Combining community participatory research with a randomized clinical trial: The protecting the hood against tobacco (PHAT) smoking cessation study

Erika Sivarajan Froelicher, RN, MA, MPH, PhD,[a,b] Daniel Doolan, RN, PhD,[a,c] Valerie B. Yerger, ND,[d] Carol O. McGruder, BA, DEF,[e] and Ruth E. Malone, RN, PhD, FAAN[d,f]

BACKGROUND: This article describes the process and results of a smoking cessation intervention randomized clinical trial (RCT) that was conducted as a community-based participatory research project. This RCT tested whether outcomes are improved by adding social justice and tobacco industry targeting messages to a smoking cessation program conducted among African American adults within a low-income community in San Francisco, California. This study provides lessons for future similar research projects that focus on urban low-income populations.

METHODS: Participants were randomly allocated to receive a smoking-cessation program (control group [CG]) or CG care plus tobacco industry and media (IAM) messages. Primary interventions were behavioral. At intake, participants reporting severe withdrawal or smoking ≥ 25 cigarettes daily were offered free nicotine replacement therapy. Baseline data were from an in-person interview. Outcome measures included self-reported smoking status; validation of quitting was by salivary cotinine assays.

RESULTS: Of 87 participants providing baseline data, 31% (27) did not join the RCT. Proportions quitting in the CG and IAM group were 11.5% and 13.6% at 6 months and 5.3% and 15.8% at 12 months, respectively.

CONCLUSION: African Americans in underserved inner-city neighborhoods can be recruited into RCTs with community participatory approaches. Differences between the CG and IAM in proportions who quit were 2.1% and 10.5% at 6 and 12 months, respectively. More than 3 years with adequate funding, high staffing ratios, and intense outreach and follow-up schedules are needed to achieve recruitment and study goals. (Heart Lung® 2010;39:50–63.)

The National Institutes of Health and other funding agencies have encouraged researchers to partner with communities to conduct community-based participatory research intervention studies aimed at addressing health disparities (eg, http://grants.nih.gov/grants/guide/rfa-files/RFA-MD-07-003.html). This is a laudable goal for shifting the research paradigm from research "on" communities to research "with" communities that is relevant and responsive to community concerns. However, conducting such studies is exceptionally challenging. This article, which reports on the process and

From the [a]Department of Physiological Nursing, School of Nursing, University of California, San Francisco, California; [b]Department of Epidemiology and Biostatistics, School of Medicine, University of California, San Francisco, California; [c]San Francisco University, San Francisco, California; [d]Department of Social and Behavioral Sciences, School of Nursing, University of California, San Francisco, California; [e]Polaris Research and Development and San Francisco African American Tobacco Free Project, San Francisco, California; and [f]Institute for Health Policy Studies, School of Medicine, University of California, San Francisco, California.

This study was supported by funding from the California Tobacco-Related Disease Research Program (grants 11BT-1701 and 12AT-1700).

Corresponding author: Erika Froelicher, RN, MA, MPH, PhD, Department of Physiological Nursing, 2 Koret Way, Room N631, University of California San Francisco, San Francisco, CA 94143-0610.

0147-9563/$ – see front matter

doi:10.1016/j.hrtlng.2009.06.004

results of a smoking cessation intervention clinical trial that was conducted as a community-based participatory research project, provides lessons for future similar research projects and other studies focused on urban low-income populations.

BACKGROUND

Among all racial and ethnic groups in the United States, African Americans have the worst outcomes from tobacco-related diseases.[1] Age-adjusted mortality rates for tobacco-related cancers[2-7] and cardiovascular disease and stroke[8] are higher among African Americans than among non-Hispanic whites, highlighting the importance of developing more effective smoking cessation interventions for this population. The benefits of quitting smoking are well documented and include major reductions in risk for tobacco-related disease.[9,10] Although African Americans, compared with whites, are less likely to be heavy smokers, some research suggests that African Americans have a higher intake of nicotine per cigarette and metabolize nicotine more slowly,[11] and that they are also less likely to quit smoking.[12] By race/ethnicity, the percentage of ever smokers who had quit in 2000 was lowest among African Americans.[13]

A review in 2000 of smoking cessation studies among African Americans concluded that no specific strategies are optimal for use with African Americans.[14] However, federal guidelines suggest that tailored interventions may be effective.[15] Although a few smoking cessation studies have tested interventions tailored for African Americans, most of them were descriptive studies or did not use an experimental design.[16] One community study showed success in reducing smoking prevalence rates from 27% to 34% in low-income African American populations.[17] The authors concluded that more research was needed to identify effective smoking cessation methods suitable for African Americans. Although previous work suggests that racial identification or acculturation may bear on success in quitting,[16,18] no previous community capacity building studies among African Americans have made use of tobacco industry documents or media deconstruction training.

In conjunction with the tobacco industry's efforts to promote smoking among African Americans, its pervasive ties with African American community organizations, and its exploitation of those ties to thwart public health policies,[19] low-income African American communities have been subjected to intensive, geographically targeted marketing of tobacco products.[20,21] Previous work has suggested that African American smokers might be mobilized toward quitting after reviewing tobacco industry documents about racial targeting by the industry.[22] The Protecting the Hood Against Tobacco (PHAT) randomized clinical trial (RCT), conducted as part of a community-based participatory project, investigated whether including tobacco industry documents in a cessation program to contextualize the social justice implications of tobacco promotion could help African Americans quit smoking. This article describes the characteristics of the sample of African American adults in the low-income urban community who enrolled or did not enroll in the PHAT RCT;[23] the study design, methods, intervention protocols, and results of the RCT; and some of the lessons learned from our experience combining community participatory and RCT research.

