Strategies for Recruitment of Healthy Premenopausal Women into the African American Nutrition for Life (A NULIFE) Study

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Abstract

Background: Although African American women have an overall lower incidence of breast cancer, African American women <40 years of age are more likely than Caucasian women of all ages and postmenopausal African American women to be diagnosed with breast cancer and exhibit tumor characteristics associated with poorer survival. To begin to address this disparity, studies must be conducted to examine breast cancer preventive factors in this subpopulation of women. However, the strategies needed to recruit younger African American women have not been well defined.

Methods: In this study, we assessed methods used for recruiting and retaining healthy premenopausal African American women into the African American Nutrition for Life (A NULIFE) Study. The number of women contacted, enrolled, and retained by each recruitment strategy and the efficiency of individual strategies were calculated.

Results: Overall, recruitment through social networking was most effective in contacting large numbers of healthy premenopausal African American women. The worksite recruitment method was the most efficient recruitment strategy employed, with a ratio of 40%. The study participants ($n = 164$) were more likely to be ≥ 35 years of age and have completed some college. Additionally, the interpersonal relationships recruitment approach proved most efficient (33%) in retaining participants who completed the yearlong study.

Conclusions: The findings from this study add to the evolving research literature on minority recruitment strategies for research studies but specifically address effective recruitment of healthy young premenopausal African American women. The results demonstrate the need to use multiple recruitment strategies when recruiting this subgroup of African American women.

Introduction

BREAST CANCER IN YOUNG WOMEN of all ethnicities is correlated with many of the characteristics associated with tumor aggressiveness and decreased survival rates.^{1–5} Although the overall incidence of breast cancer in African American women is 10% lower than in Caucasian women, African American women <40 years of age have a higher incidence of breast cancer.⁶ To begin to address the emerging breast cancer incidence disparities observed in younger African American women, multidisciplinary research studies should be conducted to examine genetic, biological, and environmental breast cancer risk factors.⁷

Historically, the participation of minority women in clinical research studies has been low, even though minorities bear a disproportionate burden of chronic diseases, including cancer.^{8–11} In 1993, the National Institutes of Health (NIH) established guidelines to enhance the inclusion of women and minorities in research in the NIH Revitalization Act. The authors of this historical act attempted to ensure that adequate data would be available to conduct subgroup analyses and observe differences between gender and ethnic groups.¹² However, studies have demonstrated that enrollment of ethnic minorities in cancer clinical trials remains low.^{10,13} African American women have been shown to have more negative perceptions of clinical trials than white women,¹⁴ yet once

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they have been contacted by study recruiters, African American women's consent rates to participate in research are not significantly different from those of other racial groups, suggesting that it is not attitudes but access to research that should be addressed in recruitment efforts.¹⁵

Hence, the recruitment of minorities remains a priority for the NIH; conferences, working groups, and systematic reviews have examined minority participation in cancer research. The findings have demonstrated that special efforts are required to identify and address the barriers associated with the recruitment and retention of minority populations into research studies.^{16–22} The recommendations include considering such factors as culture, socioeconomic status (SES), age, and gender when designing recruitment and retention strategies tailored for minority populations.

A body of literature on effective strategies for recruiting and retaining women in research studies exists, but strategies needed to specifically identify healthy young African American women for inclusion in these studies have not been well defined.²³ Increasing the accessibility and acceptability of community-based research studies for African American women likely may improve their overall participation in clinical trials. The current study was designed to determine the effectiveness of community outreach and social networking recruitment approaches in contacting, enrolling, and retaining healthy premenopausal African American women for the African American Nutrition for Life (A NULIFE) Study. The A NULIFE Study was a yearlong prospective study designed to examine hormonal and lifestyle factors associated with an increased risk of breast cancer.²⁴ Specifically, the study examined the effect of a low-fat, high-fiber diet and the role of bioavailable estrogen in breast cancer prevention in healthy premenopausal African American women 25–45 years of age residing in the Houston metropolitan area.

The A NULIFE Study was conducted at The University of Texas M.D. Anderson Cancer Center in the Center for Research on Minority Health, with Institutional Review Board approval. Written patient consent was obtained from each study participant.

