

5-1-2014

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Penny A. Ralston

Florida State University, pralston@fsu.edu

Jennifer L. Lemacks

University of Southern Mississippi, jennifer.lemacks@usm.edu

Kandauda (.K.A.S.). Wickrama

University of Georgia, wickrama@uga.edu

Iris Young-Clark

Florida State University, iyoungclark@fsu.edu

Catherine Coccia

Florida International University, ccoccia@fiu.edu

See next page for additional authors

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Recommended Citation

Ralston, P., Lemacks, J., Wickrama, K., Young-Clark, I., Coccia, C., Ilich, J., Harris, C., Hart, C., Battle, A., O'Neal, C. (2014). Reducing Cardiovascular Disease Risk In Mid-Life and Older African Americans: A Church-Based Longitudinal Intervention Project At Baseline. *Contemporary Clinical Trials*, 38(1), 69-81. Available at: https://aquila.usm.edu/fac_pubs/20220

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Authors

Penny A. Ralston, Jennifer L. Lemacks, Kandauda (.K.A.S.). Wickrama, Iris Young-Clark, Catherine Coccia, Jasminka Z. Ilich, Cynthia M. Harris, Celeste B. Hart, Arrie M. Battle, and Catherine Walker O'Neal

Published in final edited form as:

Contemp Clin Trials. 2014 May ; 38(1): 69–81. doi:10.1016/j.cct.2014.03.003.

Reducing cardiovascular disease risk in mid-life and older African Americans: A church-based longitudinal intervention project at baseline

Penny A. Ralston^a, Jennifer L. Lemacks^b, Kandauda (K.A.S.) Wickrama^c, Iris Young-Clark^a, Catherine Coccia^d, Jasminka Z. Ilich^e, Cynthia M. Harris^f, Celeste B. Hart^g, Arrie M. Battle^h, and Catherine Walker O'Neal^c

Penny A. Ralston: pralston@fsu.edu; Jennifer L. Lemacks: jennifer.lemacks@usm.edu; Kandauda (K.A.S.) Wickrama: wickrama@uga.edu; Iris Young-Clark: iyoungclark@fsu.edu; Catherine Coccia: ccoccia@fiu.edu; Jasminka Z. Ilich: jilichernst@fsu.edu; Cynthia M. Harris: Cynthia.harris2@famu.edu; Celeste B. Hart: hart@thyroidcenter.com; Arrie M. Battle: arriebattle@comcast.net; Catherine Walker O'Neal: cwalker1@uga.edu

^aCenter on Better Health and Life for Underserved Populations, Florida State University, C2200 University Center, P.O. Box 3062641, Tallahassee, FL 323062641, USA

^bNutrition and Food Systems, University of Southern Mississippi, 118 College Drive, #5172, Hattiesburg, MS, USA

^cHuman Development and Family Science, University of Georgia, 103 Family Science Center I, Athens, GA 30602, USA

^dDepartment of Dietetics and Nutrition, Florida International University, 11200 SW 8th Street, AHC I-450, Miami, FL 33199, USA

^eNutrition, Food, and Exercise Science, Florida State University, 418 Sandels Building, Tallahassee, FL 32306, USA

^fInstitute of Public Health, Florida A&M University, College of Pharmacy & Pharmaceutical Sciences, Tallahassee, FL 32307, USA

^gNorth Florida Regional Thyroid Center, 1705 S Adams St, Tallahassee, FL 32301, USA

^hMother Care Network, Inc., 919 Hardin Street, Quincy, FL 323513733, USA

Abstract

Introduction—African Americans (AAs) experience higher age-adjusted morbidity and mortality than Whites for cardiovascular disease (CVD). Church-based health programs can reduce risk factors for CVD, including elevated blood pressure [BP], excess body weight, sedentary lifestyle and diet. Yet few studies have incorporated older adults and longitudinal designs.

Purposes—The aims of this study are to: a) describe a theory-driven longitudinal intervention study to reduce CVD risk in mid-life and older AAs; b) compare selected dietary (fruit and vegetable servings/day, fat consumption), physical activity (PA) and clinical variables (BMI, girth

circumferences, systolic and diastolic BP, LDL, HDL, total cholesterol [CHOL] and HDL/CHOL) between treatment and comparison churches at baseline; c) identify selected background characteristics (life satisfaction, social support, age, gender, educational level, marital status, living arrangement and medication use) at baseline that may confound results; and d) share the lessons learned.

Methods—This study incorporated a longitudinal pre/post with comparison group quasi-experimental design. Community-based participatory research (CBPR) was used to discover ideas for the study, identify community advisors, recruit churches (three treatment, three comparison) in two-counties in North Florida, and randomly select 221 mid-life and older AAs (45+) (n = 104 in clinical subsample), stratifying for age and gender. Data were collected through self-report questionnaires and clinical assessments.

Results and conclusions—Dietary, PA and clinical results were similar to the literature. Treatment and comparison groups were similar in background characteristics and health behaviors but differed in selected clinical factors. For the total sample, relationships were noted for most of the background characteristics. Lessons learned focused on community relationships and participant recruitment.

Keywords

Cardiovascular disease; African Americans; Church-based health promotion

1. Introduction

Cardiovascular disease (CVD) is the leading cause of death in the U.S. [1]. For African American adults, CVD is of particular concern. For example, national data show that African Americans experience higher age-adjusted morbidity and mortality rates than Whites for both heart disease and stroke [1]. Both African American men and women have higher mortality rates attributed to CVD (390.4 and 277.4 per 100,000, respectively) compared to Caucasian men and women (287.2 and 200.5, respectively) [1]. African American deaths associated with CVD arise from several risk factors, including elevated blood pressure, cigarette smoking, high cholesterol, excess body weight, and sedentary lifestyle [2]. Clearly, reducing the risk for CVD is a top priority to improve the health of African Americans. Using community-based approaches, including churches, to address chronic disease risk is a key recommendation of Healthy People 2020 [3].

