus addressing some of the many health disparities between black and white seniors.

Methods

“Delivering a Dose of Hope”

This research project draws upon evidence generated by the primary Dose of Hope intervention. The “Dose of Hope” study was intended to positively influence attitudes of older (age ≥ 50 years) black/African American adults towards medical research and clinical trials. In this intervention, the faith-based setting acts as a conduit for reaching the study population and influencing norms. The general outcome of interest examined in the main study is increased enrollment of intervention participants in ongoing clinical trials at one year follow-up from baseline activities.

The longitudinal, mixed-methods study was implemented in six churches constituting three different Christian denominations (i.e., Baptist, Seventh-Day Adventist, and African Methodist Episcopal) with three data collection points at baseline, three-months, and six-months and longitudinal outcome tracking to one year. Intervention participants engaged in three workshops at each of the timepoints about health disparities, clinical research, and health risks, each session lasting approximately 1.5-3 hours. The intervention employed a combination of educational strategies such as didactic instruction, group discussion, and interactive games. Sessions were led by Dose of Hope staff, physicians, health ministers, external health practitioners, and church staff.

Data collection methods included the gathering of surveys before each session. Control groups were given basic health information relevant to seniors and took the survey at baseline, three-months, and six-months. In addition, about 10 participants in the intervention and control arms were asked for informal qualitative interviews related to their perceptions of the Dose of Hope study as well as perceptions of health concerns and barriers to health education and clinical trials within their communities. All participants were compensated $50 for each survey completed as well as an additional $20 for each qualitative interview.

In between sessions, intervention and control group participants were sent a bimonthly Dose of Hope newsletter that highlighted study staff, ongoing research projects, and information about typical medical concerns and screenings. Participants in both intervention and control groups were invited to participate via phone and email in other health-related studies that were recruiting participants in their demographic.

Study Procedures

The Dose of Hope study was conducted by Emory faculty and staff in collaboration with participating pastors and health ministry leaders from the churches. The study is two years in duration to allow for nine months of implementation and baseline data collection at each church, followed by three-month and six-month waves of follow up survey administration. All data utilized in this specific analysis result from baseline and three-month surveys.

A community randomized sampling method was used to create the study sampling frame of churches. Initially the principal investigator (Paula Frew, PhD) and a staff member of the Emory Office of Community Partnerships (Nathaniel Smith) drew up a list of all churches in the Atlanta metropolitan area that had a history of collaboration with Emory University and were comprised of ≥60% black/African American congregants. From the list of twenty churches representing various denominations, each was enumerated for subsequent randomization. All churches on the sampling frame were then subjected to randomization, of which six primary churches were selected and paired.

A set of secondary selections were also drawn to substitute churches as needed in the event that some declined to participate. All churches were randomly assigned “intervention” or “control” status.

The team from Emory (PI and project staff) conducted subsequent outreach to all selected churches to determine interest in participation. Each church was then visited by the PI and study staff to establish relationships between the groups to ensure implementation viability. Only one church declined to participate thereby necessitating a substitution from the alternate randomization roster.

The selected congregations included three intervention churches that were matched to control churches on denomination and size. They included two Baptist congregations with approximately 1000 members, two Seventh Day Adventist churches with about 500 members, and two African Methodist Episcopal churches with 1001-5000 members. Within each church, pastors and other faith leaders reached out to their respective congregations and elicited participation from members who fit the inclusion criteria.

All study administrators were CITI certified in Social and Behavioral Research and the study was approved by the Emory IRB. At baseline, all participants were given consent forms, which were both read individually and aloud by study staff. The purpose of the study was described, as were all procedures utilized to protect data and ensure confidentiality and anonymity. Staff answered any questions related to the consent forms and the study and provided all appropriate IRB and study coordinator contact information.

Participants signed the consent forms before beginning the survey or intervention. All participants were asked to fill out a 134-item baseline questionnaire that included demographic questions as well as several instruments measuring various domains including social support, attitudes about clinical research, and discrimination. The three-month questionnaire consisted of 137 items and the six-month 192 items.

The surveys were stored in a locked and secured file cabinet at the Emory Hope Vaccine Clinic. Data was deidentified with a participant identification number (PTID) and entered into IBM SPSS Statistics software, version 21 and stored on the secure Emory drive. The three-month and six-month surveys were identified with the PTID and no identifiable information was collected. Any qualitative interviews were immediately transferred onto the secure Emory drive and recordings were destroyed after transfer. Surveys will be stored for the required five years, after which they will be destroyed.

Participants

Participants were selected from the membership base of these six participating churches in the metro-Atlanta region. Two hundred and twenty-one (N=221) black/African American congregant members participated in the Dose of Hope program. Participation requirements included being: over the age of 50 years, being a standing member/congregant of the participating church, being a resident of the metropolitan Atlanta area, and identifying as black/African American. Exclusion criteria included: moving within the next 12 months, having previously participated in a clinical trial or faith-based intervention, and inability to attend all three intervention sessions.

Participants were nearly evenly divided between the intervention and control cohorts with a total baseline count of 221 participants with 112 participants in the intervention arm and 109 participants in the control arm. Each church solicited at least 29 members at baseline and held an average retention rate of 95% at the three-month timepoint. (Table 1).

The study took place at each of the six churches in either the sanctuary or a meeting room that could accommodate the participants and solicited participation. Utilizing church space was intended to incorporate faith-based influences into the study such as social networks, approval from church leaders, and familiar peer networks. The locations were also convenient, familiar, and comfortable for the participants.

