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The Effect of a Randomized Controlled Physical Activity Trial on Health Related Quality of Life in Metabolically Unhealthy African-American Women

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Abstract

Purpose—African-American women have a higher incidence and mortality from breast cancer compared to most other racial/ethnic groups. African-American women are also more likely to be metabolically unhealthy than White women. Several studies have suggested that metabolic syndrome affects health-related quality of life (HRQoL). Despite numerous exercise studies reporting improvements in metabolic syndrome, no study to date has examined the effect of exercise on HRQoL in metabolically unhealthy African-American women.

Methods—This study examined the effect of the Focused Intervention on Exercise to Reduce CancEr (FIERCE) trial, (a 6-month, 3-arm: (supervised exercise, home-based exercise, control) randomized exercise controlled trial (RCT)) on HRQoL among 213 obese, metabolically unhealthy, postmenopausal African-American women at high projected risk of breast cancer.

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CONTRIBUTORS

LLA-C originated the idea. KM and XM analyzed the data in consultation with TT, LLA-C, CD and VS. TT wrote the first and subsequent drafts of the manuscript, with important intellectual input from all the coauthors. All authors contributed in designing the study and to the interpretation of the results and to the writing and approval of the final article.

COMPETING INTERESTS

The authors declare that they have no conflict of interest.

ETHICS APPROVAL

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study was approved by the Georgetown University Institutional Review Board.

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Assessments (socio-demographics, lifestyle, BMI and HRQoL) were measured at baseline and 6 months. Change scores from baseline to 6 months in HRQoL were observed by study group.

Results—Baseline education level, marital status, smoking, and BMI were related to dimensions of baseline HRQoL. There were no significant differences in HRQoL change scores between the 3 study groups, however although non-significant, data indicated that HRQoL was more favorable in the supervised group.

Conclusion—Our findings suggest that certain dimensions of HRQoL are associated with baseline participant characteristics. While we did not observe any significant effects of exercise on HRQoL over time, we did see a non-significant trend for improved HRQoL in the supervised exercise group. Additional research is needed to further explore this topic.

Keywords

Quality of life; exercise; metabolic syndrome; Blacks; women

BACKGROUND

African-American women have a higher incidence and mortality from breast cancer compared to most other racial/ethnic groups [1]. Also, African-American women are more likely to be metabolically unhealthy, 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 [2]. Moreover, metabolic syndrome is associated with a 17% increase in breast cancer risk [3–5] and breast cancer recurrence [6].

Several studies have suggested that metabolic syndrome affects health-related quality of life (HRQoL) [7]. In a recent report, Saboya et al. [7] reviewed a total of 30 studies (62,063 patients) and found that almost all studies suggested that metabolic syndrome was significantly associated with lower quality of life. In fact, only one study did not find an association [8]. The conclusions drawn from this review indicate there is a real association between metabolic syndrome and health related quality of life but more longitudinal studies are necessary to confirm this association.

The role of weight loss in reducing metabolic syndrome and favorably modifying components of metabolic syndrome has also been reported [9, 10]. Evidence from multi-site intensive lifestyle intervention studies, such as the Diabetes Prevention Program (DPP) [11], the Weight Loss Maintenance (WLM) trial [12], and the PREMIER trial [13], have shown that interventions are more likely to succeed if targeted to medically at-risk Black women.

Despite numerous exercise studies reporting improvements in metabolic syndrome, no study to date has examined the effect of exercise on HRQoL in metabolically unhealthy African-American women. 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.

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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 assessment. This study was approved by the Georgetown University Institutional Review Board. The study protocol has been previously published [14].

This study was guided by the Theory of Planned Behavior (TPB) [15]. 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/diet), and perceived control (confidence and control over performing exercise/diet) are postulated to independently influence behavioral intention [16]. 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 [17–19].

