RECRUITMENT OF AFRICAN-AMERICAN PRE-ADOLESCENT GIRLS INTO AN OBESITY PREVENTION TRIAL: THE GEMS PILOT STUDIES

Objective: The objective of this report is to describe the methods used to recruit 8- to 10-year-old African-American girls into four 12-week randomized controlled pilot studies on obesity prevention.

Design: The Girls health Enrichment Multi-site Study (GEMS) involved 4 field centers which independently developed and tested interventions designed to prevent excess weight gain in African-American girls. Each field center developed its own recruitment plan, but used a standardized recruitment reporting form. The goal was to recruit 40–60 girls, depending on the center.

Measures: Recruitment yields were computed at each site. Socio-demographic data and weight status were collected for 210 African-American girls who were randomized into the study, as well as for their parents/caregivers. Data were collected on the sources from which participants heard about the study, and the reasons for their interest in the project.

Results: The 4 field centers used multiple, but different, recruitment strategies. The most commonly used approaches were mailings, flyers, radio announcements, and group presentations. Caregivers were most likely to hear about the program from the radio (29%), a flyer from the school (23%), or from their child (18%). Among caregivers, the most common reasons for participating were: interest in health (56%), interest in diet/health (51%), and believing the program would be fun for their child (46%). The most frequent reason given by girls was that the program sounded like fun (70%). Three of the 4 field centers met their recruitment target goals.

Conclusions: The GEMS experience demonstrates the feasibility of recruiting and enrolling African-American girls in short-term intervention studies of behavior change. The multiple recruitment strategies, which included developing trusting relationships in the respective communities, were considered critical to the success of recruitment. (*Ethn Dis.* 2003; 13[suppl1]:S1-78–S1-87)

Key Words: African-American, Pre-adolescent Girls, Obesity, Recruitment, Enrollment

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INTRODUCTION

Participant recruitment is among the most challenging aspects of conducting clinical trials, as participants must meet established eligibility criteria, be willing to be randomized into a treatment or comparison group, adhere to the study conditions, and participate in the required data collection.1 Recruitment of minority populations into clinical trials presents special challenges, and past participation by minority populations has been limited.² Research within minority populations has somewhat improved,3 and studies have recently begun to address the unique issues and concerns associated with recruitment and retention of minority participants in communitybased trials.4-14 Nevertheless, there is a need to better understand barriers to minority accrual in clinical trials.^{2,3,8,15,16}

Swanson and Ward² described 4 general barriers to minority recruitment and participation in clinical trials: sociocultural, research, economic, and individual. Socio-cultural barriers include

Tennessee (BMB); Stanford Center for Research in Disease Prevention, Stanford University, Palo Alto, California (NST, ASO); Children's Nutrition Research Center, Baylor College of Medicine, Houston, Texas (JCB); Biostatistics Center, George Washington University, Washington, DC (JR, MM); Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute (NHLBI), Bethesda, Maryland (EO).

Address correspondence and reprint requests to Mary Story, PhD, RD; Division of Epidemiology; University of Minnesota; 1300 S 2nd St, Suite 300; Minneapolis, MN 55454; 612-626-8801; 612-624-9328 (fax); story@epi.umn.edu the long-standing fear, mistrust, and apprehension of research experienced by minority populations. Medical research, academic medicine, and federally sponsored studies may be viewed with suspicion. There may be confusion, mistrust, or disinterest in being randomized into a no-treatment control group. Benefits to the participant and community may not be evident. Economic barriers, such as financial instability, lack of telephones or transportation, lack of childcare, and high mobility, can create difficulties in reaching participants, and maintaining their participation in the study. Individual barriers may include thought processes about health and disease, or lack of time, due to involvement in community activities.

Recently, focus groups were conducted with African-American adults in Alabama to determine their perceptions of participation in clinical research.3 Most participants said they would take part in clinical trials if the research was beneficial to their family or community, and was supported by the church. Barriers to participation included time commitment, blood collection or radiation, lack of trust, lack of information, and past experiences. Recommended solutions to increase participation of African Americans in clinical trials included workshops to provide more information about trials, and community education, which would involve churches, schools, and other community organizations or institutions in the recruitment efforts.

Recruiting children from minority groups, and conducting trials with these children in community settings, raise many additional concerns. Parents, regardless of race and ethnicity, are likely to be suspicious of research involving children. Common research methods in clinical trials such as clinic visits, physical exams, blood draws, and randomization, take on another dimension when children are involved. Recruiting parents, as well as children, presents challenges for health behavior research with minority populations. A literature search revealed no articles describing experiences and effective strategies for recruiting children of diverse ethnic and racial groups into community-based trials.

