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# Hispanic ethnicity as a moderator of the effects of aerobic and resistance exercise on physical fitness and quality-of-life in breast cancer survivors

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## Abstract

**Background** Exercise can profoundly affect physical fitness and quality of life in breast cancer survivors; however, few studies have focused on minorities. This secondary analysis examines Hispanic ethnicity as a moderator of the effects of a 16-week aerobic and resistance exercise intervention on physical fitness and quality of life in breast cancer survivors.

**Methods** Eligible breast cancer survivors ($n = 100$) were randomized to exercise ($n = 50$) or usual care ($n = 50$). The exercise intervention consisted of supervised moderate-vigorous aerobic and resistance exercise thrice weekly for 16 weeks. Physical fitness and quality of life were measured at baseline, post-intervention, and 28-week follow-up (exercise only). Linear mixed-models adjusted for baseline value of the outcome, age, disease stage, adjuvant treatment, and recent physical activity were used to evaluate effect modification by ethnicity.

**Results** The study sample included 57% Hispanic and 43% non-Hispanic breast cancer survivors. Hispanic breast cancer survivors were younger, less fit, and diagnosed with more advanced cancers compared with non-Hispanic breast cancer survivors ($p < 0.001$). Ethnicity was found to moderate the effects of exercise training on all physical fitness and quality-of-life measures including $VO_{2max}$ (8.4 mL/kg/min; 95% confidence interval (95% CI) 3.2 to 13.4), physical well-being (12.3; 95% CI 4.2 to 18.4), and emotional well-being (11.4; 95% CI 5.9 to 15.5). In all cases, Hispanics experienced larger benefits than non-Hispanics.

**Conclusions** Hispanic breast cancer survivors have poorer cardiorespiratory fitness, muscle strength, and quality-of-life and therefore may derive larger benefits from exercise than non-Hispanic breast cancer survivors. Clinical exercise interventions may attenuate existing health disparities among minority breast cancer survivors.

**Implication of Cancer Survivors** Here we report psychosocial and fitness-related disparities among Hispanic breast cancer survivors when compared with their non-Hispanic counterparts. Our exercise intervention highlights the importance of exercise for minority cancer survivors and the need for distinct, culturally tailored exercise intervention approaches to reduce psychosocial and fitness-related disparities among this understudied population of cancer survivors.

**Keywords** Hispanic · Breast cancer survivors · Obesity · Physical fitness · Quality of life

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## Introduction

Racial and ethnic disparities in breast cancer are well documented and persistent in the USA [1–4]. Hispanic breast cancer survivors (BCS) engender a particularly high-risk minority population with a 1.1–1.5 greater risk of breast cancer mortality than their non-Hispanic white counterparts [5]. Contributing factors to poor prognosis may include higher rates of obesity [6] and lower adherence to meeting physical activity guidelines [4]. Such factors, in addition to increasing risk of mortality, propagate comorbid health concerns such as poor physical fitness, inadequate cardiovascular capacity, and substandard quality-of-life [7, 8]. Given the potential of lifestyle-modifiable behaviors, like exercise, in attenuating comorbid conditions and directly improving survivorship [9], it is vital to investigate the role of exercise interventions aimed at improving physical fitness and quality-of-life among Hispanic BCS.

The American College of Sports Medicine (ACSM) exercise guidelines for cancer survivors include 150 min per week of moderate-intensity aerobic exercise, or 75 min per week of vigorous aerobic exercise and 2 resistance exercise training sessions per week [10]. A plethora of studies to date have reported the positive impact of exercise on physical fitness and psychosocial health among breast cancer survivors [11, 12]. This includes examinations of cardiorespiratory fitness, muscular strength, quality of life assessed by the Functional Assessment of Cancer Therapy-Breast (FACT-B) and the Short Form-36 Health Survey (SF-36), fatigue (Brief Fatigue Index; BFI), and depression (Center for Epidemiologic Studies-Depression Scale; CES-D). These measures are well established as critical measures to monitor and improve with targeted interventions during clinical survivorship care given the impact on long-term general and mental health [13, 14]. Nonetheless, the impact of exercise on physical fitness and psychosocial health among Hispanic BCS has yet to be investigated.

We have previously reported that our 16-week, moderate-vigorous combined aerobic and resistance exercise intervention mitigated metabolic syndrome and improved sarcopenic obesity in a diverse group of overweight/obese breast cancer survivors [15] and that these effects were larger in Hispanic BCS [16]. We have also reported that the exercise intervention led to significant improvements in physical fitness and quality of life [17]. In this exploratory analysis, we report on the ethnic differences in response to exercise on physical fitness and quality of life. This is the first randomized controlled trial, to our knowledge, that focuses explicitly on utilizing an exercise intervention to explore and potentially mitigate ethnic differences in physical and psychosocial comorbidities between distinct ethnic groups. We hypothesized that Hispanic BCS will have poorer physical fitness and quality of life and may derive greater benefits from exercise than non-Hispanic BCS.