MATERIALS AND METHODS

This RCT was designed to assess the efficacy of an evidence-based smoking cessation program for a control group (CG) compared with that of the same program supplemented with a tobacco industry and media (IAM)-related smoking cessation intervention. The PHAT project, which engaged neighborhood residents in tobacco control and encouraged smoking cessation, included community residents in the planning of the research and as both paid and volunteer program staff.

Setting

The study took place at Southeast Health Center, an established public clinic geographically accessible to residents of the Bayview–Hunters Point (BVHP) neighborhood of San Francisco, California. This predominantly African American neighborhood includes a large proportion of smokers, according to an earlier survey showing that 48% of BVHP households included smokers.[24] Residents of the community had well-documented health disparities, including higher than average rates of tobacco-related disease and preventable hospitalizations.[25] In addition, 50% of African Americans in this neighborhood reported that people smoked indoors, compared with just 25% of the Asian/Pacific Islanders living in the same community.[24] Moreover, in the earlier survey, 55% of BVHP African Americans "believed that health and illness were entirely beyond their control," compared with 15% of BVHP whites.[24-25] This RCT focused on empowerment and social justice to address these factors within a smoking cessation program for African Americans.

Table I
Industry and media intervention program

Key activities-curriculum content	Purpose/objective
Week 1	
- Prioritization of community issues/ problems - Tobacco 101 "tidbits"-game - Introduction to community capacity building process	- Reframing tobacco use as grave community concern - Group bonding-introduction of tobacco industry facts - Community empowerment-capacity building
Week 2	
- Continuation of community capacity building process - Introduction to tobacco industry tactics targeting African American community. - Case study of NAAPI and Uptown Cigarettes	- Community empowerment-Capacity building
Week 3	
- Deconstruction of tobacco advertising and media campaigns	- Media literacy
Week 4	
- Tobacco industry documents review-"*Smoking with the Enemy*" - "Personalization of Loss" exercise - Letter writing exercise	- Community education and empowerment re: true nature and breadth of tobacco industry's predatory behavior. - Education re: scope and impact of tobacco-related deaths on African American community.
Week 5	
- Finish letter writing exercise - Complicity of African American leadership groups and the tobacco industry- - Deputization of study participants as tobacco control advocates	- Community empowerment - Build community tobacco control capacity

NAAPI = National Association of African Americans Positive Imagery.

Sample

We recruited residents of the BVHP neighborhoods by using the following inclusion criteria: self-identification as African American; age ≥ 21 years; tobacco use during the past month; willingness to quit smoking as assessed by an intake interview; and agreement to be available by telephone for follow-up reviews at 6 and 12 months after the intervention and to provide salivary cotinine samples. Exclusion criteria were inability to read or speak English, which would preclude participants being able to use intervention components; dependence on other addictive substances, except marijuana; because people dependent on such substances require dual intervention and referral to other resources; disabling health conditions that could prevent attending and involvement in the RCT for up to 1 year of follow-up review; and potential subjects not affirming that they would be in the area and able to take part in the study for the next 12 months. On the basis of a sample size calculation, approximately 270 participants were required to accommodate a 25% attrition rate and obtain approximately 200 participants, or 100 in each group. This sample size would be sufficient to have 80% power to detect a difference between groups at the $p < .05$ level.

Recruitment

PHAT community research partners and BVHP community residents who took part in a pilot phase of the PHAT project[26] conducted outreach to community organizations that had expressed interest in PHAT's efforts to reduce tobacco use.[27] Recruitment flyers were widely distributed in the community. Content from the flyers was placed as advertisements in a local BVHP newspaper, and flyers were distributed at community events, such as wellness fairs, at cultural events, and in beauty salons, barber shops, libraries, and other venues. Working with a local community member, we created a website to invite participants into the program, and public service announcements featuring community residents were aired on local public access television and radio stations. To facilitate recruitment and retention, incentives were offered, including free child care, free nicotine replacement therapy (NRT), free cessation program materials, $5 in payment for each session attended, and, as a bonus to those who completed all program sessions, entry into a "Quit and Win"[28,29] drawing for $500 at the end of the study. In addition, those confirmed smoke-free at 6 and 12 months were entered into a second "Quit and Win" drawing for an additional $500. Recruitment was conducted over a period of 25 months, starting on April 21, 2004, and ending on May 31, 2006.

Initial contact methods. Potential enrollees initiated contact as suggested on recruitment flyers, telephoning the project director (V.B.Y.), who managed eligibility screening and randomization to groups.

Consent process and documentation. The project director explained the study to callers, answered questions, and screened for eligibility. If a person was eligible and wanted to participate, an in-person enrollment appointment was scheduled at his/her convenience. Informed consent was explained, and written signed consent was obtained by using procedures approved by the University of California, San Francisco's institutional review board.[26]

Randomization procedures

Randomization was by random permuted blocks for groups of participants, each group having an equal chance of assignment to the CG or the IAM intervention group. Because true blinding is not possible with a behavioral intervention, all baseline data were collected before random allocation to blinded data collectors to subsequent group assignment.[30-37]

Group assignment

The CG received a 1-hour pre-class orientation session followed by a standard 5-week smoking cessation intervention, including established evidence-based behavioral interventions. The program was delivered by a community health nurse trained in smoking cessation techniques, who provided educational and cognitive behavioral smoking cessation interventions based on established guidelines.[15,30,31] At the time, this was the only smoking cessation program offered in the neighborhood. The program was free and included lectures, written handouts about preparation for quitting smoking, and discussions of quitting strategies and relapse-prevention strategies. Participants received an edited version of *Pathways to Freedom* (PTF)—a smoking cessation guide from the Centers for Disease Control and Prevention specifically tailored for African Americans[38]—to use in the group setting and to take home. The editing consisted of removing sections of PTF focused on social justice messages, because this conceptual component was a key part of the intervention delivered only to the IAM group. To prepare participants in both groups for relapse prevention,[39] they were referred to the California Smokers' Helpline and encouraged to make a call during one of the sessions to familiarize themselves with this telephone support service.

