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Comparison of Enrollment Rates of African-American Families Into a School-Based Tobacco Prevention Trial Using Two Recruitment Strategies in Urban and Rural Settings

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Abstract

Purpose—This study evaluated similarities and differences of enrollment rates using two different recruitment strategies for a tobacco control trial in rural and urban African-American (AA) elementary school families.

Design—A comparative study, nested within a larger randomized controlled trial, was used to test the effectiveness of two recruitment approaches on enrollment rates in rural and urban AA families.

Setting—The study was conducted in 14 Title 1 elementary schools in the southeastern United States: 7 rural and 7 urban.

Subjects—There were 736 eligible AA families, and 332 (45%) completed informed consent and were enrolled into the study.

Intervention—The Facilitate, Open and transparent communication, Shared benefits, Team and tailored, Educate bilaterally, and Relationships, realistic and rewards (FOSTER) approach guided the two recruitment strategies: (1) written informational packets provided to fourth graders to take home to parents; and (2) proactive, face-to-face family information sessions held at schools.

Measures—Enrollment rates were based on responsiveness to the two recruitment strategies and completion of the informed consent process.

Analysis—Chi-square, Cochran-Mantel-Haenszel, and Breslow-Day tests were performed.

Results—Higher enrollment rates occurred during the family session for both rural and urban families (100% rural, 93.6% urban; p=.0475) than informational packets alone (28.7% rural,

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22% urban; p < .0001). Rural family enrollment rates were overall higher than urban rates regardless of recruitment strategy (52.0% rural vs. 39.6% urban; p= .0008).

Conclusion—The findings suggest the FOSTER approach, although effective in both rural and urban settings, was more successful in recruiting rural families.

Keywords

African-Americans; Children; Families; School Systems; Rural; Urban; Recruitment Strategies; FOSTER Approach; Tobacco Control; Prevention Research

PURPOSE

In conducting research, one of the most important and often challenging components is the recruitment of study participants. Although there are established guidelines on the inclusion of racial and ethnic minorities in research,¹ these populations continue to remain underrepresented in research trials, and their recruitment can be exigent and resource and time intensive.² Community-engaged approaches, including community-based participatory research (CBPR), are showing promise for recruiting African-American (AA) and Latino minorities.^{3–9} Important components for successful recruitment include building trust among community members, establishing community advisory boards (CABs), and providing assistance for child care and transportation, incentives or honorariums for participants, and culturally sensitive and ethnically appropriate study materials.^{7–12} Also, personal contacts and face-to-face meetings in efforts to build relationships with potential research participants have been cited as pivotal in recruiting minority populations.^{13,14}Although community-engaged approaches are demonstrating some positive effects, recruitment of minorities remains challenging, and enrollment becomes more complex when recruiting families.

In addition to the importance of successfully recruiting minorities, an emerging aspect of research related to strategies for recruitment is geographical location, specifically rural and urban areas.^{15–21}Research studies often focus on populations within a specific location (i.e., rural or urban), and there is limited research that explores differences in response rates to different recruitment strategies between rural and urban populations who are being offered enrollment into the same randomized controlled trial (RCT). Furthermore, many studies that focus on recruitment strategies pertaining to rural and/or urban locations usually target individual participants, but not families.^{8,9,11,22} With regard to school-based research, comparisons have been made of children's health behaviors and disease status factors.^{23,24} However, none have evaluated recruitment strategies and response differences for a RCT in rural and urban schools, much less a RCT focused upon recruitment of AA families.

Schools, especially elementary and middle schools, provide a promising setting for reaching children and parents for health promotion behavioral interventions,^{25–27} including tobacco control clinical trials.^{28–30} School-based interventions aimed at tobacco prevention and cessation are appealing, because a federal mandate now dictates that all schools have an evidence-based drug education program,³¹ there is a captive audience where both intervention exposure and outcomes can be measured effectively,³⁰ and efforts are consistent with the Centers for Disease Control and Prevention's *Guidelines for School Health Programs: Preventing Tobacco Use and Addiction.*³²

This comparative study was nested within an ongoing school-based RCT that targets tobacco control in southern rural and urban AA families. The RCT examines the efficacy of a multicomponent, family approach using both the child (school-based prevention) and parent (home-based prevention with antitobacco socialization) components in combination with culturally tailored cessation for parent smokers for the intervention arm and attention-

matched general health education components for the control arm. The purpose of this paper is to present the process of the recruitment strategies that resulted in the development of the Facilitate, Open and transparent communication, Shared benefits, Team and tailored, Educate bilaterally, and Relationships, realistic and rewards (FOSTER) approach and the implementation of the two strategies, and to evaluate the responsiveness (as measured by enrollment) of the rural and urban families to each strategy.

