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Minority Participation in a School-Based Randomized Clinical Trial of Tooth Decay Prevention in the United States

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Abstract

Purpose—To describe the strategies--based on the social triad concept of a partnership of researchers, school personnel and community-- employed to recruit low-income, minority parent/ caregivers of kindergarten children into a school-based tooth decay prevention trial in the United States.

Methods—The study site was an urban school district with five elementary schools. Recruitment was carried out once each year for three years. Recruitment involved strategies at the school district, school, classroom, and student-parent level. A coalition of researchers, school personnel and community individuals was established for communication and recruitment. Outreach workers from the community were hired to promote, recruit, and disseminate oral health information. Study promotion included both print materials (logos, flyers, pictorial story boards) and presentations at school and community events.

Results—The School District Superintendent and administrators approved the study, and all five school principals and kindergarten teachers participated. All children within the classrooms were eligible: the overall participation rate of was 86% (580/672). Community outreach workers actively facilitated the recruitment and participants were recruited at open house for parent-teacher meeting (37% of all participants), sending letters and consent forms home (31%), at a prearranged convenient time during drop off and pick up of the child at their respective schools (30%), curriculum nights and health fairs (2%).

Conclusion—Utilizing the social triad concept led to success in planning and carrying out the recruitment of predominantly minority school children with high participation rates.

Keywords

randomized clinical trial (RCT); recruitment; school children; minority participation

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INTRODUCTION

Minority Participation in Clinical Trials in the United States

Participants from minority groups have previously been reported as being less likely to participate in randomized clinical trials because of distrust of researchers, limited access to primary care, failure of researchers to recruit minorities actively, alienation of minority health professionals, lack of knowledge of clinical research, and language and cultural differences [1]. Yet, representative participation from a target population is essential if the results are to be widely applied and eliminate health disparities [2]. A recent review found few studies include data on individuals offered enrollment and consent rates by race/ethnicity [3]. In contrast to widely held perceptions, 17 clinical/surgical treatment trials reviewed revealed higher participation of African-Americans and Hispanics when eligible and invited to participate compared to non-Hispanic Whites [3]. Minority participation ranged from 16% to 88% for various medical conditions and was statistically similar to Whites [3]. The Tuskegee Legacy Project Study [4, 5] also found that African-Americans and Non-Hispanic Whites were equally likely to participate in biomedical research. In recent medical prevention trials, once minority participants were invited to participate the consent rates (33% to 72%) were similar or higher compared to White participants [6, 7].

School Based Prevention Trials in Minority Communities in the United States

School-based trials present challenges: access to schools [8, 9]; recruitment strategy at the district, school, and individual levels [10]; reluctance of schools/classrooms to be randomized [11, 12]; retention [13, 14]; and lower participation rates among African-Americans and those of low socio-economic status [10]. A few previous studies have addressed these school-level challenges as follows: establishing credibility of the research team with the school district in terms of expertise, and ability to conduct the project; developing a clear message about the value of participation; persistence; buy-in and support from the superintendent and schools; maintenance of a close working relationship between researchers and school personnel; and enlisting/hiring research staff familiar with the school district and community [9, 11, 14]. On a subject-level, a shorter consent form written in simple language, classroom teachers influence and incentives, regular visits by research staff to collect returned consents, and culturally compatible materials [10, 15, 16, 17] were successful in increasing minority participation. The participation rates reported for ethnically diverse elementary school children in some of these previous studies ranged from 60 to 79% [10, 15, 16]. Where active consent is required, a 73% participation rate is considered average [15]. In previous studies, the lowest participation was indicated (actual rates not reported) in a predominantly African-American low SES school district compared to predominantly white and upper middle SES school district [10]. In a more recent study [15] differences were not found.

Studies have not reported methods and participation of minority children in school-based tooth decay prevention trials in the United States. Further, our study uniquely used the social triad approach to engage the various stakeholders and by utilizing community outreach workers. Thus, the purpose of this study is to describe the design and recruitment strategies in the Healthy Bear for Healthy Teeth project.

