# It Is Not Just About Enrollment: Recognizing the Impact of RCT Recruitment Approaches on Prediabetes Awareness, Screening, and Capacity Building in African American Communities

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## Background

Diabetes is a growing epidemic in the USA. Compared to white Americans, African Americans are 1.8 times more likely to have diabetes [1]. Additionally, African Americans with diabetes experience higher rates of morbidity and mortality than other racial groups. Compared to whites, African Americans are twice as likely to suffer from diabetes-related blindness, 1.5 to 2.5 times more likely to suffer from lower limb amputations and 2.6 to 5.6 times more likely to suffer from kidney disease [1, 2]. Prediabetes is a common precursor to diabetes and characterized by blood glucose levels that are above normal but below the criteria for a diagnosis of diabetes [3]. Approximately 30% or 88 million US adults have prediabetes [4] with African Americans disproportionately affected. During the average 3 years of follow-up of the landmark Diabetes Prevention Program, prediabetes developed into type 2 diabetes in approximately 11% of the subjects who participated in the standard care or control group [5]. Other estimates show that if prevention strategies are not implemented, individuals with prediabetes will be diagnosed with type 2 diabetes within 10 years [6]. While African Americans with prediabetes are at significant risk for developing diabetes, this outcome is not inevitable. Diagnosis of prediabetes is an example of secondary prevention, screening to identify diseases at an early stage, before symptoms begin [7]. The identification of prediabetes, and subsequent secondary prevention efforts to thwart or delay transition to diabetes, can reduce morbidity, impaired quality of life, monumental healthcare costs, and mortality rates [1, 2, 8, 9].

There is compelling evidence that prevention strategies (e.g., physical activity for at least 30 min per day for 5 days per week and a 5–10% reduction in body weight) can significantly delay the onset of, or reduce, development of diabetes [6]. Although primary prevention strategies are the most successful approach in reducing diabetes risk, health professionals are challenged in motivating individuals to initiate and sustain these strategies [8].

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Our research team aimed to address these challenges by designing and implementing the "We Can Prevent Diabetes" research study [10]. The primary aim of the study was to investigate the feasibility of conducting a randomized trial comparing a novel mindfulness-based stress management program combined with diabetes risk-reduction education versus a conventional diabetes risk-reduction education program among African American adults with prediabetes and self-reported life stress. Our approach involved addressing psychological stress, which has been reported as a major roadblock to weight control behavior [11]. Unmanaged stress can limit the time and energy available to partake in physical activity as well as influence behavior and physical health directly [12]. While stress exposure may not be controllable, there is great potential value for stress management interventions to decrease diabetes risk in individuals with prediabetes [13].

The "We Can Prevent Diabetes" clinical trial conformed to Consolidated Standards of Reporting Trials [CONSORT] [14] guidelines. The components of the study integrated adapted curricula from the three evidence-based programs, the *Diabetes Prevention Program* [5], the *Power to Prevent* Program (National Diabetes Education Program) [14, 15], and *Mindfulness-Based Stress Reduction.*[19] Study procedures and consent forms were reviewed and approved by the Institutional Review Board of the University of North Carolina at Chapel Hill (UNC). The attention-control design of the study, described in a previous publication [15], involved eight, 2.5-h, weekly intervention sessions held at a local middle school, supplemented by a half-day retreat between weeks 5 and 6. Then, participants attended six, once-per-month booster sessions. Sixty-eight participants were randomized to the mindfulness-based diabetes risk-reduction education program for prediabetes (MPD; $n = 38$) or the conventional diabetes risk-reduction education program for prediabetes (CPD; $n = 30$). Self-report and biomarker assessments were conducted at baseline and 2 weeks, 3 months, and 6 months post intervention. Participation and engagement demonstrated general feasibility, with enrollment of 79% of eligible participants, engagement of 76.5% of participants in 6 or more intervention sessions, and retention of 90% of all enrolled participants in the intervention components. Furthermore, post-intervention data collection attendance was 83% of participants at 2 weeks post intervention, 82% of participants at 3 months post intervention, and 78% of participants at 6 months post intervention. Compared to participants in the control group, those in the mindfulness-based diabetes risk-reduction intervention arm experienced lower levels of stress and BMI and reduced intake of calories, carbohydrates, and fats.

Challenges related to implementing interventions that effectively assist individuals in initiating and sustaining the necessary behavioral changes leading to improved health begin with recruitment and screening. This is particularly relevant for studies that target *prevention* of chronic illness, like the "We Can Prevent Diabetes" study. Although prediabetes awareness has increased over the past decade, prediabetes is still a "silent condition" with potentially devastating effects [16]. Researchers targeting samples of African American adults with prediabetes are tasked with identifying a condition in potentially eligible participants who may not even know that they are at risk. Therefore, recruitment strategies are optimal when they integrate culturally sensitive screening and education components to enhance participation in clinical research to reduce diabetes risk among African American adults with prediabetes. Furthermore, identifying which recruitment strategies are most effective at yielding enrollment is a critical step to designing and implementing future successful studies to reduce or prevent diabetes risk.

