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A Randomized Controlled Exercise Training Trial on Insulin Sensitivity in African American Men: The ARTIIS study

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Abstract

Background—Lack of regular physical activity at prescribed intensity levels is a modifiable risk factor for insulin resistance and the development of diabetes. African American men are at increased risk for developing diabetes and most African American men are not meeting the current recommended levels of physical activity. The primary objective of the Aerobic Plus Resistance Training and Insulin Resistance in African American Men (ARTIIS) study is to determine the effectiveness of an exercise training intervention aimed at reducing diabetes risk factors in African American men at risk for developing diabetes.

Methods—Insufficiently active 35–70 year old African American men with a family history of diabetes were eligible for the study. The 5-month randomized controlled trial assigns 116 men to an exercise training or healthy living control arm. The exercise training arm combines aerobic and resistance training according to the current national physical activity recommendations and is conducted in community (YMCA) facilities. The healthy living arm receives information promoting healthy lifestyle changes.

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Outcomes—Insulin response to an oral glucose load is the primary outcome measure, and changes in physiological parameters, cardiorespiratory fitness, strength, body composition, and psychological well-being comprise the secondary outcomes.

Conclusions—The ARTIIS study is one of the first adequately powered, rigorously designed studies to investigate the effects of an aerobic plus resistance exercise training program and to assess adherence to exercise training in community facilities, in African American men.

Keywords

African American; male; exercise training; community; diabetes risk; diabetes; health disparity

Introduction

Diabetes represents a health disparity for African American men. Age-adjusted estimates show that 9.9% of African American men have been diagnosed with diabetes compared to 6.5% of white men. [1] This high prevalence of disease warrants intervention studies that focus on the prevention of diabetes in this population. Insulin resistance is a precursor to the development of diabetes, [2–4] and therefore can serve as an intervention target. Physical activity is inversely associated with both insulin resistance [5, 6] and the risk of developing diabetes, [7, 8] and most African American men do not engage in the amount of physical activity that is recommended. [9] Interventions that increase physical activity in African American men to the recommended levels are needed in order to determine the effect on diabetes risk factors including glucose and insulin sensitivity.

Exercise training studies have resulted in reductions in insulin resistance and hyperinsulinemia. [10–24] However, these studies have been conducted in predominantly white samples and did not contain a sufficient number of African American men to conduct separate analyses. Several other exercise training studies have been conducted in exclusively African American men, [25–30] though none of these interventions measured diabetes related outcomes (i.e. glucose, insulin, HbA1c). To the best of our knowledge only one exercise training study to date has included a sufficient number of African American men to conduct separate analyses on changes in insulin. The results of the HERITAGE study showed decreased fasting insulin and increased insulin sensitivity in African American men after 20 weeks of training. [11] However, the study did not contain a control group and these positive findings have not been replicated. Therefore, there is a need for more studies assessing the effects of exercise training on diabetes related outcomes in this population.

The current recommendation for physical activity is 150 minutes of moderate intensity physical activity per week or 75 minutes of vigorous intensity activity. The recommendation also includes two days of resistance training of major muscle groups at moderate or vigorous intensity. No study has tested the effects of adhering to this recommendation in African American men, so it is unknown if the current recommendation has beneficial effects on diabetes related outcomes in African American men. The primary objective of the current study, entitled The Aerobic Plus Resistance Training and Insulin Sensitivity in African American Men (ARTIIS), is to determine the effectiveness of an aerobic plus resistance training intervention on insulin sensitivity in African American men at risk for developing

diabetes. As studies have shown that community-based interventions are viable among African Americans, [31–34] the current study will take place in community-based facilities.

Materials and Methods

Aims and hypotheses

The overall aim of ARTIIS is to test the efficacy of a community-based aerobic plus resistance training program to produce improvements in insulin resistance in a group of African American men at risk for developing diabetes. It is hypothesized that men in the aerobic plus resistance training intervention will have a greater reduction in 2-hour insulin response to an oral glucose tolerance load and will have greater improvements in secondary outcome variables compared to men in the healthy living group. In addition, it is further hypothesized that men in the aerobic plus resistance training intervention will exhibit high attendance (>80% of scheduled sessions).