Churches are key organizations for providing health programming to African Americans because members share history, culture and religious values, and have infrastructures that allow for sustainability [4,5]. There is considerable evidence that health behavior change in African Americans, such as increased fruit and vegetable consumption, increased physical activity, lower BMIs and lower blood pressure, can occur as a result of church-based health programming [5–9]. Yet, there are several limitations to the current body of research. For example, there are few studies that incorporate strong research designs. This is illustrated in an analysis of published studies concerning CVD interventions, including faith-based, that showed that of the 524 studies examined, only 33 met the criterion of intervention research [6]. Further, many of the interventions that have been conducted are limited due to lack of

theoretical frameworks, comparison groups, longitudinal designs, and adequate power for analyses, among other issues [5,6,10]. Finally, few church-based health interventions have focused on mid-life and older African Americans, which is an important population given that generally more older than younger people are prevalent in church congregations [11]. To address these issues, church-based intervention studies are needed that incorporate longitudinal designs to examine sustainability in behavior change and clinical outcomes in mid-life and older African Americans.

The purposes of this paper are fourfold: a) describe a theory-driven longitudinal intervention study to reduce CVD risk in mid-life and older African Americans including conceptual framework, background literature and methods; b) compare selected dietary, physical activity and clinical variables for treatment and comparison churches at baseline; c) identify selected background characteristics (life satisfaction, social support, age, gender, educational level, marital status, living arrangement and medication use) at baseline that may confound diet, physical activity and clinical results; and d) share the lessons learned and implications for the study at baseline.

2. The Reducing CVD Risk Project

The Reducing Cardiovascular Disease Risk in Mid-life and Older African Americans Project (Reducing CVD Risk Project) was initiated in 2008 as a result of local community initiatives to promote church-based health and in conjunction with Florida State University (FSU) as the lead institution, and Florida A&M University (FAMU) and University of Georgia (UGA) as collaborators in partnership with six churches in a two-county area in North Florida [12]. This geographical area was selected because of the high prevalence of CVD risk factors and mortality rates in these counties compared to the overall Florida population. Specifically, at the initiation of the study, both counties had a majority of African Americans reporting their weight as either overweight or obese (60%); consuming less than five vegetables/fruits a day (range from 77 to 82.5%); and reporting no moderate (59–69.4%) or vigorous (75.2–86.3%) physical activity [13]. Further, both counties had a high risk of strokes (203–228 per 100,000 of those 35 years of age or older) that exceeded the state average (181 per 100,000) [13]. Finally, the counties selected represented socioeconomic and geographic diversity, with one county primarily rural with more low income (27.1% with household incomes of \$50,000+) and the other more urban county with a medium-sized community (250,000+) and slightly higher incomes (37.5% with household incomes of \$50,000+).

The local community initiatives to promote church-based health were led by a major church located in the larger, urban county that developed an active outreach component in its health ministry. This outreach led to the development of an ongoing volunteer-driven, faith-based annual community seminar, the first held in January 2007, and an advisory committee comprised of representatives from churches in the four county area, including two of the designated counties for the study. The initial community seminar included panels of health experts that highlighted health disparities in the local area and discussions regarding the kind of programming that should be conducted within the community. Data from the evaluations along with discussions highlighted church-based strategies as one mechanism of

programming thus providing the impetus for a possible multi-church health ministry project in the two-county area.

The project, which incorporated a quasi-experimental design, involved working with the health leaders and pastors from three treatment and three comparison churches in developing a three-phase, 18-month intervention designed to reduce cardiovascular risk in mid-life and older African Americans. In developing the intervention, the community-based participatory research (CBPR) approach was used where the church leaders themselves were involved in all decision-making regarding the project with key community leaders guiding the inception [14]. CBPR is increasingly used in church-based health research to ensure that interventions are culturally tailored to meet the needs of the community involved [5,7].

3. Theoretical perspectives and review of literature

3.1. Theory and conceptual framework

The theoretical perspective that undergirds the Reducing CVD Risk Project is the Transtheoretical Model of Behavior Change (TTM). TTM is an integrative theory that focuses on individual decision-making processes as a basis to explain intentional behavior change and is used broadly in health promotion of various populations [15] including older adults [16–18]. TTM is based on the premise that people move through a series of changes in their attempt to change a behavior [18] and consists of interrelated dimensions, including the organizing construct—stages of change (the temporal dimension which includes six steps in successful behavior change, from precontemplation through termination)—and three additional dimensions (decisional balance, process of change, and self-efficacy) that identify individual resources that influence change [15,18–20].

The overall logic model for the project is presented in Fig. 1. Based on TTM, the model includes *antecedents*, *the intervention*, *outputs* and *outcomes*. *Antecedents* include background characteristics (life satisfaction, social support, age, gender, educational level, marital status, living arrangement and medication use); baseline dietary, physical activity and clinical measures; and resources provided by community, church and research advisors. *The intervention* includes the conceptual elements of the 18-month intervention, based on input from the churches as well as the literature on effective interventions with African Americans [5–9]. *Outputs* include differential influence of the intervention components in relation to achieving diet and physical activity goals, and variables that might mediate outcomes (TTM variables of decision balance, process of change, and self-efficacy). Finally, *outcomes* include participants' diet, physical activity and clinical assessments at four points: baseline, six months, 18 months and 24 months. Outcomes also include an examination of *antecedents* (background characteristics, pre-test scores), *concurrent processes* (TTM measures; repeated measures of goal achievement) and *consequences* (diet, physical activity and clinical assessments at last data collection point) across stage progression groups. Studies using a TTM framework show progression in stage of change in adult populations, including African Americans [17,21].

For this paper, the *antecedents* of the model will be presented. Specifically, baseline data for food choice (daily servings of fruits and vegetables) and dietary quality (fat consumption),

physical activity, and clinical outcomes (BMI; girth circumferences including abdomen, hip and waist and waist-to-hip ratio; systolic and diastolic blood pressure [BP]; and low-density lipoprotein [LDL], high-density lipoprotein [HDL], total cholesterol [CHOL] and HDL/CHOL ratio) for treatment and comparison churches will be compared, and selected background characteristics (life satisfaction, social support, age, gender, educational level, marital status, living arrangement and medication use) that may influence diet, physical activity and clinical outcomes for treatment and comparison churches will be examined as possible confounding factors.

3.2. Review of literature

This brief review of literature provides background on African Americans' food choice and dietary quality, physical activity and clinical factors highlighting previous church-based intervention studies in relation to the variables to be examined. The review concludes with a discussion of successful approaches used in church-based interventions with African American populations.

