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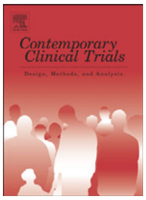

Recruitment of a rural, southern, predominantly African-American population into a diabetes self-management trial

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ABSTRACT

We are conducting a community-based cluster-randomized trial in rural Alabama, testing a peer-support intervention designed to improve diabetes self-care behaviors. We describe recruitment and data collection approaches used, focusing on strategies that created community partnerships and facilitated recruitment in underserved, rural, largely minority communities. Key recruitment and data collection strategies included early community engagement; pilot testing of procedures; inclusion of community members as study team members, recruiters, and data collectors; data collection at community venues to minimize participant travel requirements; and provision of a multi-disciplinary diabetes education program to both intervention and control participants. A total of 424 participants were recruited and enrolled (400 targeted). Of the 759 referrals received, 78.9% ($n = 599$) successfully completed telephone screening. Of these, 78.8% ($n = 472$) were eligible and scheduled for a local enrollment day, and 81.4% ($n = 384$) attended and enrolled in the study. In addition, community members who walked in and expressed interest were screened, and 40 eligible and willing individuals were consented and enrolled.

We exceeded recruitment goals in underserved, rural communities in Alabama. This success was due in large part to community partnerships that facilitated community involvement on several levels: engaging the community early in study proposal and design; hiring community members to fill various capacities as research team members, recruiters, and data collectors; conducting data collection within communities; and collecting additional contact information to maintain communication. Providing diabetes education to all participants, including intervention and control, helped ensure that everyone stood to benefit and likely enhanced overall participation.

1. Introduction

African Americans bear an excess burden of chronic diseases such as type 2 diabetes, hypertension, and obesity [1]. Nowhere is this burden greater than in the southeastern United States, where high rates of uncontrolled hypertension and diabetes are accompanied by high stroke and coronary heart disease mortality [2–4]. In Alabama, for example, where 10.8% of adults have been diagnosed with diabetes, the highest rates are concentrated in the Black Belt, 18 counties in the state's southern region named for the rich, black topsoil. In this region, 75% of the population is African-American, one in three adults over age 50 has diabetes, and over half of the population is overweight or obese [3,5].

The burden of chronic disease particularly affects rural, southern residents, who face considerable barriers in meeting their chronic disease self-care needs, including distance, paucity of medical resources, low educational attainment, high poverty rates, and scarce sources of healthful foods. Chronic disease management is complicated further in the South by the legacy of Tuskegee, Alabama, site of the infamous Tuskegee syphilis experiment, which is well-known

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to area residents and continues to engender widespread mistrust in the healthcare system in general and medical research in particular [6].

Under these circumstances, it is perhaps unsurprising that few diabetes self-management interventions focus specifically on rural, southern African Americans. Minorities are generally underrepresented in clinical trials [7,8], but even fewer southern African Americans participate, although they represent over 10% of African Americans nationwide, and nearly all rural African-American residents live in the South. Nevertheless, this region urgently needs effective interventions to improve diabetes self-care.

A growing body of literature focused on improving minority participation in research has revealed some key areas that researchers should address [9–11]. One study identified three viewpoints that were unique but equally important to ensure successful recruitment and retention efforts: potential study subjects, their healthcare providers, and staff at the health centers where they receive their care [12]. Researchers also have identified the importance of building a trusting, reciprocal relationship between the study team and members of the community [13,14]. In addition, being randomized to the control group, which can frustrate any participant wishing to receive the intervention, may particularly disappoint individuals with limited access to much needed resources [15–17]. This literature has an important gap, however, because much of the current information on recruitment and retention of minority populations comes from studies limited by small sample sizes or by being medical center-based clinical trials rather than community-based research studies [10,12,14].

This paper aims to expand the currently limited literature on strategies for recruitment of rural African-American populations into randomized trials. The authors present their experience with recruitment and baseline data collection in the rural Alabama Black Belt for a community-based, cluster randomized controlled trial of a community-based peer-support intervention designed to improve diabetes self-care. This paper includes results of the recruitment efforts as well as a summary of challenges, barriers, and lessons learned during successful recruitment and baseline data collection.

2. Methods

2.1. Community engagement

Prior to developing and submitting the study proposal for funding, study investigators carried out community engagement activities by partnering with an ongoing community coalition established for cancer prevention improvement. Coalition meetings had consistently included calls for diabetes programs, prompting this proposal, and when the study team received notice of funding, they collaborated with this coalition to hold a discussion group with community members. With this discussion group, study investigators solicited input on study design as well as advice on recruitment approaches.

Early in the funding period, study investigators employed three part-time community coordinators as members of the research team. Community coordinators, who lived within the target population, already held leadership roles or had been involved previously in University of Alabama at Birmingham's community-based programs. Because of this experience, they were able to liaise with members of the community, including primary care practices. They also provided input regarding the design and implementation of recruitment approaches. Their early involvement proved to be invaluable in achieving cultural concordance and enhancing the acceptability of study procedures.

In addition to partnering with a community coalition and employing community coordinators, study investigators involved local community primary care practices located in Wilcox, Dallas, Perry, Hale, Greene, and Sumter Counties in Alabama (Fig. 1) in order to obtain critical buy-in. After community coordinators identified potential clinics for engagement, investigators made an initial telephone contact with physicians to provide a brief overview of the study. If providers expressed interest, then a luncheon at the practice was scheduled, during which an investigator and community coordinator presented the study to the clinic physicians and staff members. The study team emphasized the trial's randomized design, making it clear that practice participants who enrolled in the study could receive either of these conditions. The luncheon also served as an occasion to designate a practice champion, who agreed to both promote recruitment

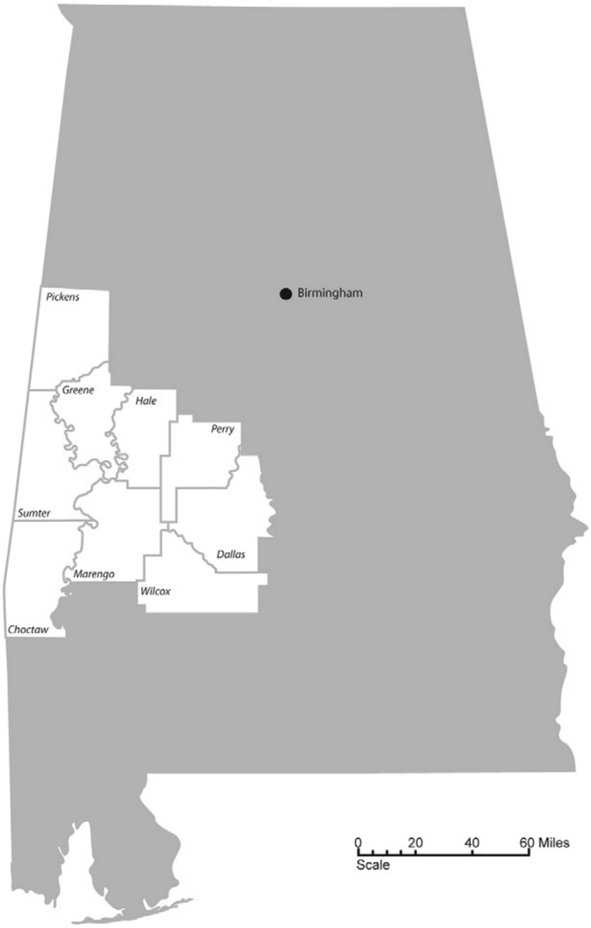

Fig. 1. Map of Alabama showing Encourage partner communities and Birmingham, the site of University of Alabama at Birmingham.