We explored potential differential impact upon recruitment between an approach of information packets distributed to the students to take home to parents and a refined process of a proactive, face-to-face interactive family (i.e., parent and child) meeting in rural and urban elementary schools. The following research questions were addressed: (1) Do enrollment rates differ between rural and urban AA families when using the information packet recruitment strategy? (2) Are there differences in enrollment rates among rural and urban families when using refined, proactive recruitment strategies? (3) Are there similarities and differences between enrollment rates by recruitment strategies in rural and urban families? For this study, families are defined as at minimum one fourth-grade child and one parent. Parent is defined as the adult 18 years of age that the fourth-grade child resides with at least 50% of the time, and may be a biological parent, other relative, or guardian. Urban is defined as "core census block groups or blocks that have a population density of at least 1000 people per square mile," and "surrounding census blocks that have an overall density of at least 500 people per square mile."³³ Rural is defined as anything outside of the urban classification.³³

METHODS

Design

Fourteen Title 1 elementary schools with high enrollment percentages of AA children (65%) in fourth grade and across five counties were randomly selected from 25 eligible schools in a Southeastern state and randomly assigned to cohort 1 (recruited year 1 of the study) or cohort 2 (recruited year 2 of the study), and to intervention or control treatment arms based on their location (rural or urban; seven schools to each arm). Decisions on class inclusion were made with a collaborative approach among the school administration and the research team when there were multiple fourth-grade classrooms within a school. Any accelerated, learning-disabled, or behavioral disorder classes were excluded, because the goal was to test the treatment arms with the typical representative fourth-grade student population.

Sample

The parent RCT power analyses revealed that a total of 280 fourth-grade AA children (ages 8-11 years) and at minimum one parent per child (total N = 560; total family N = 280) were needed to detect clinically relevant effects between the intervention and control treatment arms for various child and parent outcomes. The parent study was adequately powered for this comparative research to examine recruitment approaches and response rates across rural and urban locations. Inclusion criteria stated that because this was a "family" study, voluntary participation from both the child and, at minimum, one parent was needed for study enrollment. AA eligibility was determined by parental self-report of the child's race/ ethnicity. If the parental report was AA or black, the family unit (child and parent) was eligible. Exclusion criteria were families in which the parent did not have access to a telephone or cellular phone. Please note: We obtained additional funding to recruit and include all other racial/ethnic groups, based on early feedback from the study advisory board regarding concerns of excluding children in the classroom based on race/ethnicity. However, the comparative study being reported here includes only the participants for the RCT, who

were all AA. This study received approval regarding human research protection from the Institutional Review Board at Georgia Health Sciences University. Parents completed written informed consent and children provided written assent for participation in the study.

The Process and Development of the FOSTER Approach Used for Recruitment

The principal investigator (PI) met with school district officials/school boards and school superintendents on an individual basis as a first step to explain the study, including potential benefits, any risks, and basic logistics. All superintendents in the five counties agreed to participate and then made the initial contact with their respective principals regarding their support of the study. The PI then arranged meetings with each individual school, and meetings across the 14 schools varied based on the respective school principal's preferences (e.g., individual meetings vs. including school personnel). At these meetings, which were all held at the respective administrator's offices (if a superintendent) or respective schools (for the principals and school personnel), refreshments were provided by the research team, as well as study-specific logo materials (pens, pencils, magnets, highlighters, personalized coffee cups, etc.). A detailed written information packet about the study was provided, along with creative flyers that included a toll-free number and all team members' contact information. The three goals of this initial meeting were (1) for school personnel involved with fourth-grade children to meet and begin a dialogue with the research team, (2) for these school personnel to garner an understanding and support of the research study goals, and (3) for a school navigator to be identified who would work closely with the research team. At this meeting, the investigative team and school staff began to formulate study processes and procedures based on school-specific recommendations that focused on facilitating success of each step of study implementation. Suggestions for membership and inclusion on the CABs were also provided.

