



# The effect of a randomized controlled physical activity trial on health related quality of life in metabolically unhealthy African-American women: FIERCE STUDY



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## ABSTRACT

**Purpose:** African-American women (AAW) are more likely to be metabolically unhealthy than White women (WW). Metabolic syndrome (MetS) is associated with increased breast cancer risk and mortality from breast cancer is greater in AAW compared to WW. Data show MetS affects health-related quality of life (HRQoL). Exercise studies report improvements in MetS, however, no study to date has examined HRQoL in metabolically unhealthy AAW enrolled in an exercise trial.

**Methods:** This report examined the effect of a 6-month, 3-arm (supervised exercise, home-based exercise, control) randomized exercise controlled trial on HRQoL among 213 obese, metabolically unhealthy, post-menopausal AAW at high risk for breast cancer.

**Results:** Certain baseline participant characteristics were related to baseline HRQoL dimensions. The “exercise group” (supervised group combined with the home-based group) showed significantly greater improvement in health change scores ( $M = 13.6$ ,  $SD = 3.1$ ) compared to the control group ( $M = 0.7$ ,  $SD = 4.4$ ) ( $p = 0.02$ ) over the 6-month study period. There were no significant differences in HRQoL change scores between the 3 study groups, however, although non-significant, data indicated most HRQoL change scores were more favorable in the supervised group.

**Conclusion:** While significant improvement occurred in health change scores in the combined supervised and home-based group compared to the control group, we did not observe any significant differences on HRQoL change scores between all three study groups. However, while non-significant, there was a trend for more favorable HRQoL change scores in the supervised group versus the home-based and control groups. Additional research is needed to further explore this topic.

## 1. Background

African-American women have a higher prevalence of certain metabolic syndrome components (such as abdominal obesity and hypertension) and are more likely to be metabolically unhealthy than White women [1]. This is particularly important because metabolic syndrome is associated with a 17% increase in breast cancer risk [2–4] and mortality from breast cancer is greater in African-American women compared to White women [5].

Because several components of the metabolic syndrome such as

obesity, hypertension, and diabetes have been associated with decreased health-related quality of life [6–9], it is reasonable to assume that individuals with metabolic syndrome have diminished quality of life. In a recent report, Saboya et al. [10] reviewed a total of 30 studies and found that almost all suggested metabolic syndrome is significantly associated with lower quality of life. In fact, only one study did not find an association [11]. Among the studies in this review, two [12,13] revealed the impact of metabolic syndrome components on diminishing quality of life, specifically in the domains of Physical Health, although the studies demonstrated that this association was only significant in

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women. In a cross-sectional study of 4463 participants, the decrease in quality of life was directly proportional to the increase in metabolic syndrome components in both men and women but the association was only significant in women [14]. Likewise, two other studies [13,15] showed that the association between metabolic syndrome and decreased quality of life scores was only significant in women. The conclusions drawn from Saboya et al.'s [10] review indicate there is a real association between metabolic syndrome and decreased quality of life, especially among women. Elucidating this relationship in African-American women, a group known to have poorer metabolic health, is a reasonable next step.

A study by Hu [16] examined HRQoL among 83 older African-American adults with chronic diseases (73% women) and found that participants reported lower scores on HRQoL than the SF-36 norms for age 60 or older in the general U.S. population. Therefore, understanding ways to improve HRQoL, especially among African-American women at risk for metabolic syndrome and breast cancer, is a necessary research pursuit. Review studies tend to show positive associations between physical activity and HRQoL [17,18] in the general population. In fact, intervention studies [19–22] testing the effects of lifestyle changes, including exercise, have produced significant improvements in HRQoL among metabolic syndrome patients. Also, in a study exploring the effect of a 6-month aerobic intervention on metabolic variables among postmenopausal breast cancer survivors, it was found that exercisers classified as adherers (participating in at least 80% of the recommended exercise amount (i.e. 120 min of exercise/week)) demonstrated a significant decrease in metabolic syndrome z-score from baseline to 6 months when compared to non-adherers [23].

Unfortunately, a lower percentage of African-American women, as a whole, meet recommended guidelines for aerobic activity (38%) compared to Non-Hispanic Whites (52%) [24]. Despite studies reporting the benefits of exercise on HRQoL among metabolic syndrome patients, no study to date has examined the effect of exercise on HRQoL in metabolically unhealthy African-American women also at risk for breast cancer. Therefore, the primary aim of the current study was to examine the effect of the Focused Intervention on Exercise to Reduce CancEr (FIERCE) trial, (a 6-month, 3-arm randomized exercise controlled trial (RCT)) on HRQoL among 213 obese, metabolically unhealthy, postmenopausal African-American women at high projected risk of breast cancer.