Formative research

Prior to developing or submitting the study for funding, focus groups were held with African American men to delineate the key elements in program design that would be acceptable to this population. Fifty-four African American men participated in one of seven focus groups. These focus groups revealed several key elements that aided in the design of the ARTIIS study. First, the men indicated that social support was a key component of initiating a regular physical activity routine, and that this social support could come from a variety of sources (e.g. friends, family members, fitness instructor). Second, the men revealed that they were more likely to exercise if they had access to an exercise facility. Third, the men were receptive to engaging in resistance training. Based on these findings, it was determined that a successful exercise training program would provide African American men with 1) a fitness instructor, 2) access to an exercise facility, and 3) a resistance training component. These elements were then incorporated into the exercise training arm of the study (See Interventions below).

Study design

ARTIIS is a 5-month randomized controlled trial in which circulating insulin response two hours after a 75 gram glucose load (oral glucose tolerance test (OGTT)) serves as the primary outcome variable. African American men are randomly assigned to either an aerobic plus resistance training intervention conducted in a community-based facility or a healthy living control group. Participants are recruited from the community at large. The study is funded by the National Institute of Diabetes and Digestive and Kidney Diseases (DK09523301) and is registered in clinicaltrials.gov [NCT01787617]. The study is annually reviewed and approved by the Pennington Biomedical Institutional Review Board. In addition, a Data Safety and Monitoring Board (DSMB) has been established and includes a cardiologist (MD), biostatistician (PhD), exercise physiologist (PhD), and lay person. The DSMB members receive study progress updates quarterly throughout the study and have unanimously recommended continuation of the trial.

Participants

Potential participants are eligible for the study if they 1) self-identify as an African American man; 2) are between the ages of 35 to 70 years; 3) have a BMI $\leq 25.0 \text{ kg/m}^2$ and $\leq 45 \text{ kg/m}^2$; 4) are insufficiently active at baseline, defined as being physically active $\leq 3 \text{ d}\cdot\text{wk}^{-1}$ for 20 min each bout during the previous 6 months, and are not currently participating in regular resistance exercise; and 5) have a nuclear family member (i.e. their biological mother, father, or sibling/s) who was diagnosed with diabetes. The exclusion criteria included individuals 1) with a history of cardiovascular disease (e.g. arrhythmias, cardiomyopathy, congestive heart failure, peripheral vascular disease with claudication, etc.), though patients who received cardiology clearance from their cardiologist are eligible if the condition was not significant and they were currently being treated; 2) with other significant medical conditions (e.g. chronic respiratory, gastrointestinal, neuromuscular disorders, autoimmune or collagen vascular diseases, malignancies within the past 5 years except non-melanoma skin cancer therapeutically controlled, any conditions that prevent regular exercise or are exacerbated by regular exercise, etc.); 3) with lab values outside of the acceptable range or showing abnormalities on assessments of blood pressure or cardiac function (at rest and under stress), (see Measurements below) or 4) taking any antihyperglycemic medication (e.g. exenatide, liraglutide, etc.). Potential participants with LDL-C $\geq 190 \text{ mg/dL}$ or TG levels $\geq 300 \text{ mg/dL}$ and who are not under the care of a physician to treat the elevated LDL-C and/or triglycerides or who failed to provide written documentation from their physician approving of their entering the study, are excluded. Potential participants displaying cardiac abnormalities during the ECG (e.g. elevated t-wave, arrhythmias, etc.) or during the fitness testing (e.g. elevated blood pressure, elevated t-wave, arrhythmias, etc.) are referred to their cardiologist. Their cardiologist must provide written medical clearance in order for the potential participant to continue in the screening process. Resting systolic blood pressure is required to be $\leq 159 \text{ mmHg}$ and diastolic blood pressure ≤ 99 in order for potential participants to be eligible. Participants are also excluded if they have diabetes. Diabetes is defined as 1) having a previous diagnosis of Type 1 or Type 2 diabetes mellitus; 2) currently taking medications for diabetes (e.g. metformin); or 3) having baseline lab values clinically diagnostic of diabetes (fasting glucose values $> 125 \text{ mg/dL}$ or 120 minute oral glucose tolerance test glucose values > 200). Diagnosis of diabetes based on baseline lab values was initially defined as fasting glucose values $> 125 \text{ mg/dL}$ given that this is a test that physicians would regularly administer in a clinic setting. After a year of recruiting, we realized that while clinically relevant, this definition was scientifically limited. Therefore, 120 minute oral glucose tolerance test (OGTT) glucose values $\geq 200 \text{ mg/dL}$ is also used to define diabetes. Participants whose baseline 120 minute glucose lab value is $< 200 \text{ mg/dL}$ are eligible for the study. Participants whose baseline 120 minute glucose lab value is $200 - 209 \text{ mg/dL}$ are required to have a repeat OGTT. An upper limit of 209 mg/dL was selected because our within lab glucose analyses demonstrated a standard deviation (SD) = 3.0 mg/dL , and therefore we choose a value that was three SDs from the diagnostic value. A participant is eligible for the study if the physician supervised OGTT results in a 120 minute glucose value that is $< 200 \text{ mg/dL}$, and they are excluded if this value is $\geq 200 \text{ mg/dL}$. Those with a baseline glucose lab value $\geq 210 \text{ mg/dL}$ are excluded from the study without physician retesting.