Eligibility criteria included the following: (1) African-American women; (2) between the ages of 45 and 65 years; (3) postmenopausal (last menstrual period ≥ 12 months); (4) waist circumference > 35 inches (88 cm); (5) 5-year individual invasive breast cancer risk ≥ 1.40% using the “CARE” model; (6) at least two of the following: elevated fasting glucose (≥ 100 mg/dL), reduced HDL cholesterol (< 50 mg/dL), or elevated triglycerides (≥ 150 mg/dL), and elevated blood pressure (≥ 130/85 mmHg); (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); (9) able to provide meaningful consent (i.e., women with severe cognitive impairment were excluded); (10) no physical limitat ions that prevented exercising; and (11) could provide evidence of medical clearance by healthcare provider, if required. The exclusion criteria include 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 minutes 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

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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.

Intervention

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 exert ion (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 exercise 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 [20].

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 [21]. Thereafter, women maintained 150 minutes or more of moderate-intensity physical activity per week. Participants were provided with daily exercise diaries to record exercise adherence and activity. The post-randomizat ion 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.

Arm 2: Home-Based Exercise Intervention—Participants randomized to this intervention arm were required to meet and maintain a goal of 10,000 steps per day as measured by a pedometer. At Week 1, participants were required to meet a goal of 5000 steps per day. Each week thereafter, the required number of steps was increased by 500 steps until 10,000 steps per day were reached. An Omron digital pedometer with a 7-day memory was provided to all participants randomized to the home-based exercise group. Participants were encouraged to meet their exercise goal through moderate-intensity activities such as, walking or slow jogging. Participants were also provided with an “exercise training log” – an adherence form to record their pedometer reading at the end of each day, as well as, the type and duration of exercise activities. Participants randomized to this arm were provided a 12-week adherence log at the time of the baseline visit to record adherence to the intervention for weeks 1 to 12, and another 12-week log at the time of the first follow-up visit to record adherence to the intervention for weeks 13 to 24. Participants were requested to turn in the adherence logs during their follow-up visits. In addition, participants in this arm received text messages once a week to promote and reinforce exercise adherence. All text messages were sent via Google Voice, which allowed specifications of text message

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content, delivery options, and carrier/receiver information, as well as the capability to send text messages to individuals or groups of users at a particular time of day on a regular basis.

Arm 3: Control Group—Control group participants were asked to maintain their current daily activities and exercise habits for the duration of the study (6 months). In addition, these participants received weekly text messages on general health topics and healthy lifestyle information, such as "Be tobacco free! Tips on how to quit www.smokefree.gov" and "Stay healthy year-round. Get a flu shot". After the end of the study, control group participants were offered the chance to exercise at the OMH facility for 6 months.

Measures

Three assessments, one at baseline and two follow-up assessments at 3 and 6-months, were conducted. As previously mentioned, for this investigation Assessments included the following:

Socio-Demographics/Health Behaviors

Information on age, educational attainment, marital status and smoking status was obtained via a self-report questionnaire.

Health-Related Quality of Life

The SF-36 instrument was used to measure health-related quality of life [22]. The SF-36 measures eight health concepts: physical functioning (10 items), role limitations due to physical health problems (4 items), role limitations due to personal or emotional problems (3 items), energy/fatigue (4 items), emotional well-being (5 items), social functioning (2 items), pain (2 items) and general health perceptions (5 items). It also includes a single item that provides an indication of perceived change in health. Items within each subscale are averaged. Scores range from 0 to 100 with higher scores indicating a better quality of life. For the pain subscale, higher scores represent less pain. The SF-36 has been frequently used in minority samples [23, 24].

Anthropometrics

Anthropometric measures of height and weight were collected. Weight was measured using a beam balance scale while participants are wearing light clothing and no shoes, and recorded to the nearest 1/2 pound. Height was measured using a stadiometer. Participants stood erect against the board, without shoes, looking straight ahead. Height was read to the nearest 1/4 inch. BMI was calculated based on height and weight.

Statistical Analyses

Baseline characteristics were compared across the 3 study arms using analysis of variance (ANOVA) and chi-square tests, as appropriate. T-tests were used to compare differences in baseline HRQoL by subgroups defined by baseline characteristics: age: defined by median split (< 59.2 years versus ≥ 59.2 years), education (less than high school/high school/some college versus ≥ college), marital status (single/never married/divorced/separated/widowed

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versus married or living with partner), smoking (current smoker versus non-smoker (never or former smoker)), and anthropometrics (< BMI 34.6 kg/m^2 versus ≥ BMI 34.6 kg/m^2).