## Methods

**Participants/consent** Detailed methods are published [15]. Eligible participants were < 6-month post-treatment for chemotherapy or radiation therapy for stage 0–III breast cancer and were non-smokers, sedentary (< 60 min of structured exercise/week), with BMI ≥ 25.0 kg/m$^2$ (or body fat >30%) and waist circumference > 88 cm. Participants were verbally screened for eligibility at time of consent. Participants self-identified as Hispanic or non-Hispanic. All study methods were conducted in English or Spanish as needed. Treatment history and diagnosis were confirmed by medical record abstraction.

Participants were recruited between August 1, 2012, and December 31, 2016, from the USC Norris Comprehensive Cancer Center and Los Angeles County Hospital. The protocol and informed consent were IRB-approved (HS-12-00141) and registered (ClinicalTrials.gov: NCT01140282). Signed informed consent was obtained from each participant. Participants were randomized to exercise or usual care following the completion of baseline testing using concealed randomization lists.

**Experimental design** This randomized controlled trial compared a progressive combined (aerobic and resistance) exercise intervention with usual care on baseline to 4-month changes in physical fitness, bone health, and patient-reported outcomes. Detailed methods [18] and primary outcomes related to metabolic syndrome were published previously [17]. Endpoints were assessed at baseline, post-intervention (month 4), and 3-month follow-up (exercise group only). To enhance participation, usual care participants were offered the exercise program upon completion of the study period.

**Cardiorespiratory fitness** A single-stage submaximal treadmill test was used to estimate maximal oxygen uptake, $VO_{2max}$ [19]. Participants first performed a 4-min warm up by walking on a treadmill (Desmo Woodway, Waukesha, WI) at a speed (2.0, 3.0, 4.0, or 4.5 mph) that increased their heart rate between 50 and 70% heart rate maximum. This was followed by the 4-min test at the same speed with a 5% grade; heart rate was measured during the final 30 s of the test. Using heart rate, speed, age, and gender, estimated maximal oxygen uptake was predicted using the test-specific regression formula [19].

**Muscular strength** Estimated maximal voluntary strength (1-repetition maximum; 1-RM) was assessed for the chest press, latissimus pulldown, knee extension, and knee flexion using

the 10-repetition maximum (10-RM) method (Tuff Stuff, Pomona, CA) [20]. Participants completed a warm-up load of ~ 5–8-RM before attempting 10-RM. A 2-min rest period was given between attempts; 3–5 attempts were performed.

**Patient-reported outcomes** Quality of life was assessed using the FACT-B and the SF-36. Breast cancer–specific QOL was assessed by the FACT-B uses 37-items (5-point Likert scale; high score indicates better quality of life) to assess five subscales: physical well-being, social well-being, emotional well-being, functional well-being, and breast additional concerns [21]. This includes the FACT-general (sum of all subscales except additional concerns) and the trial outcome index (sun of FACT-G plus additional concerns). The Short Form-36 Health Survey (SF-36) is a 36-item patient-reported survey of global health status health [22] and is a reliable and valid tool among breast cancer survivors [23]. The SF-36 consists of eight sub-scores (i.e., physical functioning, social functioning, role-physical, role-emotional, mental health, vitality, pain, and general health), which are weighted sums of the questions in their section. Each scale is directly transformed into a 0–100 scale on the assumption that each question carries equal weight. The lower the score is, the greater the disability. The BFI was used to assess fatigue, where a lower score indicates less fatigue [24]. Risk for depression and depressive symptoms were assessed using the 20-item CES-D. The presence and severity of depressive symptoms are scored on a scale of 0 to 60; high depressive symptoms are indicated by a score of equal to or greater than 16; a lower score indicates the presence of less symptomatology [25].

**Covariate measures** Weight was measured to the nearest 0.1 kg on an electronic scale with the participants shoeless and in a hospital gown; height was measured to the nearest 0.5 cm with a fixed stadiometer. Body mass index (BMI = kg/$m^2$) was calculated. Waist circumference was measured at the midpoint between the lower margin of the last palpable rib and the iliac crest. Physical activity history was assessed at baseline using an interviewer-administered, validated questionnaire to assess historical, past-year, and past-week physical activity [26]. Three-day dietary records (2 weekdays and 1 weekend day) were completed at baseline, post-intervention, and 3-month follow-up (exercise group only) within 1-week of each assessment and analyzed using Nutritionist Pro™ (Woodinville, WA). Participants completed the Charlson comorbidity questionnaire [27]. Cancer-related information (i.e., time since treatment completion, time since diagnosis, disease stage, hormone-receptor status, endocrine therapy, and surgery) was abstracted from medical records.