Recruitment

African American men represent a population that has traditionally been very difficult to recruit into clinical trials. [35, 36] Therefore, a community-based approach is utilized, partially based on strategies that have been effective in recruiting African Americans into previous clinical trials. [37–39] First, the support of community leaders, including prominent African American politicians, pastors, and civic leaders is obtained. The support of the leaders helps to establish trust within the community. Second, recruitment efforts take the form of personal appeals. These appeals are conducted through African American churches, social and fraternal organizations, and community events. Third, advertisements, in the form of flyers, are placed within the community, including churches, barber shops, shopping markets, residential areas, medical settings and other places of congregation by African Americans. Fourth, we recruit through local businesses that have a high proportion of African American men as employees.

A designated recruiter executes the recruitment plan. The recruiter's sole responsibility is to recruit potential participants into the study. The recruiter is a long-standing resident of the city, is familiar with research and the research team, is comfortable with public speaking, has a flexible work schedule, is a personal trainer at the YMCA, and is an African American man. The designated recruiter works collaboratively with the PI, and designated members of the research team, to develop and continuously refine the recruitment strategies. The recruiter maintains frequent communication with the study team related to recruitment activities.

Screening procedures

An initial web and/or telephone screen is performed with all potential participants to determine initial eligibility. Potential participants who are still eligible following the telephone screen are scheduled for a group orientation session. During the orientation session, participants receive detailed study-related information including the study objectives, number and type of assessments, randomization, the study arms, and the time commitment required to complete the study. Following the orientation session, potential participants sign a specific informed consent to complete the two run-in sessions. The purpose of the run-in sessions is to maximize the likelihood that randomized participants will be good adherers to the intervention and measurement schedules (See Figure 1).

The two run-in sessions occur over the course of one week and potential participants are required to attend both in order to be eligible for the study. During the first run-in session, potential participants complete preliminary screening procedures including anthropometrics (height, weight, BMI, and blood pressure), medical history information, and detailed information on the purposes, goals, procedures, participant flow, timeline, and randomization of the study. During the subsequent session, they are asked to provide contact and demographic information and are educated on the development and prevention of diabetes. After successful completion of the two run-in visits, potential participants who are still interested and eligible are scheduled for the baseline clinic visits.

All of the main study outcomes, which are described below under Measurements, are assessed during the two baseline clinic visits. Each clinic visit begins between 7:00 and 9:00 am. The main study informed consent is completed at the first clinic visit, prior to the completion of any procedures. The first clinic visit requires a 10-hour fast and participants are instructed to refrain from consuming alcohol and participating in exercise 24 hours before the visit, and food intake is not standardized. Participants undergo anthropometric, clinical, and laboratory assessments (height, weight, waist and hip circumference, blood pressure, and heart rate), a brief physical exam, medication inventory, a resting electrocardiogram, blood draw to test blood sugar, cholesterol, lipoproteins, and triglycerides, and the oral glucose tolerance test. Participants also complete questionnaires, mostly on a tablet computer, pertaining to mood, quality of life, food intake, and physical activity. The second baseline clinic visit is scheduled no earlier than 72 hours after the first baseline clinic visit and participants are instructed to refrain from caffeine and nicotine for five hours, and alcohol and exercise 24 hours before this visit. During this second visit, body composition (Dual Energy X-ray Absorptiometry), cardiorespiratory fitness, and strength (Biodex) testing are performed. The orientation, run-ins, and baseline clinic visits are conducted at the Pennington Biomedical Research Center. Randomization occurs after the potential participant has completed both baseline clinic visits and their eligibility is confirmed, at which time they are officially enrolled in the study.