Baseline characteristics that significantly altered HRQoL scores were included as covariates in the subsequent analyses. Models were also tested without these covariates (unadjusted model). The 6-month change in HRQoL was compared among the 3 study arms using the analysis of covariance (ANCOVA) adjusting for baseline scores and covariates identified in the analysis described above.

RESULTS

Baseline questionnaire and HRQoL data were available from 213 participants. Table 1 displays the baseline characteristics of the study participants. Overall, the mean age of participants was 58.3 years and at least 41% of the sample had a college degree or more. There were no differences in baseline participant characteristics or HRQoL scores among the 3 study arms.

Table 2 displays mean HRQoL scores at baseline stratified by baseline characteristics. Women with a college degree or greater displayed higher physical functioning, role-physical, and social functioning scores compared to women with some college or less years of education ($p<.05$). Married women or women living with partner displayed higher role functioning/emotional and general health ($p<0.01$) and higher energy/fatigue and pain scores ($p<0.05$) compared to single/never married/divorced/separated/widowed women. Non-smokers had higher physical functioning and better pain scores ($p<0.01$) as well as higher role-physical, energy/fatigue, and general health scores ($p <0.05$) compared to current smokers. Women with lower BMI (<35.6 kg/m^2) scores displayed higher physical functioning scores ($p<0.01$) and higher role-physical, pain, general health and health change scores ($p<0.05$) compared to women with higher BMI (≥35.6 kg/m^2).

Overall, there were no significant differences in change scores from baseline to 6-month follow-up between the 3 study groups on any dimension of HRQoL (Table 3). However, the data clearly indicate that HRQoL was more favorable in the supervised group compared to the home-based and control groups, although not statistically significant.

DISCUSSION

The goal of this study was to evaluate the effect of a 6-month, 3-arm randomized exercise controlled trial on HRQoL among obese, metabolically unhealthy postmenopausal African-American women at high projected risk of breast cancer. To our knowledge, this was the first study to investigate the impact of exercise on quality of life in a similar sample. We found that at baseline, women with more years of education had better HRQoL (physical functioning, role-physical, and social functioning) compared to women with fewer years of education. We also found that women who were married or living with a partner had better HRQoL (role functioning/emotional, energy/fatigue, less pain, and general health) compared to women who were single/married/divorced/separated/widowed. In addition, non-smokers reported better HRQoL (physical functioning, role-physical, energy/fatigue, less pain, and general health) compared to current smokers. Finally, women with a lower BMI had better

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HRQoL (physical functioning, role-physical, less pain, general health and health change) compared to women with higher BMI. Similar studies [25–27] support these findings. For example, Imayama et al. [27] reported in a group of overweight/obese postmenopausal women, baseline values of HRQoL, as measured by the SF-36, were associated with baseline socio-demographic (age, employment status) and anthropometric characteristics. For the most part, HRQoL scores were relatively high in this group, younger age, unemployment and lower weight was associated with higher HRQoL scores.

Several studies have shown that lifestyle modifications, including physical activity, improve HRQoL [28–30]. Despite our expectations, we did not observe any significant differences in 6-month HRQoL change scores between the study groups. A possible reason for our null results could be related to a relatively short follow up period of only 6-months. Preference for type of exercise could also have had an effect. In our study we only focused on aerobic exercise and Courneya et al. [31] reported that participants randomized to a resistance training group showed greater increases in HRQoL when compared to aerobic exercise group or the control group. It is also worth noting that the FIERCE study was not powered to measure HRQoL which could have impacted our findings.

Despite the lack of significant findings, a trend was observed for HRQoL improvement in the supervised group compared to the home-based and control groups. Previous research shows that inactive individuals can successfully sustain an exercise program with appropriate guidance, particularly from an exercise specialist [32–35]. Our data indicate that supervised exercise programs may also have positive effects on quality of life. More research using a similar study design in this population is necessary.