Table 1. Participation by Congregation

	Church	**Baseline**	**3-Month**	**Retention %**
Intervention	Greater Traveler's Rest Baptist	37	34	92
Control	Greater Piney Grove Baptist	41	40	98
Intervention	Maranatha SDA	44	40	91
Control	Decatur SDA	39	38	97
Intervention	St. Philip AME	31	31	100
Control	Turner Chapel AME	29	28	97
	Total	**221**	**211**	**95**

Measures

Measures for analysis of individual-level constructs were collected in the baseline and three-month surveys and consisted of sociodemographics, including age, gender, education level, income, and relationship status, as well as functional disability scales. Age was assessed through a self-report fill-in-the-blank and verified by participant reported birthdate. Participants were able to indicate their gender as male or female. Education level was measured by asking participants to select their "highest level of school that [they] completed" from seven categories with response options ranging from *K-8 grade* to *Doctorate*. Participants were asked to report their annual household income with responses ranging from *Less than $20,000* to *More than $100,001* demarcated in $20,000 increments. Last, relationship status was identified through five options including, *Single/Never Married, Married/Domestic Partner, Divorced/Separated, Widowed,* and *Other (specify).*

Functional Impairment was measured on the three-month survey through a series of 15 questions on abilities and daily living and four questions on long-term physical abilities developed from the Functional Status Questionnaire (Appendix A) [55]. Social Support was assessed on the baseline questionnaire and was measured through a validated instrument on medical outcomes and social support consisting of 19 questions (Appendix B) [56]. Social Support and Functional Impairment items were transformed into a factor score for analysis.

Missing data were analyzed to determine if mean scores could be used for missing values. An expected maximum (EM) imputation was used to impute missing items using other components of the same scale; scores were imputed only when more than 50% of the scale was completed. A principle component extraction was performed followed by a varimax rotation with factors run separately. Significant loadings were identified as loadings over 0.5 and crossloading items were removed—for the analyzed scales, only two items were removed from the functional impairment scales, “Someone to take you to the doctor if you needed it” and “someone to confide in or talk to about yourself or your problems.” The number of factors were selected for both an Eigenvalue over one and for interpretability.

Table 2. Functional Impairment Factors (n=200)

In the past month, have you had difficulty with… * 1='No Difficulty', 4='Too Difficult To Do'	
Factor	**Items**
Basic Ability α = 0.879, 5 items	L1: Feeding yourself? L2: Dressing yourself? L3: Moving in and out of bed? L4: Bathing yourself? L5: Walking around your home?
Strength and Mobility α = 0.861, 5 items	L6: Walking several blocks? L7: Doing house chores such as cleaning? L10: Using public transportation? L11: Lifting heavy objects? L12: Doing physical activity such as running?
Social Ability α = 0.803, 3 items	L13: Visiting other peoples' homes? L14: Participating in community activities, such as religious services, social activities, or volunteer work? L15: Taking care of other people such as family members?
Errand Transportation α = 0.752, 2 items	L8: Doing errands, such as grocery shopping? L9: Driving a car?

Table 3. Social Support Factors (n=219)

How often are each of the following kinds of support available to you? * 1=’None of the Time’, 5='All of the Time'	
Factor	**Items**
Social Support α = 0.974, 14 items	H5: Someone who shows you love and affection H6: Someone to have a good time with H7: Someone to give you information to help you understand a situation H9: Someone who hugs you H10: Someone to get together with for relaxation H11: Someone to prepare you meals if you were unable to do it yourself H12: Someone whose advice you really want H13: Someone to do things with to help you get your mind off things H14: Someone to help with daily chores if you were sick H15: Someone to share your most private worries and fears with H16: Someone to turn to for suggestions about how to deal with a personal problem H17: Someone to do something enjoyable with H18: Someone who understands your problems H19: Someone to love and make you feel wanted
Crisis Support α = 0.847, 3 items	H1: How often do you have: someone to help you if you were confined to a bed H2: Someone you can count on to listen to you when you need to talk H3: Someone to give you good advice about a crisis
Items removed from analysis	H4: Someone to take you to the doctor if you needed it H8: Someone to confide in or talk to about yourself or your problems

Factor internal reliability was assessed with Cronbach's alpha and all resulting factors had alphas greater than 0.75 suggesting very strong internal consistencies. The four individual items (M1-M4) relating to long term physical abilities were analyzed via factor analysis but alphas were below 0.70 and so they were considered as individual items. Last, factor scores were computed using the regression method. The fifteen functional impairment items were divided into four factors (Table 2), *Basic Ability* (5 items, α = 0.97), *Strength and Mobility* (5 items, α = 0.97), *Social Ability* (3 items, α = 0.97), and *Errand Transportation* (2 items, α = 0.97). The resulting factors for social support were divided into *Crisis Support* (3 items, α = 0.85) and *Social Support* (14 items, α = 0.97) (Table 3).

The primary outcome variable was the likelihood that participants would participate in clinical research. It was measured through a single item on the baseline survey, "On a scale from 0 (definitely not) to 10 (definitely so), rank your likelihood of joining a medical research study within the next 6 months." Participants were given a scale from zero to ten and circled their corresponding response. It was transformed into a dichotomous variable through a median split of responses with those reporting a six or below categorized as not likely to join a study and those selecting a seven or higher categorized as likely to join a clinical study.

Analysis

All analyses were completed using SPSS version 21 (SPSS, Inc., Chicago, IL, USA.). Descriptive statistics and correlations were obtained for all variables of interest. Chi-squared (χ^2) tests were used to identify differences between the sample used for these analyses (n=191) and the baseline sample of 221 participants. ANOVA tests were run to assess differences between church congregations. Logistic regression models were run to assess the effect of different and cumulative variables. Logistic models were also stratified by age, gender, income, education, and partnership. Finally, colinearity of each model was examined using the Variance Inflation Factor (VIF).