The Girls health Enrichment Multisite Study (GEMS) was a National Heart, Lung, and Blood Institute-sponsored multi-center research program to develop and test 4 interventions designed to prevent excess weight gain in African-American girls as they enter adolescence. The purpose of this article is to examine the feasibility of recruiting African-American children into community trials, and to describe the recruitment methods used to recruit 8- to 10-year-old African-American girls into four 12-week randomized controlled pilot studies. GEMS' experiences with recruitment and enrollment may be relevant to other researchers interested in conducting and evaluating studies on health behaviors for ethnic and racial minority youth.

Methods

Study Description

GEMS was a multi-center research program in which 4 field centers independently developed and tested pilot interventions designed to prevent excess weight gain by African-American girls, as they enter and proceed through adolescence. The four GEMS field centers were: Baylor College of Medicine (Houston, Tex), University of Memphis (Memphis, Tenn), University of Minnesota (Minneapolis, Minn), and Stanford University (Palo Alto, Calif). Phase 1 of GEMS consisted of: 1) conducting formative research to guide intervention development, recruitment methods, and acceptability of measures; and 2) conducting a 12-week randomized controlled pilot study, during which measurements are taken at baseline, and again at the end of the 12 weeks. All 4 centers enrolled girls according to commonly developed eligibility criteria, allowing for some center-specific differences. The common design elements of GEMS are described elsewhere in this supplement.¹⁷

While all field centers targeted 8- to 10-year-old African-American girls who were at risk for obesity, each field center developed its own intervention. The intervention at Baylor involved a 4-week summer day camp, followed by an 8week Internet-based program, accessed in the home, for both girls and parents.18 Because participation in the intervention required a computer, middleto upper-middle income families were recruited. The Memphis intervention consisted of 2 active, culturally tailored, family-based interventions: a child-targeted family intervention, which took place after school once a week at 2 neighborhood centers, and a parent-targeted intervention with parents only, held one evening a week at 2 neighborhood centers.19 The Minnesota intervention took place 2 afternoons a week, in schools, but after school hours, and also included a family component.20 The Stanford intervention offered afterschool dance classes 5 days a week in community centers, and included a family component conducted in participants' homes, and focusing on reducing television watching.21

Overview of Recruitment Goals and Procedures

As is typical for multi-center studies, even those that follow a common protocol, recruitment methods varied across the 4 sites because of different population and community characteristics. The recruitment goals were to enroll and randomize 40 girls at Baylor, 60 girls at Memphis, and 50 girls each at Minnesota and Stanford. At each center, girls were randomized to either intervention or comparison groups. It was anticipated that recruitment would take approximately 2 months. Center-specific recruitment strategies are described in the "results" section.

Prior to initiating recruitment efforts, each center conducted formative research. In focus groups with girls and parents/caregivers, questions were asked regarding the best ways to recruit and retain the target population, including motivational factors for clinical trial participation, reactions to being part of a study population, potential barriers to participation, and interest in proposed interventions. This formative research was instrumental in guiding recruitment strategies and study design. For example, researchers at 3 of the field centers learned that blood draws with children from their respective communities would be acceptable (Minnesota, Stanford, Baylor), while staff at the Memphis field center discovered that this would be unacceptable. Staff at all field centers learned that randomizing girls to a traditional no-treatment control group would be unacceptable to their communities, and that this method would jeopardize recruitment efforts. Therefore, an "active placebo" group was used at all field centers, where some type of alternative intervention (eg, self-esteem, African arts) was delivered. A common theme from the focus groups was that while parents were motivated by the idea of enrolling their daughters in a health program, they were also interested in programs on self-esteem issues for their children. The major motivating factor for the girls was that the programs were fun.

Center-Specific Recruitment Methods

Baylor College of Medicine (BCM)

Multiple recruitment strategies were used to target parents of 8-year-old African-American girls. The BCM Chil-

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dren's Nutrition Research Center (CNRC) Web master created a GEMS-Fun, Food, and Fitness (FFF) recruitment web site. The home page included photos of African-American girls participating in camp activities, GEMS-FFF camp, and Internet program details, CNRC information and map, and an on-line registration form. The recruitment Web address was included on all correspondence, promotional materials, (eg, pencils and t-shirts), radio announcements, and newsletters. Recruitment ads were included in the quarterly CNRC "Nutrition and Your Child" newsletter, which is circulated to over 11,000 parents across Texas and the United States, and one issue included a recruitment article.

Daily radio announcements ran on 2 Houston African-American stations for two 3-week periods, targeting 25- to 40-year-old women with children. The ads ran at prime listening time, 9 AM to 11 AM weekdays, and during a popular African-American Sunday morning religious talk show. Recruitment staff distributed flyers to eligible employees at the Texas Children's Hospital annual employee appreciation picnic. A Shell Oil Company public relations employee provided access to the company's African-American Human Resource Association. An e-mail with recruitment information was sent to all members.