STRENGTHS AND LIMITATIONS

The main strength of our study is that it the first study to explore the impact of exercise on HRQoL in African-American women who are metabolically unhealthy and at risk for breast cancer. This study also utilized a randomized control design allowing the comparison of two exercise groups (home-based and supervised) to a control group. Also, this study used a well-validated measure of HRQoL, the SF-36, used in other African-American samples [23, 24].

A limitation of this study could potentially be the 6-month follow-up period. A longer follow-up, perhaps 12 months, would show significant changes in HRQoL between the study groups. Also, while the SF-36 is a well-validated HRQoL scale, it relies on self-report, which may have caused under- or over-reporting.

Future studies could address the noted limitations and allow for a longer follow-up period as well as a broader choice of exercise types. It would also be of interest to incorporate a dietary component to the exercise groups. For example, Imayama et al. [27] observed the individual and combined effects of a 12- month dietary weight loss and/or exercise intervention on HRQoL in overweight/obese postmenopausal women. Women were assigned to 12 months of dietary weight loss, moderate-to-vigorous aerobic exercise, combined diet and exercise or a control group. The SF-36 was used to assess HRQoL. The study revealed

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that the combined dietary weight loss and exercise group improved more aspects of HRQoL with larger increments compared with diet or exercise alone. While Imayama et al's [27] finding revealed impactful results, their sample consisted primarily of non-Hispanic White women who, outside of being overweight/obese, did not have any other major medical conditions. Adding a dietary component to a future FIERCE trial would determine if a combined exercise and dietary intervention would have the greatest impact on HRQoL in a group of obese, minority post-menopausal women with co-morbid conditions.

CONCLUSION

In summary, our findings suggest that certain dimensions of HRQoL are associated with baseline socio-demographic and lifestyle characteristics in a group of obese, post-menopausal metabolically unhealthy African-American women at risk for breast cancer. While we did not observe any significant effects of exercise on HRQoL over time, the potential to further study this research question in a similar population still exists.

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Table 1

Baseline characteristics of study participants by trial arm

Characteristic	Control (N=71)	Home-Based Exercise (N=69)	Supervised Exercise (N=73)
Age (years)			
< 59.2	36 (50.7)	36 (52.2)	35 (47.9)
≥59.2	35 (49.3)	33 (47.8)	38 (52.1)
Education level, n(%)			
Less than high school/High school/Some college	41 (57.7)	45 (65.2)	40 (54.8)
≥ College degree	29 (40.8)	24 (34.8)	33 (45.2)
Missing	1 (1.4)	0	0
Marital status, n(%)			
Single/never married/divorced/separated/widowed	53 (74.6)	49 (71.0)	55 (75.3)
Married or living with partner	18 (25.4)	20 (29.0)	18 (24.7)
Smoking, n(%)			
Current smoker	11 (15.5)	14 (20.3)	5 (6.8)
Non-smoker (Never or former smoker)	60 (84.5)	55 (79.7)	68 (93.2)
BMI			
< 34.6 kg/m^2	35 (49.3)	33 (47.8)	38 (52.1)
≥ 34.6 kg/m^2	36 (50.7)	36 (52.2)	35 (47.9)
METs			
< 2.7	38 (53.5)	36 (52.2)	35 (47.9)
≥ 2.7	33 (46.5)	33 (47.8)	38 (52.1)
Health-Related Quality of Life Mean (SD)			
Physical Functioning	75.8(25.0)	76.27(25.0)	79.13(20.7)
Role-Physical	84.51(30.9)	83.46(30.1)	75.69(32.8)
Role-Emotional	82.38(33.9)	81.86(32.8)	81.02(33.5)
Energy/Fatigue	61.57(18.5)	62.57(17.6)	63.75(18.9)
Emotional Well-being	80.49(15.8)	82.23(12.2)	81.44(15.1)
Social Functioning	83.63(22.4)	84.74(24.2)	79.34(23.8)
Pain	73.9(23.1)	76.7(20.8)	73.2(21.6)
General Health	67.5(13.9)	70.2(13.2)	71.5(14.4)
Health Change	56.07(24.24)	51.44(27.08)	56.69(27.04)