The IAM intervention group program included all features of the CG program plus a tailored, community co-developed IAM intervention (Table I). Participants were scheduled to attend a 1-hour pre-class orientation session followed by a total of five 2-hour group sessions, each of which included both presentation and reinforcement of previously discussed educational and behavioral strategies to avoid relapse, plus the IAM components.[40,41] The IAM group received an unedited PTF smoking cessation guide.[38]

The IAM program, consisting of a denormalization/deconstruction educational intervention that had been pretested,[42] was delivered to all IAM group sessions to convey and reinforce the key messages about tobacco industry targeting, community empowerment, and social justice. This component included content (Table I) shown to participants weekly from internal tobacco industry documents that revealed the industry's targeting and psychographic studies of African Americans. It provided didactic content about how African Americans are disproportionately harmed by tobacco, used advertising analysis exercises to show how the tobacco industry uses Africans to market to African Americans and vice versa, and provided exposure to guest speakers, including successful quitters from the community who discussed

Table II
Demographics and health problems in African Americans enrolled and not enrolled in RCT

	In RCT		Not in RCT	
Demographics				
Age (mean, SD)	46.62 (±10.3)	60	47.53 (±9.4)	27
	%	n	%	n
Women	71.7[a]	43	44.4[a]	12
Education				
No high school	1.7	1	0	0
Some high school	16.7	10	29.6	8
High school graduate	23.3	14	25.9	7
Some college	45.0	27	29.6	8
College graduate	11.7	7	14.8	4
Post graduate	1.7	1	0	0
Marital status				
Single	41.75	25	40.1	11
Married	13.3	8	25.9	7
Widowed	6.7	4	11.1	3
Divorced	25.0	15	14.8	4
Separated	10.0	6	7.4	2
Employment				
Employed full-time	20.0	12	7.4	2
Employed part-time	11.7	7	7.4	2
Unable to work	15.0	9	14.8	4
Unemployed	18.3	11	33.3	9
Annual income				
$0-$4999	23.3	14	29.6	8
$5000-$14,999	35.0	21	37.0	10
$15,000-24,999	11.7	7	0	0
$25,000 to > $50,000	18.3	11	22.2	6
Do not know/refused	11.7	7	11.1	3
Health problems				
Hypertension	43.3	26	25.9	7
Heart disease	11.7	7	3.7	1
Diabetes mellitus	16.7	10	18.5	5
Psychiatric problems Hx	21.7	13	11.1	3
Ever been hospitalized	60.0	36	66.7	18
Life-threatening illness	38.3	23	44.4	12

SD = standard deviation; RCT = randomized clinical trial.
[a]Statistically significant $P = .02$.

their quitting experiences and how it felt to be smoke-free. Community partners helped with final selection of the documents and advertisements to be presented. The IAM protocol, standardized for use in the PHAT RCT, was delivered by an experienced community tobacco control advocate (C.McG.) who also served as community co-Principal Investigator.

Participants completing the IAM program were also referred to telephone support services for relapse prevention sessions. Because federal guidelines suggest that advice from a health professional may enhance smoking cessation, a health care practitioner provided initial smoking cessation education and counseling by using established guidelines in the group's pre-class orientation session.[15] The education, counseling, and behavioral intervention focused on relapse triggers and planning for situational coping. Because of challenges in recruiting and retaining participants, an experienced community tobacco control advocate assisted the health professional at the initial pre-class orientation by delivering a social justice "teaser" to motivate participants at the pre-class sessions.

Table III
Smoking patterns for those in and not in RCT

	In RCT n = 60				Not in RCT n = 27			
Instrument	Mean	SD	Range	n	Mean	SD	Range	n
Self-efficacy	50.63	24.6	0-100	60	56.39	24.8	1-100	27
Pack years smoked	14.21	10.8	0.2-38	56	11.30	11.1	0.2-38	27
No. of daily cigarettes	11.35	7.1	1-35	58	8.40	6.2	1-20	27
Years smoked regularly	24.4	11.2	0.5-50	58	25.28	12.0	1.5-50	27
Duration of longest quit attempt (d)[a]	351.3	614	0-3650	54	452.6	775	0-3650	26

RCT = randomized clinical trial; SD = standard deviation.
[a]Longest quit year skewed to the right with 2 participants reporting quit for 10 y.

Table IV
Health perceptions and knowledge for those in and not in RCT

	In RCT		Not in RCT	
	%	n	%	n
My overall health is				
Excellent/very good	25.0	15	22.2	6
Good	41.7	25	40.7	11
Fair/poor	33.3	20	37.0	10
How likely are you to avoid future health problems if you quit smoking now?				
Very likely/likely	80.0	48	81.5	22
Uncertain/unlikely/very unlikely	20.0	12	18.5	5
If you have smoked > 20 y, there is little benefit from quitting?				
Strongly disagree/disagree	75.0	45	59.3	16
Neither disagree or agree/agree/strongly agree	16.7	10	25.9	7
Smoking is harming my health				
Strongly disagree/disagree	20.0	12	14.8	4
Neither disagree or agree/agree/strongly agree	75.0	45	74.0	20

RCT = randomized clinical trial.