3.2.1. Food choice and dietary quality—In general, the literature related to food choice shows that African Americans have a pattern of low consumption of fruits and vegetables and high consumption of cultural foods that are often high in salt, fat and sugar [22–24]. As an example, McClelland and others [25] found, in their baseline study of fruit and vegetable consumption of African American church members in North Carolina, that participants had mean intakes of 3.7 (± 2.4) servings daily, considerably below the recommended 5–6 servings [26]. There is evidence that church-based health interventions can improve food choice in African Americans, including increasing daily consumption of fruits and vegetables and decreasing consumption of high fat foods [5,19,27,28]. For this paper, food choice regarding daily servings of fruits and vegetables will be examined.

Consistent with the findings related to dietary patterns, African Americans often have low dietary quality. For example, because of high consumption of cultural foods, intakes of fat and sodium are also high [29,30]. While historically high sodium intake frequently has been identified as the main factor related to elevated BP, it is now clear that other nutrients and their interaction, as well as complete foods, are of equal importance. For example, results of the Dietary Approaches to Stop Hypertension (DASH diet) show that diets combining fruits and vegetables and low fat dairy products were most effective in reducing both systolic and diastolic pressure in a wide variety of either normotensive or hypertensive participants including African Americans [31]. Thus, examining fruit and vegetable intake in relation to lower fat consumption may influence blood pressure outcomes. Church-based health intervention studies have been successful in improving the dietary quality of African Americans, including lowering their fat consumption [5,19,27,28]. In this paper, we will examine fat consumption as a key variable in dietary quality.

3.2.2. Physical activity—National data show that African American males exceed physical activity levels in comparison to African American females, but both groups have lower physical activity levels in comparison to White males and females [32]. Specifically fewer African American males and females compared to White males and females reach the

recommended physical activity levels for moderate intensity activities of at least 30 min/5 days per week or vigorous intensity activities of at least 20 min/3 days per week [32]. Although there are few studies that examine the relationship between African American participation in habitual physical activity (e.g., heavy yard work, heavy housework, home maintenance, gardening, stair climbing, walking and spiritual dancing) and chronic disease risk factors, there is evidence from clinical studies with pre-menopausal White women that those who were more engaged in walking and/or heavy housework were able to lose more weight during a 10-week weight loss regimen [33] and those with higher habitual activity had more favorable body composition outcomes [34]. Further, in a 12-week intervention study with African American women, walking and resistance training improved several body composition measures [35]. There is evidence that church-based health programs emphasizing physical activity can increase participation [36,37] and result in a positive change in clinical outcomes (i.e., BMI, waist circumference) [38]. Thus this study investigates habitual physical activity as a key health behavior outcome.

3.2.3. Clinical factors—Taken together, food choice, dietary quality and physical activity have been shown to influence clinical outcomes in African American adults such as BMIs, girth circumferences and BP in church-based studies [9,39,40] and CHOL in similar community interventions [41,42]. Thus, we also examine these clinical outcomes in this paper.

3.2.4. Background characteristics—Various background characteristics are related to health behaviors in African Americans. Psychosocial factors such as life satisfaction and social support have been shown to be linked to food choice related to fruit and vegetable consumption and physical activity, with African Americans with higher life satisfaction and higher levels of social support more likely to consume fruits and vegetables [43,44] and participate in physical activity [45,46]. Age influences food choice and overall health behaviors due to changes in health status and physical functioning as one ages [47–50]. Socioeconomic status (SES) is associated with food choice, dietary quality and physical activity because of lack of access to healthy foods due to financial limitations, availability within low resource neighborhoods, and safe, affordable places to exercise [51]. Bowman [52], using National Health and Nutrition Examination Survey (NHANES) data, found that those with lower income and low educational levels have lower intakes of nutritious foods. The literature shows that gender, marital status, and living arrangement can intersect in relation to health behaviors, with for example African American men having better diets when they are married or living with someone [53]. Thus, in this paper we examine life satisfaction, social support, age, gender, education (as an indicator of socioeconomic status), marital status, and living arrangement as possible factors influencing food choice, dietary quality, physical activity and clinical outcomes. BP and CHOL medication use were included in the analysis to determine their possible relationship to the study variables.

3.2.5. Church-based interventions—Church-based health interventions have been shown to be effective in physical health changes for African Americans [5–9], a major health benefit even at mid-life [54]. Yet, few church-based health interventions have focused on mid-life and older Africans. Further, few church-based interventions have incorporated

longitudinal designs [5]. One of the rare longitudinal studies that also focused on mid-life and older African Americans is “Project Joy” [9]. This study was conducted with over 500 African American women (>40 years) from 16 churches, with the treatment group receiving a standard intervention (20 weekly sessions on diet and exercise with spiritual components) developed with input from the community with a control group receiving a self-help intervention [9]. The results after one year showed significant clinical (decreased body weight, waist circumference, blood pressure) and dietary (reduced energy, fat and sodium intake) improvements in the treatment group compared to the self-help group [9]. This landmark study emphasizes the need for comprehensive interventions for older African Americans that use community-based approaches, that are of even longer duration, and that include both males and females.

Other guidance provided from the literature regarding effective interventions in improving dietary and lifestyle behaviors with African Americans points toward three key approaches: a) broad environmental approaches that promote overall awareness [55,56]; b) clinical learning that includes small group educational sessions [57–59] using culturally-tailored communications [21,60], and c) efficacy development or the confidence to sustain health behavior change through follow-up support [21,60–64] and recognition activities. These studies highlight the need for church-based interventions with mid-life and older African Americans that include multiple components and encompass organizational, group and individual levels. This information provided the initial knowledge base for intervention development in the project.

4. Methods

4.1. Establishment of community advisors

Consistent with CBPR, we established an organizational structure gathering input and guidance for the study from the community. This structure included a community advisory committee, other stakeholders, research advisory committee, and project staff (see Fig. 2). Development of this advisory network was strengthened by pre-existing relationships formed through the community seminar in the larger, urban community. Given these pre-existing relationships, we used the advisory committee for the community seminar to gather input for the study. However, fewer pre-existing relationships were established in the smaller, rural county. Thus we used a key community stakeholder active in the community seminar advisory committee to help establish a community advisory committee (CAC) for this county which included pastors, government officials, and health agency representatives. A research advisory committee (RAC) was established that included the principal investigator; co-investigators from FAMU, FSU and UGA; project coordinator and graduate assistant; medical advisor; and the key community stakeholder from the CAC. The RAC held conference calls on a monthly basis to guide the study, including approvals of the project timeline and protocols. The project staff, which included the principal investigator, graduate assistant, and student assistants, finalized the research design and implemented the project protocol with the guidance and approval of the CAC, RAC, church steering committees and other community stakeholders. The principal investigator, nutrition faculty

member who served as co-investigator, medical advisor, and project coordinator also held meetings to finalize clinical protocols.

