PERCEPTIONS OF AFRICAN-AMERICAN CULTURE AND IMPLICATIONS FOR CLINICAL TRIAL DESIGN

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Objective: To identify unique cultural variables for African Americans that might limit the effectiveness of behavioral interventions in clinical trials.

Design: Focus group discussions lasting 90 minutes.

Setting: Outpatient, clinical research center.

Patients: Twenty-six African-American men and women, who completed the screening process but were ineligible for the PREMIER study, participated in six focus group sessions. PREMIER is a multicenter, randomized clinical trial that studies the effects of three different lifestyle interventions designed to reduce blood pressure without medication.

Measurements and Main Results: Participants used a value sort of cultural characteristics to select items that make them unique as African Americans. The following seven themes were consistently identified: 1) extensive use of nontraditional support systems; 2) general mistrust of European Americans; 3) African Americans' being undervalued as human beings and members of American society; 4) effective use of improvisation; 5) uneven playing field as a result of persistent discrimination; 6) preservation of a unique ethnic identity; 7) socioeconomic status as a major influence and predictor of behaviors.

Conclusions: Cultural variables can affect African-American perceptions of the feasibility of certain behavior modifications as health interventions and their perceptions of clinical research. Using these themes, investigators can design trials and interventions that capitalize on certain cultural variables and avoid strategies that conflict with others. The identification of such cultural characteristics unique to African Americans may help to enhance the outcomes achieved by African Americans in clinical trials, improving the generalizability of results from behavior modification research. (*Ethn Dis*. 2005;15: 292–299)

Key Words: African American, Clinical Trial, Culture, Focus Group

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INTRODUCTION

Major, multicenter, randomized, controlled clinical trials have demonstrated the effectiveness of lifestyle interventions for weight loss, blood pressure reduction and diabetes control.[1–4] However, closer inspection of some of these trials reveals that for a given intervention, African-American participants were less successful at modifying cardiovascular disease (CVD) risk factors than non-African Americans.[4,5] Differences in outcomes could be attributed to a lack of efficacy of the given intervention in African-American populations. However, few data support this argument. On the contrary, significant evidence from subgroup analyses of feeding studies such as DASH and DASH-Sodium suggests that the efficacy of a healthy dietary pattern is more dramatic for African Americans than non-African Americans.[6,7] However, we have struggled to demonstrate effectiveness in the typical clinical trial setting for the African-American population.

One variable that might impede the demonstration of effectiveness is culture. Culture can logically be considered a potential effect modifier because health behaviors such as physical activity, body weight, and dietary patterns are strongly influenced by culture.[8,9] Culture, as defined by Resnicow et al, is a highly specific pool of information, categories, rules for categorization, intersubjective meanings, collective representations, and ways of knowing, understanding, and interpreting stimuli, as a result of a common history.[8] For African Americans, the influence of culture on health behaviors and attitudes extends beyond food preferences to include historical perspectives on participation in clinical trials, attitudes about clinical trials, and beliefs about what a healthy lifestyle entails.[8] With such a large domain of potential influence, culture can directly affect the number of African-American participants recruited, their degree of adherence to study protocols, and their acceptance of a lifestyle intervention. Understanding the role these cultural factors play in promoting or inhibiting new behaviors in a clinical trial setting may be helpful in improving the outcomes of African Americans seeking to abolish unhealthy lifestyle habits and establish new, healthier habits.