Results

Participants

At baseline there were 221 participants who completed the survey and at three-months, 211 completed the instrument. Seven participants did not complete the outcome item at baseline (3% missing) and thirteen participants did not have complete factor scores for the independent variables, leaving a pool of 191 complete cases (Table 4) included in the analysis via list wise deletion (6% missing cases from 3-month, 14% overall). The mean age was 63.6 years (SD=7.50), though ages ranged from 50 to 90 years old. There were 147 females (77.0%) and 44 males (23.0%). The vast majority of participants identified as African American/black (n=187, 97.9%) and 4 participants identified as multiracial/multicultural (2.1%); one participant also identified as Hispanic/Latino/Chicano (0.5%), 157 participants identified as non-Hispanic (82.5%), and 33 participants did not describe their ethnicity (17.2%).

The majority of participants had an associate's degree or higher (n=123, 64.4%). There was a moderate spread of household income, with the plurality claiming an income below $20,000 (n=50, 26.2%) and fewest claiming a household income over $100,001 (n=13, 6.8%). Participant employment varied with fewest claiming part-time employment (n=18, 9.4%) and the most responding that they were retired (n=85, 44.4%). Participants were most likely to be married (n=89, 46.6%) or divorced/separated (n=51, 26.7%). Nearly all identified as straight (n=180, 94.2%) while two identified as bisexual (1.0%) and three as don't know/questioning (1.6%). There were no noticeable demographic differences between the 221 baseline cases and the 191 complete cases.

Table 4. Demographics of Study Sample and Complete Cases

	Total Sample (n=221)		Analysis Sample (n=191)	
Item	**Frequency**	**%**	**Frequency**	**%**
Mean age (range) (missing=3)	64.0 (SD=7.7)	50 - 94	63.6 (SD=7.5)	50 - 90
Gender				
Female	174	78.7	147	77.0
Male	47	21.3	44	23.0
Race				
African American/black	217	98.2	187	97.9
Multiracial/Multicultural	4	1.8	4	2.1
Ethnicity (missing n=45)				
Non-Hispanic	175	79.2	157	82.5
Hispanic/Latino/Chicano	1	0.5	1	0.5
Highest Level of Education				
K-8 grade	3	1.4	2	1.0
9-11 grade	10	4.5	6	3.1
High School Grad/GED	66	29.9	60	31.4
Technical/Vocational/Associates	66	29.9	55	28.8
Bachelor’s Degree	37	16.7	33	17.3
Master’s Degree	33	14.9	29	15.2
Doctorate	6	2.7	6	3.1
Household Income (missing n=23)				
Less than $20,000	61	27.6	50	26.2
$20,001 - $40,000	49	22.2	42	22.0
$40,001 - $60,000	36	16.3	34	17.8
$60,001 - $80,000	20	9.0	18	9.4
$80,001 - $100,000	19	8.6	17	8.9
More than $100,001	13	5.9	13	6.8
Employment (missing n=8)				
Employed – Full Time	43	19.5	38	19.9
Employed – Part Time	18	8.1	18	9.4
Unemployed	37	16.7	32	16.8
Other (Retired n=85, 44.4%)	115	52.0	97	50.8
Relationship Status				
Single/Never Married	24	10.9	20	10.5
Married/Domestic Partner	102	46.2	89	46.6
Divorced/Separated	59	26.7	51	26.7
Widowed	35	15.8	30	15.7
Other	1	0.5	1	0.5
Sexual Orientation (missing n=7)				
Straight	209	94.6	180	94.2
Bisexual	2	0.9	2	1.0
Don’t Know/Questioning	3	1.4	3	1.6

Descriptives

Items included in the Functional Impairment factor scales demonstrated low levels of disability (Table 5). Within Basic Ability, average scores ranged from 1.03-1.09 (1= no difficulty, 4= too difficult to do). In the factor of Strength and Mobility, the 5 items ranged from 1.24 to 1.89 representing high levels of strength or low mobility impairment. Within the category of Social Ability, scores ranged from 1.16 to 1.28 indicating higher levels of social abilities, and within Errand Transportation, scores averaged 1.08 (SD= 0.306) for “Driving a car” and 1.16 (SD= 0.390) for “Doing errands” demonstrating a low level of impairment for completing errands.

Table 5. Functional Impairment Factor Scores

Factor	**Mean***	**SD**	**Min**	**Max**	**Factor Loading**
Basic Ability (α = 0.879, 5 items)					
L1: Feeding yourself?	1.03	0.212	1	3	0.775
L2: Dressing yourself?	1.05	0.252	1	3	0.904
L3: Moving in and out of bed?	1.09	0.314	1	3	0.756
L4: Bathing yourself?	1.05	0.232	1	3	0.901
L5: Walking around your home?	1.09	0.293	1	3	0.588
Strength and Mobility (α = 0.861, 5 items)					
L6: Walking several blocks?	1.42	0.747	1	4	0.799
L7: Doing house chores such as cleaning?	1.24	0.531	1	4	0.617
L10: Using public transportation?	1.28	0.694	1	4	0.614
L11: Lifting heavy objects?	1.82	0.922	1	4	0.821
L12: Doing physical activity such as running?	1.89	1.046	1	4	0.848
Social Ability (α = 0.803, 3 items)					
L13: Visiting other peoples' homes?	1.20	0.502	1	4	0.801
L14: Participating in community activities, such as religious services, social activities, or volunteer work?	1.16	0.441	1	4	0.817
L15: Taking care of other people such as family members?	1.28	0.639	1	4	0.531
Errand Transportation (α = 0.752, 2 items)					
L8: Doing errands, such as grocery shopping?	1.16	0.390	1	3	0.627
L9: Driving a car?	1.08	0.306	1	3	0.877

The Social Support factors had mean scores ranging from 3.87 to 4.30 (1= none of the time, 4= all of the time) indicating high average availability of social support (Table 6). Similarly, items included in the Crisis Support factor had means of 3.67 to 4.03, also indicating moderately high levels of crisis support.