4.2. Church and participant recruitment

Churches for the study were identified through making contact with religious leaders in the two counties, under the guidance of the community advisors. In the larger, urban community, contacts were made with members of the community seminar advisory committee to identify possible churches. For the smaller, rural community, the CAC met to identify possible churches and to discuss recruitment strategies. Criteria for church selection included medium size (>150 members), no health ministry/inactive health ministry, and similarity in religious values. Nominated churches were placed on a list for further review. Interviews were conducted with pastors to determine size of church congregation, extent of support for evidenced-based health, and availability of health ministry. With input from community advisors, six churches were selected for participation with two located in the larger urban county and four in the smaller rural county (see Fig. 2). Size of church and community were used as criteria in the assignment of churches to treatment or comparison groups based on feedback from community advisors. This was particularly important in the rural county where contamination within the smaller communities was a concern. Once pastors agreed to participate, they were asked to identify at least three health leaders who would serve as a steering committee to guide the implementation of the project in each church. Criteria for identification of health leaders included an interest in health and an established record of leadership in the church. Comparison churches were asked to identify a health leader to assist with contacting participants and orientation sessions. However, the steering committees in the comparison churches were established on a delayed basis, after the intervention was developed and implemented and the first three waves of data were collected. Steering committees and pastors from the comparison churches had positive perceptions of their involvement throughout the project since their church members were engaged in the four-phases of data collection and had regular visits to Sunday services by the project team. All participating churches received an annual appreciation contribution of \$500 at the conclusion of each data collection phase.

To identify participants for the study, a list of church members was obtained from the pastors in the six churches. The project staff reviewed the lists with the pastor and church staff to determine members who fit the age criterion and who regularly attended church services (at least twice monthly). The list was then used to randomly select participants from each treatment and comparison church, stratifying by age (mid-life = 45–64 years of age; older = 65 and older) and gender (see Fig. 3). Participants were not matched across the two groups.

4.3. Instruments and clinical assessment protocol

The 80-item food and lifestyle habits questionnaire was compiled using instruments that provided assessments of food choice, dietary quality and physical activity. Cognitive interviewing [65,66] was used with selected church steering committee members to determine if items in the instruments would be understood and comprehended by the study population with revisions made as needed. The instruments were pilot tested with a group of

mid-life and older African Americans not included in the study and then reviewed for appropriateness of content and length by the steering committees in the treatment churches. The average time for completion of the questionnaire was about 1 h. For this paper, the following items were used in the analysis to reflect the variables in the antecedent portion of the logic model:

- *Daily fruit and vegetable intake* was measured by the item: “On average, what is the number of fruit/vegetable servings that you eat daily?” Possible responses ranged from zero to six or more. This single item measure, which has been used extensively in previous dietary studies [67–69], is considered valid for use in health behavior studies [67]. Validity of this item was determined in a major study that compared its use with multi-pass 24 h recalls (24HR), considered the gold standard in food consumption surveys. The single item was positively correlated overtime with 24HR ($r = 0.45$ baseline, 0.50 follow-up), slightly underestimated fruit and vegetable intake, indicated no treatment effects, and was considered adequate when investigating intervention effects [67]. The single item has an inter-measure reliability of $r = 0.56$ when correlated with mean servings from a 61-item food frequency questionnaire [70].
- *Fat consumption* was determined by using the single item of the NCI Fat Screener: “Overall, when you think about the foods you ate over the past 12 months, would you say your diet was high, medium, or low in fat?” Thompson and others [71] validated the broader NCI Fat Screener and reported estimated correlations of 0.64 and 0.58 between true intake and this instrument. With regard to reliability, Williams and colleagues [72] examined the ability of the NCI Fat Screener to predict change in percent energy from fat in dietary intervention studies, using a diverse sample of 278 participants from four study sites. They found that the correlations, by gender, for the NCI Fat Screener and 24 HR were consistent from baseline to follow-up (6 or 12 months depending on site) (women, $r = 0.45$ and 0.51 ; men, $r = 0.68$, 0.58 , respectively).
- *Habitual physical activity* was measured using the Yale Physical Activity Scale (YPAS) [73], which provides estimates of caloric expenditure from activity time (minutes per day or week) and activity dimensions (working, yard work, caretaking, exercising, and recreational activities) during a typical day or week. Moore’s [74] validation study, which compared four self-report physical activity measures with performance-based physical function using a culturally diverse adult sample that included African Americans, found that the YPAS had moderate correlations ($r = .40$, 90% CI = $.19$ – $.57$, $p < .01$).
- *Other items.* Psychosocial characteristics assessed life satisfaction, fruit/vegetable social support, and physical activity social support. Life satisfaction was measured using the 4-item Satisfaction With Life Scale, a 7-point Likert scale ranging from “strongly disagree” to “strongly agree” (e.g., “In most ways my life is close to my ideal”; “I am satisfied with my life”) [75]. Sum scores were computed and recoded so that higher scores indicate life satisfaction ($\alpha = .86$). Social support related to fruit and vegetable consumption was measured using five items (e.g., “I had

someone I could rely on to support my decision to eat more vegetables and fruits”) from the Fruit and Vegetable Processes of Change instrument [17]. Items were summed, and higher scores indicate the presence of more social support in relation to eating fruits and vegetables ($\alpha = .80$). Social support related to physical activity was measured by 4-items from the Physical Activity Processes of Change instrument [17] (e.g., “I have to exercise alone”, reverse coded, $\alpha = .84$). Other items included age (eight categories from 43 to 49 to over 91 years of age, coded 1–8), gender (coded 1 = female, 2 = male), marital status (single, married, divorced/separated, widowed and other which were recoded as 1 = single, 2 = married), education level (six categories ranging from some high school to Ph.D., M.D., or Law degree, coded 1–6), living arrangement (“Is anyone living with you in your home?”, coded no = 1, yes = 2), and medication use (“Please check which, if any, health problems you have. For health problems marked please check if you take medication.” List of medications included high blood pressure and high cholesterol, coded no = 1, yes = 2).