One useful tool for examining complex issues such as culture is the focus group method. Focus groups allow for a more in-depth exploration into participants' experiences and explanation of certain beliefs and traditions. The focus group method has been used extensively in the literature to capture African-American ideas about perceptions of specific illnesses, various aspects of behavioral interventions, and participating in clinical trials.[10–12] In general, these types of focus groups seek opinions about given diseases or areas of intervention from African-American participants who have varying levels of experience or knowledge about the topic area, ranging from minimal to extensive. Therefore, the usefulness of the participants' observations may depend on their level of experience or knowledge about the topic of discussion. In addition, lim-

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> *. . .significant evidence from subgroup analyses of feeding studies such as DASH and DASH-Sodium suggests that the efficacy of a healthy dietary pattern is more dramatic for African Americans than non-African Americans.*[6,7]

iting the focus group discussion to a specific disease process or area of intervention limits the applicability of the focus group results. A novel approach to the use of focus groups for developing culturally appropriate clinical trials and interventions would be to pose questions that focus only on participants' culture and ethnic experiences. Using this route of questioning taps into the real expertise of the African-American participant as a member of his/her unique culture and experiences as an ethnic minority. It also allows the investigative team to understand the potential cultural barriers that might be encountered during implementation of all aspects of a research protocol, including recruitment, intervention delivery, and data collection, regardless of the disease process or behavioral intervention.

This paper describes the results of focus groups that dealt with the uniqueness of African-American culture. Specifically we wanted to determine cultural variables that were unique to a group of African Americans seeking to participate in a lifestyle modification clinical trial for blood pressure reduction.

METHODS

Design

To determine some of the common behaviors, beliefs, and perceptions that are thought to be specific to African Americans, we conducted several focus groups of African-American men and women; each session included both sexes. Sessions were held for 90 minutes in the early evening hours. The participants attended only one focus group discussion held at the Duke Hypertension Center. An African-American male (JDA) facilitated all of the focus group discussions.

Participants

Eligibility criteria included African-American men and women who completed the screening process but were ineligible for the PREMIER study. PREMIER is a multicenter, randomized clinical trial that studied the effects of three different interventions designed to reduce blood pressure without medication. Ineligible participants for PREMIER were contacted by telephone or at the end of their screening session and asked to attend the 90-minute focus group. Participants in this focus group study were considered ineligible for the PREMIER trial either because of blood pressure that was not in the specified range (120 to 159 mm Hg systolic and 80 to 95 mm Hg diastolic) or use of antihypertensive medications. Catered dinner was provided to all participants as a form of compensation.

Data Collection

Informed consent was obtained prior to study enrollment. At the start of each focus group, the facilitator discussed the purpose of the session, the selection process, and participants' roles in the focus group. Instead of the standard audiotape recording used in most focus group research, all sessions were videotaped for accuracy and to allow review of nonverbal communication.[13,14] In addition an assistant facilitator took written notes to record verbal and nonverbal communication.

A questioning route was developed and tested by using a pilot focus group composed of African-American staff members at the Duke Hypertension Center. Based on this experience, minor adjustments were made to the route of questioning to improve the flow of discussion. The facilitator opened the focus group by asking participants to comment on what they thought of when they heard the phrase "African American." To initiate discussion of the key question, a value sort of 12 cards containing nonspecific cultural characteristics such as family, religion, food, and music was given to each participant (Table 1). Participants were asked to rank the top five characteristics that made them unique as African Americans compared with other ethnic groups in this country. The discussion proceeded based on the characteristics selected by the participants. Probes were used to elicit a better understanding of what prompted a participant to select certain characteristics (Table 2). At the conclusion of the discussion, the facilitator posed an ending question—"Is there anything that we have not mentioned that makes African Americans a unique ethnic group?" Demographic information was gathered from participants' initial screening forms for the PREMIER study when available or after the completion of the focus groups.

Table 1. Value sort

Physical Appearance
Friends
Music
Community
History
Clothing
Religion
Food
Money
Health Beliefs
Superstitions
Education
Work Ethic
Family
Political Beliefs

Data Analysis

Videotapes of the focus group sessions were transcribed and reviewed in-

Table 2. Focus group discussion probes

Are there any specific beliefs or practices regarding religion?
Is the concept of family different?
What are the beliefs and practices regarding health? (physical/mental)
Are there any unique work habits?
Are your preferences for certain things (food, clothing, entertainment, neighborhood, schools, friends) based on the fact that you are African-American?
Authority figures? (what types of people are you more likely to respect and take advice from)
Are there any specific beliefs or practices regarding money and economics?

dependently by three investigators (JA, LCE, RD). Each investigator identified comments that were felt to represent specific cultural features pertaining to the African-American ethnic group. These comments were coded as cultural variables when agreed upon by at least one other participant in the group and repeated independently in another focus group session. Once the primary set of variables was agreed upon, the variables were grouped together based on unifying concepts. The moderator reviewed the variable groupings to ensure consistency and relevance and proposed unifying themes for each variable grouping. All investigators reached a consensus on the final set of themes.