METHODS

Study Setting

The parent study is assessing the effectiveness of xylitol-sweetened versus placebo gummy bears as snack food during school hours plus topical fluoride varnish and health education in kindergarten children followed until 2nd grade in a cluster (classroom) randomized design.

The study sites are kindergarten classrooms in all five elementary schools of East Cleveland School District, Ohio within close proximity to the University. Cohorts of children were recruited in each of three school years (2007–2008, 2008–2009, 2009–2010). There were 10 to 12 classrooms in the five schools for each of the three years. The school district is 96% African American, with 94% of the children served by the federal reduced cost/free school lunch program, and English speaking parent/caregivers.

Eligibility

Children needed to be healthy and free of severe stomach illnesses (ex. Crohn's disease, ulcerative colitis, Celiac disease, irritable bowel syndrome, etc.) or strict dietary restrictions (ex. Diabetes). Parents gave their written active informed consent. The University Hospitals Case Medical Center Institutional Review Board approved the study. While the school district did not have a formal approval process for protection of children from research studies, the school district superintendent reviewed and approved the consent materials, script, and forms that were used for recruitment.

Study Staffing from the Community

Five outreach workers were employed by the study. The outreach workers were recommended by the elementary school principals, and had previously served as parent-liaison in the school, substitute teacher, or as parent volunteers. Prior to recruitment, the outreach workers were trained in a week long session that included background and prevention of tooth decay, study and recruitment procedures, oral health education curriculum, protection of human subjects, and completion of data collection forms. During the course of study implementation, the outreach workers were monitored periodically by the research staff regarding proper completion of consent documents and other study procedures.

Pilot Testing Consent Procedures

The consent form was written at the eighth grade reading level, and the language was pilot-tested with parent/caregivers of three children enrolled in the kindergarten class prior to study initiation. This pilot testing was useful to develop a consent form script that the outreach workers and research staff could use at the time of recruitment. The consent package also included a one-page description of the study interventions written in simple English for the parent/caregiver to keep.

Recruitment Design

The recruitment strategies were based on successful methods/best practices reported [2, 8] for minority populations and school-based research. The research team utilized a social triad [18, 19] to establish a coalition (research team, school administrators and personnel, community) for effective communication and collaboration about oral health issues, and by doing so, recruit and retain minority school children in the research project.

Multi-level recruitment strategy within the school district and schools were used beginning prior to, and continued after funding of the research. The strategic plan for recruitment is given in Figure 1. The strategies were: (1) district level participation (granting permission for researchers to approach parent/caregiver of children, promotion of study) by the school superintendent, school board president, parent-liaison, and other key individuals; (2) school level contact with the principal and kindergarten teachers; (3) class room level outreach by workers employed from within the community; and (4) individual level contact with student-parent pairs by outreach workers and the research team.

1. School District Level: Prior to the start of funding, the principal investigator met individually with the school superintendent, school board president, and other key individuals at the district level to provide an overview of the study (presentation with accompanying materials on the study specifics and a checklist of information/expectation needed from the school district). With the approval of the superintendent, an elementary school principal was approached for participation in a dental needs assessment pilot study. The result of this pilot study showed a high level of untreated tooth decay and was reported to the school district administrators. Thus, the necessity for prevention activities was established and explained.

At the district level, engagement of the administrators/staff continued after funding of the research. A district level community advisory board was formed with input from the school district administrators. The five-member board included the School District Wellness Committee coordinator (Facilitator of the School District's wellness policy and creation of a healthier environment for students), school district administrator (curriculum director), two school principals, and a parent liaison. Board meetings were held annually prior to study recruitment and continued over the three years. Input was sought regarding study promotion and recruitment materials, logistics of intervention, hiring of community outreach workers, recruitment methods, and language for the informed consent scripts and document. The research team also regularly attended the annual School District health fairs and the Wellness Committee meetings held two to three times/year to describe and promote the Healthy Bear for Healthy Teeth project.