Recruiters had extensive contacts with Houston-area African-American churches, which enabled them to meet with, and gain the support of, the Black Baptist Ministers Association. The ministers promoted the project to their parishioners during church services. Recruiters attended these church services and other group meetings (eg, Kujichagulia-girls' rites of passage group), in order to recruit parents and girls. Recruiters met with Houston Girl Scout leaders, and recruited from African-American Girl Scout troops. Flyers and study information were given to the girls to take home and discuss with their parents. Mailing lists were obtained

from 3 local school districts with large enrollments of African-American girls. Recruitment postcards were mailed to 10,000 households that included potentially eligible 8-year-old African-American girls. The project was also presented to parents at several private African-American schools.

Recruitment flyers, and fruit and vegetable snacks, were available at all events. As a reward for attending, girls received Fun, Food, & Fitness pencils, which advertised the Web address. Consent, screening, and eligibility forms were completed on all interested 8-yearold girls and their parents at these sessions. If the girls met eligibility criteria, baseline visits were scheduled. At the baseline visits, girls received T-shirts with the GEMS-FFF logo on the front, and the recruitment web address on the back.

University of Memphis

The overall recruitment strategy, which targeted parents and caregivers, was to provide a brief description of the GEMS study with contact information, so that those interested could call for further details. Multiple recruitment strategies were utilized, including live radio talk shows; public service announcements (PSAs), including radio announcements played on the University of Memphis telephone system for callers placed on hold (under "radio announcements" in Table 2); announcements, posted flyers, and presentations at local community centers; announcements in church bulletins; no-obligation orientation meetings at community centers; flyers distributed following brief meetings with age-eligible girls at local elementary schools; and word-ofmouth.

Several innovative recruiting methods were implemented. The Recruitment Coordinator and one of the project investigators were featured on a popular, local, live radio call-in show. Following a brief discussion of background information related to the study (the decrease in physical activity among children and the concomitant increase in weight), details regarding the pilot study were discussed at length. Recruitment staff phone numbers were provided several times during the one-hour broadcast. The show concluded with a question-and-answer segment between listeners and GEMS project staff.

Brief PSAs (20-seconds) were broadcast on 6 local radio stations with large African-American audiences. A description of the study, benefits of participating, and contact information, were provided. Approximately 600 radio PSAs were made during the first month of recruitment. In addition, PSAs were also utilized to recruit potential participants by playing announcements on the University of Memphis telephone system for callers placed on hold.

Caregivers of 8- to 10-year-old African-American girls were also recruited from local community centers. Using demographic information (child's age and ethnicity) from the community centers, informational mailings were sent to potentially eligible families, who had participated in previous recreational and programmatic activities. To maintain the confidentiality of potential participants, community center directors sent letters inviting participation in the study, along with GEMS recruitment material, directly to caregivers. along with GEMS recruitment materials.

Each of the recruitment strategies required interested caregivers to contact the University of Memphis for further details. This approach allowed GEMS staff to disseminate information about the study, answer preliminary questions, and then complete the screening and eligibility forms, by telephone, with interested caregivers. Baseline clinic visits were scheduled with eligible girls, and consent forms were signed at the beginning of the clinic visit.

University of Minnesota

A multi-pronged staged recruitment approach was used, targeting both girls

and their parents. The goal was to get parents and their daughters to attend evening information meetings held at the schools to learn more about the project, and then to sign up, if interested in participating. The first step in recruitment was to have GEMS staff arrange with the schools to meet with groups of 8- to 10-year-old African-American girls during the school day, to generate interest in the program. At these meetings, girls were told about the program, and were given flyers to take home to their parents, inviting them to attend an informational meeting held at the school. At the same time, a letter describing the GEMS project, and a flyer with the dates of the information meetings, were mailed directly to parents, using mailing lists obtained from the schools. To recruit girls at high risk of obesity, recruitment materials for parents were framed around the concept of chronic disease risk, asking, "Is there a family history of heart disease, diabetes, high blood pressure, or overweight?" The materials also announced that a fun program, just for African-American girls aged 8-10, would be offered. Parents were asked to call if they were interested, and could attend any of the meeting dates, or if they were interested but unable to come.

Daycare, including dinner, was provided for younger children at the information meetings. Door prizes were awarded as incentives for attending. At the meeting, the GEMS project and the consent process were described, and a video was shown featuring a GEMS girl at the clinic going through all the steps and procedures (DEXA, blood draw, physical measurements, etc) to demonstrated explicitly what the clinic visit would entail. GEMS staff met individually with interested caregivers and girls to sign consent forms, to complete the screening and eligibility forms, and to schedule the baseline clinic visit, if eligible. Follow-up telephone contact was made with families who were undecided about participating.

Stanford University

Recruitment strategies reflected a community-oriented approach. The goal was to meet with community leaders, groups, and individuals who worked with African-American girls, in order to recruit participants (both parents and girls), while raising community awareness about the project. The project was introduced as promoting healthy lifestyles for African-American girls and their families. Recruitment staff collaborated with a variety of community organizations to publicize the project, and flyers were posted at these sites with a hotline number. Leaders of local organizations helped to identify families who might be interested in the project, and the project was also made known to local churches and health clinics. All recruitment efforts were in the catchment area of the community sites where the program would be held.