Table 3. Selected participant characteristics

	%
Sex	
Male	31
Female	69
Education	
Some college	21
Completed college	46
Graduate work	33
Income	
≤$30,000	22
$31,000–$44,999	25
$45,000–$90,000	32
>$90,000	17
No answer	4
Personal history of high blood pressure	37
Positive family history	
High blood pressure	67
Kidney failure	17
Diabetes	54
Stroke	29
Behaviors	
Attempts to decrease salt	75
Attempts to lose weight	96
Attempts to increase exercise	96
Attempts to reduce alcohol consumption	42

RESULTS

A total of 26 persons participated in the six focus groups. Of the 26 participants, 18 were female. The average age of the participants was 41. Other demographic characteristics of the group are highlighted in Table 3. Thirty-seven percent responded that a physician had told them that they had high blood pressure. Also, most participants had embarked on some type of lifestyle modification, including weight loss and dietary sodium reduction.

Seven cultural themes (Table 4) emerged from the focus group discussions.

Extensive Use of Nontraditional Support Systems

This theme emerged as a result of many participants choosing values such as religion, family, and community. Participants often commented that church for African Americans was more than just a religious institution, stating that "you can go there to get your blood pressure measured, get a good meal, socialize, exercise, and all sorts of other things." Many participants viewed the African-American concept and structure of family as being unique and a key source of support. The matriarchal family structure was clearly depicted, such that the mother or grandmother is the "glue that holds the family together." Participants also offered alternative definitions of family for African Americans. The African-American perspective of family includes close friends or neighbors; for many African Americans family is not limited to those related by birth or marriage.

Participants expressed a feeling of kinship to all African Americans because of common societal perceptions about ethnicity. This larger definition of family leads to a sense of being responsible for other African Americans and being linked to their failures and successes.

> *"When I hear someone did something bad on the news, I say 'I hope he's not Black.'. . . I don't want them whispering about somebody of our race. We are related by what any of us do. We are responsible for each other."*

Concurrent with this sentiment is the idea that African Americans find their community to be a source of support. This sense of community as expressed by the focus group participants is literal as well as symbolic and extends well beyond the local neighborhood; it includes "all members of the Black race."

Table 4. Focus group themes

Extensive use of non-traditional support systems
General mistrust of European Americans
African Americans are not valued as human beings and members of American society
Effective use of improvisation
Socioeconomic status is a major influence and predictor of behaviors
Uneven playing field as a result of persistent discrimination
Preservation of a unique ethnic identity

General Mistrust of European Americans

Using the values of history and health, many participants expressed a substantial degree of mistrust in European Americans. Participants cited civil rights violations and the Tuskegee experiments as examples of reasons why some European Americans cannot be trusted. Although many of the examples were historical examples, several participants cited present-day experiences that made them less trustful of European Americans. One participant stated that part of her mistrust stemmed from some prior visits to the physician: "White doctors judge you based on race. They don't take time to hear you out." Some of the participants also felt that European Americans were responsible for distorting African-American history, leading to more mistrust.

African Americans Are Not Valued as Human Beings and Members of American Society

This theme emerged as a result of discussion about values, health, and political beliefs. Again, the Tuskegee experiments were mentioned as an example of how African Americans have less value in this society. One participant remarked that in this experiment "they were using us as guinea pigs. . .we have less value." Other participants supported the notion that African Americans have less value in American society based on their perceptions of this country's political and research agendas. For example, participants felt that issues of particular interest to African Americans, such as sickle cell anemia, are low priorities on the country's research agenda.