Participation in the fairs and committee meetings included professionals from the school district--school nurses, social workers, physical education specialists, teachers, nutritionist--and members of other organizations such as Cuyahoga County Board of Health, Parks and Recreation department, Cleveland Clinic and Northeast Ohio Neighborhood Health Services. These contacts were important in promoting the study, creating awareness regarding study recruitment, as well as serving as a means to learn about the resources available in the community that could be communicated to parents whose children were enrolled in the study.

2. School Level: The principal investigator and project coordinator contacted all five elementary school principals at the start of funding to provide an overview of the study and to garner support. At the same time project staff met with all of the teachers individually to brief them about the study and gain help with recruitment and the plans for implementation of the study procedures in the classroom. The research staff gave kindergarten teachers toothbrushes and paste, and a gift certificate of \$25 two times per year as incentives for assisting with collecting parent consent forms.
3. Classroom Level: Five paid outreach workers familiar with the community/neighborhood carried out the recruitment of children and implementation of study procedures at the classroom level. The outreach workers were helpful in cementing relationships between the research team, the children and their parent/caregivers. At the time of recruitment the outreach workers together with research staff attended the kindergarten parent-teacher annual open house meetings conducted over a two-day period sponsored by the school district and they spoke to parents/caregivers about the study.
4. Student-Parent/Caregiver Level: Several recruitment venues were used by the outreach workers and other research staff in approaching parents and caregivers about enrolling their child into the prevention trial. The venues included parent-teacher open house meetings (two days at the beginning of school year), curriculum

nights (two hours in September), health fairs (two hours in Spring), and pre-arranged convenient times during drop-off and pick-up of child from school. At these venues, researchers explained the informed consent process in clear, simple, and adequate language to parents/caregivers using the consent form script, pictorial story boards and study fliers. Parents/caregivers were also informed about the potential benefits of the test intervention (xylitol), other prevention methods available to all participants in the study (for example, topical application of sodium fluoride varnish), and dental screening and referral for care. The parents and caretakers were also advised that the interventions were available to their child at no cost and that they had the option of withdrawing their child from the study at any point. Parent/caregiver consent was obtained at these various community venues. Recruitment incentives included tooth brushes and paste for parents/caregivers.

When the project staff members were unable to make contact with the parent/caregiver, consent forms were sent home (with the child) with a flier about the study and a note from the teacher to return the form the following day. The teacher placed a follow-up telephone call when a consent form was not returned.

Data Collection—The study describes recruitment at the school support level (school district administrators, school principals, classroom teachers) and at the individual child-parent/caregiver level (accrual rate by cohort and recruitment venues). The primary outcome was the consent rates at the school (stratified by schools and classrooms) and individual levels (stratified by cohort and recruitment venues). School support was measured by the willingness of the school administrators, school principals, and kindergarten teachers to participate after a brief introduction of the study and its protocol. Accrual rates was measured for each cohort as the number of parent/caregiver consenting for their children to participate divided by the total number of parent/caregiver approached and eligible for participation. Further, accrual rates were calculated for each recruitment venue through which parent/caregivers gave consent for participation in the study.

RESULTS

School Support

The study had complete verbal and written support from the school district superintendent, school board, and other administrators prior to obtaining funding. Later, the school superintendent briefed the five elementary school principals about the dental project, and this facilitated entry into the schools and classrooms. Each of the principals agreed to have their individual school's participation and offered unconditional support. Although teachers varied in their enthusiasm, all agreed to assist the project personnel to accomplish the research objectives. All five schools, principals, and 12 kindergarten teachers participated in the trial.