- *Clinical data* included measurements of weight (in kilograms to the nearest tenth), height (using stadiometer, standing stature without shoes recorded in cm), calculation of BMIs (kg/m^2), circumferences (waist, abdomen, hip), blood pressure (three readings using non-dominant arm, sitting position), and blood lipids (Total CHOL, LDL, HDL).

4.4. Data collection

The study was approved by the Florida State University Institutional Review Board. Each participant in the study received a letter outlining the purposes and benefits of the study, the data collection protocol, and an invitation to attend an orientation session. The letter was followed up with a personal telephone call from project staff to confirm interest in the study and attendance at the orientation session. The orientation session included further explanations of the study and data collection procedures and distribution of consent forms for participants who agreed to take part in the research. Data collection sessions were held at the participating churches where the food and lifestyle habits questionnaire was administered and clinical measurements were taken in private rooms by clinical staff. Any participants needing assistance with the questionnaire were interviewed by trained staff. Fasting blood samples were collected by phlebotomists at data collection sessions held on Saturday mornings at the participating churches. A medical advisor for the project reviewed all clinical data collection protocols. Participants who completed all data collection requirements at baseline received a \$25 discount store gift card with this same amount provided after each phase of the study.

4.5. Data analysis

This section reports the analyses performed for the baseline data reported in this paper along with the overall data analysis plan, power estimates and handling of missing values for the broader study.

4.5.1. Analysis for baseline study—For the analysis of the baseline data reported in this paper, descriptive statistics (means and standard deviations) were used to examine the background characteristics of the treatment and comparison participants. In addition, independent t-tests were used to determine if there were mean differences between treatment and comparison participants in dietary, physical activity and clinical outcomes at baseline. Pearson correlations were computed to determine the possible bi-variate relationship between background characteristics and the study variables for the total sample. For medication use, Chi-square test for categorical variables and t-tests for continuous variables were used to determine a possible relationship to background characteristics and to study variables.

4.6. Analysis plan, power estimates and handling of missing values for broader study

- *Analysis plan.* For the larger project, repeated measures MANOVA will be used to assess the differences in mean levels of outcomes (e.g., physical activity) over time (trends) and across intervention and comparison groups. Analysis of covariance (ANCOVA) will be used to partial out the influence of any covariates such as age and marital status. In the MANOVA procedure, variables are assumed to be measured without error. To address this concern, we also will use an individual trajectory (growth curve) approach. Individual trajectories and the variation in these trajectories can be estimated as latent growth curve (LGC) models in a structural equation framework (SEM). LGC estimation begins by constructing line segments (individual trajectories) that describe change over time in an outcome variable (e.g., physical activity, fruit/vegetable consumption) for each individual in the study. To describe these individual trajectories two latent variables (growth parameters) (e.g., initial level of physical activity and rate of change in physical activity) are defined using SEM. Although each individual trajectory varies in initial level and rate of change, these are aggregated in terms of means and inter-individual variances across individuals. These variances in the initial levels and rates of change can be explained by predictors (intervention/control condition). Furthermore, growth parameters of a primary outcome or individual resources (e.g., efficacy) can also be related to subsequent outcomes (e.g., fruit/vegetable consumption) as well as to interventions. That is, the LGC approach will allow for the investigation of the mediational processes between interventions and dietary goal and physical activity achievement through the development of individual resources.
- *Power estimates.* For the broader study, power calculations were performed to determine the appropriate sample size. The power calculations show that the power will be adequate for the proposed MANOVA tests. Previous TTM intervention studies [17] have shown that standardized mean differences ($d = (\text{intervention mean} - \text{control mean}) / \text{pooled standard deviation}$) in outcome variables such as dietary and physical activity goal achievement measures between intervention and control groups are in the medium range. Expected effect sizes for the group differences in relation to our outcome variables will be at least in the medium range ($>.30$). If $d = .30$, $n = 220$, and $p = .05$, the power would be more than .90 [76]. Because we will estimate LGC in a SEM framework, we also are concerned with the power of

testing parameters in LGC SEM models. Duncan et al. [77] suggest that, in SEM models, test statistics of a freely estimated parameter (e.g., t-statistics for each path) can be used to approximate the non-centrality parameter (square of t-statistics is equivalent to the Wald test which can be used as a non-centrality parameter in relation to non-central Chi-square distributions to assess the power). We expect that t-values of most of the paths (e.g., intervention to rate of change in physical activity) will be more than 2.80. For a medium effect size, with a centrality parameter of $2.80 \times 2.80 = 7.84$, a .05 significance level, and a sample of 220, we will be able to achieve adequate power (more than .85).

- *Management of missing values.* Traditional approaches such as list wise deletion, pair-wise deletion, and mean substitution can produce biased estimates, distorted statistical power, and invalid conclusions when non-random missingness exists [78]. We will use the full information maximum likelihood (FIML) method, which offers substantial improvements over traditional measures. FIML can be used to manage missing data successfully for up to 30% of missing data under the missing at random (MAR)/completely at random (MCAR) conditions, which enhances the efficiency of subsequent analyses [79].

5. Results

5.1. Baseline results

A total of 221 participants provided completed questionnaires and a subsample ($n = 104$) provided clinical assessment data. Table 1 presents the background characteristics for the treatment and comparison participants at baseline. The treatment and comparison groups were similar with regard to life satisfaction, social support (fruit/vegetable, physical activity), gender, education, marital status, living arrangement, and medication use. Comparison participants were slightly younger than the treatment participants (45.4% versus 34% between 45 and 56 years of age, respectively). There were no significant differences between treatment and comparison participants in dietary and physical activity outcomes (Table 2). However, there were significant differences between the two groups in clinical outcomes with the comparison participants having significantly higher diastolic BP ($83.2, \pm 9.8$ mm Hg, $p < .05$) and total CHOL ($180.4, \pm 35.3$ mg/dL, $p < .05$) but significantly lower LDL ($112.7, \pm 26.6$ mg/dL, $p < .05$) than the treatment participants ($78.1, \pm 12.8$ mm Hg; $129.1, \pm 31.1$ mg/dL; and $196.9, \pm 35.3$ mg/dL, respectively). The between church differences in all these variables were not significant ($p < .05$).