Table 6. Social Support Factor Scores

Factor	Mean*	SD	Min	Max	Factor Loading
Social Support (α = 0.974, 14 items)					
H5: Someone who shows you love and affection	4.30	.872	2	5	0.723
H6: Someone to have a good time with	4.15	.936	1	5	0.810
H7: Someone to give you information to help you understand a situation	4.12	.946	1	5	0.733
H9: Someone who hugs you	4.18	1.030	1	5	0.798
H10: Someone to get together with for relaxation	4.04	1.025	1	5	0.883
H11: Someone to prepare you meals if you were unable to do it yourself	3.96	1.169	1	5	0.702
H12: Someone whose advice you really want	4.06	.957	1	5	0.811
H13: Someone to do things with to help you get your mind off things	4.00	.986	1	5	0.848
H14: Someone to help with daily chores if you were sick	3.87	1.168	1	5	0.743
H15: Someone to share your most private worries and fears with	4.06	1.042	1	5	0.806
H16: Someone to turn to for suggestions about how to deal with a personal problem	4.07	.998	1	5	0.792
H17: Someone to do something enjoyable with	4.08	1.008	1	5	0.872
H18: Someone who understands your problems	4.02	1.000	1	5	0.760
H19: Someone to love and make you feel wanted	4.18	1.015	1	5	0.789
Crisis Support (α = 0.847, 3 items)					
H1: How often do you have: someone to help you if you were confined to a bed	3.67	1.367	1	5	0.781
H2: Someone you can count on to listen to you when you need to talk	4.03	1.079	1	5	0.807
H3: Someone to give you good advice about a crisis	4.01	1.065	1	5	0.859
Items removed from analysis	**Mean**	**SD**	**Min**	**Max**	
H4: Someone to take you to the doctor if you needed it	4.11	1.097	1	5	
H8: Someone to confide in or talk to about yourself or your problems	4.22	.936	1	5	

The outcome variable of likelihood of joining a clinical study at baseline had a mean score of 5.83 (n=214, SD= 2.68) and a median score of 6 (0= definitely not, 10= definitely so). The most frequently selected score was a 5 with 42 responses and 19.0% of all responses (Figure 1).

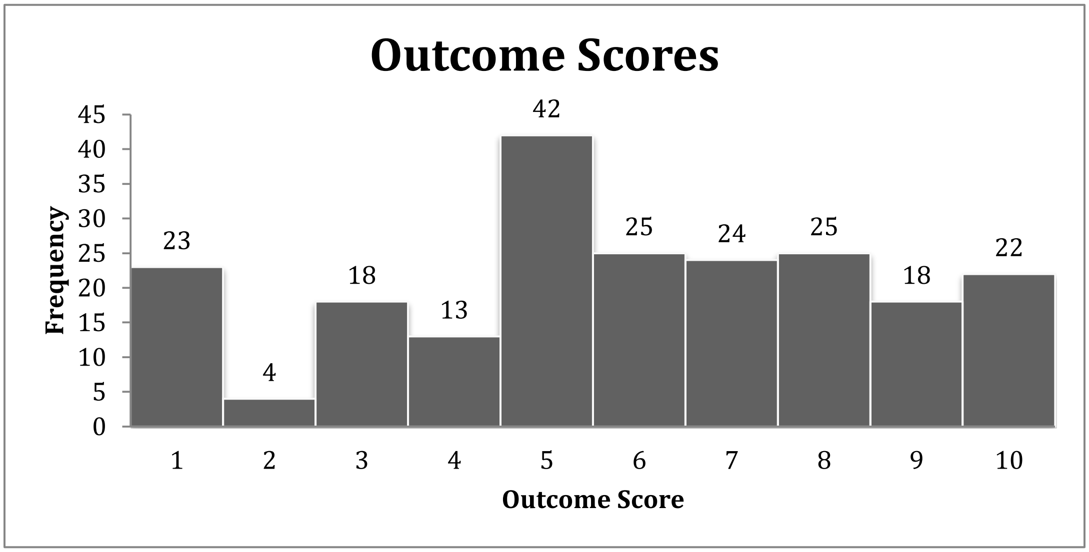

Figure 1. Outcome Score Histograms

Church Differences

An ANOVA analysis with Tukey's post hoc test demonstrated that there were no significant differences between the churches in mean outcome score (F= 2.170, p= .059). In addition, the majority of the independent factor variables did not demonstrate differences among churches including, *Social Support*, *Crisis Support, Basic Ability, Social Ability*, and *Errand Transportation*. However, *Strength and Mobility* was significantly different between churches (F= 2.468, p= .034); Turner Chapel scored an average of .774 points higher than Maranatha Seventh Day Adventist (p= .030), demonstrating higher levels of mobility impairment. Of the four individual long-term physical impairment items, three were not significantly different between churches:

reading the newspaper (F= .886, p= .492), *hearing a person* (F= .647, p= .664), *and walking up and down one flight of stairs* (F= .588, p= .709). One, *speaking without difficulty*, was significantly different (F= 2.530, p= .030) although the specific significance differences were not discovered by the post hoc test.