CABs (one per school, with meetings occurring at the school) were established during the formative and pilot stages, and members represented school personnel and influential parent leaders, all of whom lived in the respective community. The CABs were indigenous members (i.e., ethnically, linguistically, socioeconomically, and experientially) of each community and had unique contextual knowledge and experiences. CABs were established to assist the investigative team with fostering trust and culturally sensitive plans for recruitment, retention, and study implementation. They recommended two recruitment approaches that were used as presented here. They also suggested numerous strategies for reaching the fourth-grade families, which included suggesting ethnically preferred food and entertainment (e.g., school's dance/step performers at family meetings), often scheduling concurrently with other school events (e.g., open houses, fourth-grade Parent-Teacher Association meetings, school carnivals, etc.), using recruitment incentives (e.g., gift cards) from local merchants, reaching families without transportation through use of the school bus and driver, using the school gymnasium and/or cafeteria for the informational recruitment meeting, utilizing the media center with assistance of school personnel to provide child care for younger siblings during the recruitment meetings with parents, and publishing in the fourth-grade weekly newsletter reminder information about the study. The CABs also emphasized developing a presence in the community, and thus not only did the team strive to develop relationships with the school officials, but significant efforts were made toward maintaining a presence on the school campus and in the community to foster relationships and to build trust among the community members. These efforts of the research team resulted in school and community acceptance and fostered bonding, supportive, and collaborative relationships. The research team worked diligently to be accountable and responsive to the school's needs (i.e., timely appointments, meetings, follow-up communication, flexibility in scheduling, and other requests). The process of identifying and arranging meetings with the school administrators and school CABs took on average 1

month (i.e., 2 months maximum) to achieve per school. Multiple meetings occurred simultaneously over a month such that all needed steps for recruitment of an entire cohort (seven schools) could be prepared within the month timeframe.

From these lessons learned and experiences during the early stages of study planning, a stepwise approach adapted from principles of CBPR ^{3–7} was developed and coined as "FOSTER." The approach includes both structural and deep cultural sensitivity of the AA population as guided by the CABs, the use of familiar indigenous school personnel to serve as navigators, and recruitment of families, all of which are appealing to both kinship and collectivism ideals of the AA population.^{34–36} The FOSTER approach facilitated further trust among all parties and helped further engage the communities and schools in the research study. Table 1 presents the specific strategies, definitions of the characteristics, and application of the FOSTER approach used with recruitment efforts in the rural and urban school settings.

Measures: Recruitment Procedures

As identified in initial school meetings, school navigators were trained for both cohorts to assist the team in navigating the recruitment process and also to assist with study implementation. These individuals were typically influential leaders (counselors, teachers, assistant principals, or principals) at the school who provided direction for timing of recruitment events, given they were fully involved with and knowledgeable of the respective schools' calendars. Recruitment occurred in two waves (cohort 1 and cohort 2) because this was a more manageable approach for the research team and as per the study timeline. The FOSTER approach was used in both cohorts; however, additional strategies were used that differed among cohort 1 and cohort 2. Researchers did not plan *a priori* to explore recruitment strategies experimentally. A different strategy with more proactive participation with parents was used in year 2 (cohort 2) based on the CAB recommendations and to improve efficiency and costs with the recruitment process.

Recruitment for Cohort 1/Packet Distribution to Fourth-Grade Students

(Children Only)-Recruitment for cohort 1 occurred in seven schools based on randomization (two rural and five urban). A seven-step process was used: (1) Eligible fourth-grade classrooms were individually visited by the PI and research team at a prearranged and agreeable time by the school navigator. A scripted protocol was used by the presenter, who was a trained research team member with engaging and excellent interpersonal communication skills who could easily connect with the children and had either prior teaching or recruitment experience. (2) The study was explained using clear and developmentally appropriate language, the chalkboard or electronic media were utilized, and each child received a detailed packet of information to take home to their parents (included cover letter, informed consent documents, toll-free number, e-mail addresses of study team, and simple, literacy-appropriate directions of how to complete the consent documents). (3) Based on the advisement of each school navigator, a time limit or deadline (ranging from 2 to 7 days) for returning the packets to the navigator was given to the children. (4) Children then placed the packet in their backpack. (5) Teachers and navigators included reminders on the board and had children record returning the study packet in their assignment folders that were to be signed weekly by the parents. Small incentives (pencils, erasers, pens, magnets, etc.) were used to encourage the children to return the packet regardless of the participation decision. All children who returned the packets, whether choosing to participate or not, received incentives. (6) A research team member followed up and contacted the navigator daily after the presentation to check on packet returns. (7) The navigator provided vigorous support for following up with daily reminders to the children for returning the packets, and any family (parent) with an outstanding packet was contacted by telephone, often in

collaboration with a research team member. Written notes to the parents by the navigator were also used as a strategy until all packets were returned, regardless of the participation decision.