The correlations between dietary, physical activity and clinical outcomes for the total sample showed significant variations by age (systolic BP, $r = .21$ (CI; .015, .390), $p < .05$; diastolic BP, $r = -.25$ (CI; $-.425, -.390$), $p < .01$; waist circumference, $r = .21$ (CI; .015, .390), $p < .05$; hip circumference, $r = -.32$ (CI; $-.132, .485$), $p < .01$), gender (BMI, $r = .28$ (CI; .089, .451), $p < .01$; HDL, $r = .38$ ($-.199, .536$), $p < .001$; waist/hip ratio, $r = .44$ (CI; .267, .585), $p < .001$), education (systolic BP, $r = -.21$ (CI; .015, .390), $p < .05$), marital status (waist, $r = .27$ (CI; .078, .442), $p < .01$; hip, $r = .22$ (CI; .014, .392), $p < .05$), life satisfaction (daily servings of fruit and vegetables, $r = .15$ (CI; .012, .282), $p < .05$; BMI, $r = -.24$; abdomen circumference, $r = -.27$ (CI; $-.442, -.078$), $p < .05$; hip circumference, $r = -.28$ (CI; $-.451,$

-.089), $p < .05$), and fruit/vegetable social support (daily servings of fruit and vegetables ($r = .24$ (CI: .105, .356), $p < .05$; physical activity, $r = .14$ (CI: -.042, .313), $p < .05$). All the variables showed good distributional properties. For example, except for BMI, all the variables had skewness values of less than 1. BMI had a skewness of 1.95.

For the total sample, some significant associations were noted for medication use in relation to the other variables studied. With regard to BP medication, there were no significant differences in those who reported they had high BP and took medication ($n = 131$) (BP medicated group) and those who reported they had high BP but did not take medication ($n = 33$) (BP non-medicated group) in background characteristics (life satisfaction, age, gender, education and living arrangement [living alone]), health behaviors (fruit/vegetable, physical activity), and clinical variables (BMI, waist, hip, waist/hip, LDL, HDL/CHL). However, respondents in the medicated group had a higher mean level of HDL ($52.32, \pm 14.25$) than the non-medicated group ($39.43, \pm 8.77$, $p < .05$). In addition, more married respondents were in the BP medicated group (47%) compared to the BP non-medicated group (40%) ($p < .05$). With regard to CHOL medication, there were no significant differences in those who reported they had high CHOL and took medication ($n = 78$) (CHOL medicated group) and those who reported they had high CHOL and did not take medication ($n = 22$) (CHOL non-medicated group) in background characteristics (life satisfaction, gender, education, marital status, living arrangement [living alone]), in health behaviors (fruit/vegetable, physical activity) and in clinical variables (BMI, hip, waist/hip, diastolic BP and systolic BP). However, there were more older respondents in the CHOL medicated group than the CHOL non-medicated group ($M = 7.69, \pm 1.54$, and $6.47, \pm 1.31$, respectively; $p < .01$).

5.2. Lessons learned

There were several lessons learned during the baseline phase of this study, centered on development of community relationships and participant recruitment. We found that a particular strength, especially in the larger, urban county, was the pre-existing relationships established through the annual community health seminar. However, in the smaller, rural county, we had fewer relationships and thus the need for the community advisory committee (CAC) in that county. Using the lead person for establishing the CAC, an active member of the advisory committee for the community health seminar in the larger urban community, demonstrates that having these relationships established was the key to identifying individuals for the CAC. This individual assisted with making the initial contacts with the churches in the smaller, rural county and regularly attended church services and other events during the church recruitment process.

With regard to participant recruitment, we were pleasantly surprised that there were few barriers noted in getting individuals to enroll in the study, most likely influenced by the pre-established relationships in the larger, urban county and the relationships with the key community stakeholder in the smaller, rural county. However, we faced three key challenges during the enrollment process that led to adjustments in our protocol. The first challenge was the length of the orientation process. We initially developed a two-phase protocol, with informational meetings held in the evenings at each church where potential participants learned about the study and then returned for a subsequent evening meeting (usually in the

same week) to sign the consent form and to pick up the questionnaire packet. We found that fewer people showed on the second evening requiring labor intensive follow-up. Thus, as we moved forward in the baseline phase, we combined the informational meeting with the consent/packet distribution meeting. A second challenge was the length of the questionnaire (actually separated into three questionnaires for data collection purposes), which contributed to participant burden and incomplete responses. To address this issue at baseline, we developed a checking procedure when questionnaires were returned at the data collection site where a team member was designated to review questionnaires and identify missing data. Participants were then interviewed in a confidential setting (usually a separate room with door) to obtain answers to missing responses. To reduce participant burden, especially with participants who were interviewed, we separated data collection into two sessions. As we continued into phase II of the study, we worked on reformatting the questionnaire to reduce length and improve readability. A final challenge was communicating with participants to complete data collection at baseline. We found some participants were extremely hard to reach due to work hours and disconnected phone numbers. Further, most respondents did not use email. Thus we developed participant follow-up protocols based on contacting participants via a preferred phone number and at preferred times, with three calls made in the following time intervals leading to a data collection session: one week, three days and prior/same day. If numbers were disconnected, we contacted the church steering committee leadership to contact the participant at a church service to get the new phone number or any additional information on the participant's status. This phone call protocol improved data collection session attendance.

6. Discussion and implications

This paper described at baseline an intervention study to reduce CVD risk in mid-life and older African Americans, using TTM as the theoretical framework and CBPR approaches. An organizational structure of community advisors was tailored for each county and guided the recruitment process, resulting in the successful selection of six churches. A total of 221 participants completed the study at baseline. The baseline data were consistent with the literature in that both treatment and comparison participants consumed slightly more than two servings of fruits/vegetables per day [25], perceived their fat consumption as moderate [22–24], and had low to moderate physical activity levels [32,37,62]. Clinical results showed that both treatment and comparison groups had BMIs in the obese range, systolic blood pressure at hypertensive levels, and LDL and HDL cholesterol outside of recommended levels [2,9,39,40]. These findings demonstrate that this sample of mid-life and older African Americans have health indicators consistent with the general population of African Americans in this age range and are an appropriate group for an intervention to reduce CVD risk.

Treatment and comparison groups were similar in background characteristics and in dietary and physical activity variables, but there were significant differences in some of the clinical findings. For the total sample, statistically significant associations were identified between four of the background characteristics (age, gender, education, marital status) and clinical results. In addition, more married participants reported taking BP medication and more older participants reported taking CHOL medication. These differences in clinical variables and

confounding factors will need to be considered in future analyses that examine the effectiveness of the intervention.