There were several demographic variables that differed between multiple congregations (Figures 2 and 3). These included *age* (F= .7.224, p= .000), *gender* (F= 5.690, p= .000), and *education* (F= 4.353, p= .001). *Partnership status* differed between two congregations (F= 3.774, p=.003) with Turner Chapel participants less likely to have a partner compared to Decatur Seventh Day Adventist participants (difference= .494, p= .001).

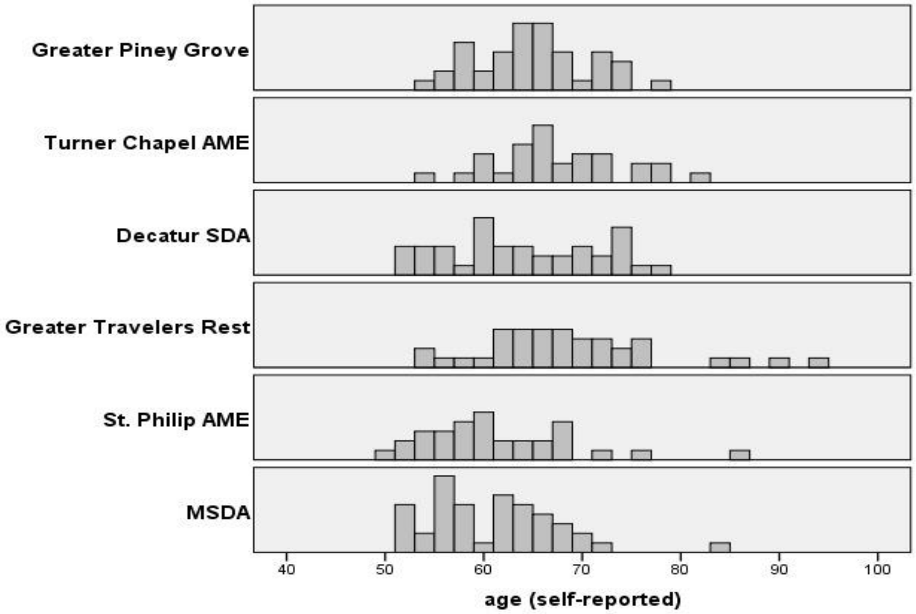

Figure 2. Age by Church

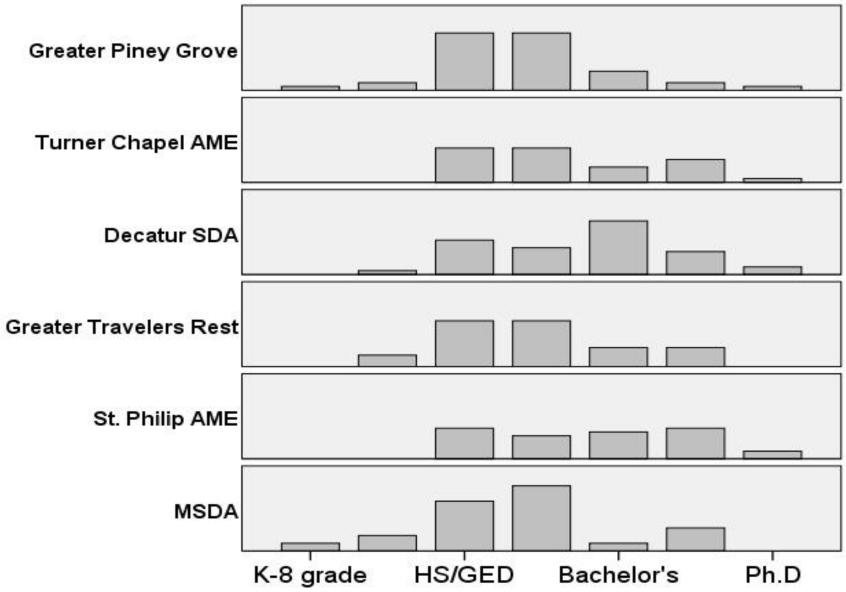

Figure 3. Education by Church

Correlations

A bivariate analysis was run to determine correlating factors. Several items were significantly related although the outcome variable was only significantly correlated with two factors. A negative correlation with gender (r= -.145, p= .039) suggests that women indicated lower likelihood to participate in clinical trials compared to men. The individual long-term physical impairment item, “walking up and down the stairs” was also significantly correlated (r= -.222, p= .002) indicating that those who experience more difficulty using stairs are less likely to participate in clinical studies.

Within the independent factor items, Social Support was related to Strength and Mobility (r= -.150, p= .035) and walking up and down stairs (r= -.197, p= .005). The negative correlations indicate that lower social support is associated with more difficulty in strength and mobility factors as well as more difficulty using stairs. Crisis Support was associated with hearing conversation (r= -.193, p= .007) proposing that a higher level of crisis support is related to better hearing.