Pharmacologic component offered to both groups

Although the primary treatments for both programs were behavioral, nicotine patches or lozenges were made available for participants highly addicted to nicotine and those who requested them. Participants were offered NRT at no cost if they reported severe withdrawal, such as symptoms of craving during previous attempts to quit, or reported use of ≥ 25 cigarettes daily. Pregnant and lactating women were not offered the pharmacologic portion of the intervention, because NRT patches have not been approved for use in those populations, but they were eligible for the primary behavioral component of the intervention. An African American registered nurse from the community instructed participants in proper use, including cautions against smoking while using patches or lozenges and a tapering schedule following manufacturer's guidelines.[39]

Procedures for data collection. The initial phase of the study consisted of the following steps:

Table V
Smoking practices and beliefs of African Americans in and not in RCT

Most frequent brand	In RCT %	n	Not in RCT %	n
Newport	51.7	31	59.3	16
Generics	10.0	6	14.8	4
Kool	8.3	5	3.7	1
Other	30.0	18	22.2	6
Nicotine-dependence measures				
First A.M. cigarette within 30 min	60.0	36	44.4	12
Smoke most in A.M.	28.3	17	25.9	7
Smoke when ill	36.7	22	25.9	7
Smoking unrestricted in home	25.0	15	29.6	8
Lives alone	31.7	19	25.9	7
Others in house smoke	48.3	29	29.6	8
Closest person smokes	38.3	23	40.7	11

RCT = randomized clinical trial.

participants' recruitment, informed consent, baseline data collection, and randomization to the control program or IAM intervention program. Baseline data were obtained directly from participants in an in-person interview before their randomization to the CG or IAM intervention group. Data collection included questions about demographics, smoking history, knowledge and beliefs about health, addiction screening, confidence to quit smoking, childrearing status, and smoking practices in the home. This feature provided baseline data unbiased with respect to subsequent group assignment. After all baseline procedures were completed and before the beginning of the first group intervention session, participants were randomly assigned to the CG or IAM group. Each participant was contacted for follow-up data collection in a telephone interview at 6 and 12 months after randomization.

Measurements

Data from the following assessments were obtained identically in both groups.

Baseline assessment included self-reported *demographic data* (age, ethnicity, education, marital status, employment status, and income). Clinical data included risk factors, prior admissions to the hospital, and life-threatening conditions.

The *smoking history* consisted of a 22-item instrument originally developed for the Women's Initiative of Nonsmoking "WINS" trial[30,31] that assesses levels of addiction, quitting smoking, years of smoking, average number of cigarettes smoked daily, intent to stay off cigarettes, and confidence in being able to remain off cigarettes. We also included questions concerning secondhand smoke.

The *Stanford Dependency Index*[32,33] was used to measure degree of addiction to nicotine. This instrument, derived from the Fagerstrom Tolerance Questionnaire,[20] classifies addiction on the basis of 5 questions. Scores can range from 0 to 25; test–retest correlations for the 5 questions ranged from 0.71 to 0.90. Beliefs and knowledge about the benefits of smoking cessation[34] were ascertained from 3 standardized questionnaire items developed and tested in more than 4000 smokers in 20 communities in the United States in 1989 by the National Cancer Institute's Community Intervention Trial for Smoking Cessation.[7] Each item had 4 response choices: 1) How likely do you think it is that you will avoid or decrease serious health problems from smoking if you quit? ("very likely" to "very unlikely"). 2) If you have smoked more than 20 years, there is little benefit from quitting? Response options were ("strongly agree" to "strongly disagree"). 3) Smoking is harming my health ("strongly agree" to "strongly disagree").

The Self Efficacy assessment used a Confidence Questionnaire[35] (scale of 1-10)[35,36] that lists 14 high-risk situations likely to cause a relapse to smoking. Participants were asked to rank their confidence that they could resist the urge to smoke in each situation on a scale of 0% (not at all confident) to 100% (very confident). A score of less than 70% denoted a high risk of relapse.

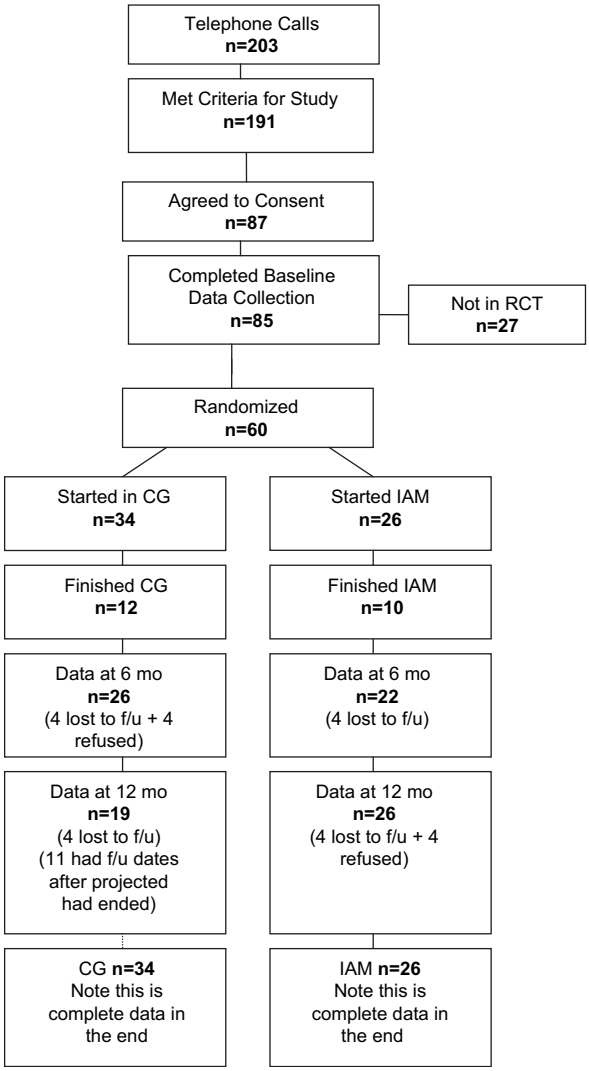

Fig 1 Recruitment, Enrollment and Retention Statistics for the Sample. RCT = randomized clinical trial; CG = control group; IAM = industry and media.