Recruitment for Cohort 2/Refined Proactive Strategy With Families (Session With Parents and Children)-A family (parent and child) session was held at each school at a prearranged and agreeable time as suggested by the school navigator. Specific and tailored strategies of FOSTER were used for the family session to include ethnically preferred food and entertainment, prayer, small gift incentives for attendees (e.g., manicure sets for parents, notepads and pens for children), family transportation through use of the school bus and driver, use of the school gymnasium or cafeteria, and use of the media center with assistance of school personnel to provide child care for younger siblings during the recruitment session. A stepwise approach was utilized for the family session and included the following seven steps. (1) Prior to the meeting, flyers were distributed to each child to take home to parents and parents were asked to respond (yes or no on the flyer as to attending) and also indicate if transportation to the school was needed. All flyers were returned to the navigator, who communicated to the research team as to the response rate and who also arranged for school bus use if needed. (2) All families signed in as they arrived at the evening session and were provided research informed consent and assent documents to follow along when the study was explained. Families were asked to sit together (i.e., parent, fourth grader) during the informational meeting, and on-site child care was provided to families who brought younger children. (3) A welcome by a school official or navigator with introduction of team members began the session and then appreciation was expressed to the school. (4) At schools that requested a prayer prior to serving food, prayers were conducted by a familiar community member. (5) A scripted protocol with the appropriate literacy level of the parent population was used by a trained research team member who had excellent interpersonal communication skills, engaged and connected readily with the families, and had either prior teaching or recruitment experience. (6) Refreshments were served. (7) Prior to leaving the family session, all parents were provided a colorful flyer with full research team contact information, and a small gift was offered to the children and parents.

Predominant differences between cohort 1 and cohort 2 recruitment strategies pertained to the delivery methods of the study information. With cohort 1, all information was provided through an individual classroom packet distribution approach, with children as the vehicle to reach the parents. School navigators provided follow-up through classroom announcement reminders, written reminders to parents, and telephone contact. Research team members maintained follow-up with the navigators until all packets were returned, regardless of the decision to participate in the study. Although cohort 1 recruitment was somewhat successful with this approach, it was not efficient and was labor intensive for both the navigators and research team members. Thus, for cohort 2, refined, proactive information sessions for families (parents and children) were conducted through the advice and guidance of the CABs and school navigators and specific and tailored strategies of the FOSTER approach were more fully enhanced (e.g., food preferences, prayer, small gifts for attendees, child care, design of the room setup). This provided a more efficient recruitment strategy, as research team members were able to interact face-to-face with the decision makers (i.e., the parents) and to fully engage with the families, school personnel, and the community, and the PI was able to set the tone and purpose of the study for all to hear at once. We observed at minimum a 50% reduction in overall time for dissemination of study information, recruitment, and enrollment efforts with cohort 2 compared to cohort 1. Specifically, although the classroom packet distribution to the children used in cohort 1 took on average 15 minutes per class, numerous contacts by telephone, notes, etc. with the parents were frequently required by the school navigator and/or team members, and this often took

several days and up to a week to bring to closure for one class of students. The family session with face-to-face interaction with the parents and children used in cohort 2 allowed questions to be answered immediately, decision making to occur, and informed consent and assent documents for study enrollment to be completed. The time involved with the family session averaged 60 to 90 minutes. Although this was longer than the classroom distribution method (i.e., 15 minutes), it was more efficient and time saving overall given that much more was accomplished with the families who chose to enroll, as in addition to the informed consent process, baseline data measures (self-report surveys and biological samples [in the school nurse's clinic]) were collected at this same session. Collection of baseline data at the family session was an additional benefit over the packet distribution method. It is important to note that for the packet distribution (cohort 1), eligible classrooms at each school were visited only once and the family sessions (cohort 2) were held once per school with all eligible students and parents invited to the scheduled session.