Table 7. Pearson Correlation of Variables

	Age	Gender	Edu.	Income	Income Dichot.	Partner Status	Social Supp.	Crisis Supp.	Basic Ability	Stren. Mobile	Social Ability	Errand Ability	Read News	Hear Speech	Speak Easily	Walk Stairs
Gender	.103 (.131)															
Education	**-.150** **(.027)**	-.100 (.137)														
Income	**-.163** **(.022)**	**-.191** **(.007)***	**.415** **(.000)***													
Income Dichotomized (below 175% FPL)	-.096 (.182)	-.067 (.347)	**.321** **(.000)***	**.698** **(.000)***												
Partnership Status Single/partnered	-.126 (.062)	**-.317** **(.000)***	**.151** **(.025)**	**.419** **(.000)***	**.293** **(.000)***											
Social Support	.112 (.100)	-.100 (.141)	.097 (.151)	**.187** **(.008)***	.123 (.085)	**.238** **(.000)***										
Crisis Support	-.022 (.753)	-.059 (.387)	**.135** **(.045)**	**.210** **(.003)***	.127 (.075)	**.138** **(.050)**	.000 (1.000)									
Basic Ability	**.200** **(.005)***	.072 (.310)	**-.183** **(.009)***	-.084 (.261)	-.102 (.172)	.019 (.788)	.025 (.723)	.009 (.903)								
Strength and Mobility	**.254** **(.000)***	**.240** **(.001)***	-.135 (.056)	**-.309** **(.000)***	**-.227** **(.002)***	**-.268** **(.000)***	**-.150** **(.035)**	-.028 (.692)	.000 (1.000)							
Social Ability	.103 (.150)	.033 (.645)	-.076 (.283)	-.111 (.135)	-.103 (.168)	-.023 (.735)	-.076 (.287)	.057 (.428)	.000 (1.000)	.000 (1.000)						
Errand Transportation Ability	.032 (.655)	.012 (.870)	-.108 (.127)	-.059 (.430)	.041 (.580)	.045 (.529)	-.079 (.266)	-.049 (.496)	.000 (1.000)	.000 (1.000)	.000 (1.000)					
Reading Newspaper	.163 (.021)	-.045 (.526)	-.118 (.094)	**-.262** **(.000)***	**-.226** **(.002)***	-.014 (.838)	-.068 (.338)	-.134 (.058)	**.213** **(.003)***	.062 (.383)	**.166** **(.019)**	**.178** **(.012)**				
Hearing Conversation	.124 (.087)	.035 (.627)	-.060 (.407)	**-.159** **(.037)**	-.107 (.162)	-.027 (.708)	-.120 (.099)	**-.193** **(.007)***	.094 (.196)	**.188** **(.010)***	.120 (.099)	**.277** **(.000)***	**.335** **(.000)***			
Speaking With No Difficulty	.110 (.121)	-.070 (.325)	-.205 (.004)*	**-.181** **(.014)**	-.138 (.063)	.056 (.431)	-.051 (.475)	-.130 (.067)	**.249** **(.000)***	.074 (.301)	**.500** **(.000)***	**.363** **(.000)***	**.398** **(.000)***	**.529** **(.000)***		
Walking Stairs	**.300** **(.000)***	**.159** **(.024)**	**-.227** **(.001)***	**-.219** **(.003)***	-.128 (.083)	**-.182** **(.009)***	**-.197** **(.005)***	-.088 (.214)	.137 (.054)	**.619** **(.000)***	**.195** **(.006)***	**.178** **(.012)**	**.211** **(.003)***	**.319** **(.000)***	**.301** **(.000)***	
Likelihood of Joining Study	-.133 (.059)	**-.145** **(.039)**	.013 (.855)	.028 (.712)	.002 (.974)	.093 (.187)	-.004 (.955)	.027 (.699)	-.010 (.885)	-.103 (.154)	-.022 (.758)	-.072 (.318)	-.073 (.308)	-.031 (.676)	-.023 (.750)	**-.222** **(.002)***

$p \leq 0.05$, *$p \leq 0.01$

Logistic Models

Several multiple logistic models were run to assess the relationships between sociodemographics, independent variables and the outcome variable. The final model included four measures of sociodemographics, the two social support factors, the four functional impairment factors, and two interaction terms. Multicolinearity was assessed using Variance Inflation Factors (VIF), and all factors were below five and therefore within an acceptable range. The final overall model was significant (X^2= 22.46, p= .03) with a Naglekerke R^2 score of .15. The Hosmer and Lemeshow fit test was non-significant (X^2= 6.95, p= .54), indicating a lack of evidence for poor fit. Three of the independent variables were significantly related to likelihood to join a clinical study, Basic Ability (coefficient= -1.174, p= .03), Social Ability (coefficient= -.570, p= .02), and Errand Transportation (coefficient= -.750, p= .007). When stratified by age, Crisis Support also became significant for those over 65 years and the interaction term of age by crisis support was included as a significant factor (coefficient= -.750, p= .04).

Table 8. Logistic Regression on Likelihood of Joining Study

	Coefficient	Standard Error	Significance	Point Estimate	95% Confidence Interval
Age (0= <65, 1= ≥65)	.474	.329	.149	1.607	.844, 3.061
Gender (0=m, 1=f)	.275	.408	.500	1.317	.592, 2.929
Education (0=K-12, 1=A.A.-PhD)	-.040	.339	.907	0.961	.494, 1.868
Partnership (0=single, 1=partner)	.413	.366	.259	1.511	.738, 3.094
Social Support	-.188	.177	.290	0.829	.585, 1.174
Crisis Support	.195	.237	.411	1.215	.764, 1.932
Basic Ability	-1.174	.524	*.025	0.309	.111, 0.864
Strength & Mobility	-.113	.179	.528	0.893	.629, 1.268
Social Ability	-.570	.245	*.020	0.566	.350, 0.914
Errand Transportation	-.736	.274	**.007	0.479	.280, 0.820
Age*Crisis Support	-.750	.358	*.036	0.472	.234, 0.953
Partnership*Basic Ability	1.385	.757	.067	3.995	.906, 17.62

*p<.05, **p<.01

Additional models were run stratifying by demographic factors. As mentioned previously, the model stratified by age showed Crisis Support and Errand Transportation as significant among those over 65 years demonstrating that age is a modifier of crisis support among older adults. When stratified by gender, the model for women included significant variables of *Basic Ability*, *Social Ability*, and *Transportation*, while there was no significance in the model for men. Gender was introduced to the final model and was neither significant itself nor did it significantly modify any of the other variable coefficients and so it was discarded in the final model.