Measurements

All measurements are assessed at baseline and five months (See Table 1). All clinic visits are conducted no sooner than 48 hours after the last exercise bout. The oral glucose tolerance test is also administered at 10 weeks. Assessors are blinded to participant randomization (intervention group identity). Participants receive \$100 for the successfully completing baseline assessment, \$75 for the Week 10 OGTT, and \$75 for the end of study assessments, and therefore, can receive up to \$250 for completing the study.

Anthropometry—Height and weight are measured using a standard stadiometer and balance beam scale. Measurements are taken without shoes and recorded to the nearest 0.1 cm (height) and 0.1 kg (weight). Waist circumference is measured under the clothing and in the area midway between the inferior border of the rib cage and the superior aspect of the iliac crest. The measuring tape remains horizontal and does not compress the bodily tissue. Measurements are taken until two readings are within 0.5 cm of each other. Hip circumference is measured at the level of the trochanters. The tape measure remains horizontal and does not compress the bodily tissue. Measurements are recorded to the nearest 0.1 cm and are taken until two readings are within 0.5 cm of each other.

Blood draw—An IV line is placed in the participant's arm vein for blood draw purposes and remains there throughout the testing. The first blood draw, approximately 5 mL, is taken to test their blood sugar, cholesterol, proteins and triglycerides.

Oral Glucose Tolerance Test (OGTT)—The IV line is also used to draw blood for the OGTT following the blood draw for physiological parameters. The participant is given a 75 g glucose-equivalent oral glucose challenge over the course of 5 minutes. Blood samples are

taken at minute 0, 30, 60, and 120 to evaluate glucose levels. Insulin levels at 120 minutes serve as the primary outcome variable.

Blood pressure—Blood pressure is measured at rest, under highly-controlled conditions, and at each submaximal and maximal power output on the treadmill. Resting blood pressure is measured using a standard mercury manometer. Two measurements are taken after a 5 minute rest, with 30 seconds between each measurement. The average of the two readings is recorded, regardless of the difference between the values. Blood pressure measurements during the exercise test are obtained using a Colin STBP-780 automated blood pressure monitor. The first value is discarded and the average of the last 3 values is used.

Dual Energy X-ray Absorptiometry (DXA)—DXA is performed using the General Electric Lunar iDXA (General Electric; Milwaukee, WI); software version- enCORE, version 13.4. Participants wear only a hospital gown during testing and the whole body scan protocol is performed.

Resting electrocardiogram (ECG)—A 12-lead ECG assesses heart function over 60 seconds. Participants lie supine with the appropriate clothing removed to allow access to the chest area. Each electrode location is rubbed with an alcohol swab prior to electrode placement.

Cardiorespiratory Fitness Testing—All exercise testing is conducted using a standardized graded exercise testing protocol administered on a treadmill (Trackmaster 425, Newton, KS). Participants are allowed to self-select a comfortable, yet brisk walking pace to initiate their test. Following this selection, each treadmill stage lasts 2 min, whereby the first stage began at 0% grade and increased in grade by 2% every 2 minutes until exhaustion. Several measures suggestive of altered cardiorespiratory function are examined during each test inclusive of VE, VO₂, VCO₂, and RER. Following each exercise test, maximal heart rate, maximal oxygen uptake (VO₂), pulmonary ventilation (VE), ventilatory equivalents for oxygen (VE/VO₂), carbon dioxide (VE/CO₂), end-tidal partial pressure of oxygen (PETO₂), and carbon dioxide (PETCO₂) is measured using a Parvomedics True Max 2400 Metabolic Measurement Cart (Salt Lake City, UT). Ratings of perceived exertion (RPE) are obtained using the Borg scale. [40]

The VO₂max criteria is set as a plateau in oxygen utilization (≥ 150 mL/min) with an increase in workload. Two of the following relative criteria for a maximal effort are also evaluated, including a rating of perceived effort (RPE) of 19 or 20 on the Borg scale, a respiratory exchange ratio of 1.1 or higher, or a heart rate greater than 10 bpm below age predicted heart rate maximum. Any two of the relative criteria are considered a “true” maximal effort.

Muscular strength and endurance—Muscular strength and endurance are measured via isokinetic testing on a Biodex System Isokinetic Dynamometer. Isokinetic testing allows for the measurement of the force velocity and power velocity curves as well as peak force and peak power. Quadriceps muscular strength (peak force and power) is assessed with three

sets of five repetitions at 60 degrees/second. Quadriceps muscular endurance is examined across one set of 30 repetitions at 180 degrees/second.