Greater satisfaction with the recruitment process used in cohort 2 (family session/proactive) was reported by school navigators, families, and research team members. In summary, the delivery process was the primary difference in the two recruitment strategies. Also, cohort 1 was offered recruitment using the packet distribution strategy only, and cohort 2 utilized the family session approach initially, which was followed by the packet distribution to children in the classroom for those unable to attend the family session. Of importance is that the packet materials for dissemination in the classroom for each of the cohorts were the same. Both recruitment strategies involved recommendations from the school systems; however, the proactive face-to-face family session involved the incorporation of more school-specific suggestions and was more tailored to the particular populations.

Analysis

To examine differences in study enrollment and consent rates by the two recruitment strategies in cohort 1 (packet distribution to student/reactive) and cohort 2 (family session/ proactive) overall, between rural and urban schools, and between cohorts 1 and 2, χ^2 tests and Cochran-Mantel-Haenszel tests were performed. A Breslow-Day test examined whether the association between consent rates by recruitment strategy was the same or different between rural and urban schools. Data analysis evaluated enrollment rates based on attendance at the recruitment sessions (classrooms with the students or family evening sessions). Thus, analyses were performed on the numbers who received the information and the opportunity to enroll. Statistical significance was assessed using an alpha level of .05. All statistical analyses were performed using SAS 9.1.3.

RESULTS

Of the total 736 eligible families for whom either their child received a packet in the classroom or they as a family attended a session at school, 45% (N = 322 families) were recruited. These 322 families included a total of 673 participants: 329 fourth-grade children, mean age 9.88 years (SD = .56) and 50.5% female; and 344 parents, mean age 36.59 years (SD = 9.21), 90.1% female, 57.5% single-parent homes, with a mean educational level of 10.5 years (SD = 4.1), and 35% self-reporting annual incomes of <10,000. The Figure presents school location (rural or urban), cohort, and eligible families by recruitment strategy of attending the evening school family session and students who attended the classroom session, and number and percentage consented and enrolled. In cohorts 1 and 2, despite the recruitment strategy differences, the percentage of families recruited and consented at each of the rural schools was always significantly greater than the percentage recruited in the individual urban schools (see Figure). Table 2 gives the overall total recruitment and consent rates, regardless of recruitment strategy, by cohort and location. Cohort 2 had significantly higher consent rates than cohort 1 (49.4% vs. 40.2%; *p*= .0125).

Analyses to examine differences in overall consent rates between locations for cohort 2 only were performed, and the rural locations had overall higher consent rates than the urban locations, although this was not statistically significant (52.1% rural vs. 44.9% urban; p=. 1714).

Table 3 presents the consent rates by recruitment strategy by cohort and location. Statistically significant differences in consent and enrollment rates were seen between cohorts 1 and 2 for the packet distribution recruitment strategy, with significantly higher rates of consent occurring in cohort 1 (40.2% vs. 26.2%; p= .0003). It is important to note that the low recruitment rate in cohort 2 for packet distribution is reflective of the fact that this strategy was a secondary effort to reach the families, whereas cohort 1 did not have family sessions and the packet distribution in the classroom was the only recruitment strategy utilized. In examining the location consent rates by strategy, the family session recruitment strategy differed among rural and urban locations, with the rural location having significantly higher consent rates than the urban location (100% vs. 93.6%; p= .0475).

Table 4 reflects the tests for differences and similarities in consent rates by location and group for cohort 2 only. Controlling for location (rural or urban), analyses revealed that consent rates, overall, differed by recruitment strategy, with higher consent rates occurring during the family sessions for both rural and urban families (100% rural; 93.6% urban) than packet distribution (28.7% rural; 22% urban; p < .0001). The Breslow-Day test to examine homogeneity or heterogeneity in consent rates by recruitment strategy was statistically significant (heterogeneous/different) for the rural and urban locations (p= .0473).