For those earning below $20,000, the only significant remaining factor was *Social Ability*. There were no significant factors for those earning above $20,000. Income was added into the model as a variable and it excluded *Errand Transportation* as a significant factor, which indicated a pathway association between income and *Errand Transportation*. With respect to *Errand Transportation* neither income nor the interaction term were significant and were both excluded from the final model.

The effect of education level was tested with an education scale dichotomized between high school and technical school. The stratified factors for those earning a high school diploma or less did not differ from those earning a technical degree or higher. Education as a factor was also not significant. The effect of having a spouse/domestic partner was also examined. All factors dropped out of significance for both the partnered and non-partnered groups, although partnership status affected *Basic Ability* somewhat. The interaction term of partnership and *Basic Ability* was not significant (coefficient= 1.385, p= .067).

Discussion

Findings

This study intended to discover various factors at the individual, interpersonal, and community levels of the Social Ecological Model that were predictive of enrollment in clinical trials among a population of black/African American church congregants over the age of 50. Results of the logistic regression models indicated that sociodemographics were not significantly related to likelihood of joining a clinical study. Multiple factors of social support were also not significantly related to likelihood of joining a clinical study; however, *Crisis Support* significantly predicted the outcome among seniors over the age of 65. Within the entire sample, the lower functional impairment scores within the factors of *Basic Ability*, *Social Ability*, and *Errand Transportation* significantly predicted higher likelihood of joining a clinical study.

The significance of three out of the four functional impairment factors indicates a high association between overall physical function and the willingness to participate in clinical trials. It is understandable that the barriers associated with ability to perform daily tasks would also contribute to the decreased likelihood of joining a study. The types of physical abilities for these factors include components such as basic hygiene like bathing and dressing, getting out into the community, and driving and performing errands. These are skills that are needed to independently interact with and participate in the community and also to participate in a clinical trial. Conversely, the functional impairment factor of *Strength and Mobility* was not associated with clinical trial participation. This particular factor identified abilities such as walking longer distances, performing chores, or more exertive physical activities—abilities that are generally not required in order to participate in a research study.

Among older participants, the interaction of *Crisis Support* is indicative of the special considerations that should be given to seniors over 65. The items in this scale included having “someone to help if you were confined to a bed,” having someone to “listen to you when you need to talk,” and having “someone to give you good advice about a crisis.” In the factor analysis, these measures clustered together and were interpreted as similarly serious requirements of social support, above and beyond the other items. The significance of this particular group among older participants suggests that their concerns are more serious and they may require greater support to overcome larger barriers to daily living activities.

The secondary research aims of this study were to understand which socio-demographic components were predictors of likelihood to join a clinical study as well as if specific church membership played a significant role in research participation. Among our sample, there were no significant sociodemographic factors that indicated clinical trial participation. Similarly, specific church membership had no significant effect on the outcome variable. However, there were relationships between particular congregations and various sociodemographics, even within the same denomination. This suggests that researchers utilizing churches as an intervention site or network for enrollment will want to take into account the specific demographic characteristics of the church with which they are working.

Finally, bivariate analyses did indicate associations between sociodemographics and *Social* and *Crisis Support* factors. *Social Support* had a significant positive correlation with income and partnership status (partner= 1, single= 0). *Crisis Support* was positively correlated with income, education level, and partnership status. Therefore, higher levels of education, income, and having a partner (themselves all significantly positively correlated) indicate higher levels of support. While these are not related to the outcome variable, it is important to note that disparities in social support may exist within a congregation based on demographic factors.

Conclusions

The most significant predictor of enrollment was related to functional impairment. Basic function may have greater impact on clinical trial enrollment than other commonly perceived factors such as historical distrust of medical research and lack of knowledge about the medical field [10-12]. In turn, the lack of significance for social support demonstrates that barriers may play a larger role in clinical trial enrollment than facilitators, a premise that has not yet been thoroughly investigated in the literature. Even if individuals have those around who are willing to drive them to the clinic or support their decision to enroll, the inability to get dressed in the morning is, understandably, a greater hurdle to overcome. That sociodemographics were not found to be significantly related to clinical study enrollment encourages researchers to continue to recruit diverse participants, enhancing the generalizability of their outcomes while not limiting their enrollment goals.

The interaction of *Crisis Support* and age indicates that special consideration for seniors over 65 should be taken. They may have unique needs that are not alleviated from more common forms of support and would need special encouragement to participate in clinical studies. Reviews of past research have shown that enrollment drops dramatically after the age of 35 and continues to fall as participants age; this especially impacts black seniors who are already disproportionately less likely to participate due to race [39-41]. Research staff may want to reach out to nursing or personal care aides for help reaching those who need added assistance with their living functions. In addition, the items related to a support system that includes both someone who listens and someone who gives advice hearkens to the strategy of partnering with trusted sources of care and community members who may have a broad reach to seniors. As tested in the Dose of Hope study—as well as other faith-based projects—a church-based recruitment strategy that enlists pastors and other church leaders may address those very forms of crisis support that older seniors depend upon [50, 53].

Finally, the results of this study are a good reminder that the black church is not a monolith. While there is strong evidence of the many protective factors that the church offers to congregants, large differences in sociodemographics were clear in this study and represented educational and income diversity both between and among congregations [16, 48, 49]. Church leaders and especially health ministers will want to take this range into account when developing programs and not assume a singular base of knowledge or level of accessibility across their congregants.