The objective of this paper is to describe the strategies implemented to recruit African American adults with prediabetes into the "We Can Prevent Diabetes" trial. We describe the multi-step, culturally sensitive, community- and stakeholder-engaged recruitment and screening process, which provided education and awareness about prediabetes and its risk factors. We also describe which recruitment approaches contributed the most to the final randomized sample. Implications for designing studies to maximize efficiency of recruitment processes while also raising awareness of chronic health risk in African American communities are discussed.

## Implementing Culturally Sensitive Screening and Recruitment Approaches for African Americans at Risk for Prediabetes via Community and Stakeholder Engagement

As described in our previous publication [10], the study design included a three-step screening and recruitment process: (1) Step one involved screening of potential

participants to determine their scores on a Diabetes Risk Questionnaire (DRQ), (2) step two involved completion of a telephone-based screening questionnaire to share additional information about the study and to assess potential participants' status regarding study inclusion/exclusion criteria, and (3) step three involved baseline assessment, which included completion of self-report questionnaires and laboratory testing to identify or confirm prediabetes status (fasting blood glucose (100–124 mg/dL; 5.6–6.9 mmol/L), an oral glucose tolerance test (OGTT) (140 mg/dl–199 mg/dl), or glycosylated hemoglobin A1C levels (5.7–6.4%; 39–46 mmol/mol). Study procedures and consents were reviewed with participants at each stage of the screening process.

We describe the multi-step, culturally sensitive, community- and stakeholder-engaged recruitment and screening process, which provided education and awareness about prediabetes and its risk factors. We also describe which recruitment approaches contributed the most to the final randomized sample ($n$=68). The step one screening phase included multiple approaches including (1) in-person community screening events (workplaces, African American churches, and fraternal organizations); (2) cultural events; (3) written advertisements (newspaper ads and flyers); (4) multimedia recruitment (television and radio appearances); (5) referrals by healthcare providers, friends, family members, and previous study participants; and (6) utilization of a major healthcare system's patient registry (Data Warehouse).

The in-person community screening events were elaborately conducted with goals for providing education and enrolling engaging potential participants. On average, two to six research team members set up tables, the study banner, prediabetes and diabetes educational resources, the study brochure, DRQ screening worksheets, and information for eligible and interested individuals to follow-up for more information about the second stage of screening. At some events, study staff completed point-of-care random capillary glucose testing. Venues included lobbies of large healthcare institutions, employee wellness events at a historically black college/university (HBCU), a community college, a large black-owned insurance company, a senior center, and a local parks and recreation branch. Screening and announcements at African American churches and fraternal/sorority organizations provided opportunities for study staff to meet with clergy and parishioners. A total of three churches were involved. Study staff were invited to make announcements at Sunday Service, Bible Study, and a board meeting of a sorority. The busiest screening event ironically took place at a recently closed fast food restaurant connected to a large, popular retail story. Patrons were attracted to the study team's screening set-up and the opportunity to have random blood glucose levels assessed.

Study team members were also invited to educate, screen, and recruit participants at cultural events. At one event, our study team collaborated with another project aiming to recruit African American adults with type 2 diabetes. The two study teams had adjacent booths and formed a relationship during the life of both studies that resulted in referral to one another's research studies. Another cultural event was sponsored by the major African American radio syndicate in the region, and another event included a conference for African Americans who identified as LGBTQIA+. Study staff also appeared on a local network television show and a local radio show to discuss prediabetes, risks, outcomes, and diagnostic approaches. All of these approaches resulted in "snowball" effects, as well as referrals from family members, friends, and former study participants. Another notable referral source included healthcare provider officers. For example, study staff were invited to provide an "in-service" to physicians and nurses of a large medical office that provided care to members of the local African American community. A relationship was nurtured between the healthcare professionals and the study staff, which resulted in referrals and sharing of prediabetes educational resources to the medical office's patient population.

Over 34% of all randomized participants were recruited from newspaper advertisements. A series of ads describing the study were placed in three distinct newspapers: a mainstream newspaper with one of the highest circulation rates in the region, a 90-year-old, historic African American newspaper, and a 40-year-old regional, independent newspaper. The highest number of participants was recruited from ads placed in the mainstream newspaper (26%).

The second highest number of participants (14%) were recruited from the Carolina Data Warehouse for Health (CDW-H), "a central data repository of clinical, research, and administrative data sourced" from a large multi-campus, healthcare system (North Carolina Translational and Clinical Sciences Institute, 2021) [17]. To identify likely eligible African American adults with prediabetes, we work with the CDW-H analyst by

providing relevant patient demographics, diagnostic codes, and lab test results to obtain a names, addresses, and phone numbers of patients who did not voluntarily opt-out of being contacted for participation in potential research studies. Our team of study staff mailed letters and made phone calls to CDW-H-identified individuals to enhance enrollment.