DISCUSSION

Overall, results indicated AA family consent rates were higher in rural locations than urban locations, irrespective of recruitment approach (packet distribution vs. proactive family session). This is the first comparison of response rates of AA families by geographic area to two recruitment strategies of an ongoing RCT. There are numerous plausible explanations for this finding that include both contextual and quantitative factors. One possible reason for increased participation in rural areas may be related to the heightened interest of an unknown group of people and the opportunity to have exposure to a well-known academic health care organization with which participants were personally unfamiliar. This is consistent with prior research.¹⁷ For this study, the urban schools were located much closer geographically to the academic health care center than the rural schools, and most urban families were familiar with the academic enterprise. Also, the urban schools had experienced more opportunities from various investigators over the prior years to participate in research studies than had been offered to the rural schools. However, it is also important to note that whereas certain populations may be interested in information from outside sources, there are a considerable number of people who are hesitant and may be mistrustful.37

Observation by eligible families of the FOSTER approach and the resulting collaborations, engagement, and team spirit among the community, school personnel, school-identified navigator, and research team appeared to spark interest in the eligible families in becoming a part of the study. The importance of the attributes of tailored communications, well-designed logistics, incentives,^{8,38–40} an advocate in the school,^{39,40} and avoidance of being burdensome to the school and family schedules is consistent with other studies.⁴¹ Another explanation for the higher consent rates in the rural areas may include the scarcity and

limited availability of resources to rural families and schools. This may include the lack of access to health promotion opportunities for children; thus, parents may have decided to participate to allow their children to gain knowledge that they would not have otherwise obtained. Our FOSTER approach, although well received by both geographical locations, appears to have been particularly effective with developing relationships and collaborative engagement among the rural families and schools. These findings of community engagement to include developing trust appear to be highly important in working with rural school and family populations and are consistent with prior studies that focused on rural and urban, nonschool and individual, nonfamily populations.^{18,21,22}

Another plausible explanation and potentially an advantage for rural schools and families having higher recruitment rates is the interpersonal connectedness of the community. Rural communities are unique and different from urban areas, as most often rural settings have only one large school per student grade levels (i.e., elementary, middle, and high schools), and thus parents meet and see each other year after year because their children are in school together. Also typical for rural communities is that school personnel live in the local area, know the children and parents, and are engaged with the study's success. The mistrust among one's own community members that is often seen in urban populations was not as apparent in the rural settings. Contextual observations at the family sessions supported this premise. The rural families appeared to enjoy the family sessions and were affectionate to each other and the school personnel, socialized together, requested prayer, and were very talkative. However, in contrast, the urban school families in our study often sat alone, by themselves, and had minimal interaction with the other families. These observations are presented based on meetings at the school for both urban and rural families. Although rural areas have larger land space for living and are more spread out, so to say, than urban living areas, the sense of connectedness when rural families get together at their school is different than for urban families. Urban children living close together may enter different schools, and for rural students, there is typically only one school choice for their area per school level. Additionally, the rural school personnel were consistently welcoming to the research team and often greeted the team in the parking lot upon their arrival to assist with unloading study-related materials. The rural school navigators were typically more attentive, took the study-related responsibilities very seriously, always responded quickly to e-mails or calls from study team members, and followed up with the children and families about the packets and the family session. These characteristics and commitment were not as apparent among the urban schools and navigators in our study. There was an overarching positive atmosphere among the rural schools that included acceptance and trust of the research team; a focused and energized attitude that the study offered a common good for their children, families, schools, and communities; and appreciation that their school had been selected for offering their families the opportunity to participate.

Our data reveal that a refined proactive strategy with a face-to-face family recruitment session resulted in higher enrollment rates for both rural and urban AA families than an inclass packet distribution and presentation to children only. Other studies have found that proactive approaches to recruiting minorities have been successful.^{2,14,15,20,40,42} However, our findings are different from some reports in the literature, as the work of Chang et al.²² emphasized the importance of recruiting mothers on an individual basis as more successful than meeting with two or more at one time. Chang et al.²² recruited both AA and white mothers only, not children, and their study occurred in urban clinics in the northwest United States. Several studies that have aimed to recruit families have focused on largely white (62.5%) and highly educated samples (e.g., 60.9% college graduates).⁴³ Semeniuk et al.⁴⁴ aimed to recruit families through flyers sent via the U.S. mail and through sending information home from school in students' backpacks, a strategy similar to one of the recruitment approaches in this study. The study sample was again different than ours in that

73% of the parents were white, 37% were college graduates, the study occurred in the Midwest, and *the* authors reported a recruitment rate of 17%.

