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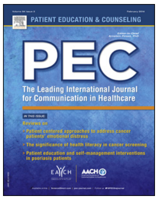

Enrollment in clinical trials

# Outcomes from the Body & Soul Clinical Trials Project: A university-church partnership to improve African American enrollment in a clinical trial registry

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ABSTRACT

*Objectives:* Historically, African Americans have been underrepresented in clinical trials (CTs) compared to whites. A growing number of research institutions have created CT registries to match volunteers with appropriate studies. In a sample of 745 African Americans from 16 churches, we tested the impact of a culturally tailored intervention aimed at increasing enrollment in a university-based CT registry.

*Methods:* Half of the churches received a culturally tailored CT education program (intervention) and half of the churches received a program about healthy eating (comparison). The main outcomes were the odds of post-test self-reported enrollment and verified enrollment. Using linear regression, post-test willingness to participate in a CT was also assessed.

*Results:* Odds of verified enrollment were higher in the intervention than comparison group ($OR = 2.95$, 95% CI: 1.33–6.5, $p = 0.01$). Post-test self-reported enrollment in the registry was also higher among the intervention group than comparison group members ($OR = 1.94$, 95% CI: 1.08–3.47, $p = 0.03$). Willingness to participate in a future CT was higher in the intervention group ($\beta = 0.74$, $p = 0.02$).

*Conclusions:* A culturally tailored education program about CTs can increase enrollment of African Americans in a university-based clinical trials registry.

*Practice implications:* Community engagement and health education workshops may improve minority CT enrollment over time.

## 1. Introduction

Clinical trials (CTs) are the mechanism by which new methods of screening, prevention, diagnosis, or treatment of disease are developed and tested. In addition to benefitting society at large, CTs may benefit individual volunteers by providing access to new treatments before they become available to the general public. Since 1993, the NIH has required that all sponsored research include adequate representation of women and minority groups [1]; however, participation of African Americans (AAs) in CTs remains low [2,3]. Without adequate representation of AAs and other minorities in CTs, it is impossible to know if therapies will work equally well across populations and how, if at all, progression of disease may differ by racial/ethnic subgroup.

Over the last 10 years, the use of registries as a method to recruit study participants has grown. registrymatch.org was the first national registry to promote clinical trials across NIH-funded Clinical and Translational Science Award (CTSA) programs [4]. A small number of research institutions have created local registries to match potential volunteers with relevant clinical trials [5]. These newer "opt-in" registries allow healthy volunteers and patients with health conditions to proactively enroll in the registry. Once a profile is created, members of the registry begin receiving "personalized study recommendations" [6], thus eliminating the need for health care providers to serve as gatekeepers.

Commonly reported reasons for lower CT participation among AAs include distrust of health care institutions, fear of experimentation, lack of awareness of CTs and how to find them, and limited representation of minority investigators [7–10]. Logistical factors such as transportation, protocol design, and lack of social support may also impact participation [11]. There is a growing body of evidence showing that minorities are just as willing to participate

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in health research as their white counterparts when provided with a culturally appropriate opportunity or invitation [12,13]. Although the predictors of CT registry participation have not been adequately examined, many of the same factors associated with CT participation are likely to be associated with registry use among AAs.

Previous efforts to improve the CT knowledge of AAs have largely focused on building trust or addressing the history of medical abuse in the AA community [14,15]; however, relatively little has been done to investigate the best strategies for improving awareness of local CT registries. More specifically, the role of faith-based interventions as a means to enhance minority participation in CTs has not been adequately explored. Faith based interventions have been conducted around a variety of health issues such as healthy eating and physical activity [16–21]. However, a faith-based setting has not been used as a vehicle to enroll AAs in a CT registry. To assess the efficacy of a CTs education program in a faith based setting, we collaborated with black churches in Southeast Michigan to implement the Body & Soul Clinical Trials Project.

The primary aim of this study was to examine the effect of a culturally tailored CTs education program on church members' enrollment in the University of Michigan Clinical Studies Registry.