Implications from this study at baseline are twofold. First, the success in the recruitment of churches and participants was influenced by the strong relationships with community stakeholders. These relationships, which were well-established in the larger, urban county and developed positively in the smaller, rural county, were clearly related to the project team's involvement in on-going volunteer community efforts in church-based health. A key principle in CBPR is to give back to the community on a regular basis, which can be difficult to actually achieve due to the time constraints and lack of funding. Yet making this effort to have parallel activities—volunteer as well as funded-projects—clearly helped our research team in establishing credibility and trust in the community and served as a positive model in training students about CBPR. As an example, the principal investigator continues to co-lead the advisory committee for the annual community health seminar, which now has expanded to eight counties in North Florida. This ongoing role has facilitated the strengthening of relationships with church leaders in the smaller rural county where some of the community health seminars have been held. The principal investigator's involvement in the community health seminar also strengthened the relationship with the key volunteer from the smaller rural county.

A second implication was related to the adjustments made in the challenges faced in participant recruitment. The project team's ongoing efforts to listen to and observe participants and to make decisions with input from all staff members—including project coordinator, graduate assistants and student assistants who did much of the day-to-day work in contacting participants—helped in fostering an environment of co-learning with more effective decision-making as a result. These implications provide a basis for a successful start to this longitudinal study to reduce CVD risk in mid-life and older African Americans.

Acknowledgments

The project described was supported by Award Number R24MD002807 (P.I. Penny A. Ralston) from the National Institute on Minority Health and Health Disparities. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute on Minority Health and Health Disparities or the National Institutes of Health.

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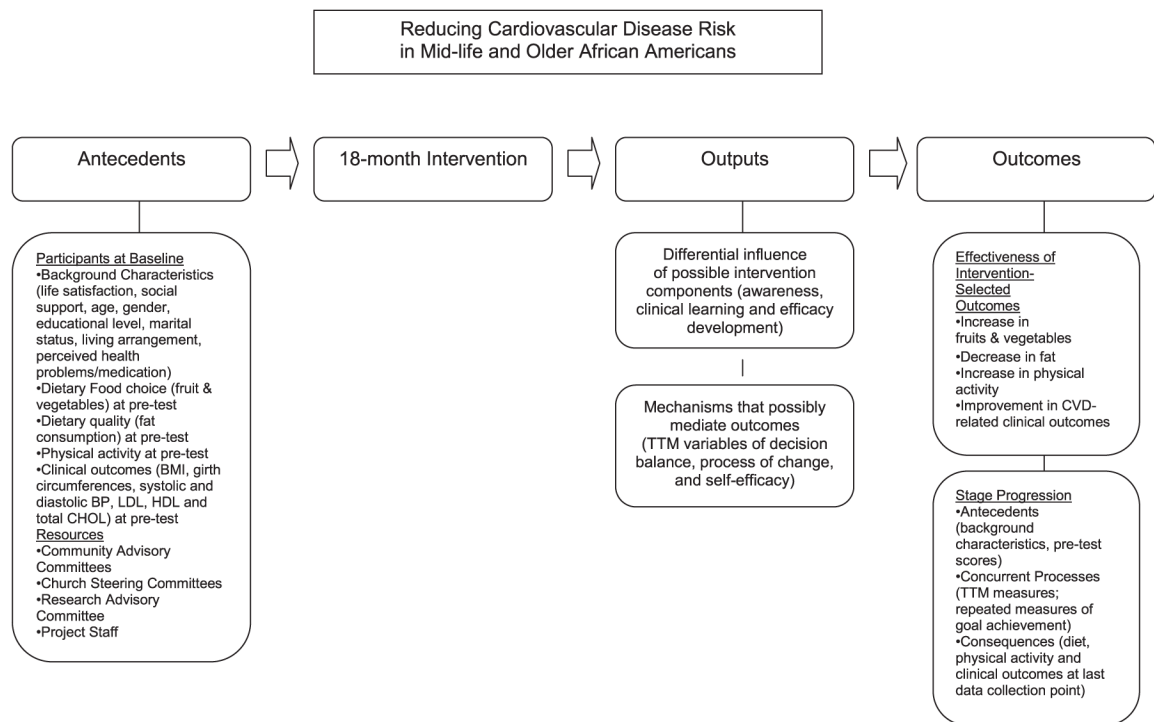


Fig. 1.
Logic model.

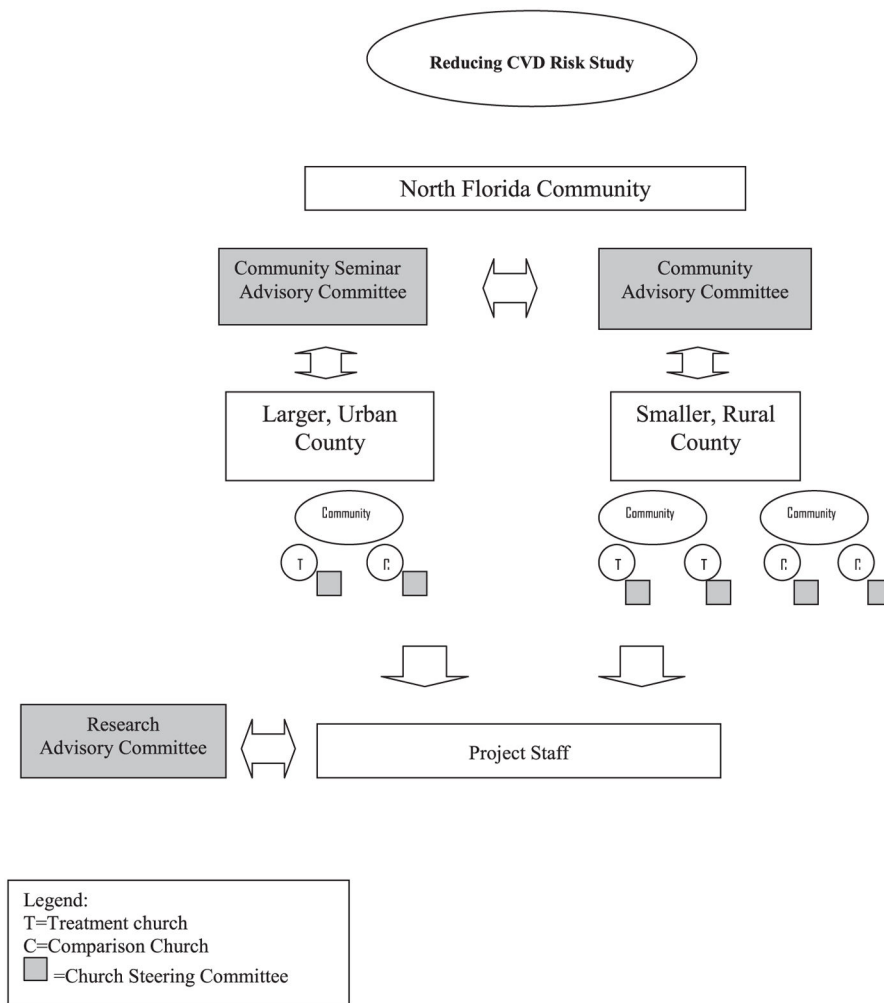


Fig. 2.
Organizational structure for reducing cardiovascular risk study.