Presentations were made to girls and parents at schools, PTA meetings, parent group meetings, school events and performances, and community fairs. Events and gatherings at community centers, such as community group meetings, and basketball tournaments that involved African-American girls and their families, were targeted for recruitment efforts. At each of these events, either formal group presentations were made or flyers with information about the project were handed out to individuals. In both cases, the aim was to obtain a phone number from the parent so that staff could call and conduct a phone-based screening and eligibility assessment.

Data Collection

Information relevant to recruitment activities was collected from recruitment activity logs, screening and eligibility forms, and baseline forms. A common monthly recruitment activity form was developed to document and describe recruitment strategies at each field center, and recruitment yields were computed from these forms. The form listed spe-

cific recruitment activity categories, and the recruitment coordinator at each site provided a brief description of the activity and entered the quantity of items for type of recruitment channel used. For example, each recruitment coordinator documented the number of flyers. mailings, newspaper ads, or radio announcements during the previous month. The screening and eligibility form was staff-administered, and obtained demographic and personal information including age, gender, ethnicity, height and weight, and other questions designed to determine eligibility. The form also included questions on the sources from which caregivers and girls had heard about the study, and the reasons for their interest in the project. The questions were worded, "How did you hear about the project? You may choose all that apply" and "What interested you in participating in this project? You may choose all that apply." Each question had 10-16 close-ended response categories, as well as an "Other" category. At the baseline visit, girls' height and weight were measured using a stadiometer and an electronic scale. Caregivers' height and weight were measured at 3 field centers, and self-reported at one field center (Stanford). The baseline visit took 2-3 hours to complete.

Specific data collection retention approaches were also employed. At baseline, caregivers were asked to provide contact information, which was then included in a site-specific tracking database. This information included name of the girl's school, address(es) and phone number(s) of the participant and caregiver, cell-phone numbers and addresses and phone numbers of 2 relatives, and a close family friend. This database allowed for follow up with participants who missed intervention meetings, or follow-up evaluations.

Data Analysis

All analyses were conducted using SAS (SAS/STAT, release 8.1, 1999, SAS Institute, Cary, NC). Descriptive statis-

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tics were calculated for examining baseline characteristics of GEMS participants and their caregivers. Analysis of variance and chi-square tests were used to compare baseline characteristics across the field centers. Frequency counts were generated to assess the number of recruitment activities by field center, and percentages were used for examining reasons for girls' and caregivers' interest in participating in the study. Because different recruitment approaches were used at each of the field centers, formal tests of significance on recruitment approaches were not performed across field centers.

RESULTS

Characteristics of Participants

Data are presented on 210 African-American girls who were randomized to the study. All girls met the eligibility criteria, completed baseline measures, and were randomized into either an intervention or comparison group. The socio-demographic characteristics and mean body mass index (BMI) of the participants and their caregivers are summarized in Table 1. The mean age of the parent/caregiver was 37 years (SD=8.3), 45% were single parents, and 84% were overweight or obese. Three of the 4 field centers targeted low-income families, whereas Baylor recruited higher income families. Over half (57%) of the caregivers at Baylor had a college degree, compared to about 20% of caregivers at Memphis and Stanford, and 11% in Minnesota. Mean age of the girls was 8.8 years (SD=0.8), and 44% were overweight (BMI≥95th percentile for age and gender).

Recruitment Targets

Across field centers, 210 girls were recruited and randomized into the GEMS study. Recruitment goals were achieved in 3 of the 4 centers. The Memphis center recruited and randomized 60 girls; the Minnesota center, 54 girls; the Stanford center, 61 girls; and the Baylor center, 35 girls.

Overall Recruitment Strategies

As exhibited in Table 2, the four field centers used a variety of different recruitment strategies, designed to meet the needs of their particular community and intervention program. The most commonly used recruitment approaches were mailings, flyers, radio, and presentations at schools, churches, and in the community. Center-specific recruitment experiences are described in more detail below.

Sources from which Caregivers and Girls Heard about the Study, and Reasons for their Participation

Table 3 examines the sources from which the caregivers of the randomized girls learned of the study. Overall, the 3 most frequent sources cited by caregivers were radio ads, announcements, stories, and interviews (29%), a flyer from the child's school (23%), and from their daughter (18%). The methods by which caregivers heard about the project reflected the varied center-specific recruitment strategies. For example, the most effective recruitment strategy used at both Baylor and Memphis was the radio. In contrast, Minnesota and Stanford directly targeted girls through small group meetings at school, during which they were given a flyer to take home.

Across field centers, randomized girls most frequently reported hearing about the program from their caregivers (38%), a school flyer (23%), or a presentation at school (17%) (Table 3). Again, site-specific differences were evident. At Baylor and Memphis, the majority of the girls heard about the program from a caregiver, whereas fewer than 15% of the girls at Stanford and Minnesota reported hearing about the program from a caregiver.