Primary outcome measurement

At 6 and 12 months, all participants in both groups who reported that they had not smoked in the past 7 days, "not even a puff," were asked for a saliva sample that was analyzed for cotinine to verify nonsmoking status.[37] If cotinine testing was not available, we attempted to verify smoking status through the participant's family and friends. Participants with cotinine levels of less than 14 ng/dL were considered nonsmokers for their latest follow-up period.[37] If a self-report of not smoking was contradicted by either cotinine testing or the participant's family or friends, then we assumed that the participant had resumed smoking. If neither cotinine verification nor verification from family or friends could be obtained, then the participant's status was considered "missing."

Quality assurance was established through an initial 8-hour training session for all data collectors and interventionists. Initial biweekly and subsequent monthly meetings of the research group and interventionists (registered nurses) ensured consistency of the protocol, and all protocol modifications were communicated to all study staff orally and in writing. These measures aimed at ensuring high quality and consistency of data collection, as well as integrity of the intervention.

Data management and analysis

The Statistical Package for the Social Sciences (SPSS Inc, Chicago, IL) was used for data entry, management, and analysis. This report describes the intention-to-treat analysis approach and conforms to CONSORT[43,44] guidelines in the reporting of the results of the RCT.

Study execution issues

The study team initially had the impression that the BVHP public clinic had a smoking cessation intervention program available for its patients, and that participants in that intervention would serve as the usual care or CG. As planning for this study evolved, it became apparent that the program was no longer a viable control program. The medical and nursing team of the public clinic requested, on ethical grounds, that our research team provide a cessation program to the CG as a condition for clinic participation. This additional unbudgeted requirement resulted in diversion of half the intervention program funds to mounting the CG. Additional funding was sought but not granted. We analyze the implications of this circumstance and other issues that arose in the "Discussion" section.

RESULTS

Sample characteristics

On the basis of a sample size calculation, we planned for a study sample of approximately 200 participants, 100 in each group. A total of 203 calls were received by the PHAT project regarding the program; 196 participants obtained information and agreed to be screened for the study. Of that number, 191 met the eligibility criteria. We recruited 87 African American adults who took part in baseline data collection between April 21, 2004, and May 31, 2006. Of the 87 participants, 60 took part in the RCT and the other 27 took part in baseline data

Table VI
Demographics and health problems in African Americans by group assignment

Demographics	CG	IAM	
	Mean	Mean	SD
Age, y	46.7	46.5	(10.8)
	%	%	n
Women	64.7	80.8	21
Education			
Some high school/less	17.6	19.2	5
High school graduate	23.5	23.1	6
Some college	50.0	38.5	10
College graduate +	8.8	19.2	5
Marital status			
Single	44.1	38.5	10
Married	11.8	15.4	4
Widowed	5.9	7.7	2
Divorced/separated	38.2	38.4	10
Employment			
Employed full-time	8.8[a]	34.6[a]	9
Employed part-time	11.8	11.5	3
Unable to work	14.7	15.4	4
Unemployed	23.5	11.5	3
Annual income			
$0-$14,999	55.9	61.5	16
$15,000-$24,999	11.8	11.5	3
$25,000+	14.7	23.5	7
Do not know/refused	17.6	3.8	1
Health problems			
Hypertension	44.1	42.3	11
Heart disease	8.8	15.4	4
Diabetes mellitus	23.5	7.7	2
Psychiatric problems Hx	23.5	19.2	5
Ever been hospitalized	58.8	61.5	16
Life-threatening illness	41.2	34.6	9

CG = control group; IAM = industry and media.
[a]Statistically significant difference $P = .01$.

collection but did not enroll in the RCT. Tables II to V describe the characteristics of participants in the RCT and those not in the RCT. This information may be useful to future researchers in assessing the number of persons who need to be approached and screened to obtain a desired sample size.

An evaluation of participants who followed through to take part in the RCT and those who did not reveals only minor differences between these 2 groups (Tables II-V). Of the 55 participants who were women, 71.7% were in the RCT and 44.4% were not in the RCT, a statistically significant ($p = .02$) difference. The average age, education, marital status employment, and income were similar in those in the RCT versus those not in the RCT. Similarly, descriptions of the chronic health problems, life-threatening illness, previous hospitalization, perceived general health status, and knowledge, attitudes, and beliefs about smoking were not significantly different across the 2 groups (Table II). Smoking patterns (Table III), health perceptions (Table IV), and smoking practices (Table V) did not differ between the participants who were in or not in the RCT.

Figure 1 shows numbers and proportions in regard to the study sample, recruitment, baseline data collection, and enrollment into the RCT. Randomization resulted in the assignment of 34

Table VII
Smoking patterns by group assignment

	CG				IAM			
Instrument	Mean	SD	Range	n	Mean	SD	Range	n
Self-efficacy	50.5	25.1	10-100	34	50.8	24.4	0-89	26
Pack years smoked	16.5	10.7	0.3-38	31	11.4	10.3	0.2-37	25
No. cigarettes/d	11.9	6.0	2-30	32	10.7	8.3	1-35	26
Years smoked	26.1	10.8	0.5-50	33	22.2	11.5	2-40	25
No. of quit attempts	2.2	2.1	0-10	30	2.6	1.6	0-7	22
Duration of longest quit attempt (d)[a]	345.6	692	0-3650	30	358.3	515	1-1825	24

CG = control group; IAM = industry and media; SD = standard deviation.
[a]One outlier removed from each group reporting 20.