Effective Use of Improvisation

Many of the participants felt that music, food, education and health beliefs made African Americans unique. Within each one of these variables, many participants expressed the ability of African Americans to make the best out of bad situations, or improvisation, which leads to unique cultural styles. For example, with regard to improvisation and health beliefs, participants often felt that the persistent use of home remedies originated from not being able to afford conventional medical treatment or having a fear of doctors. These situations prompted many African Americans in need of medical attention to devise self-made strategies for dealing with illnesses. Soul food was identified as being unique to African Americans because it was developed as a response to the situation of slavery.

> *"We adapted the scraps to suit the needs of slavery." "Black slaves had to eat what Whites didn't want. We now have a taste for this food."*

Music, in particular jazz and gospel, were identified as being uniquely African American because of the style of improvisation. Several participants stated that even African-American education is a result of effective improvisation. They felt that many historically Black colleges and universities were founded because of the need for an alternative educational system for African Americans during times of segregation.

Socioeconomic Status (SES) is a Major Influence and Predictor of Behaviors

A consistent theme across several focus groups was the impact that socioeconomic status (SES) has on African-American behavior. This theme evolved through discussion of the values, money, health, work ethic, and education. Several participants felt that the general lack of money shifted the focus of many African Americans from health to day-to-day survival. This factor was cited as a significant reason for fewer visits to physicians and poor medication compliance. Lower SES was also perceived as being a reason for decreased use of healthy behaviors. As one participant stated, "A lot of African Americans don't work out, but it's more related to socioeconomic status." She went on to explain that many African Americans cannot afford to purchase memberships at local health clubs or live in areas where they feel safe to walk.

Uneven Playing Field as a Result of Persistent Discrimination

This theme was embedded in the values, work ethic and education. Many groups agreed that African Americans must work harder or be smarter than European Americans to have similar opportunities for advancement and success. Two major reasons for this belief include the perception that teachers or people in positions of authority label African Americans as slow learners and that non-African Americans view African Americans as lazy. Participants also expressed a sense of frustration when discriminatory practices directed toward African Americans resulted in limited opportunities for advancement and attainment. One participant remarked, "Sometimes it doesn't matter how much education you have. African Americans will still be discriminated against."

Preservation of a Unique Ethnic Identity

This theme appeared in the discussion of many of the values. It was most apparent in the discussions of food, physical appearance, religion, music, and community. Participants generally expressed pride and a sense of ownership in the characteristics that made them unique as an ethnic group. Even when a particular cultural characteristic was thought to have potentially negative effects (ie, soul food perceived as negatively affecting health), some participants expressed reluctance about changing this aspect of their lives.

> *"We got the scraps that the Whites didn't want. If it wasn't for pork, some Blacks wouldn't be alive today. We raised our own pigs; salted and smoked them. We had no choice. I could have changed my diet, but I've developed a taste for it now."*

This theme was possibly best captured by one participant who expressed her concern over African Americans who become successful and "try to emulate Whites." She made it clear that she was happy when other African Americans became successful, but she was clearly disappointed when successful African Americans did not continue to identify with the African-American culture, perhaps as they had done before achieving success.

DISCUSSION

Some of the factors that play a substantial role in disparities in African-American clinical trial participation, retention, and outcomes might be revealed with further examination of African-American cultural values, practices, and experiences. In this study, focus group discussions were used to determine cultural factors and experiences that are specific to African Americans. Ideally, this information can be used to design clinical trials that incorporate pieces of the African-American cultural framework, ultimately facilitating African-American participation, adherence, retention, and improved outcomes. Improving these four factors can potentially lead to a higher degree of generalizability to African-American populations, or external validity. With improved external validity, the resulting interventions from clinical trials can be translated into public health and health services interventions that have a higher level of evidence to support their systematic use.

Ideally, this information can be used to design clinical trials that incorporate pieces of the African-American cultural framework, ultimately facilitating African-American participation, adherence, retention, and improved outcomes.