At the baseline visit, caregivers and girls were asked to respond to the question, "What interested you in participating in this project?" Across field centers, the most frequent responses among caregivers were: interest in health (56%), interest in diet and physical activity (51%), would be fun for her (46%), and would help her (41%) (Table 4). Among girls, the 3 most frequent responses were: sounded like fun (70%), wanted to be with other kids (21%), and sounded interesting (20%) (Table 4). Only 7% of the girls responded that they were interested in diet or physical activity. Less than 1% of the caregivers, and only 7% of the girls, said they were interested in participating because they could get money or gifts. At Stanford, caregivers and girls who responded for "Other" reasons, reported interest in the proposed interventions of dance and TV reduction. Roughly one third (36%) of the girls in the "Other" category were particularly interested in dance.

Field Center-Specific Experiences

Baylor College of Medicine (BCM)

As shown in Table 2, Baylor broadcast 90 one-minute radio ads, mailed more than 10,000 postcards, and distributed almost 400 flyers. By far their most effective recruitment channel was radio ads. Sixty percent of parents of enrolled girls said they heard about the program from this medium (Table 3). Twenty percent of parents heard about the program by word-of-mouth from a friend or family member. Only 11% of parents heard about the program from the postcard mailings. As most of the recruitment strategies targeted parents, almost all the girls (91%) heard about the program from a parent. Nine percent of girls heard about it on the radio (Table 3).

University of Memphis

This center's most frequently used recruitment approaches were live radio talk shows, PSAs on the radio, and played on the telephone system at University of Memphis for callers on hold, and flyers distributed at local commu-

	Overall (N=210)	Baylor (N=35)	Memphis (N=60)	Minnesota (N=54)	Stanford (N=61)	P value*
Parent/caregiver age, yr (mean, SD)	36.6 (8.3)	36.7 (6.2)	35.5 (7.2)	36.8 (7.6)	37.6 (10.7)	.580
Girl age, yr (mean, SD)	8.8 (0.8)	8.0	8.9 (0.1)	8.8 (0.1)	9.0 (0.1)	.001
Girl age, %						.001
8-yr-old 9-yr-old 10-yr-old	48.6 25.7 25.7	100.0 0.0 0.0	35.0 35.0 28.3	50.0 20.4 29.6	31.1 34.4 34.4	
Education, %	2017	0.0	2013	2010	5	.001
Some high school High school graduate Tech school/some college College graduate/post graduate	3.8 19.0 52.9 24.3	0.0 5.7 37.1 57.1	3.3 16.7 58.3 21.7	5.6 25.9 57.4 11.1	4.9 22.9 52.5 19.7	
Total household income, %						.065
<\$20,000 \$20,000-\$40,000 ≥\$40,000	27.4 38.9 33.6	11.4 34.3 54.3	35.0 33.3 31.7	25.0 46.1 28.8	31.1 41.0 27.9	
Female single-parent household, %	44.8	37.1	50.0	44.4	44.3	.683
Owns home, %	41.4	57.1	50.0	40.7	19.7	.001
Parent caregiver BMI, kg/m² (mean, SD)	31.7 (7.3)	33.6 ^b (8.1)	NA†	32.8 ^a (7.4)	29.7 ^a (6.4)	.017
Parent/caregiver weight status, % Normal weight (BMI <25) kg/m ² Overweight (BMI ≥25 and <30) kg/m ²	16.3 31.3	14.3 25.7	NA† NA†	7.7 32.7	25.0 33.3	.095
Obese (BMI \geq 30) kg/m ²	52.4	60.0	NA†	59.6	41.7	
Girl BMI, kg/m² (mean, SD)	22.2 (5.9)	23.5 ^a (6.7)	23.7 ^a (6.3)	20.7 ^b (4.9)	21.4 ^{a,b} (5.3)	.013
Girl weight status, % overweight‡	44.3	60.0	56.7	29.6	36.1	.072

Table 1. Baseline characteristics of GEMS participants and their caregivers (N=210)

* For comparison among field centers ANOVA and chi-squared analyses were conducted.

+ Data not collected.

 $\pm \geq 95$ th percentile of age-and-sex-specific BMI from the CDC growth charts.

^{a,b} Means in a row with different superscripts are significantly different.

nity centers (Table 2). About two-thirds (65%) of the caregivers of randomized girls said they heard about the project from the radio (Table 3). Girls were most likely to have heard about the project from a parent (60%), a flyer at school (17%), or the radio (12%).

University of Minnesota

As shown in Table 2, this center distributed more than 900 flyers at schools and community centers, and generated 670 mailings. Twelve presentations were made to parents and girls at schools and community sites, and 12 presentations were made to small groups of girls at schools. Initially, one of the intervention sites was to be a neighborhood community center. However, it was difficult to recruit enough girls to have the intervention at this site; therefore, it was held at 3 schools. The number of flyers and mailings reflected the attempt to recruit at this community center site, which was not included in the pilot study.