Table VIII
Health perceptions and knowledge by group assignment

	CG		IAM	
	%	n	%	n
My overall health is				
Excellent/very good/good	58.8	20	77.0	20
Fair/poor	41.2	14	23.1	6
How likely are you to avoid future health problems if you quit smoking now?				
Very likely/likely	85.3	29	73.1	19
Uncertain/unlikely/very unlikely	14.7	5	26.9	7
If you have smoked > 20 y, there is little benefit from quitting?				
Strongly disagree/disagree	76.5	26	73.1	19
Neither disagree or agree/agree/strongly agree	14.7	5	19.2	5
Do not know or refused	8.8	3	7.7	2
Smoking is harming my health				
Strongly disagree/disagree	14.7	5	26.9	7
Neither disagree or agree/agree/strongly agree	82.4	28	65.4	17
Do not know	2.9	1	7.7	2

CG = control group; IAM = industry and media.

participants to the CG and 26 participants to the IAM group. Tables VI to X compare the CG and IAM group. The 2 groups were similar in regard to important sociodemographic, smoking patterns, health perceptions, and knowledge variables (Tables VI-IX), except that 8.8% in the CG versus 34.6% in the IAM group were employed, a statistically significant difference ($p = .01$). Follow-up data were provided by 80% of participants in the CG and 75% in the IAM group at both the 6-month and 12-month follow-up data collection points.

Table X shows intention-to-treat analyses at 6 and 12 months; 11.5% of the CG and 13.6% of the IAM group were smoke-free at 6 months, whereas only 5.3% of the CG but 15.8% of the IAM group remained smoke-free at 12 months. None of the smoking

Table IX
Smoking practices and beliefs of African Americans by group assignment

Most frequent brand	CG %	n	IAM %	n
Newport	50.0	17	53.8	14
Generic	8.8	3	11.5	3
Kool	14.7	5	0	0
Other	26.5	9	34.6	9
Nicotine dependence measures				
First A.M. cigarette within 30 min	58.8	20	34.6[a]	9
Smokes most in morning	35.3	12	80.8[a]	21
Smokes when ill	35.3	12	38.5	10
Smoking unrestricted in home	29.4	10	19.2	5
Lives alone	23.5	8	42.3	11
Others in house smoke	58.8	20	34.6[a]	9
Closest person smokes	47.1	16	26.9	7

CG = control group; IAM = industry and media.
Statistically significant $P = .01$.
[a]$P = .06$.

Table X
Comparison of smoking cessation differences by group assignment

Follow-up Time	CG		IAM		
	%	n	%	n	*P*
6 mo	11.5	3/26	13.6	3/22	NS
12 mo	5.3	1/19	15.8	3/19	NS

CG = control group; IAM = industry and media; NS = not significant.

cessation outcomes were significantly different, presumably because of the low numbers per group.

DISCUSSION

The PHAT project, a combined community participatory and randomized trial of a smoking cessation intervention for African American residents of a low-income, urban community, was designed to test the efficacy of an evidence-based smoking cessation program alone compared with efficacy of the same program supplemented with a tobacco IAM social justice intervention. However, although we were successful in sustaining the community partnership for more than 4 years, the trial itself was unsuccessful in enrolling a sufficient sample size of participants.

Our research approach had several limitations: First, we failed to include a measure for chronic obstructive pulmonary disease, which is highly correlated with tobacco use and often serves as a motivation for quitting. Second, our use of the brief social justice "teaser," decided on after our recruitment difficulties became apparent, could have made it more difficult for us to find a difference between groups had we achieved sufficient sample size. However, the primary limitations of our study were our inability to recruit and enroll a sufficient number of participants, and the resulting inability to answer our research questions.

Although careful preliminary work had been conducted in the community using principles of community participatory research, the actual participation in recruitment and completion of intervention and follow-up fell short by a higher degree than estimated in the planning phase. In view of the well-documented challenges to enrolling sufficient numbers of African Americans in clinical research, our inability to reach our recruitment goals within the BVHP community is not unusual. One of the most obvious explanations for the inadequate participation rate is that the challenges facing the particular community under study were significant, including poverty, violence, and other drug problems. The competing everyday demands faced by community members are such that long-term participation in health-promotion activities seemed to be a luxury few could afford, despite their sincere

expressed desire to gain assistance with their smoking cessation efforts and the multiple incentives offered.

Although 27 (31%) of the 87 participants who provided baseline data were subsequently unable to take part in the PHAT RCT, an evaluation of their data can provide an estimate for sample-size calculations in the future. These participants' level of commitment may have been greater than their non-enrollment would suggest. Those who enrolled in the RCT also had more years of education and more accurate knowledge about the potential health benefits of quitting smoking, as shown by their more often answering correctly the question on being able to achieve health benefits after having smoked for more than 20 years. Those enrolling in the RCT also had a higher frequency of hypertension, the diagnosis of which might motivate quitting.

The time frame and limited funding of the study were also contributors to our failure to recruit sufficient participants to achieve the necessary sample size for adequate statistical power. Undertaking to mount both control and intervention programs with a budget that was designed to handle only the intervention program was a challenge in terms of staff resources. The number of participants proposed within the time frame (n = 270) and the number actually recruited (n = 60) represents a shortfall of 73.7%.

Although the findings were suggestive that our intervention might help, we were unable to answer our research question because of the inadequate sample size, which precluded the intended intention-to-treat statistical analysis. Nevertheless, our study and similar studies[16-19] may provide guidance for future research in this field. Understanding more about the characteristics of African American residents of underserved urban areas who seek to quit smoking may help others seeking to conduct similar studies.

Despite our inability to achieve an adequate sample size, this trial yielded several important observations. First, most participants were single, widowed, divorced, or separated; only a small proportion were married. Some research suggests that social support promotes health behavior change; however, in the literature on smoking cessation, this seems to apply only if the provider of social support does not smoke.[31]

Less than half of this sample was employed either part-time or full-time, and approximately 60% reported an annual income of $15,000 or less, suggesting a group with few social and financial resources. The medical histories indicated that many in the sample had serious medical problems, including hypertension in approximately 43%, and that high proportions of participants had a history of psychiatric problems, prior hospitalizations, or life-threatening illness, beyond what would be anticipated in this relatively young cohort. Knowledge about the harms of smoking and belief in the benefits of quitting were substantial, yet smoking histories indicated very low levels of self-efficacy. This suggests that, despite low self-reported cigarette intake, the level of addiction of smokers in socioeconomically marginalized circumstances may require more aggressive interventions, possibly the more recent approach of offering pre-cessation pharmacologic therapy.[45]

We were interested to find that, despite a high level of knowledge about the harmful effects of tobacco and despite a high prevalence of tobacco-related diseases such as hypertension, most participants rated their health as "good" to "excellent." This finding raises the question of whether participants accurately translated general knowledge about tobacco's harmfulness into their own risk appraisal and would be consistent with findings in other studies suggesting that smokers are vulnerable to a denial of risk and that information alone is not sufficient to fully inform smokers.[46-50] It may also suggest a lack of specific knowledge about what particular diseases are caused by tobacco use.