All screening for prediabetes risk included completion of the 10-item DRQ to determine or confirm known risk factors among the potential African American participants, including prior delivery of baby weighing 9 pounds or more, sibling or parent with diabetes, previous diagnosis of high blood pressure or abnormal lipid levels, BMI over 25, less than 150 minutes of exercise per week, and aged 45 or above. A score of 10 or higher was indicative of increased risk of diabetes. A total of 442 persons were screened during the "We Can Prevent Diabetes" study. Among those 358 individuals had a DRQ score > 10, which indicated increased risk for future cardiometabolic conditions. Those individuals were then contacted for a telephone-based screening (screening step two) to further determine eligibility for randomization. Inclusion criteria for study enrollment were (1) self-identification as African American; (2) 25–65 years of age; (3) meeting the ADA criteria for prediabetes (either by fasting plasma glucose (FPG) of 100–125 mg/dl or glucose of 140–199 mg/dl at 2 h in an oral glucose tolerance test (OGTT) or a HbA1c of 5.7–6.4%; (4) reporting "some" degree of stress; and (5) willing to attend 1 1/2-h group meetings once weekly for 8 weeks, followed by monthly booster sessions for 6 months, and to complete assessment instruments. Exclusion criteria were (1) diabetes diagnosed by a physician; (2) past or current use of hypoglycemic medication (except for gestational diabetes); (3) disease associated with disordered glucose metabolism (e.g., Cushing's syndrome); (4) regular use of medications associated with impaired glucose metabolism (e.g., oral or parenteral steroids); (5) active treatment for or history of a major medical illness such as coronary heart disease, congestive heart failure, malignancy, and autoimmune or immune deficiency disorder; (6) previous formal training in meditation and other mind/body practices including yoga, tai chi, or qi gong; (7) psychosis or significant depression, anxiety, or substance abuse under active care (> 2 mental healthcare visits per month) or requiring more than 2 psychotropic medicines daily or hospitalization within the past 2 years; (8) pregnancy or anticipated pregnancy; or (9) impaired cognition (inability to follow and respond appropriately during screening). If passed this stage, the telephone screen concluded with screening for endorsement of life stress; they were screened for a 14-item Perceived Stress Scale [18] score higher than 7.5 or an endorsement of significant life stress.

After telephone screening, 165 of the 358 individuals completed clinical laboratory assessment to determine or confirm prediabetes status, the third screening step. At the CTRC visit, written consent was obtained after laboratory procedures were described. Next, height, weight, blood pressure, and WHR were measured. Then a capillary glucose test was conducted to ensure that subjects were at safe glucose levels to receive the glucose solution for the OGTT. Next, a butterfly catheter was placed and blood samples taken for fasting lipids, HbA1c, and for glucose and insulin at 0, 30, and 120 min during the oral glucose tolerance test (OGTT). Subjects used laptop computers to complete web-based study measures while awaiting their 30- and 120-min OGTT. Subjects were informed of their laboratory test results as soon as they were available. All subjects were asked to follow-up with their health providers.

## Conclusion: It Is About More Than Just Enrollment

As a result of our study team's robust and comprehensive approaches to recruitment, 442 were screened for prediabetes risk factors using the DRQ, 165 participants were screened at the clinical laboratory visit, and 68 met criteria for the study based on one of three prediabetes diagnostic criterion, fasting glucose, OGTT, and or A1c and were randomized to one of the clinical trial intervention groups. Without a doubt, the study staff put in a numerous hours and physical labor to set up and carry out the various recruitment and screening events. At first glance, a yield of 15% (68 randomized from 442 screened) may seem inadequate in comparison to the efforts made to engage community collaborators and clinical stakeholders. However, the recruitment and screening process was about more than just enrollment. The platform for sharing information about prediabetes and strategies to reduce diabetes risk reached countless recipients in the African American community and beyond. Our team engaged in this work at a critical time when prediabetes became more than an indication of having "just a touch of sugar." Awareness of prediabetes risk factors and status provided an opportunity for intervention and prevention through lifestyle behavioral, as

evidence by the Diabetes Prevention Program's outcomes.

Furthermore, our culturally sensitive, community- and stakeholder-engaged approaches provided opportunities to hire and mentor numerous undergraduate work study, health professions, and postdoctoral trainees. The screening processes required an "all hands on deck" approach to engage and develop trust among key community leaders and citizens, as well as healthcare partners. The tracking and follow-up procedures to navigate potential participants to relevant next steps of the study process required mailings, phone calls, and laboratory visit scheduling and screening. As a result, our project provided opportunities for nursing, medical, public health, psychology, physical therapy, and other students to get firsthand experiences of community-engaged research approaches to address health inequities in the African American community. Thus, our approach to recruitment and enrollment had a threefold impact: awareness-raising regarding prediabetes, access to preventive and intervention efforts, and mentoring of the next generation of healthcare professionals and leaders. We have kept in touch with our student staff members, and they are now healthcare executives, attorneys, public health researchers, university faculty, and healthcare professionals. Future studies may benefit from this approach to screening, recruitment, and enrollment to improve the lives of the target population and the capacity for addressing and resolving health inequities.

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