Questionnaires—The Center for Epidemiology Studies Depression Scale (CES-D) and Health Related Quality of Life (SF-36) questionnaires are administered to assess the impact of the exercise on mood and quality of life, respectively. The factor structure of the CES-D and SF-36 has been shown to be valid in African American samples. [41, 42] The Block Food Frequency Questionnaire [43] is used to estimate daily intake of selected nutrients (macronutrients (e.g. percent calories from fat), and micronutrients), food group servings, and alcohol intake. The Aerobics Center Longitudinal Study Physical Activity questionnaire is used to measure self-reported physical activity. [44]

Randomization

Potential participants meeting all of the eligibility criteria and who sign the informed consent, are randomly assigned in a 1:1 ratio to either the aerobic plus resistance training intervention (n = 58) or the healthy living group (n = 58). Block randomization is the method used to generate the allocation sequence, with each block size equal to four. The randomization sequence is computer generated by SAS.

Interventions

Healthy Living control group—Participants randomized to the healthy living control group receive health information through newsletters via email or standard mail monthly throughout the study. These newsletters feature topics including nutrition and healthy recipes, but focus heavily on diabetes education and prevention. These participants do not receive personal training or an exercise prescription. The study coordinator manages retention of the participants in the healthy living control group by making monthly phone calls to participants inquiring about their physical and mental health, capturing any adverse events that occurred during the preceding month, reminding participants of the importance of their study group, thanking them for their participation, and scheduling follow-up clinic visits at Weeks 10 and 20. We have found that participants assigned to these health information control groups report being satisfied with the information and their assignment. Such minimal interventions have not been shown to alter participants' physical activity level. [45] After the participants complete their five month clinic testing, they are provided with a five month membership to the YMCA.

Aerobic plus Resistance Training group—All exercise sessions are conducted at the YMCA of the participant's choice. There are nine YMCA facilities available within the parish (county) in which the study is being conducted. Contracts are established with five of these nine that allow each participant to work with a fitness instructor at a designated facility. The participant and fitness instructor meet for three sessions during the first week of exercise training in which the fitness instructor demonstrates the specific exercises that the participant will engage in, ensures the participant is exercising properly, adjusts the aerobic and resistance training as appropriate, and works with the participant to develop an exercise training schedule. The pair meets one day per week the following nineteen weeks of the study. The fitness instructors are responsible for monitoring sessions weekly, problem-

solving any difficulties, adjusting the aerobic and/or resistance training regimen as appropriate, and entering the participants exercise data into a Research Electronic Data Capture (REDCap) database specifically designed for the study.

Participants randomized to this group engage in both aerobic and resistance exercise training in accordance with Physical Activity Guidelines for Americans, [46] that is 150 minutes of moderate to vigorous aerobic training and 2 days of 20–30 minutes of resistance training. The participants engage in aerobic exercise at least 3 days per week, but the number of days per week, and therefore the time spent engaged in aerobic exercise, is individualized for each participant based on initial fitness level, travel, and any other scheduling issues. The target training intensity (treadmill speed and grade) is self-selected at 65% to 85% of VO_2 max which is considered to be within the moderate to vigorous intensity range. [47] The aerobic training component is completed on a treadmill and heart rate is assessed with a polar heart rate monitor (Polar FT1, Lake Success, NY) during the treadmill sessions. The resistance training regimen remains constant at 2 days per week, for 20–30 minutes, regardless of the number of aerobic training days. Each resistance training session consists of 2 sets of 9 exercises with each set consisting of 12 repetitions. The Physical Activity Guidelines state that resistance training should involve all major muscle groups, and therefore, the circuit resistance machines include the abdominal crunch, vertical chest press, shoulder press, leg press, leg extension, leg curl, triceps extension, lat pull-down, and seated row. Although generally well described and thus leaving very little room for consideration of other components of the resistance regimens, the guidelines do not specify the intensity at which the resistance exercise should be done. Participants initiate resistance training at a low relative intensity where the participant is able to lift two sets of 12 repetitions for a given exercise. The weight is gradually increased until the participant cannot engage in the required repetitions. Once the participant is again able to lift two sets of 12 repetitions for a given exercise for two consecutive sessions, the load is again increased. This ramping protocol helps participants adapt to resistance training and may decrease injuries, dropouts, and other adverse events. Participants self-monitor all exercise training session activities on prescription cards specifically designed for the study. After completing an exercise session, the participants provide this prescription card to their fitness instructor if present, or they leave it in a designated drop box at their specific YMCA facility.