Accrual Rates

1. By Cohort—The original goal of the clinical trial was to recruit 300 children in each of the first and second years, but, a drop in school enrollment made this impossible. Hence, the recruitment plan was modified to allow recruiting in a third year in order to meet the planned sample size. Thus, meeting recruitment goals required three cohorts: Cohort I in 2007, Cohort II in 2008, and Cohort III in 2009. The overall participation rate was 86% (580/672). In cohort I, there were a total of 227 kindergarten children enrolled in the school district, with 202 consenting to participate (89%); In cohort II, there were 227 kindergarten children in the school district, with 193 new children giving consents to participate (85%)

which also included 11 already enrolled children who were retained (i.e. not promoted to 1st grade) from cohort I; In cohort III, there were 218 kindergarten children enrolled in the school district, with 185 new children giving consents (85%) which also included 7 already enrolled children who were retained from cohort II. A total of eighteen children were retained in kindergarten from the first/second cohort, and 92 refusals, resulting in 562 children who had parental permission to participate in the project (Figure 2).

In any given cohort, the majority of parents/caregivers were approached for participation during the baseline period of August-September. This School District also had an open enrollment throughout the year for kindergarten children. Thus, 78% of the children were recruited into the study during the baseline period of August-September, 10% in October, and the remaining 12% between November and December.

Figure 2 gives a summary of the recruitment numbers and the active subjects at the end of school year. A total of 92 parent/caregivers refused to participate in the study, with a 14% refusal rate. While most parent/caregivers did not report a reason for non-participation, a subset of 11 out of 92 parents indicated the following reasons for not participating. For the subset, the reasons given were:

- Anticipation of the family to move out of the school district/state (1/11, 9%).
- Family not interested in the child participating in a research study (1/11, 9%).
- Parent could not understand the protective effects of xylitol gummy bears in the study and they simply viewed the gummy bears as candy and did not want their child to participate in the trial (1/11, 9%).
- One parent felt the questionnaire was intrusive and did not want to fill them out nor allow their children to participate in the trial (1/11, 9%).
- Other parents did not understand the HIPAA rules and felt intimidated by the paperwork related to informed consent (5/11, 45%).
- Some parents said that their children were receiving dental care routinely and would not like to subject their children through this trial for more dental exams (2/11, 18%).

2. By Recruitment Venues—A number of recruitment venues were used. In descending order the strategies are listed from most to least successful: that resulted in recruitment included open house for parent-teacher meeting (215/580, 37%), through sending letters and consent forms home (180/580, 31%), at a prearranged convenient time during drop off and pick up of the child at their respective schools (174/580, 30%), curriculum nights (6/580, 1%), and health fairs (5/580, 1%). This did not vary from by cohort to cohort.

DISCUSSION

The Healthy Bear for Healthy Teeth project is a controlled clinical prevention trial in a largely minority community. The recruitment strategic plan was based on previous research on the social triad concept that enumerated successful approaches to gaining support and involvement of the schools and community. Our study employed similar strategies such as engagement of school district and schools, direct and repeated contact with parent/caregivers, incentives to teachers, and data collection by research team as reported recently in a review [20]. The study was successful in gaining support from the school district and schools, and recruiting 86% of the eligible school children. Participation exceeded rates reported in other elementary school based studies in ethnically diverse populations [10, 15, 21, 22] and in a predominantly lower socioeconomic urban minority population [16].

African-American caregivers of school children were willing to take part, a finding contrary to that reported in a previous study [10] that found participation rates to be lowest in a predominantly African-American school district. In a study reported by Harrington and colleagues [10], the teachers were involved in explaining project goals, distributing consents, reminding students to return signed consents, and sending reminders and replacement forms. This study [10] reports that principals and teachers in the lowest participating school district theorized informally that the parents had a mistrust of the research community and could not understand the lengthy consent form documents. Our study did not primarily use teachers to obtain consent, an approach that also enhanced participation rates in an earlier school study [15]. However, the teachers were helpful in following up with a parent/caregiver if the consent forms were not returned within an appropriate time. Our study results also point to similar findings from the Tuskegee Legacy Project [4, 5] in that African-Americans were willing to participate in this clinical trial, when research personnel and school staff are actively engaged in the consent process and follow-up in a timely manner.