Strengths

This study had many strengths which facilitated the identification and validity of significant outcomes. The measures, including the four functional ability factors and two social support factors, had very high reliability scores, all over 0.75. This increased confidence in the ability of our instruments to capture the intended constructs. In addition, there was a large variation in the outcome variable. Responses ranged from one to ten (median= 6), demonstrating that we had captured attitudes from those who were both definitely interested and definitely not interested in participating in clinical research. Finally, the sample was drawn from a unique population. While faith-based institutions are becoming increasingly common venues to develop interventions for and recruit from, there is still insubstantial evidence of the effectiveness of the church as a recruitment location. This study uniquely examines which other factors relative to the experience of seniors may hinder or motivate their participation in clinical trials.

Limitations

There were unavoidable components of this study that limited our findings. There was little variation in the independent variable scores. Most of the congregants indicated on average very low levels of functional impairment and moderately high levels of social and crisis support. This lack of variation may indicate that those who were more likely to participate in the Dose of Hope research study were also higher functioning and have higher support, perhaps through closer contact with their church's pastor or health ministry; however, that does limit our generalizability to the larger congregation. In addition, this analysis was cross-sectional and therefore could not demonstrate causality of the variables. The outcome variable was self-reported and measured likelihood of participation rather than actual enrollment in a study; there may still be fall off from those who are likely to participate to those who actually enroll in studies.

Furthermore, our sample size of 191 limited the ways in which the logistic models could be analyzed. Stratification on gender, income, education, and age resulted in samples that were too small and ultimately lost power for significance. There was also not a non-church comparison group to specifically demonstrate the effects of church membership on clinical trial participation. These limitations do open opportunities for future research.

Implications and Recommendations

Researchers should focus on reducing barriers to clinical study participation among seniors. Specifically, working on increasing transportation options and finding ways to increase participation of those who are homebound or unable to access traditional recruitment venues may reduce the existing barriers presented by functional impairments. New recruitment venues such as nursing homes may be necessary to adequately incorporate participants who cannot be recruited in traditional settings. In addition, studies may need to be relocated to those very institutions where seniors reside such as senior living facilities or nursing homes so that they can fully participate in the study with fewer impediments.

Additional research should examine specifically the role of social support within the church by including a comparison group of seniors who are not members of a congregation. While matching with a non-church control would be challenging due to the many distinctive characteristics in sociodemographics and other factors that follow church attendance and membership (beliefs, social support, social networks, etc.), perhaps comparing church members with participants in a well-established community organization will single-out the associations with religiousness. In addition, comprehensive instruments including several scales may be able to capture many of the characteristic differences between the samples, which may be accounted for in statistical models.

New interventions may want to test alternative recruitment possibilities for seniors with impairments and identify if there are yet additional barriers even if items related to daily living are removed. Finally, other studies may investigate ties between partnership and basic abilities—an interaction that was not significant ($p= 0.067$) in our model but may still have a relationship with a larger sample. Having a partner or spouse to assist with the activities included in the Basic Ability scale could be influential in determining whether those who were inhibited by impairments could be potential clinical trial participants if their partner were able to help them participate. This study opens the possibility for many future avenues of research and encourages the use of a multi-layer, comprehensive model, such as the social ecological model, in considering factors that may affect clinical trial enrollment, especially among black seniors.

Appendices

Appendix A: Functional Impairment Instrument

L1-L15. Please place an x in the appropriate box to indicate if during the past month you had difficulty with the following statements due to your health restrictions (1='No Difficulty,' 4='Too Difficult to Do').

	1 No difficulty	**2 Some difficulty**	**3 Much difficulty**	**4 Too difficult to do**	**5 Not Applicable**
Feeding yourself?					
Dressing yourself?					
Moving in and out of bed?					
Bathing yourself?					
Walking around your home?					
Walking several blocks?					
Doing house chores such as cleaning?					
Doing errands, such as grocery shopping?					
Driving a car?					
Using public transportation?					
Lifting heavy objects?					
Doing physical activity such as running?					
Visiting other peoples' homes?					
Participating in community activities, such as religious services, social activities, or volunteer work?					
Taking care of other people such as family members?					

Long-term Physical Abilities

M1-M4. Please place an x in the appropriate box to indicate if on a normal day you have difficulty with the following statements. If you have any temporary health issues at the moment, do not include them when choosing an answer.

	1 No difficulty	**2 Some difficulty**	**3 Much difficulty**	**4 Too difficult to do**	**5 Not Applicable**
Reading the newspaper? (with glasses if normally worn)					
Hearing a person during conversation? (with a hearing aid if you usually wear one)					
Speaking without difficulty?					
Walking up and down one flight of stairs?					

Appendix B: Social Support Instrument

Please place an x in the appropriate box for each question to indicate how often each of the following kinds of support are available to you if you need it (1 = 'None of the Time,' 5 = 'All of the Time')

	1 None of the Time	**2 A Little of the Time**	**3 Some of the Time**	**4 Most of the Time**	**5 All of the Time**
Someone to help you if you were confined to a bed					
Someone you can count on to listen to you when you need to talk					
Someone to give you good advice about a crisis					
Someone to take you to the doctor if you needed it					
Someone who shows you love and affection					
Someone to have a good time with					
Someone to give you information to help you understand a situation					
Someone to confide in or talk to about yourself or your problems					
Someone who hugs you					
Someone to get together with for relaxation					
Someone to prepare your meals if you were unable to do it yourself					
Someone whose advice you really want					

Someone to do things with to help you get your mind off things					
Someone to help with daily chores if you were sick					
Someone to share your most private worries and fears with					
Someone to turn to for suggestions about how to deal with a personal problem					
Someone to do something enjoyable with					
Someone who understands your problems					
Someone to love and make you feel wanted					

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