Materials and Methods

A NULIFE Study design

Stringent inclusion criteria were used to determine the women's eligibility for the A NULIFE Study.²⁴ Premenopausal African American women who reported a lack of preexisting chronic illness and who consumed at least 28% of calories from fat were eligible to participate in this study. Women who were currently using hormone replacement therapy (HRT), oral contraceptives (OC), or other lipid or endocrine hormone-altering medications; women who were planning a pregnancy, currently pregnant, or breastfeeding; and women previously diagnosed with cancer (except for nonmelanoma skin cancers and carcinoma *in situ* [CIS] of the cervix) were also excluded from the study. The preexisting chronic illness exclusion criterion included a history of myocardial infarction (MI), stroke, documented coronary artery disease (CAD, coronary artery bypass surgery (CABG) or angioplasty, coronary heart failure, cardiac arrhythmia, angina, diabetes mellitus, liver disease, chronic renal failure, uncontrolled hypertension, and nonmalignant

systemic disease, as well as a history of tobacco use or unstable mental illness. The dietary exclusion criterion was based on the fat intake recommendations of the American Dietetic Association (ADA), which suggests that healthy Americans consume no more than 30% of total calories from fat.²⁵ Additionally, the criterion was used to ensure that the study would be beneficial to the participants' overall health and consistent with the ADA recommendations. However, to compensate for underestimation, which often is observed with self-reported dietary recall,²⁶ we chose to lower the minimum dietary fat intake value to 28%. Ineligibility status may also have been based on the potential participants' unwillingness to adhere to study guidelines and requirements. Some of the specific requirements involved the participants attending scheduled on-site sessions, completing all study-related questionnaires and clinical examinations, and adhering to the suggested dietary intervention for the 12-month study period.

Coordination of A NULIFE recruitment efforts

A community advisory committee, consisting of African American women within the age range of the study population who were breast cancer survivors or advocates with a vested interest in the African American community, generated ideas for subject recruitment strategies. Cultural factors believed to maximize the participants' trust and increase participants' engagement were considered. The committee recommended that an African American woman within the age range of eligible participants be responsible for recruiting participants for the A NULIFE Study. A recruiter was chosen for her established rapport and involvement with African American women's organizations and extensive experience with community outreach, all of which were thought by the committee members to be essential in facilitating their recommended recruitment efforts. Several recruitment methods were selected for use in the A NULIFE Study; they were broadly categorized into recruitment through community outreach and social networking, and the methods were used concurrently.

Recruitment through community outreach. The community outreach phase of recruitment focused primarily on community presentations and participation in health fairs and similar community events. Its objective was to use community outreach events to contact large numbers of young African American women. Community calendars were reviewed to effectively schedule presentations at local events and health fairs. The number of women recruited during events, such as health fairs and health or African American empowerment conferences, is included in the health fairs category. We used lists generated from local government and community groups to identify organizations (sororities and other civic, social, and professional groups) whose members were predominantly African American women. We then gave presentations at regularly scheduled meetings and events for members of the groups' local chapters. A standard presentation about the A NULIFE Study was created and modified depending on the target audience. The community presentations provided women with information about the goals of the project, inclusion and exclusion criteria, expectations upon enrollment, the importance of minority enrollment in clinical trials, the

informed consent process, and how to enroll in the study. The number of women enrolled using community presentations included those recruited after events for community organizations.

Recruitment through social networking. U.S. Census data obtained for the Houston metropolitan area were used to identify communities with large numbers of African American female residents. Multiple social networking recruitment methods were then employed to establish and sustain project awareness. These methods included interpersonal relationships, fliers/brochures, worksite, media advertisements, community events, and websites.

The social networking recruitment strategy included an interpersonal approach whereby participants' relatives, co-workers, and friends, community members, and the A NULIFE Study personnel shared information about participation. The community outreach coordinator widely distributed fliers/brochures and mass media public service announcements. Fliers/brochures were dispersed throughout the Houston metropolitan area in churches, physicians' offices, grocery stores, restaurants, shopping centers, hair salons, local businesses, educational institutions, community centers, and events frequented by African American women. In addition, study staff members and participants were asked to distribute fliers/brochures to potentially eligible women.

Recruitment through social networking also involved contacting personnel and students at local educational institutions. We contacted administrators, faculty, staff, and graduate students at several colleges and universities in the Houston metropolitan area via broadcast E-mails. Additionally, we used African American churches for social networking recruitment by encouraging local ministers, their spouses, and church elders to speak with the congregants about our study. The various recruitment methods were used to ensure that we reached a diverse group of African American women with a range of sociodemographic characteristics.