Applying information from focus group discussions can be a daunting task. Fear of generalizing too broadly or stereotyping individuals based on a small sample can lead to limited use of valuable information. Also, it may be difficult to accurately predict how certain values, practices, or experiences may interact with various aspects of the clinical trial. For example, is knowledge of the Tuskegee experiments only a barrier to participation in certain types of clinical trials? Does knowledge of the Tuskegee experiments make collection of biologic samples more difficult? Lastly, although focus groups provide significant insight into the cultural experience of African Americans, the solutions to overcome any potential barriers are not always readily apparent. In the following discussion, we illustrate how the cultural themes derived from the focus group discussions can be used to make alterations in any given clinical trial protocol to make it more appropriate for African Americans.

The general distrust of European Americans can be a strong deterrent for African-American participation in clinical trials. Overcoming this distrust held by the African-American community at large is a difficult task, but measures can be taken to engender the trust of this community. For example, including African Americans at every level of the research team, ranging from investigators to study personnel, may serve to lessen much of the distrust. In addition, African-American community, civic, professional, and clergy leaders can serve as recruiters or consultants in the design of clinical trials to help maximize the likelihood of African-American participation and retention. Obtaining the endorsement of these leaders may assist in building confidence and trust in the research effort. The familiarity of a trusted community leader can add a sense of credibility that the research team may not be able to achieve otherwise.

While trying to promote the trust that the potential African-American study participant may have in the research team, investigators must be aware that common research designs and methods may perpetuate some of the skepticism surrounding research. One troublesome area can be the use of wording with potentially negative connotations in the description of research methods. Terms such as "placebo," "blinding," and "randomization" have very specific meanings in the context of research; however, to a layperson, these words may evoke concerns about secretive or covert tactics. By developing laymen's definitions and considering the educational level of the target group, study personnel can avoid this type of misunderstanding that can support distrust. Another rapidly proliferating and troublesome area is related to research involving genetic materials. With such a heavy emphasis in the lay press on the use of genetic material for potential cloning purposes or law enforcement, many African Americans might have additional reservations about participation in this type of research. Therefore, when research involves more sensitive issues such as the extraction of genetic material, special care must be taken to *actively* address concerns and allay any potential fears of misuse.

The focus group discussions also revealed the theme of persistent discrimination against African Americans despite advances in civil rights. This theme particularly applies to interpersonal communication and understanding rules that govern respect and fair treatment in the African-American community. Communication styles for Whites and Blacks are different, and these differences in styles also lead to a difference in how one interprets communication.[15] Because the personnel and staff of the clinical trial are in a position of power as perceived by the potential participant, efforts must be made to ensure that the participant is not disparaged in any way. Areas of communication that can lead to misunderstandings and feelings of discrimination include the use of terms of familiarity, use of technical jargon, and nonverbal communication, such as facial expressions, body posture, and eye contact. For example, using appropriate terms like "sir," "ma'am," "Mr.," "Ms.," or professional titles to address participants demonstrates that the participant is in a position of respect. This is particularly important for African-American senior citizens, clergy, and professionals. Also in the African-American community, to address someone by his or her first name is generally considered inappropriate until given permission to do so. Therefore, if staff members greet African Americans who are screening for a study by their first name, although no prejudice is intended, the African-American participant can perceive it as a lack of respect and an expression of the staff members' prejudice.

The participants in this study felt that African Americans have been undervalued as citizens and even as human beings in this country for many years. This sentiment has contributed to the perception that less care will be taken to protect African-American research participants from harm. Because informed consent is one of the main safeguards against abuses in research, investigators should continue to focus on improving this requisite dialogue with participants. Informed consent must not be approached as a mere waiver of liability for negative outcomes. If this is the perception of informed consent, investigators appearing to absolve themselves of any responsibility for potential harm will almost certainly deter potential participants. This concept is obviously of value with respect to any ethnicity; however, from our focus groups and others that have specifically discussed the topic of participating in clinical research,[10,16] these prior negative experiences are more prominently in the forefront of the collective African-American psyche and have a much larger impact on participation in clinical research.