The most frequent recruitment channels used (presentations to girls at schools, with flyers to take home, and mailings to parents) (Table 2), were consistent with the study information sources caregivers and girls cited most frequently (Table 3). For example, girls reported hearing about the study through school presentations (52%) and school flyers (54%), and the parents reported learning about the program either through the flyer sent home with their child (51%), or directly from their children (38%).

Stanford University

Stanford's main recruitment channel was distributing flyers (Table 2). Over 2400 flyers were distributed at 71 presentations to parents, girls, and community groups and organizations. Caregivers of randomized girls most often reported hearing about the project from a flyer (38%), a presentation at their child's school or in the community (28%), or from their daughter, via a flyer or presentation at school (26%) (Table 3). Of the 13 (21.3%) parents who said they heard about the project from "Other" sources, the majority (10) learned of it from a staff-initiated phone call. Participating girls were most likely to report hearing about the project from a flyer (23%), a presentation at their school, or after-school/community pro-

Туре	Overall	Baylor	Memphis	Minnesota	Stanford
Mass distribution					
Mailing	11748	10790	54	670	234
Distributed flyer	3950	392	195	935	2428
Posted flyer	61	0	61	0	0
Internet distribution	1	1	0	0	0
Media					
Newspaper ads or articles	2	0	2	0	0
Radio story, interview, PSA	783	90	693	0	0
TV story, interview, PSA	1	0	1	0	0
Presentations					
Presentation to parents at church, school, etc	8	2	2	0	4
Presentation to girls at schools, community groups	55	3	39	12	1
Presentation to parents and girls at schools, etc	67	0	4	12	51
Community presentations	16	0	1	0	15
Community outreach					
Recruitment help from community programs	13	0	6	0	7
Health fairs	1	1	0	0	0
Other	37	32†	5	0	0
TOTALS	16743	11311	1063	1629	2740

Table 2. Total number*	of GEMS recruitment	activities by field center
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* For type of recruitment activity, the number for mailing, distributed flyer and posted flyer indicates the actual number sent, posted, or handed out. For all other recruitment channels, the number of "events" is listed (eg, the number of advertisements, articles, stories, health fairs, presentations, etc).

+ The "Other" category at Baylor included responses to GEMS recruitment website and other websites (ie, Girl Scouts of America, Houston Council).

gram (39%), or from their parents, a friend, or other family member (23%) (Table 3). Of the 9 girls (14.8%) who said they heard about the project through "Other" means, three heard about it from a GEMS staff-initiated phone call, and six did not know how they heard about the project.

Reasons for Failure to Return for Baseline Evaluation

At Minnesota and Baylor, 23 and 27 girls, respectively, completed the screening and eligibility form, agreed to a baseline visit, but later declined. At Baylor, the most common reasons for not completing the baseline evaluation were: inability to contact the family (33%), scheduling conflict (30%), losing interest in the study (19%), and not wanting to be randomized (7%). In Minnesota, the most common reasons were: expressed interest but did not follow through with the clinic visit after multiple schedule attempts (78%), did not want to undergo evaluations (13%), and not interested in research studies (9%).

Retention of Participants

Retention among the 210 girls who participated in the 12-week study was high across all 4 field centers. Only 5 girls (1 from Minnesota, 1 from Stanford, 3 from Baylor), or 2.3% of the total sample, did not return for the follow-up evaluation. Reasons included: did not want to undergo evaluations (Stanford), and family moved or could not be contacted (Minnesota, Baylor).

DISCUSSION

This paper describes the recruitment strategies and efforts used to enroll and randomize 8- to 10-year-old African-American girls into GEMS, a multi-center pilot obesity prevention trial. The recruitment drive was successful, with 3 centers (Memphis, Minnesota, Stanford) meeting their target recruitment goals. At the Baylor field center, with a short recruitment period available, only 35 participants enrolled in the study, despite extensive and intensive recruitment activities. Retention in the 12-week pilot study was high across all field centers, with follow-up evaluations completed on 98% of the participants.

Each center simultaneously developed its own recruitment strategies, focusing on those perceived to be the most effective in their community. Multiple recruitment strategies were used at each field center, and effective strategies also varied greatly across the centers. The most effective recruitment strategies were media promotions (eg, radio and flyers), and school and community presentations with support from community or school leaders. Media usage, specifically radio stations serving a predominantly African-American audience, was found to be particularly effective. At Memphis and Baylor, 60%-65% of caregivers reported hearing about the project from the radio. Other studies have also suggested that radio is an effective means to reach ethnic populations.² Informal contacts or word-ofmouth connections were also a common information source for participants, es-