Inclusion Criteria:

African American, 45 year of age or older, regular church attendance (2 times a month)
 Stratification: Gender (to ensure sufficient males) and age (to ensure sufficient 45-64 age group)

Exclusion Criteria:

Race other than African American, under 45 years of age, irregular church attendance (less than two times a month)

Participants Meeting Criteria:

Treatment Churches

Comparison Churches

311

265

Randomly Selected Sample (Total/Clinical):

278/100

228/101

Participants Consented (Total/Clinical):

112/37

132/71

Participants Completing at Baseline (Total/Clinical)^a:

101/36

110/68

^aParticipation rate (those completing from randomly selected sample)=Treatment 40%, Comparison 57%

Fig. 3.

Sample selection. Inclusion criteria: African American, 45 year of age or older, regular church attendance (2 times a month). Stratification: Gender (to ensure sufficient males) and age (to ensure sufficient 45–64 age group). Exclusion criteria: race other than African American, under 45 years of age, irregular church attendance (less than two times a month).

Table 1

Background characteristics of sample.

Background characteristics	Treatment number	Participants ^a percent	Comparison number	Participants ^b percent
Age				
43–49	17	17.0	23	20.9
50–56	17	17.0	27	24.5
57–63	24	24.0	30	27.3
64–70	15	15.0	13	11.8
71–77	14	14.0	9	8.2
78–84	7	7.0	5	4.5
85	6	6.0	3	2.7
Gender				
Female	73	72.3	81	72.3
Male	28	27.7	31	27.7
Marital status				
Single	11	11.0	14	12.7
Married	48	48.0	47	42.7
Divorced/separated	18	18.0	34	30.9
Widowed	22	22.0	12	10.9
Other	1	1.0	3	2.7
Education ^c				
Some high school	8	7.9	12	11.0
High school graduate	29	28.7	32	29.4
Some college	34	33.7	31	28.4
Bachelor's degree	14	13.9	15	13.8
Master's degree	12	11.9	17	15.6
Ph.D., M.D. or J.D.	1	1.0	0	0.0
Living arrangement				
Live alone	25	24.8	37	29.4
Live with someone	75	75.2	77	70.6
Perceived health problems & reported medication use ^d				
High BP	76	76.8	71	76.0
Medication use	68	89.0	63	90.0
High CHOL	50	50.0	49	44.1
Medication use	40	80.0	40	81.0
Psychosocial characteristics			Mean (SD)	
Life satisfaction ^e	19.13 (6.28)		18.11 (6.59)	
F/V social support ^f	13.32 (4.71)		13.05 (4.72)	
PA social support ^f	13.02 (4.51)		13.71 (4.55)	

^aTreatment sample ranged from n = 98 to n = 101 due to missing data.^bComparison sample ranged from n = 107 to n = 114 due to missing data.

^c Education served as the socioeconomic (SES) indicator. Due to over 50% with high school or some college, we added occupation and employment status in Phase II data collection to provide an additional SES indicator.

^d Participants completed survey information to indicate whether they had high blood pressure and/or cholesterol and subsequently selected if they received medication treatment for the condition(s).

^e Treatment n = 100, comparison n = 98.

^f Treatment n = 100, comparison n = 100.

Table 2

Results of independent T-tests for treatment and comparison participants at baseline.

Variable	N ^a	Treatment Mean (SD)	Comparison Mean (SD)	T-value	p-Value
<i>Self-report variables (total sample)</i>					
Fruit/vegetable (serving/day)	219	2.4 (±1.2)	2.2 (±1.2)	-0.914	0.362
Fat (serving/day)	219	2.1 (±0.5)	2.0 (±0.6)	-1.077	0.283
Physical activity (YPAS) ^b	221	4733.3 (±4894.3)	5474.6 (±5459.7)	-1.056	0.292
<i>Clinical variables (sub-sample)</i>					
BMI	104	34.5 (±8.2)	35.1 (±9.8)	-0.326	0.745
Waist (cm)	104	105.9 (±17.4)	105.2 (±17.9)	0.117	0.907
Abdomen (cm)	104	112.1 (±21.7)	110.3 (±15.6)	0.505	0.615
Hip (cm)	104	118.6 (±17.3)	118.10 (±15.7)	0.146	0.885
Waist/hip ratio	104	0.9 (±0.1)	0.9 (±0.1)	-0.027	0.978
Systolic BP ^c (mm Hg)	104	133.4 (±21.3)	131.8 (±15.9)	0.449	0.655
Diastolic BP (mm Hg)	104	78.1 (±12.8)	83.2 (±9.8)	-2.265	0.026 [*]
LDL CHOL ^d (mg/dL)	87	129.1 (±31.1)	112.7 (±26.6)	2.844	0.006 ^{**}
HDL CHOL ^d (mg/dL)	88	48.6 (±12.4)	50.2 (±16.1)	-0.360	0.720
Total CHOL (mg/dL)	88	196.9 (±35.3)	180.4 (±35.3)	2.079	0.041 [*]
HDL/CHOL	88	4.2 (±1.1)	3.9 (±1.3)	1.125	0.264

^{*} p < .05.^{**} p < .01.^aTotal sample ranged from 219 to 221. Clinical subsample was 104 for anthropometric and blood pressure variables and ranged from 87 to 88 for cholesterol variables. Differences in clinical subsamples due to rate of participation in fasting blood data collection sessions.^bYale Physical Activity Scale score.^cBP = blood pressure.^dLDL CHOL = low density lipoprotein cholesterol; HDL CHOL = high density lipoprotein; total CHOL = total cholesterol.