The theme of preserving a unique cultural identity can have important implications for establishing study goals and predicting outcomes. The African-American cultural identity has been shaped and developed as a collection of adaptations to social and economic circumstances in the United States. These adaptations are now the basis of many cultural norms, such as diet, and serve as a source of pride for African Americans. When designing clinical trials, investigators have to formulate interventions that satisfy research goals without directly conflicting with these cultural norms. Conflicts between cultural identity and study goals will typically lead to abandonment of study goals to maintain comfort with one's cultural identity.[9] For example, if a weight loss intervention sets a weight loss goal of 20 pounds for all participants, some African-American participants may anticipate that they will be dissatisfied with their body image if they achieve the study's weight loss goal. Therefore, they may be successful in losing a smaller amount of weight but resist lowering body weight further to maintain a body image that is consistent with their perception of being African-American. This difference does not imply that study goals and target intervention effects should not be based ultimately on what is deemed to be healthiest; however, barriers to achievement of the study goals may exist for African Americans but not for other participants. These barriers can be addressed by using co-interventions. Using the above example of a weight loss study, additional education concerning the health risks of overweight/obesity can increases the incentive for weight loss, while actively discussing issues of perceived body image that are important to maintaining a unique cultural identity.

The effective use of improvisation is a theme that has implications for creating a sense of ownership in the participation of a clinical trial. As a part of the adaptation to socioeconomic circumstances, African Americans have developed a system of using limited resources to accomplish various tasks. As expressed by members of this focus group, the ability to improvise is a source of pride and demonstrates a unique sense of creativity. Therefore, in certain instances, being a part of a regimented structure like a clinical trial that requires strict adherence to a study protocol may be counter-intuitive and, at some level, undesirable. A rigid protocol does little to promote a sense of ownership or create feelings of personal responsibility for study outcomes. However, by allowing a degree of flexibility or incorporating participant feedback and ideas, one can create this sense of ownership for African-American participants, which can lead to improved retention and adherence. For example, as an alternative to pre-determined names for small groups based on study protocol (ie, group A, B, or C), the study protocol can allow participants to create a name for their group and choose an appropriate logo to represent the group. This choice has no significant bearing on the study procedures, but might be an important gesture to create a feeling of personal involvement with the conduct of the study.

The unique experience of African Americans in this country has also led to the development of nontraditional support systems. Identifying and understanding the roles of nontraditional support systems, such as churches, civic organizations, and extended family, provides the investigator with potential resources for recruitment, intervention delivery, social support, data collection, and follow-up. For example, as pointed out by participants in this focus group, the African-American church serves not only as a center of worship, but also as a center of fellowship and education.

Therefore, churches can be an invaluable resource for reaching large numbers of potential African-American research participants in a setting that is familiar to the participant. The extended family is another example of a nontraditional support system; this example is particularly true when one considers how members of this focus group defined family. The extended family includes more than just the immediate family members and often can be very influential in determining health behaviors. Therefore, investigators must realize that educating the families of participants or actually including them in some of the interventions would likely increase participation, retention, and adherence in research trials. For instance, in a trial calling for exercise as an intervention, providing access to exercise facilities to those identified as family members might be an extra incentive toward enrollment as well as adherence to the intervention. Conversely, if family members are not included in the intervention and they do not approve of the new behaviors, the participant may have to deal with negative comments and a lack of support that can obstruct their efforts to achieve study and personal goals.