Table 3. How enrolled girls and their ca	aregivers heard about the GEMS Study*
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	Overall ($N = 210$) %	Baylor (N=35) %	Mem- phis (N=60) %	Min- nesota (N=54) %	Stanford (N=61) %
Parent/caregiver					
My daughter	18.1	0.0	3.3	37.7	26.2
Friend or other family member	10.5	20.0	10.0	5.7	9.8
Child's school (flyer)	22.9	0.0	15.0	50.9	19.7
Presentation at child's school	7.1	0.0	0.0	13.2	13.1
Church (flyer)	2.4	5.7	5.0	0.0	0.0
Presentation at church	0.5	2.9	0.0	0.0	0.0
Child's after-school program (flyer)	5.7	0.0	0.0	13.2	8.2
Presentation at child's after-school program	1.9	0.0	0.0	1.9	4.9
Other community program (flyer)	3.8	0.0	1.7	1.9	9.8
Presentation at other community program	1.9	0.0	0.0	0.0	6.6
Newspaper ad or story	1.0	0.0	3.3	0.0	0.0
Mail (letter, flyer, postcard, brochure)	6.2	11.4	0.0	17.0	0.0
Radio (ads, announcements, stories)	28.6	60.0	65.0	0.0	0.0
Internet	1.0	5.7	0.0	0.0	0.0
Work	1.0	5.7	0.0	0.0	0.0
Other	8.6	2.9	0.0	7.5	21.3
Girl					
My mother or father	37.6	91.4	60.0	6.0	13.8
Friend or other family member	8.1	2.9	11.7	6.0	9.8
School (flyer)	23.3	0.0	16.7	54.0	19.7
Presentation at child's school	16.7	0.0	0.0	52.0	14.8
Church (flyer)	0.5	0.0	1.7	0.0	0.0
Presentation at church	1.0	2.9	0.0	2.0	0.0
After-school program (flyer)	7.9	0.0	0.0	6.0	21.3
Presentation at after-school program	1.5	0.0	0.0	2.0	3.3
Other community program (flyer)	1.5	0.0	1.7	0.0	3.3
Presentation at other community program	1.0	0.0	0.0	0.0	3.4
Mail (letter, flyer, postcard, brochure)	1.5	0.0	0.0	6.0	0.0
Radio (ads, announcements, stories)	4.9	8.6	11.7	0.0	0.0
Other	9.9	5.7	13.3	2.0	14.8

* Participants could choose more than one response.

pecially at Baylor, Memphis, and Stan-ford.

While mass mailings are easy to implement and can reach a large audience, they were not sufficiently effective as a sole source for recruiting the population targeted for GEMS. For example, Baylor mailed out over 10,000 postcards, yet only 4 (11%) of the parents reported hearing about the program from a mailing, a yield of less than 0.04%. Other studies have found that flyers, brochures, or newspaper ads are not effective in reaching minority populations, and that active community-oriented approaches with personal connections and community support are necessary.4,5 In GEMS, distributing flyers and generating mailings, combined with community outreach efforts, such as endorsements from community leaders or presentations to parents and/or girls, were an effective recruitment strategy. These methods are consistent with those recommended by previous focus group studies.³

Our results, demonstrating that a variety of approaches were effective at each field center, are similar to other studies' findings that no single strategy can be used to successfully achieve recruitment goals, and that multiple strategies are essential when recruiting for prevention trials in minority communities.^{2,4} Several of the GEMS recruitment strategies were novel, and warrant further exploration in studies, such as the use of a GEMS recruitment Web site (Baylor), live radio talk shows (Memphis), playing radio announcements for callers on hold at the University of Memphis, staff-initiated phone calls and hotlines (Stanford), school presentations made directly to girls, who then persuaded parents to attend an information meeting (Minnesota), and the use of video-tapes to show a sample clinic visit (Minnesota). These may be important potential recruitment strategies for prevention trials, especially for those involving children.

Reasons for enrolling in the study provide insights into the characters of those interested in participating in community-based obesity prevention studies. The majority of African-American caregivers reported being interested in participating because of health concerns, interest in diet and physical activity, and in helping their daughters develop healthy lifestyles. This finding is similar to those of other studies. In the Dietary Approaches to Stop Hypertension (DASH) study,6 African-American adult participants overwhelmingly (89%) cited health and dietary factors as their primary reasons for participating. In contrast to White participants, Africa Americans were more likely to cite positive, health-related factors as influencing participation.6 Focus groups conducted with African-American adults in Alabama on participation in clinical trials, found that most said they would be involved if the research was beneficial to their family or community.3 In GEMS, the study's benefit for the girls of helping them develop healthy lifestyles was clearly communicated. Fewer than 1% of the caregivers, and only 7% of the girls, cited the study's financial incentives (monetary reimbursement or gifts) as reasons for participating. This is similar to the DASH study, in which only 6% of African-American adults listed financial incentives as their primary reason for participating.6 The major reason girls were interested in participating in