Because media launches were previously used as a successful precursor to recruitment for our ongoing studies, a media launch was held at an established local African American-owned restaurant, following prior recruitment at community outreach events. Members of local community organizations, radio and television media, and patrons of the restaurant were in attendance at the media launch. Local mainstream and African American newspapers published announcements, and local major television networks discussed the study in their daily news broadcasts. After the media launch, local magazine articles included information about the A NULIFE Study.

Evaluation of recruitment strategies

To determine which strategies were most useful in recruiting healthy young African American women, we examined the numbers of eligible enrolled/randomized women and ineligible women contacted for the A NULIFE Study. In addition, we calculated the effectiveness of each recruitment approach. The number of women recruited by each method was determined by asking women to sign an interest card during their primary contact with study recruiters. The primary determinant of the source of recruitment was obtained during the phone eligibility screening

when each potential participant was asked how she heard about the study.

Contact interview database

A contact database was developed to keep accurate records of the number of women contacted who completed eligibility screening and were enrolled/retained by each method of recruitment. During the eligibility screening, each woman provided demographic and health status information and was asked how she heard about this study. Eligibility screeners also used the database to record information on the women who were contacted and the number of times they received follow-up calls and follow-up information. The screeners called the women in the contact database to schedule an initial eligibility interview, left them a voice message about the study, or deemed the subjects no longer interested if they did not respond after three calls. Following the eligibility screening, if the women were deemed eligible, they were enrolled/randomized into the A NULIFE Study.

Statistical analysis

The effectiveness of each method was determined by dividing the numbers of eligible and ineligible women by the total number of women contacted in response to each community outreach or social networking recruitment strategy method. The number of women enrolled (recruitment yield) was calculated for each recruitment method by age and educational level, and the differences in recruitment yields between groups were compared. Additionally, retention efficiency (the number of women who completed the study/number of women randomized) was examined based on the recruitment method. We performed statistical analyses using SPSS software, version 11.0 (SPSS Inc., Chicago, IL).

A paired *t* test methodology was used to test for changes in bioavailable estrogen, which was the overall study objective. A sample size of 35 participants was needed to yield 80% power to detect a change in bioavailable estrogen of 0.181%. This study also considered the possibility of loss to follow-up among the participants, with an overall attrition rate of 30% assumed for the study population. Therefore, the goal of recruitment was to obtain a sample size of 50 participants for each treatment group such that the women would be stratified by age (25–34/35–45) and assigned to either the intervention or control group, yielding a total of four groups and total sample size of 200 participants.

Results

Study participants

The A NULIFE Study recruiting efforts contacted 1583 women, of whom 374 were deemed eligible, 164 were enrolled/randomized, and 96 women completed the study (Fig. 1). Of the 1583 women who provided contact information, 781 (49%) were contacted using the social networking approach and 549 (35%) using the community outreach approach. There were 851 women successfully contacted by phone; 577 (68%) of the women were recruited via social networking strategies, and 261 (31%) using community outreach methods. Eligibility status approval was obtained by 374 women, of whom 240 (64%) and 134 (36%) were recruited using social networking and community outreach strategies,

FIG. 1. Description of eligibility screening and enrollment.

respectively. Two hundred eighty women attended the A NULIFE Study orientation after receiving eligibility approval. There were 202 (72%) women who reported being recruited using the social networking strategy and 78 (28%) women recruited via community outreach strategies.

Table 1 shows the demographic and health characteristics of the 851 women contacted, the 164 women enrolled, and the 96 women who completed the 12-month nutrition intervention. The A NULIFE enrollees were predominantly single and college educated, had incomes ranging from \$25,000 to \$49,999, and were 35–45 years of age. Their mean age was 36.7 years, and their mean body mass index (BMI) was 30. The majority of enrollees described their health status as good,

and many of them reported having no maternal or paternal history of breast cancer. Similar demographic and health characteristics were observed for the women who were enrolled and retained in the yearlong intervention (Table 1).