Our findings also suggest that studies and programs that provide more comprehensive approaches are warranted. For example, the high proportion of participants with a history of hypertension (43.3%) establishes not only the need for risk reduction through smoking cessation but also the need for comprehensive health assessment and interventions in low-income, urban African American communities.

An additional limitation in our study that may have affected outcomes was the underuse of NRT as an initial adjuvant to evidence-based behavioral education, counseling, and skill-building interventions, for reasons that are not entirely clear; this topic is addressed in another publication.[23]

CONCLUSIONS

In view of the increasing interest in community-based participatory approaches to research,[46,47] it is worth noting lessons learned from this study that could prove useful and important to investigators and community workers. Our study shows that it is possible to engage and recruit African Americans living in some of the poorest inner-city neighborhoods into clinical research by using community participatory approaches. Our experience also shows that this population identified smoking cessation as an important priority for research and intervention. Research involving such

communities is urgently needed to address persistent health disparities.

Moreover, the publication of studies that do not meet their primary end point of testing efficacy is important, so that future researchers can learn from those experiences and better anticipate what may be needed for studies within low-income communities with competing priorities. Our experience also suggests that a study period of more than 3 years, a prolonged duration of recruitment, acquisition of additional sites, and establishment of sources of funding sufficient to achieve the completion of study objectives are needed to achieve recruitment goals in marginalized communities, as well as reliably high staffing ratios, a greater intensity of community outreach, and more intense follow-up schedules.

We thank Olivia Boudreaux-Harris, Ernestine Daniel, Marian Fields, Marion Fisher, Vera Harrell, Anthony Holmes, Edna James, Walter Johnson, LaShawnda Thomas, Marcia Wertz, Pamela Jones, and Catherine Waters for their contributions to the project.

REFERENCES

1. US Department of Health and Human Services. Tobacco use among U.S. racial/ethnic minority groups. A Report of the Surgeon General, 1998. Rockville, MD: Centers for Disease Control, Office on Smoking and Health; 1998.
2. Day GL, Blot WJ, Austin DF, et al. Racial differences in risk of oral and pharyngeal cancer: Alcohol, tobacco, and other determinants. J Natl Cancer Inst 1993;85:465-73.
3. Edwards BK, Brown ML, Wingo PA, et al. Annual report to the nation on the status of cancer, 1975-2002, featuring population-based trends in cancer treatment. J Natl Cancer Inst 2005;97:1407-27.
4. Harris RE, Zang EA, Anderson JI, et al. Race and sex differences in lung cancer risk associated with cigarette smoking. Int J Epidemiol 1993;22:592-9.
5. Hartge P, Silverman DT, Schairer C, et al. Smoking and bladder cancer risk in blacks and whites in the United States. Cancer Causes Control 1993;4:391-4.
6. Hussain F, Aziz H, Macchia R, et al. High grade adenocarcinoma of prostate in smokers of ethnic minority groups and Caribbean Island immigrants. Int J Radiat Oncol Biol Phys 1992;24:451-61.
7. Ries LHD, Krapcho M, Mariotto A, et al., editors. SEER Cancer Statistics Review, 1975-2003. Bethesda, MD: National Cancer Institute; 2006. Based on November 2005 SEER data submission, posted to the SEER website, 2006. Available at, http://seer.cancer.gov/csr/1975_2003; 2006. Accessed July 12, 2009.
8. American Heart Association. Heart Disease and Stroke Statistics—2008 Update. Dallas, Texas: American Heart Association; 2008.
9. State-specific prevalence of cigarette smoking among adults and quitting among persons aged 18-35 years—United States, 2006. MMWR Morb Mortal Wkly Rep 2007;56:993-6.
10. US Department of Health and Human Services. The health benefits of smoking cessation. Rockville, MD: Centers for Disease Control, Office on Smoking and Health; 1990.
11. Perez-Stable EJ, Herrera B, Jacob P 3rd, et al. Nicotine metabolism and intake in black and white smokers. JAMA 1998;280:152-6.
12. Novotny TE, Warner KE, Kendrick JS, et al. Smoking by blacks and whites: socioeconomic and demographic differences. Am J Public Health 1988;78:1187-9.
13. Centers for Disease Control and Prevention. Cigarette smoking among adults—United States, 2000. MMWR CDC Surveill Summ 2002;51:642-5.
14. Pederson LL, Ahluwalia JS, Harris KJ, et al. Smoking cessation among African Americans: what we know and do not know about interventions and self-quitting. Prev Med 2000;31:23-38.
15. Fiore MC, Bailey WC, Cohen SJ. Treating tobacco use and dependence. A clinical practice guideline. Rockville, MD: US Dept. of Health and Human Services, Public Health Service; 2000. AHRQ publication No. 00-0032. p. xiv, 179 p.
16. King G, Polednak A, Bendel RB, et al. Disparities in smoking cessation between African Americans and whites: 1990-2000. Am J Public Health 2004;94:1965-71.
17. Fisher EB, Auslander WF, Munro JF, et al. Neighbors for a smoke free north side: evaluation of a community organization approach to promoting smoking cessation among African Americans. Am J Public Health 1998;88:1658-63.
18. Lawrence D, Graber JE, Mills SL, et al. Smoking cessation interventions in U.S. racial/ethnic minority populations: an assessment of the literature. Prev Med 2003;36:204-16.
19. Yerger VB, Malone RE. African American leadership groups: Smoking with the enemy. Tob Control 2002;11:336-45.
20. Gardiner PS. The African Americanization of menthol cigarette use in the United States. Nicotine Tob Res 2004;6(Suppl 1):S55-65.
21. Yerger VB, Przewoznik J, Malone RE. Racialized geography, corporate activity, and health disparities: tobacco industry targeting of lower income inner city residents. J Health Care Poor Underserved 2007;18(S4):10-38.
22. Yerger VB, Daniel MR, Malone RE. Taking it to the streets: responses of African American young adults to internal tobacco industry documents. Nicotine Tob Res 2005;7:163-72.
23. Yerger VB, Wertz M, McGruder CO, Froelicher E, Malone RE. Nicotine replacement therapy: perceptions of African American smokers seeking to quit. J Natl Med Assoc 2008;100:230-6.
24. Grumbach K, Mann J, Pierce K, et al., editors. 1999 Community Survey. San Francisco Bayview Hunters Point Health and Environmental Assessment Task Force; 2001.
25. San Francisco Department of Public Health. 1999-2000 San Francisco Department of Public Health Annual Report. San Francisco: Department of Public Health; 2000.
26. Malone RE, Yerger VB, McGruder C, et al. "It's like Tuskegee in reverse": a case study of ethical tensions in institutional review board review of community-based participatory research. Am J Public Health 2006;96:1914-9.
27. Yerger VB, McGruder CO, Froelicher E, et al. Bayview Hunters Point project toward smoking cessation. In: Scientific Abstracts, Tobacco-Related Disease Research Program Annual Investigators Meeting. San Jose, CA; 2002.
28. Resnicow K, Royce J, Vaughan R, et al. Analysis of a multicomponent smoking cessation project: what worked and why. Prev Med 1997;26:373-81.
29. Tillgren P, Haglund BJ, Gilljam H, et al. A tobacco quit and win model in the Stockholm cancer prevention programme. Eur J Cancer Prev 1992;1:361-6.
30. Froelicher ES, Li WW, Mahrer-Imhof R, et al. Women's initiative for non-smoking (WINS) VI: Reliability and validity of health and psychosocial measures in women smokers with cardiovascular disease. Heart Lung 2004;33:162-75.
31. Sivarajan Froelicher ES, Miller NH, Christopherson DJ, et al. High rates of sustained smoking cessation in women hospitalized with cardiovascular disease: The Women's Initiative for Nonsmoking (WINS VII). Circulation 2004;109:587-93.
32. Fagerstrom KO. Measuring degree of physical dependence to tobacco smoking with reference to individualization of treatment. Addict Behav 1978;3:235-41.
33. Killen JD, Fortmann SP, Newman B, et al. Evaluation of a treatment approach combining nicotine gum with self-guided