## 2. Methods

This community-based RCT was conducted from 2012 to 2016 at the Office of Minority Health and Health Disparities Research at Georgetown-Lombardi Comprehensive Cancer Center in Washington DC. After obtaining written informed consent, participants were randomized either to a supervised facility-based exercise group, a home-based exercise group, or a control group. Endpoints were assessed at baseline, 3 months, and 6 months (study completion). For this examination, we will only report baseline and 6 month assessments. This study was approved by the Georgetown University Institutional Review Board. The study protocol has been previously published [25].

This study was guided by the Theory of Planned Behavior (TPB) [26]. The TPB proposes that an individual's behavioral intention is the most proximal determinant of their behavior. Attitudes (e.g. positive or negative evaluation of physical activity behaviors), subjective norms (perceived social pressures regarding exercise), and perceived control (confidence and control over performing exercise) are postulated to independently influence behavioral intention [27]. We selected this framework because: 1) it has demonstrated robust performance in physical activity interventions; 2) this model highlights perceived control that includes specific barriers and opportunities that African-American women may have regarding physical activity behaviors; and, 3) this model has been used to address physical activity in minorities [28–30].

Eligibility criteria included the following: (1) African-American women; (2) between the ages of 45 and 65 years; (3) postmenopausal (last menstrual period  $\geq 12$  months); (4) waist circumference  $> 35$  in. (88 cm); (5) 5-year individual invasive breast cancer risk  $\geq 1.40\%$  using the "CARE" model; (6) at least two of the following: elevated fasting glucose ( $\geq 100$  mg/dL), reduced HDL cholesterol ( $< 50$  mg/dL), or elevated triglycerides ( $\geq 150$  mg/dL), and elevated blood pressure ( $\geq 130/85$  mm Hg); (7) have a cell phone with text messaging capabilities; (8) able to read and speak English; (9) reside in close proximity to or have access to Georgetown-Lombardi Cancer Center's Office of Minority Health and Health Disparities Research (OMH); (10) able to provide meaningful consent (i.e., women with severe cognitive impairment were excluded); (11) no physical limitations that prevented exercising; and (12) could provide evidence of medical clearance by healthcare provider, if required. The exclusion criteria included the following: (1) premenopausal; (2) history of cancer, except non-melanoma skin cancer; (3) diabetes or use of anti-diabetic medications (including insulin); (4) currently exercising regularly (at least two times per week of at least 20 min of moderate or vigorous activity); (5) current enrollment in another physical activity and/or dietary clinical trial or on diet/weight loss program; and (6) inability to commit to the intervention schedule. Prior to randomization, all participants were required to complete a physical activity readiness medical examination (PARmed-X).

Participants were recruited from the predominantly African-American communities in the DC metropolitan area via OMH's community recruiter and community outreach coordinator. Interested participants called the study coordinator and were screened for eligibility via telephone. Participants eligible on the telephone screening were invited for a second-round of in-person screening at the OMH where informed consent was obtained. After confirming eligibility, participants completed baseline assessments and were randomized into one of the three study groups. Participants were randomly assigned, in a 1:1:1 ratio, to supervised facility-based exercise, home-based exercise, or control group using a block randomization scheme.

### 2.1. Intervention

#### 2.1.1. Arm 1: Supervised facility-based exercise intervention arm

Participants randomized to the exercise group were required to meet and maintain a goal of 150 min/wk. of moderate intensity exercise for 6 months. The exercise intervention was conducted at the exercise facility in OMH located in a community-based setting. Heart rate and rating of perceived exertion (RPE) were used to define moderate intensity. Polar heart rate monitors were used throughout the study in order to monitor and record heart rate. Participants were also taught how to use the heart rate monitors and RPE in order to determine the appropriate moderate exercise intensity during the intervention. Participants exercised for the prescribed duration at a heart rate in the range of 45–65% of their  $VO_{2max}$ , as determined during baseline testing, and with an RPE in the range of 11–14 on the 20-point RPE scale [31].

The exercise prescription consisted of three days per week of supervised physical activity using treadmills and/or exercise bikes. Exercise duration was increased gradually from 75 min/wk. to 150 min/wk. by week 4, using American College of Sports Medicine guidelines for progression in obese/overweight, low-risk individuals [32]. Thereafter, women maintained 150 min or more of moderate-intensity physical activity per week. Participants were provided with daily exercise diaries to record exercise adherence and activity. The post-randomization week number (1 to 24), the date of the exercise session, the type of physical activity (mode), total minutes of physical activity (duration), heart rate, and RPE (intensity) were recorded by the supervising exercise physiologist at each exercise session on an adherence form.

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