Overall, the recruitment methods employed in this study resulted in a 23.6% (374 of 1583) and a 25.6% (164 of 641) efficiency ratio for eligible and randomized participants, respectively (Table 2). We examined the distribution of eligible enrolled and ineligible study participants by recruitment strategy. Our findings demonstrated that the social networking strategy, interpersonal relationships, resulted in the largest number of contacted women, with 49 (30%) eligible enrolled and 157 (33%) ineligible women, followed by the

TABLE 1. CHARACTERISTICS OF THE A NULIFE STUDY PARTICIPANTS

Characteristic	Enrolled n = 164, n (%)	Retained n = 96, n (%)	Contacted n = 851, n (%)
Mean age, years (SD)	36.7 (5.2)	41.0 (3.2)	36.6 (6.6)
Mean BMI (SD)	30.3 (8.3)	33.3 (8.3)	30.0 (8.3)
Years of education completed			
High school	25 (15)	10 (10)	161 (19)
Technical school	21 (13)	14 (15)	101 (12)
College	90 (55)	56 (58)	383 (45)
Graduate	28 (17)	16 (17)	135 (16)
Unknown	0 (0)	0 (0)	71 (8)
Relationship status			
Single	87 (53)	49 (51)	399 (47)
Married	56 (34)	37 (39)	274 (32)
Divorced	17 (10)	10 (10)	76 (9)
Separated	3 (2)	0 (0)	26 (3)
Widowed	1 (1)	0 (0)	3 (0.4)
Unknown	0 (0)	0 (0)	73 (8)
Annual income			
\$0–\$24,999	21 (13)	9 (9)	a
\$25,000–\$49,999	71 (43)	38 (39)	
\$50,000–\$74,999	31 (19)	20 (21)	
≥\$75,000	22 (14)	15 (16)	
Unknown	19 (11)	14 (15)	
Self-reported health status			a
Excellent	32 (20)	20 (21)	
Good	96 (59)	60 (63)	
Fair	26 (16)	10 (10)	
Poor	3 (2)	1 (1)	
Unknown/unsure	7 (3)	5 (5)	
Maternal history of breast cancer			a
No	123 (75)	77 (80)	
Yes	33 (20)	17 (18)	
Unknown	8 (5)	2 (2)	
Paternal history of breast cancer			a
No	105 (64)	60 (62)	
Yes	28 (17)	19 (20)	
Unknown	31 (19)	17 (18)	

^aData not collected for women who were contacted but not enrolled.

BMI, body mass index; SD, standard deviation.

fliers/brochures recruitment strategy, with 31 (19%) enrolled participants and 83 (17%) women deemed ineligible. The community outreach approaches yielded 25 (15%) of the enrolled participants and 60 (13%) of the ineligible women from community presentations, in addition to 13 (8%) enrolled and 46 (10%) ineligible women from local health fairs (Table 2). There was a total of 173 community outreach events conducted during the A NULIFE Study.

In this study, 477 women screened for enrollment were deemed ineligible based on the intent to enroll healthy younger African American women. The most common ineligibility status factor observed was existing illnesses, reported by 155 (32.5%) women (results not shown). Other factors that led to ineligibility were pregnancy or planning a pregnancy

TABLE 2. DISTRIBUTION OF ELIGIBLE ENROLLED AND INELIGIBLE PARTICIPANTS BY RECRUITMENT STRATEGY

Recruitment strategy type	Eligible enrolled n (%)	Ineligible n (%)	Total no. of women n	Efficiency ratio (%)
Community outreach				
Community presentations	25 (15)	60 (13)	85	29.4
Health fairs	13 (8)	46 (10)	59	22.0
Overall efficiency	38	106	144	26.4
Social networking				
Interpersonal relationships	49 (30)	157 (33)	206	23.8
Fliers/brochures	31 (19)	83 (17)	114	27.2
Worksite	22 (13)	33 (7)	55	40.0
Advertisements (newspaper, media, and radio)	14 (8)	32 (7)	46	30.4
Community event	9 (6)	51 (11)	60	15.0
Website	1 (1)	5 (1)	6	16.7
Unknown (did not specify)	0 (0)	10 (2)	10	0.0
Overall efficiency	126	371	497	25.3
Total	164	477	641	25.6

(10%), age (9%), current use of prescribed medication (9%), failure to meet compliance study requirements (9%), dietary fat intake < 28% of calories (8%), loss to follow-up or inability to complete the screening process (7.5%), exceeded weight requirements (10%), and failure to complete the informed consent process (7.5%).