behavioral treatments for smoking relapse prevention. J Consult Clin Psychol 1990;58:85-92.
34. Smokers' beliefs about the health benefits of smoking cessation—20 U.S. communities, 1989. MMWR Morb Mortal Wkly Rep 1990;39:653-6.
35. American Heart Association. An active partnership for the health of your heart: workbook, video tape, audio tape. Dallas, TX: American Heart Association; 1990.
36. Miller NH, Taylor CB. Lifestyle management for patients with coronary heart disease. Champaign, IL: Human Kinetics; 1995. p. viii, 134 p.
37. Benowitz NL, Gourlay SG. Cardiovascular toxicity of nicotine: Implications for nicotine replacement therapy. J Am Coll Cardiol 1997;29:1422-31.
38. Robinson R, Sutton C, James D, et al. Pathways to freedom: winning the fight against tobacco, revised edition. Atlanta, GA: Centers for Disease Control and Prevention; 2003.
39. Mahrer-Imhof R, Froelicher ES, Li WW, et al. Women's Initiative for Nonsmoking (WINS V): under-use of nicotine replacement therapy. Heart Lung 2002;31:368-73.
40. Froelicher ES, Christopherson DJ. Women's initiative for nonsmoking (WINS) I: design and methods. Heart Lung 2000;29: 429-37.
41. Martin K, Froelicher ES, Miller NH. Women's initiative for nonsmoking (WINS) II: the intervention. Heart Lung 2000;29: 438-45.
42. Malone RE, McGruder CO, Froelicher E, et al. Protecting the Hood Against Tobacco (PHAT). In: Scientific Abstracts, Tobacco-Related Disease Research Program Annual Investigators Meeting. San Diego, CA; 2003.
43. Altman DG, Schulz KF, Moher D, et al. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. Ann Intern Med 2001;134:663-94.
44. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. Lancet 2001;357:1191-4.
45. Shiffman S, Ferguson SG. Nicotine patch therapy prior to quitting smoking: a meta-analysis. Addiction 2008;103:557-63.
46. Minkler M, Blackwell AG, Thompson M, et al. Community-based participatory research: implications for public health funding. Am J Public Health 2003;93:1210-3.
47. Viswanathan M, Ammerman A, Eng E, et al. Community-based participatory research: Assessing the evidence. Evid Rep Technol Assess (Summ) 2004;1-8.
48. Balbach ED, Smith EA, Malone RE. How the health belief model helps the tobacco industry: individuals, choice, and "information". Tob Control 2006;15(Suppl 4):iv37-43.
49. Peretti-Watel P, Constance J, Guilbert P, et al. Smoking too few cigarettes to be at risk? Smokers' perceptions of risk and risk denial, a French survey. Tob Control 2007;16:351-6.
50. Weinstein ND, Marcus SE, Moser RP. Smokers' unrealistic optimism about their risk. Tob Control 2005;14:55-9.