Both recruitment strategies in our study were active, in that the packet distribution was first presented in a face-to-face meeting with children in the classroom; however, the family session involved face-to-face contact with both the child and parent, allowing group discussion and consensus building. Additionally, the presence of school administrators, who were consistently present in the rural schools; other school personnel; and the navigator provided a visual and verbal endorsement of the study to the families, which also may have contributed to their acceptance and trust and the credibility of the research team and resulted in study enrollment. The proactive face-to-face family sessions also resulted in extremely high participation rates for those who attended, regardless of location (rural 100%; urban 93.6%). These rates exceed those of prior research for family recruitment in urban areas, which are reported to range from 9% to 66%.^{14,36,44} The total recruitment of 45% of the AA eligible families is also considered substantial, as no other studies were found that recruited minority southern AA rural and urban families for a school-based RCT.

The primary limitation of this study is that cohort 1 was not exposed to the proactive faceto-face family session and cohort 2 was exposed to the class distribution strategy only if unable to attend the family session. A second limitation is there could have been unobserved secular events that influenced differently the two cohorts' participation rates and thus interpretation of the findings. A third limitation is this study occurred in the southeastern United States and findings may not be generalizable to other parts of the United States.

There is a paucity of research involving AA family participation and recruitment strategies. Moreover, to our knowledge, this is the first study to examine differences in receptivity and resulting enrollment/consent rates of two recruitment strategies involving AA families by geographical location. The current article provides new insight about recruitment strategies for rural and urban AA families. Based on the FOSTER approach, the proactive face-to-face family session was particularly effective in recruiting 100% of rural and 93% of urban family attendees. The FOSTER approach is provided as a strategy that proved to be beneficial to all team members (community, school, family, and research personnel) and is considered to be the key determinant in facilitating successful study enrollment. Replication of these findings is needed as well as additional research that further tests the FOSTER model with other ethnically and geographically diverse populations to determine its applicability and contribution to successful recruitment into clinical trials.

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SO WHAT? Implications for Health Promotion Practioners and Researchers

What is already known on this topic?

The importance of establishing trust, developing relationships, and using culturally sensitive approaches is well established as being fundamental in recruiting underrepresented and minority populations in clinical research studies.

What does this article add?

The distinctive contribution of this article is the 93% to 100% recruitment rates of African-American (AA) urban and rural families who attended an informational session regarding the research study. The inclusion of school systems as partners and specifically having a designated and dedicated school navigator proved advantageous for recruitment of the AA families into clinical research, irrespective of geographical location.

What does this article add?

The Facilitate, Open and transparent communication, Shared benefits, Team and tailored, Educate bilaterally, and Relationships, realistic and rewards approach developed and implemented for this study may serve as a guide for other investigators working with families and schools in rural and urban settings. Face-to-face meetings with parents and children regarding the opportunity of enrolling in a clinical trial that incorporates key recommendations from the stakeholders shows great potential for reaching minority populations in different geographical areas and may assist researchers with achieving recruitment goals and milestones.