## 2. Methods

### 2.1. Formative research

Prior to recruiting churches, a pastors' advisory board (PAB) was created to provide feedback about what would be feasible and appropriate in their churches. The PAB was comprised of clergy serving as head pastors or support staff. The group included five men and two women, three with Master of Divinity degrees, and one with a PhD. All clergy were from local predominantly AA Christian churches and represented the Baptist, Apostolic, African Methodist Episcopal, and Free Methodist denominations. The PAB met quarterly in the first year of the project, then twice a year after that. The PAB provided feedback on several aspects including content for recruitment materials, content for our CTs video and educational workshops, pre-test and post-test survey items, and strategies for successful recruitment and retention. At each PAB meeting, breakfast was served and a $50 Visa gift card was given in return for the pastors' time and feedback.

Additionally, a focus group comprised of 10 church members (three men and seven women) from churches in the Detroit Metro area was conducted in August of 2011. The group provided feedback on the survey tool, recruitment materials, and specific points that should be covered in the educational materials for healthy eating and CT education (e.g., the top 10 causes of death for AAs, healthier ways to cook soul food, and protections for research participants).

### 2.2. Church recruitment

Church recruitment began in July 2011 with the mailing of an introductory letter and a brochure to approximately 200 African American churches in Southeast Michigan, all of which are in 60-mile radius of the registry housed at the University of Michigan in Ann Arbor. This mailing was followed by telephone calls and e-mails with interested pastors or health ministry members, and when possible, an in-person meeting. After personal contact was made with the pastor, both the pastor and designated church coordinator signed a commitment agreement that outlined roles and responsibilities for the church and the study team.

Power calculations assumed an enrollment rate in comparison churches of 5–10% and 10–20% among intervention churches. Due to the cluster randomized design we needed to account for the effect of sampling individuals from clusters (churches) rather than randomly sampling individuals from the population [22]. This required computing a Variance Inflation Factor based on the Intracluster Correlation (ICC). The precise ICC of enrollment was not known; however, based on our prior studies of other health behaviors in churches [17,23–25] we estimated an ICC of around 0.02. With these parameters and 40 individuals per church, power of 0.80 and alpha of 0.05, we required six churches per condition. To account for possible church attrition we oversampled churches by two per arm, leaving eight churches per arm. We randomly assigned churches to the comparison group or intervention group. We classified churches into three size categories for purposes of pair matching; small (<200 members), medium (200–400 members), and large (>400 members) churches.

### 2.3. Participant recruitment

Church coordinators were given a goal of recruiting 40–60 members from their church. The recruitment strategy was left to the discretion of the coordinators; however, we provided promotional flyers for display around the church and talking points about the study. Coordinators were encouraged to recruit individuals by making church announcements, posting information on bulletin boards, and by making appeals to groups within the church that met regularly (e.g., choir, bible study, and women's ministry).

### 2.4. Comparison group protocol

The comparison churches received an adapted version of the national Body & Soul program, which promotes fruit and vegetable intake and is tailored for AA church members. The original Body and Soul program used four program pillars: pastoral support, church activities, church environment, and peer counseling. At the suggestion of our Pastors' Advisory Board, we added information on heart disease, cancer, type 2 diabetes, stress management, how to read nutrition labels, and healthy eating recommendations since many of their church members suffer from chronic diseases. A website was created for the comparison group with general information about CTs and medical research. The information presented on the comparison group website was taken directly from the University of Michigan Clinical Studies web page and was not tailored for AAs.

### 2.5. Intervention group protocol

The intervention churches received a CTs education module that was developed from materials from the National Medical Association's Project IMPACT campaign, feedback from our Pastors Advisory Board, and input from colleagues at the University of Michigan Clinical Studies Registry (umclinicalstudies.org). The goals of the tailored CTs module were to: (1) raise awareness about CTs, (2) describe the research process, and (3) describe the role of race and culture in medical research. Given the sensitive nature of medical research for some AAs, in addition to addressing issues related to racism and medical exploitation we also provided messages about the potential positive reasons why AAs may want to participate in research and how diversity in CTs may help improve the health of AAs. Other topics in the module included epigenetics (the concept that the human genome dynamically responds to social and environmental factors such as toxins and stress), common terminology (e.g., informed consent, randomization), the process for developing new therapies (e.g., phase 1–4), and study participant rights and protections.

Participants in the intervention group watched a short, locally produced video about CTs that highlighted the need for more AAs