Fitness instructors

Training—All fitness instructors are employed by the YMCA and they all have some exercise training degree or background. Most, but not all have a personal training certification (e.g. American College of Sports Medicine, Certified Strength and Conditioning Specialist, Cooper Institute). Each fitness instructor undertakes eight hours of study-specific training prior to working with a study participant. Part of this training provides the fitness instructor with specific information related to the exercise training component of the study. This component of training consists of an orientation to the study purposes, goals, and objectives, an overview of fitness training, observing mock sessions, and an overview of the REDCap database. In addition, each fitness instructor is monitored during their two first training sessions with a participant and through at least one week of data entry in REDCap. Refresher trainings are provided every six months.

Adherence—The fitness instructors are taught behavioral strategies to promote maintenance of exercise because they are tasked with ensuring participant adherence to the exercise regimen. These strategies include motivational interviewing, problem solving, and relapse prevention. The core of this training is based on motivational interviewing, which is a collaborative, client-centered counseling style for increasing self-determination. [48] The overarching philosophy of motivational interviewing is to elicit from participants their own motivations for changing behavior. Once these motivations are expressed and the participant is prepared to make change, then problem-solving and relapse prevention can be utilized. Problem-solving is also a collaborative approach to behavior change in which the fitness instructor and participant will follow six steps to overcoming barriers. [49] These steps include identifying the problem, brainstorming solutions, weighing the pros and cons of each solution, choosing a reasonable solution, engaging in the chosen solution behavior/s, and analyzing the effects of the solution. Relapse prevention is another collaborative approach based on the philosophy that both immediate and covert antecedents contribute to relapse. Relapse prevention is utilized to anticipate future problems with adherence, and to develop strategies for preventing these situations. [50] The specific strategies include identifying specific high-risk situations, increasing a participant's self-confidence to overcome the specific high-risk situation, and managing relapses (periods of missed exercise sessions). This process is facilitated by continuous contact between the fitness instructor and the participant.

Data entry—The fitness instructors are responsible for entering the exercise training data. Each week, they transfer the information from the participant-completed prescription cards to the REDCap database. REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. It improves data entry through real-time validation rules (with automated data type and range checks) and provides easy data manipulation (with audit trails for reporting, monitoring and querying patient records). REDCap is used to efficiently maintain accurate records of each exercise session and to ensure intervention fidelity. Pennington Biomedical has a license agreement with Vanderbilt and the database and software are installed on our local servers and hosted by Pennington Biomedical, not by Vanderbilt. The Vanderbilt University Office of Research is not being used as a central location for data processing and management. More information about the consortium is available at <http://www.project-redcap.org/>.

Sustainability

YMCA session attendance is verified via card scan reports. Each participant is given a YMCA membership card. This card must be scanned by the YMCA as the participant enters the facility and the data are sent to a YMCA database. Card scan data are available during the five months of the study duration and two years post study completion for participants in both study arms. Card scan data will be used to verify the aerobic plus resistance training attendance and will be employed to assess YMCA membership usage following study completion.

Data Analyses

All data analyses will be conducted based on the intention-to-treat principle, using SAS[®] version 9.4 software. Analyses of primary outcomes will be concerned with comparing endpoints between the healthy living control group and the aerobic plus resistance training group. In addition, secondary and exploratory analyses will focus on the secondary endpoints and whether the response to exercise differs across demographic subgroups. All analyses will take into account pre-specified covariates, including age, BMI, and baseline values of outcome measures. Continuous outcome measures will be analyzed using mixed models analysis of covariance (ANCOVA) for baseline to 10 week and baseline to 20 week changes in insulin and glucose. Baseline to 20 week changes in all other outcomes will be analyzed similarly, and intervention effects will be summarized as least-squares adjusted means. [51] For outcomes measured in duplicate at a given time frame (e.g. baseline blood pressure), the mean utilized in statistical analysis will be the average value of the two measurements. Data analyses will be performed giving careful consideration to the assumptions underlying the statistical methods, using model diagnostics such as quartile plots of studentized residuals, component-plus residual plots, and examination of leverage points and outliers. [52] Mixed effects statistical models will be employed to analyze the fixed effects of interventions and time, and the random effects of participants with respect to outcome trajectories across time. ANCOVA may be employed to account for variability attributable to correlations between observed outcomes and baseline observations in considering significance of group differences in outcome means. This approach will employ estimation procedures based on maximum likelihood methods to fully utilize all available data irrespective of missing data. As a check on the sensitivity of different approaches to analytics when some data are missing, a secondary analysis will be performed using data from the subgroup of participants with per protocol complete data, using the multiple imputation procedure. When appropriate, data transformations will be performed and some analyses may be conducted using nonparametric statistical tests. Out of concern for the elevated number of Type I errors associated with performing multiple statistical tests, we have pre-specified only one primary outcome measure. Other outcomes will be categorized as “secondary” or “exploratory,” and associated results will be interpreted with appropriate caution. Attrition and attendance will be assessed using chi-square tests.