The last theme is SES as a major influence and predictor of behavior. For African Americans with limited resources who spend most of their time meeting basic needs such as housing or childcare, the implementation of healthy behaviors such as low-fat diets or exercise has less priority. In addition, some healthy behaviors are identified as being something which only certain ethnic groups (ie, Caucasians) and/or the wealthy have the luxury of doing, seemingly making these activities out of reach for a minority with limited resources. To some extent, the perception that African Americans from a lower SES do not have access to a healthy lifestyle is supported by several studies that have examined availability of fruits and vegetables, sidewalks, or other safe areas for exercise in African-American neighborhoods.[17–20] However, a pervasive misperception also maintains that a healthy lifestyle is unavoidably expensive because of cost of fresh fruits and vegetables, lean cuts of meats and fish, and health club fees for exercise. Lower-cost alternatives, such as frozen or canned foods, can certainly be a part of a healthy lifestyle. Using the DASH dietary pattern, researchers have demonstrated that the cost of eating a diet high in fruits and vegetables and low in fat is similar to other eating styles and falls well within the low- to moderate-cost plans for a family of 4.[21] The cost of maintaining a healthy lifestyle is generally of concern to most people regardless of the person's ethnicity; however, for African Americans, this concern may be more likely to affect future behavior. Actively addressing these concerns in the course of an intervention, such as using food items from grocery stores that are readily available to study participants or highlighting alternatives for free, safe exercise facilities, will demonstrate sensitivity to daily circumstances of the lower SES African-American participant. Other examples include offering flexible hours for data collection to persons who may have restricted availability because of job or family obligations and maintaining locations that are accessible to participants who may rely on public transportation. These practical considerations may help to reduce some of the logistical barriers faced by interested persons with limited resources.

The limitations of this study are based mainly on the population of the focus groups. This study only surveyed the opinions of persons living in Durham, NC, and surrounding areas, and opinions may differ regionally. In addition, our sample likely represents a higher-than-average socioeconomic group of African Americans, with almost 75% reporting annual household incomes above $30,000 and 79% reporting college degrees. However, focus groups from other regions of the United States that discussed participation in clinical research have similar responses to those seen in our group.[10,16] Indeed, other studies that included African-American focus group participants with a broader range of income and education expressed similar sentiments of distrust in medical research as we observed in our sample of participants.[22,23] While similar attitudes about clinical research from the various samples of African Americans suggest that regional and SES differences have little impact on these beliefs, additional research is needed to confirm this hypothesis, particularly with respect to other themes. Secondly, because all participants had agreed previously to participate in the PREMIER trial but were ineligible, we may be missing the perspective of persons who would normally refuse to participate in clinical research. The questioning route, however, did not include specific questions about participants' willingness to participate in clinical research or make behavior changes. Third, additional selection bias may be based on the eligibility criteria for this focus group study (ie, all ineligible African-American screenees for PREMIER). Lastly, we must remark on the limitations of the focus group method. This qualitative research tool is invaluable in performing detailed exploration of complex issues such as culture; in spite of this, the method is limited to hypothesis generation. Ultimately, these cultural themes should be validated among a larger number of people, possibly using a survey in a cross-sectional study. This validation could confirm how prevalent these themes are among a less selected sample of African Americans.

Cardiovascular disease (CVD) health disparities cannot be addressed adequately without some understanding of how to appropriately reach minority populations. In current behavioral interventions, cultural appropriateness is one potential missing element that may contribute to the lack of success achieved by African-American participants. African-American culture is separate and distinct, leading to a unique set of practices, values, and experiences. Areas of daily living that affect cardiovascular health, such as food patterns and preparation and perceptions of what is healthy, are prominently shaped by the African-American culture and experience, as illustrated by comments from these focus group discussions. What these focus group discussions fail to do is to quantify the effect on a person's cardiovascular health of holding a particular set of beliefs. Further exploration of how to quantify the effects of culture or ethnic experience on various outcomes such as blood pressure, weight, or other CVD risk factors should be undertaken. Without solving this cultural conundrum, we will continue to have difficulty demonstrating the effectiveness of behavioral interventions for CVD risk factor modification in populations that are different from mainstream America. Lifestyle interventions for reducing CVD risk will be most effective in African-American populations if they are designed and implemented with a clearer understanding of the role of culture in determining health behaviors.

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AUTHOR CONTRIBUTIONS

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