Regardless of the age or level of education reported, the study participants were more likely to be recruited using a social networking recruitment strategy than a community outreach strategy (Table 3). This was particularly true for women ≥ 35 years of age; the recruitment through interpersonal relationships, fliers/brochures, and worksite proved most successful in recruiting eligible women who were 35–45 years old. The A NULIFE Study participants were primarily college educated; therefore, 85% of the enrolled women reported completing at least a high school education (Table 1). Additionally, regardless of the age or level of education reported, the study participants were more likely to be recruited using a social networking recruitment strategy.

The enrollment and retention status of the A NULIFE Study participants was examined to determine which recruitment strategies were most effective in recruiting women who were more likely to remain in the study. The interpersonal relationship strategy was most effective in recruiting 32 (30%) of the retained participants who successfully completed the 12-month nutrition intervention (Table 4). The fliers/brochures method yielded 18 (19%) of the 96 retained study participants, and worksite yielded 11 (11%) of the retained study participants. Of the retained participants, 14 (15%) were recruited from community presentations and 7 (8%) from health fairs. Overall, the various social networking recruitment strategies employed were more efficient and resulted in the recruitment and retention of larger numbers of healthy young African American women.

TABLE 3. RECRUITMENT YIELDS BY AGE AND EDUCATION

<i>Recruitment strategy type</i>	<i><35 years of age, n (%)</i>	<i>≥ 35 years of age, n (%)</i>	<i>< 12 years of education, n (%)</i>	<i>≥ 12 years of education, n (%)</i>
Community outreach				
Community presentations	10 (40)	15 (60)	4 (16)	21 (84)
Health fairs	5 (39)	8 (62)	1 (8)	12 (92)
Overall yields	15	23	5	33
Social networking				
Interpersonal relationships	18 (37)	31 (63)	6 (12)	42 (86)
Fliers/brochures	14 (45)	17 (55)	10 (32)	21 (68)
Worksite	6 (27)	16 (73)	2 (9)	20 (91)
Advertisements (newspaper, media, and radio)	5 (36)	9 (64)	1 (7)	13 (93)
Community event	4 (44)	5 (56)	1 (11)	8 (89)
Website	0 (0)	1 (100)	0 (0)	1 (100)
Overall yields	47	79	20	105
Participant Totals	62 (38)	102 (62)	25 (15)	139 (85)

Discussion

Few studies have examined the effectiveness of strategies used for the recruitment of healthy young African American women.^{23,27} In this study, we assessed recruitment strategies tailored for the A NULIFE Study. Our findings demonstrate that of the recruitment approaches employed, the social networking recruitment strategy (interpersonal relationships) was the most effective in the recruitment, enrollment, and retention of healthy premenopausal African American women. The flier/brochure distribution method was the second most effective, followed by the community presentations method. Although more women were contacted after being made aware of the study by the recruitment through interpersonal relationships, the efficiency of this recruitment strategy was modest compared with other recruitment strategies. Fewer participants were contacted through a worksite communication, yet this recruitment approach proved most efficient when compared to the other strategies employed to identify eligible participants. Overall, the efficiency ratios for the

community outreach and social networking recruitment approaches were quite similar, demonstrating the need for multiple approaches when recruiting this targeted population. Minority women face particular barriers and concerns that may uniquely affect their enrollment and retention in research studies.^{16,19,28} Findings from our study are consistent with those from previous studies demonstrating the difficulties in minority recruitment and the need for multiple approaches to recruit and retain minority women.^{29–31} Recruiting individuals from historically underrepresented populations requires extensive efforts in identifying and understanding recruitment barriers, establishing community contacts, and building trust within the community.^{28,30,32} Recruitment strategies, such as working with faith-based institutions and existing community outreach networks, have been shown to aid in overcoming recruitment barriers and increasing African American women's participation in research, particularly in breast cancer studies.^{33,34}

Our findings are the first to demonstrate the usefulness of a social networking recruitment approach in contacting, enrolling, and retaining healthy young women in the A NULIFE Study. Similar to our findings, other clinical research studies have observed success using recruitment approaches that involve participation encouragement by community leaders, co-workers, or family members.^{19,28,31–37} A recent study concluded that relationships are essential in recruiting minority populations; moreover, the relationships may range from a short-term interaction to a long-term relationship that exists beyond the study.³⁸