Power analysis—The primary outcome variable for estimating sample size was two-hour insulin response to a glucose load (OGTT). Thus, sample size was determined from power considerations for testing equality with respect to mean change at 5-months with aerobic plus resistance exercise training versus the healthy living control group. The primary hypothesis will be tested against two-directional alternatives with a 5% significance level. Sample sizes were estimated based on a minimum power of 80% for detecting a stated minimum differential effect for the outcome of interest. Estimates of variability were based on the results of Tokmakidis. [16] The stated null hypothesis was: Mean effect with exercise training = Mean effect without exercise training. The objective was to achieve at least 80% power to detect a minimum final differential in mean effect = $-1.5\mu\text{U ml}^{-1}$ (an exercise effect resulting in a 10% reduction) with a maximum standard deviation (SD) = $2.7\mu\text{U ml}^{-1}$. A net sample size of at least 52 per group results in a minimum power = 80% for testing this hypothesis with a projected 95% CI = -2.5 to -0.5 . Drop-out was estimated at 10% based on

similar community-based interventions. [16, 53] Thus, if 10% of those enrolled drop out, 58 African American men need to be recruited for each study group resulting in a total sample size of 116.

Discussion

The ARTIIS study is a randomized controlled trial designed to determine the effect of combination training according to the current physical activity guidelines on insulin sensitivity in insufficiently active African American men at risk for developing diabetes. The study will recruit 116 African American men from the community and measure glucose, insulin, lipids, triglycerides, body composition, fitness, strength, quality of life, and depression. The intervention occurs over a period of 5 months and all men receive a 5 month membership to the YMCA, medical assessments at no charge, and up to \$250 compensation. The study is unique because it is the first study that utilizes a combination exercise training model, mimics the current physical activity guidelines, and measures a variety of cardiometabolic outcomes, in a population of African American men.

One of the strengths of the ARTIIS study is that it will provide valuable information on the effect of exercise training on a population group where little data exist, that is African American men. Only a limited number of studies have been conducted that exclusively recruited [25–30] or included a substantial number of [11] African American men. While the former studies resulted in positive outcomes, they were largely short term (<8 weeks), contained small sample sizes (<50 men), were uncontrolled, and only assessed cardiovascular-related variables (e.g. blood pressure, fitness, cardiac output). ARTIIS will advance this research base in African American men by conducting a longer term study (5 months) with a larger sample size (>100), and assessing cardiovascular and metabolic outcomes. Informing on diabetes related outcomes is important because, although the prevalence, morbidity, and mortality associated with diabetes in the African American community do not appear to differ by gender, much of the qualitative [7, 54] and empirical [55, 56] research has been conducted with samples that were either largely or exclusively African American women. In those studies including nearly equal numbers of men and women, [57, 58] gender differences were not assessed, further limiting our knowledge of the diabetes-specific health benefits of physical activity interventions for African American men. Therefore, an additional strength of the ARTIIS study is that it will broaden our knowledge of the benefits of physical activity promotion in African American men.

Another strength of the ARTIIS study is that it will empirically test the effects of combination training that matches the current national physical activity recommendations. [46]. Most of the previous exercise training studies in African American men have been aerobic training interventions. Only two studies have included a strength component, [29, 59] and no study conducted exclusively or partially with African American men has utilized a combination of aerobic and resistance training. While it has been shown that combination training results in additive effects compared to either aerobic or resistance alone in studies that recruited predominantly non-Hispanic white participants, [16, 17] it is unknown if this finding holds true in African American men. In this way, ARTIIS seeks to confirm conclusions drawn from studies of largely non-Hispanic white participants. Results in these

and other populations, however, cannot be assumed to hold for African-American men. For example, it has been shown that African American adults may show greater improvements in insulin resistance compared to Caucasians in response to a resistance training program, [59] that African Americans have a greater proportion of type II muscle fibers, [60, 61] and less visceral adipose tissue, [62] all of which could affect study outcomes. Therefore, ARTIIS will help determine if the findings from other combination training studies are generalizable to African American men.