* all p-values > 0.05 comparing study groups

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Table 2

Baseline scores of health-related quality of life stratified by baseline subject characteristics

Characteristic	N	PF	RP	RE	EF	EW	SF	P	GH	HC
Age										
< 59.2	107	74.7 (24.5)	77.8 (33.2)	80.1 (35.1)	60.3 (17.4)	80.4 (13.2)	79.4 (24.7)	73.0 (21.3)	67.9 (14.3)	54.0 (29.2)
≥59.2	106	79.6 (22.3)	84.5 (29.3)	83.5 (31.3)	65.1 (18.9)	82.4 (15.6)	85.7 (21.9)	76.0 (22.3)	71.6 (13.2)	55.6 (22.7)
Education level										
Less than high school/High school/some college	126	**74.0 *(25.8)**	**77.4 *(34.6)**	78.6 (35.7)	60.8 (18.8)	80.0 (15.9)	**79.4 *(24.6)**	72.2 (22.1)	68.8 (13.9)	55.3 (28.1)
≥College degree	86	**81.4 *(19.3)**	**86.5 *(25.5)**	86.1 (29.1)	65.1 (17.4)	83.3 (12.0)	**86.8 *(21.3)**	77.82 (21.2)	71.1 (13.9)	54.1 (23.3)
Marital status										
Single/never married/divorced/separated/widowed	157	76.3 (24.2)	79.8 (31.8)	**78.6 +(35.7)**	**61.2 *(19.0)**	80.7 (15.7)	81.0 (24.1)	**72.7 *(21.9)**	**68.0 +(13.9)**	53.2 (26.1)
Married or living with partner	56	79.4 (21.6)	85.2 (30.1)	**90.7 +(22.8)**	**66.9 *(15.3)**	83.4 (9.8)	87.0 (21.2)	**80.0 *(20.8)**	**74.8 +(12.7)**	59.3 (25.8)
Smoking										
Current smoker	30	**65.6 +(30.4)**	**68.3 *(35.9)**	71.3 (39.6)	**56.1 *(16.2)**	79.5 (14)	76.3 (25.7)	**63.8 +(25.0)**	**64.6 *(15.2)**	61.2 (33.8)
Non-smoker (Never or former smoker)	183	**79.0 +(21.7)**	**83.3 *(30.2)**	83.4 (31.9)	**63.7 *(18.4)**	81.7 (14.5)	83.6 (23.0)	**76.3 +(20.8)**	**70.6 *(13.5)**	53.7 (24.7)
BMI										
< 34.6 kg/m^2	106	**81.36 +(21.9)**	**86.2 *(26.9)**	79.4 (35.0)	63.3 (18.2)	81.1 (14.1)	82.0 (24.3)	**77.6 *(19.3)**	**71.8 *(12.9)**	**58.8 *(24.8)**
≥34.6 kg/m^2	107	**72.8 +(24.5)**	**76.2 *(34.7)**	84.1 (31.4)	62 (18.43)	81.7 (14.9)	83.0 (22.7)	**71.5 *(23.7)**	**67.7 *(14.6)**	**50.7 *(27.0)**
METs										
< 2.7	107	77.4 (22.2)	82.0 (30.5)	81.3 (33.7)	61.4 (16.8)	81.6 (12.7)	84.1 (23.1)	75.9 (20.2)	69.4 (13.3)	52.4 (25.8)
≥2.7	106	77.3 (24.5)	81.1 (31.6)	82.0 (33.1)	64.2 (19.6)	81.1 (16.2)	81.2 (23.8)	73.73 (22.62)	70.2 (14.6)	57.5 (26.3)

PF: physical functioning, RP: role-physical, RE; role-emotional, EF: energy/fatigue, EW: emotional well-being, SF: social functioning, P: pain, GH: general health, HC: health change