Table 4. Enrolled girls' and their caregivers' interest in participating in the GEMS Study*

		n 1		Minne-	<u></u>
	Overall (N =210)	Baylor (N=35)	Memphis (N=60)	sota (N=54)	Stanford (N=61)
Parent/caregiver					
Interested in diet and physical activity	51.4	77.1	81.7	43.4	14.8
Interested in health	56.2	62.9	75.0	47.2	42.6
Would be fun for me	12.0	17.1	16.7	13.2	3.3
Would be fun for her	46.2	65.7	68.3	45.3	14.8
Would help her	40.5	60.0	58.3	30.2	21.3
Wanted to learn more about the program	23.9	14.3	56.7	18.9	1.6
Wanted her to be with other kids	9.1	17.1	5.0	11.3	6.6
She wanted me to come	11.0	0.0	1.7	32.1	8.2
Sounded interesting	13.8	5.7	8.3	24.5	14.8
An important health issue	16.3	31.4	6.7	30.2	4.9
Can get money or gifts	0.5	0.0	0.0	0.0	1.6
Other	11.9	2.9	3.3	5.7	31.1
Girl					
Sounded like fun	70.0	80.0	83.3	81.2	37.7
Wanted to learn more about the program	16.5	8.6	21.7	31.2	3.5
Wanted to be with other kids	21.0	25.7	18.3	37.5	7.0
Sounded interesting	20.0	17.1	21.7	27.1	13.1
Can get money or gifts	6.5	0.0	1.7	25.0	0.0
Flyer or letter in the mail	2.5	0.0	3.3	4.2	1.7
Parent wanted me to come	20.0	37.1	38.3	8.3	0.0
Would be good for my health	14.5	25.7	13.3	18.7	5.3
Interested in diet or physical activity	7.0	22.9	3.3	8.3	0.0
Other	18.0	0.0	1.7	4.2	54.1
* Participants could choose more than one respon	nse.				

GEMS was to have fun, which is developmentally appropriate. In attracting girls, recruitment efforts must be appealing, engaging, and fun, rather than emphasizing health benefits.

Recruitment of 50 participants from each site took longer than the two months initially planned, with the actual time being 2.5 to 4 months. The general consensus of the literature is that recruitment takes longer than investigators initially plan, and that the pool of eligible persons is often over-estimated.^{2,4} Because the complexity and extent of recruitment efforts are often underestimated, adequate planning time is needed.

Selection and response biases may have influenced the results. The results are limited to randomized participants, a sample of volunteers who may differ systematically from people who declined to participate. Nevertheless, random assignment to an intervention or control group minimizes bias, because unmeasured factors are expected to be distributed equally between the treatment groups. Field centers were unable to collect information on those not interested in participating in the study. Standardized data were also not collected across centers on those who were ineligible. Calculating recruitment costs for the different recruitment methods would have been beneficial. Other studies have found that recruitment costs vary considerably, ranging from 4% to 16% of the total study budget, across field centers.² Three of the 4 centers were recruiting primarily low-income populations. Successful recruitment strategies required additional resources, such as childcare, provision of transportation and meals, flexible staff and overtime hours, and staff mileage reimbursement, since recruiting was done in the community. Clinic visits for the baseline and follow-up evaluations also required these

same support services. These services were absolutely essential to the success of recruitment and retention. Swanson and Ward² noted that investigators and researchers must realize that including economically disadvantaged populations, minorities, and rural populations will increase the costs of research.

Several researchers have presented key elements for successful recruitment and retention efforts for minority populations.^{2-4,7,12} GEMS tried to incorporate the following strategies based on these recommendations from the literature: 1) use of focus groups and interviews with key informants to identify and understand the potential barriers to participation of the defined populations; 2) determine the needs of the target populations to enable them to participate in the study; 3) develop an epidemiological and anthropological profile of the community; 4) develop an early and sustained relationship with the community, based on openness, trust, and honesty; 5) provide clear benefits to the community and participants; 6) develop a recruitment plan that includes approaches for integrating the study into the target communities; 7) use multiple recruitment strategies; 8) conduct pilot studies of specific recruitment strategies and intervention components; 9) employ study staff from the same ethnic background as the participants; 10) develop eligibility criteria to be as inclusive as possible; 11) develop flexible study procedures, where feasible; and 12) develop culturally competent methods, procedures, and instruments. In GEMS, these strategies were important contributors to our success in recruiting and retaining African-American girls and their caregivers. Flexibility, creativity, and readiness to change recruitment strategies during the recruitment period were also important factors in meeting enrollment goals.

In conclusion, the GEMS experience demonstrates the feasibility of recruiting and enrolling African-American girls into prevention trials focusing on behavior. Our success in recruiting and retaining participants was due to the multiple recruitment strategies employed, and to the development of trusting relationships with each of the respective communities. The GEMS experience supports the premise that in order to successfully conduct research in minority communities, there must be a foundation of trust and respect, and clear benefits to participants. Because this is a relatively new dimension of research, reports of experiences, successes, and lessons learned in recruiting diverse populations for health behavior research, will be beneficial in the future.

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