The ARTIIS study will provide a valuable contribution to the effectiveness of a community based clinical trial for African American men. Previous exercise training studies involving African American men have been conducted in a research facility, where participants were closely supervised every training session, limiting the study's practicality. Given a similarly designed study conducted over 20 weeks with 3 exercise sessions per week, a participant would typically be supervised for all 60 sessions while ARTIIS participants will be supervised for 22 sessions, or 64% fewer sessions compared to a standard exercise training intervention. In addition, the fact that the study is being conducted through the YMCA will allow for an assessment of the sustainability of this approach. We will obtain YMCA card scan data that indicate the time and specific YMCA facility the participant attended. The major limitations of this approach are that we will not know what the participants did during their visit to the YMCA and we will not know if they exercised at a non-YMCA facility. The major advantage is that we will know if participants continued to utilize their YMCA membership after the study ends, which will speak to the sustainability of a community-based exercise training program.

The ARTIIS study will also contribute to our knowledge of effective strategies to recruit African American men into clinical research trials. Several studies have reported on the methods that are effective in recruiting African American adults [63–66] and men [36, 67, 68] into research studies. The studies on African American adults do not report on methods specific to recruiting African American men, and many of the gender specific investigations have been epidemiological cohort studies or screening studies. [69–71] However, clinical trials such as ARTIIS place a larger time and effort requirement on the participants due to multiple screening, baseline, and intervention visits. These differences in study requirements likely impact the effectiveness of different types of recruitment methods. Most studies recruiting African Americans utilize a combination of traditional (e.g. newspaper, TV, radio) and community-based (e.g. face-to-face presentations, churches, health fairs, community events) approaches. In addition to these strategies, ARTIIS will also utilize emerging (e.g. email, social media) techniques as well as a designated recruiter. Therefore, ARTIIS will be able to provide information on the effectiveness of three different types of strategies for recruiting African American men into a clinical trial.

There are several limitations to consider in regards to the ARTIIS study. The study does not include an exclusively aerobic and resistance training arm in isolation. While we recognize that any aerobic plus resistance intervention calls into question which intervention would be best (i.e. aerobic, resistance, or the combination), we decided against this design because 1) ARTIIS is designed to determine the effects of the current physical activity guidelines which include both aerobic and resistance training, 2) recruiting the required number (~250 – 300)

of African American men for a four arm study (including a control) would be exponentially more difficult, and 3) several major studies have shown that the combination of aerobic plus resistance training results in greater changes in insulin resistance than either alone. [17, 18, 72] Relatedly, we did not entertain alterations to the aerobic or strength training components, such as incorporating high intensity interval training because the study is designed to adhere more strictly to traditional exercise routines. Our sample lacks diversity, in that African American women and non-Hispanic white men and women are not included in the study. While this may limit the generalizability of the study findings, it fills a glaring gap in the literature. The study uses fitness instructors and requires a gym membership, which all individuals may not be able to afford. Therefore, the findings may only be applicable to middle class African American men. In addition, this may result in low levels of YMCA membership or membership use at the point in which participants are financially responsible for their membership.

ARTIIS will uniquely contribute to our scientific understanding of the benefits of exercise training on risk factors for diabetes. This pragmatic exercise training trial will assess the feasibility and effectiveness of employing an exercise training intervention within the community where participants are not tightly supervised. Concomitant data may inform about the sustainability of the intervention and uniquely contribute to the literature related to physical activity interventions applied solely in African American men.

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Abbreviations

ARTIIS	Aerobic plus Resistance Training and Insulin Resistance in African American Men
CES-D	Center for Epidemiology Studies Depression Scale
SF-36	Health Related Quality of Life
REDCap	Research Electronic Data Capture

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Figure 1.
Flow diagram of ARTIIS study procedures.

Table 1

Schedule of measurements.

Measure	Week 0	Week 10	Week 20
Anthropometry	X		X
Blood draw	X		X
OGTT	X	X	X
Blood pressure	X		X
DXA	X		X
ECG	X		X
Questionnaires	X		X
Cardiorespiratory fitness	X		X
Biodex	X		X

OGTT: Oral glucose tolerance test. DXA: Dual-energy absorptiometry. ECG: Echocardiogram.