This study confirms several successful recruitment strategies that have been helpful in enhancing minority participation rates. On a district level, the engagement of various stakeholders including school administrators and community individuals were essential to promote the program within the various elementary schools, and to gain support from the principals. Our approach was very similar to other successful school-based studies to gain support for their projects [8, 10, 11, 14, 15]. We were also able to employ customized strategies since our clinical trial was implemented in a small school district with five schools. They included disseminating study information and creating awareness through recruiting materials such as flyers and picture story boards that were developed using input from school administrators, principals, and teachers. These materials were made available at central registration, health fairs, KG open house, and curriculum nights. In addition, regular newsletter about the study was circulated in the community that was organized by the County Board of Health. All of these strategies were successful in our recruitment of the three cohorts of kindergarten children. Further, there was regular ongoing communication between the research team, school personnel, and the community in keeping with the social triad model. They included research team's attendance at committee meetings to address student's wellness issues, conducting free dental screenings for children at health fairs, periodic briefing of the school administrators regarding study progress, organizing a book drive for the school library, and periodic breakfast/lunch discussions with parent/caregivers. As reported previously [19], such collaboration provides a social structure for group action, which in our study resulted in high participation rates.

On a school level, the teachers were given incentives to support the recruitment and implementation of the study within their students and classrooms. On a classroom level, our study utilized several innovative strategies, including hiring outreach workers from the community, and some were also parent-liaisons in their respective schools. They were knowledgeable about the schools and the parents, and this fostered trust among the parent/caregivers to enroll the child in the study. Additionally the outreach workers received training in human subject research, oral health education, and information about tooth decay similar to best strategies reported in prior literature [1], and they were able to carry essential oral health messages to the community. On a student-parent/caregiver level, outreach workers and research team members obtained informed consent. The pilot testing on a few parent/caregivers was helpful in developing a consent script. To reduce the complexity of the active consent process and the accompanying forms, the consent script was helpful in explaining the study in clear, simple language to the parent/caregiver.

Approximately 15% of the enrolled kindergarten children in the school district did not participate in this trial. The predominant reason for non-participation was intimidating informed consent paperwork despite, efforts to keep the process simple. The use of storyboards and cartoons in the consent process might have enhanced cooperation further.

The rigorous principles of randomized clinical trials are likely to be fostered in a school-based setting [13]. In fact, in the United States, many obesity, diabetes, and smoking prevention trials are conducted in schools as because the schools are in a unique position to use the results of studies promote healthy eating, physical activity, and decrease tobacco use in children and adolescents [13, 14, 23]. Similarly, there are several school based dental caries (tooth decay) prevention programs in the United States [24, 25], but there have been no randomized dental caries prevention trials for many years.

Some of the challenges we encountered was that our accrual rate could not be accomplished with two cohorts of kindergarten children due to a dramatic drop in school district wide enrollment. Further 15% of the children transferred out of the district within the school year. Such external factors such as out-migration of individuals for economic reason were beyond our control and resulted in district-wide lower enrollment and retention. Other factors included the relocation of one of the elementary schools to another school temporarily for construction, and the opening of charter schools in the area. Due to the lower enrollment, classrooms were also downsized for cohorts II and III. So, future investigators conducting clinical trials in urban school districts should anticipate such problems and have appropriate contingency plans for accrual. Additionally, if the trial is group-randomized such as the use of classrooms as the unit of randomization, then adequate plans have to be made to ensure that children continue to receive the same treatment that they were originally assigned.

In conclusion, ongoing communication between researchers and the schools, community outreach workers, and utilizing previously reported best practices was instrumental in achieving a high participation rate among predominantly minority elementary school children.

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Figure 1.
Strategic plan for recruitment for the Healthy Bear Healthy Teeth Study

Figure 2. Flow chart of recruitment of kindergarten school children (Cohort I, Cohort II, Cohort III) in 2007, 2008, and 2009 in the Healthy Bear Healthy Teeth (HBHT) Study