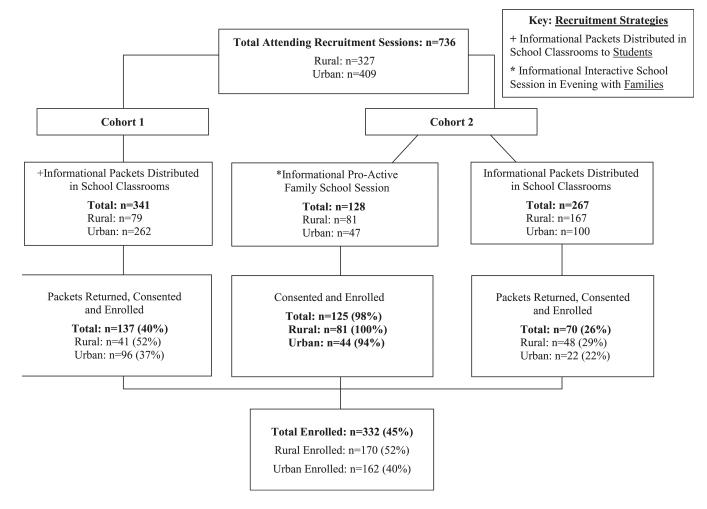




Table 1

The FOSTER Approach for Optimizing Recruitment*

FOSTER Strategy	Definition of Characteristic	Application With Rural and Urban Schools and Families
Facilitate	Team's attitude and actions	Team approach = we (the research team) are visitors and all responsibilities are with us and not a burden to school and families; participating in the study is easy for schools and families due to planning and nonobtrusiveness of school schedule.
Open and transparent communication	Clear and consistent communication methods	Team approach = the study is not secretive; toll-free numbers provided; communication methods reviewed and validated for literacy level and clarity prior to dissemination: follow-up appreciation communication provided directly by Pl/key research team leaders to school team.
Shared benefits	Everyone benefits from the study	Team approach = PI set tone with superintendents, school personnel, and community members about the value and benefits of the study; all research team members "walk the talk."
Team and tailored	Attitude and approach	Team approach = engaged and collaborative to foster alignment with school leadership and key personnel to serve with the research team as navigators; facilitated PTA meetings, open house, school-based events; advised on dissemination of critical study materials and follow up; maintained a consistent and primary point of contact: research team provided personalized gifts and incentive pay from \$100 to \$250 per school year; all recruitment sessions occurred with school personnel on site to help facilitate; culturally appropriate activities such as food preference, prayer, and including same ethnicity (AA) as the school navigator; diverse research team with ethnicity and gender.
Educate bilaterally	Learning from each other	Team approach = learning recruitment incentives from community and school members such as gift cards from local merchants and provision of childcare for recruitment sessions.
Relationships, realistic, and rewards	Reasonable and positive	Team approach = messaging "improved health; improved family communication": incentives for parents and children maximum \$50 and \$20/y, respectively; small gift incentives for all who attended recruitment sessions regardless of study participation decision; relationships and partnerships considered priority reward for research and school team.

* FOSTER indicates Facilitate, Open and transparent communication, Shared benefits, Team and tailored, Educate bilaterally, and Relationships, realistic and rewards; PI, principal investigator; PTA, Parent-Teacher Association; and AA, African-American. Some of the principles of FOSTER are adapted from community-based participatory research approaches.

Table 2

Overall Recruitment Rates by Cohort and Location*

		Cons	Consent Rate		Ρ
Variable	Level	Variable Level No. Approached No. Enrolled %	No. Enrolled	%	
Cohort	1	341	137	40.2	40.2 0.0125
	2	395	195	49.4	
Location	Urban	409	162	39.6	0.0008
	Rural	327	170	52.0	

* No. Approached = families attending the parent session or receiving a packet by distribution; No. Enrolled = families consenting and enrolling in the study at the parent session or by returning the packet.

Table 3

Consent Rates by Recruitment Strategy for Cohort and Location*

		Pare	Parent Session			Packet 1	Packet Distribution		
Variable	Level	Variable Level No. Approached No. Enrolled %	No. Enrolled	%	Ρ	P No. Approached No. Enrolled %	No. Enrolled	%	Ρ
Cohort	-	0				341	137	40.2	137 40.2 0.0003
	2	128	125	7.79		267	70	26.2	
Location	Urban	47	44	93.6	0.0475	362	118	32.6	0.3603
	Rural	81	81	100.00		246	89	89 36.2	

* No. Approached = families attending the parent session or receiving a packet by distribution; No. Enrolled = families consenting and enrolling in the study at the parent session or by returning the packet.

Table 4

Cochran-Mantel-Haenszel (CMH) Test for Difference in Consent Rates and Breslow-Day Test for Homogeneity of Consent Rates Between Groups by Recruitment Strategy Controlling for Location Within Cohort 2*

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			Con	Consent Rate			
Control Variable	Control Variable Control Variable Level Recruitment Strategy No. Approached No. Enrolled % CMH <i>p</i> Breslow-Day <i>p</i>	Recruitment Strategy	No. Approached	No. Enrolled	%	CMHp	Breslow-Day p
ocation	Urban	Parent session	47	44	93.6	<0.0001	93.6 <0.0001 0.0473
		Packet distribution	100	22	22.0		
	Rural	Parent session	81	81	100.0		
		Packet distribution	167	48	28.7		

No. Approached = families attending the parent session or receiving a packet by distribution; No. Enrolled = families consenting and enrolling in the study at the parent session or by returning the packet.