* $p < 0.05$,

\+ $p < 0.01$ comparing differences between subgroups

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Table 3

Change in HRQoL scores by group at baseline and 6-month follow-up

	Baseline Unadjusted Mean (SD)	6 months Unadjusted Mean (SD)	$\Delta_{0\text{-}6}$ Unadjusted Mean (SD)	$\Delta_{0\text{-}6}$ Adjusted Mean	P* (ANCOVA adjusted for baseline and significant covariates in Table 1)
Physical Functioning					
Control	75.8 (25.0)	81.1 (20.4)	2.34 (18.9)	5.32 (3.8)	
Home-based	76.3 (25.0)	75.7 (21.3)	2.4 (21.5)	−0.56 (4.0)	0.79
Supervised	79.1 (20.7)	79.17 (21.3)	1.22 (23.4)	0.03 (3.5)	
Role-Physical					
Control	84.5 (30.9)	83.8 (29.9)	−3.4 (35.0)	−0.70 (5.1)	
Home-based	83.5 (30.1)	73 (39.1)	−9.2 (38.8)	−10.5 (5.9)	0.57
Supervised	75.7 (32.8)	78.72 (37.6)	−0.53(42.8)	3.0(5.8)	
Role-Emotional					
Control	82.4 (33.9)	76.5 (34.8)	−2.6 (36.4)	−5.9 (5.8)	
Home-based	81.9 (32.8)	79.3 (33.6)	−1.4 (33.3)	−2.5 (5.7)	0.14
Supervised	81.0 (33.5)	89.4 (26.1)	5.0 (36.1)	8.3 (5.0)	
Energy/Fatigue					
Control	61.6 (18.5)	63.1 (18.5)	2.1 (16.2)	1.6 (3.1)	
Home-based	62.6 (17.6)	66.9 (15.6)	5.0 (15.2)	4.3 (2.8)	0.28
Supervised	63.8 (18.9)	70.0 (15.9)	4.2 (19.9)	6.3 (2.9)	
Emotional Well-being					
Control	80.5 (15.8)	80.9 (13.8)	1.3 (15.7)	0.4 (2.5)	
Home-based	82.2 (12.2)	82.1 (12.5)	−0.1 (12.5)	−0.1 (2.1)	0.33
Supervised	81.4 (15.1)	85.3 (11.6)	2.4 (17.1)	3.8 (2.2)	
Social Functioning					
Control	83.6 (22.4)	83.2 (20.4)	−0.7 (27.5)	−0.5 (3.6)	
Home-based	84.7 (24.2)	78.8 (24.7)	−4.60 (27.8)	−6.0 (4.2)	0.46
Supervised	79.3 (23.8)	84.4 (23.1)	3.1 (27.4)	5.0 (3.9)	
Pain					
Control	73.9 (23.1)	71.7 (25.6)	−3.4 (35.0)	−2.2 (4.1)	
Home-based	76.7 (20.8)	70.3 (25.4)	−9.2 (38.8)	−6.4 (4.0)	0.43
Supervised	73.2 (21.6)	76.0 (22.0)	−0.5 (42.8)	2.8 (3.6)	

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	Baseline Unadjusted Mean (SD)	6 months Unadjusted Mean (SD)	$\Delta_{0\text{-}6}$ Unadjusted Mean (SD)	$\Delta_{0\text{-}6}$ Adjusted Mean	P* (ANCOVA adjusted for baseline and significant covariates in Table 1)
General Health					
Control	67.5 (13.9)	65.38 (13.28)	−2.4 (16.4)	−2.1 (2.3)	
Home-based	70.2 (13.2)	68.4 (15.7)	−0.3 (11.0)	−1.8 (2.5)	0.41
Supervised	71.5 (14.4)	70.3 (13.8)	−1.0 (16.2)	−1.2 (2.3)	
Health Change					
Control	56.1 (24.2)	56.7 (28.1)	2.9 (33.8)	0.7 (4.4)	
Home-based	51.5 (27.1)	67.9 (26.0)	14.3 (36.4)	16.4 (4.5)	0.090
Supervised	56.7 (27.0)	67.6 (25.5)	10.9 (36.0)	10.9 (4.4)	