Use of a community outreach professional with in-depth knowledge of pertinent recruitment issues, a cultural identification with the targeted study population, and extensive experience in community outreach has been shown to be important for enhancing the recruitment of minority participants.^{34,39} Recruitment efforts for the A NULIFE Study were facilitated by an African American woman who was within the age range of eligible participants to enhance a sense of similarity and trust between participants and research personnel. It is worth noting, however, that these findings are relevant for the recruitment of this group of African American women in a large metropolitan city; they may not be applicable in smaller, rural, or suburban African American

TABLE 4. RETENTION STATUS OF A NULIFE STUDY PARTICIPANTS BY RECRUITMENT STRATEGY

<i>Recruitment strategy type</i>	<i>Eligible enrolled n (%)</i>	<i>Retention n (%)</i>	<i>Efficiency</i>
Community outreach			
Community presentations	25 (15)	14 (15)	
Health fairs	13 (8)	7 (8)	
Overall yield	38	21	55.3%
Social networking			
Interpersonal relationships	49 (30)	32 (33)	
Fliers/brochures	31 (19)	18 (19)	
Worksite	22 (13)	11 (11)	
Advertisements (newspaper, media, and radio)	14 (8)	10 (10)	
Community event	9 (5)	3 (3)	
Website	1 (1)	1 (1)	
Overall yield	126	75	59.5%
Participant totals	164	96	58.5%

communities with fewer means for implementing the various recruitment strategies.

Recommendations

Although the recruitment methods used here have been employed in previous studies to recruit minority participants, they have not been widely used for this subpopulation of minority women.^{19,28,30–32,36} Therefore, it is important to develop useful strategies for contacting and enrolling healthy young African American women. In this study, we determined the number of women contacted by each method of recruitment by asking women to sign an interest card or confirm the method during eligibility screening. Not everyone who visited an exhibit booth, health fair, or community presentation, however, was willing to complete an interest card, suggesting that the efficiency of this method is even lower than reported here. Similarly, women potentially contacted by the other social networking recruitment strategies used in this study may have been underreported because of the method used to determine the number of women contacted. It is important to have several methods in place to capture information on the number of women contacted using each recruitment method. It is also imperative to collect these data to accurately predict and plan the time commitments for outreach recruitment efforts, examine the cost of each recruitment approach, and establish a recruitment budget when designing this type of study. Additionally, accurately assessing the efficiency of each method proves difficult because of the synergism of multiple recruitment methods.³⁶ Therefore, we recommend the following strategies when designing community-based prevention studies.

Use of an outreach coordinator who can be identified with the study population's characteristics, including age, gender, race/ethnicity, culture, and education. Existing literature corroborates the importance of the use of a community outreach professional with experience in local community outreach in enhancing the recruitment and retention of minority participants.^{11,20}

Use of social networking methods. The social networking recruitment strategy includes an interpersonal approach that relies strongly on relationships among relatives, co-workers, friends, and community members.

Use of community-based approaches to develop study recruitment strategies. Working closely with the community of interest at the onset of the study will result in the development of useful and successful recruitment strategies. Although modifications to the developed strategies may occur, the changes should be discussed and completed with community input.

Use of multiple recruitment methods. A variety of strategies is needed to successfully recruit young healthy African American women. This subpopulation of women may be difficult to enroll in research studies because of various personal and study-related factors. The use of multiple overlapping recruitment methods may help demonstrate the meaningfulness of the study and the benefits of research participation.

Use of recruitment strategy evaluations. Future studies should include assessments of each recruitment method's cost-effectiveness and the participants' opinions of the methods to provide evidence of best practices.

Conclusions

Impediments to the enrollment of African American participants into research studies include, but are not limited to, psychological, socioeconomic, cultural, linguistic, geographic, and historical factors.^{17,22,30} A broad range of recruitment barriers has been observed specifically for cancer-related trials.¹⁶ The findings demonstrated the need to increase the quality of studies examining minority recruitment approaches and recommended more hypothesis-driven studies focused on recruitment and retention.¹⁸ The findings we have presented here for the A NULIFE Study advance that effort by providing a quantitative assessment of recruitment and retention of community outreach and social networking recruitment approaches for a high-risk population.

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The authors have no conflicts of interest to report.

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