Adjusted mean change indicates adjustment for the baseline health-related quality of life (HRQOL) scores and covariates

*p-value for group effects on 6-month changes in HRQoL adjusting for the baseline scores and covariates (Physical Functioning: education level, smoking status, baseline BMI; Role-Physical: education level, smoking status, baseline BMI; Role-Emotional: marital status; Energy/Fatigue: marital status, smoking status; Social Functioning: education level; Bodily Pain: marital status, smoking status, baseline BMI; General Health: marital status, smoking status, baseline BMI; Health Change: baseline BMI)

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Table 4

Change in HRQoL scores by exercise group (home-based + supervised) versus control group at baseline and 6-month follow-up

	Baseline Unadjusted Mean (SD)	6 months Unadjusted Mean (SD)	$\Delta_{0\text{-}6}$ Unadjusted Mean (SD)	$\Delta_{0\text{-}6}$ Adjusted Mean	P* (ANCOVA adjusted for baseline and Significant covariates in Table 1)
Physical Functioning					
Control	75.8 (25.0)	81.1 (20.4)	2.3 (18.9)	5.3 (3.8)	0.37
Home-based/Supervised	77.7 (22.8)	77.4 (21.2)	1.8 (22.3)	−0.3 (2.6)	
Role-Physical					
Control	84.5 (30.9)	83.8 (29.9)	−3.4 (35.0)	−0.7 (5.1)	0.29
Home- based/Supervised	79.5 (31.6)	75.8 (38.3)	−5.0 (40.8)	−3.7 (4.2)	
Role-Emotional					
Control	82.4 (33.9)	76.5 (34.8)	−2.6 (36.4)	−5.9 (5.8)	0.23
Home- based/Supervised	81.4 (33.0)	84.2 (30.5)	1.7 (34.7)	2.8 (3.8)	
Energy/Fatigue					
Control	61.6 (18.5)	63.1 (18.5)	2.1 (16.2)	1.6 (3.1)	0.11
Home- based/Supervised	63.2 (18.2)	68.4 (15.7)	4.6 (17.6)	5.2 (2.0)	
Emotional Well- being					
Control	80.5 (15.8)	80.9 (13.8)	1.3 (15.7)	0.4 (2.5)	0.36
Home- based/Supervised	81.8 (13.7)	83.7 (12.1)	1.1 (14.9)	1.9 (1.5)	
Social Functioning					
Control	83.6 (22.4)	83.2 (20.4)	−0.7 (27.5)	−0.5 (3.6)	0.98
Home- based/Supervised	82.0 (24.1)	81.5 (24.0)	−0.8 (27.7)	−0.5 (2.9)	
Pain					
Control	73.9 (23.1)	71.7 (25.6)	−3.4 (35.0)	−2.2 (4.1)	0.74
Home- based/Supervised	74.9 (21.2)	73.0 (23.9)	−5.0 (40.8)	−1.8 (2.7)	
General Health					
Control	67.5 (13.9)	65.4 (13.3)	−2.4 (16.4)	−2.1 (2.3)	0.22
Home- based/Supervised	70.9 (13.8)	69.3 (14.8)	−0.6 (13.7)	−1.5 (1.7)	
Health Change					
Control	56.1 (24.2)	56.7 (28.1)	2.9 (33.8)	0.7 (4.4)	0.020
Home- based/Supervised	54.1 (27.1)	67.7 (25.6)	12.6 (36.1)	13.6 (3.1)	

Adjusted mean change indicates adjustment for the baseline health-related quality of life (HRQOL) scores and covariates

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* p-value for group effects on 6-month changes in HRQoL adjusting for the baseline scores and covariates (Physical Functioning: education level, smoking status, baseline BMI; Role-Physical: education level, smoking status, baseline BMI; Role-Emotional: marital status; Energy/Fatigue: marital status, smoking status; Social Functioning: education level; Bodily Pain: marital status, smoking status, baseline BMI; General Health: marital status, smoking status, baseline BMI; Health Change: baseline BMI)