**Exercise intervention** The exercise program aligned with ACS/ACSM exercise guidelines for cancer survivors (150 min of aerobic exercise and 2–3 days of resistance exercise training/week). [28] Participants received three supervised one-on-one exercise sessions/week. Days 1 and 3 consisted of aerobic and resistance exercise of ~ 80 min and Day 2 included ~ 50 min of aerobic exercise. All sessions were led by a certified ACS/ACSM Cancer Exercise Trainer. Participants wore a Polar® heart monitor (Lake Success, NY) during each exercise session. Each session began with a 5-min aerobic exercise warm-up at 40–50% estimated $VO_{2max}$. Sequenced resistance exercise followed in circuit training fashion with no rest periods between exercises: leg press + chest press, lunges + seated row, leg extensions + triceps extensions, and leg flexion + biceps curl. Initial resistance was set at 80% of the estimated 1-RM for lower body exercises and 60% estimated 1-RM for upper body exercises. When the participant was able to complete three sets of 10 repetitions at the set weight in two consecutive sessions then the weight is increased by 10%. Repetitions increased from 10 (week 4) to 12 (week 8) to 15 (week 12) every 4 weeks to safely build muscular endurance. Compression garments were required during the exercise sessions for all participants who held prescriptions.

Resistance exercises were followed by self-selected aerobic exercise: treadmill walking/running, rowing machine, and stationary bicycle. HR was monitored throughout the aerobic sessions to maintain a HR at 65–80% of maximum HR. Target HR was increased every 4 weeks to safely build cardiorespiratory endurance and to maintain the prescribed intensity as participants improved their cardiorespiratory fitness. Duration of the aerobic sessions was increased from 30 min (week 1) to 50 min (week 16) as cardiorespiratory fitness increased to meet the exercise guidelines for cancer survivors. Participants ended each session with a 5-min cool down at 40–50% estimated $VO_{2max}$. The trainers documented attendance and minutes of exercise per session.

**Follow-up period (exercise group only)** A 12-week follow-up was instituted in the exercise group to assess intervention durability. During the 12-week period, participants were encouraged to exercise on their own without study team supervision. Participants were asked to maintain weekly physical activity logs and wear an accelerometer on a daily basis during this period; they repeated outcome measure testing upon completion of the 12-week period. Sustainability was assessed at 28-week follow-up in this group by 7-day accelerometer monitoring (Model GT3X Actigraph, Fort Walton Beach, FL). Participants were asked to wear the accelerometer during waking hours for 7 consecutive days, perform their normal or usual activity, and remove the device while bathing, showering, or swimming. Participants received verbal and written instructions and a wear time log to encourage adherence. Devices were returned at time of follow-up testing. Accelerometer data were used to estimate minutes and

intensity of physical activity performed according to the manufacturer's directions.

**Statistical analyses** This is a secondary analysis of the parent trial, which focused on metabolic syndrome. Therefore, the sample size was based on projected changes in insulin [29]. Enrollment of 100 women provided 80% statistical power ($\alpha = 0.05$) to detect a 2.6 μU/ml (SD = 4.0 μU/ml) difference in mean insulin levels assuming 20% drop-out using a two-group *t* test.

Within-group differences in mean changes for individual outcomes measured at post-intervention and 3-month follow-up (exercise group only) were evaluated using general linear models repeated-measures analyses of variance (ANOVAs). Linear regression was used to assess effect modification of the intervention by ethnicity. A priori covariates explored included age, adjuvant treatment, stage of disease, and recent physical activity. We adjusted our final models for baseline values of the outcome, age, and recent physical activity. Analyses were performed using SAS (Version 9.4, Cary, NC).

## Results

The CONSORT diagram is reported elsewhere [15]. The overall sample included 56 Hispanic BCS and 41 non-Hispanic BCS (Table 1); the three African American women in the study were excluded from this analysis. As compared with non-Hispanic BCS, Hispanic BCS were younger (higher percentage being premenopausal women), more likely to be obese (higher percentage of BMI ≥ 30 kg/m$^2$), of greater stage (hence treated with both radiation and chemotherapy), less physically active at baseline ($p < 0.001$), and less educated (lower percentage of some college/college degree) [16]. Both groups had high session attendance (96%) and adherence with the intensity or volume of aerobic and resistance exercise (95%).

**Physical fitness** Table 2 shows the baseline to post-intervention changes in physical fitness and the interaction by ethnicity. Ethnicity moderated the effect of exercise on $VO_{2max}$ (8.4 ml/kg/min; 95% CI 3.2 to 13.4), chest press (2.1 kg; 95% CI 0.5 to 3.6), latissimus pulldown (6.4 kg; 95% CI 1.9 to 15.5), knee extension (10.5; 95% CI 5.6 to 15.4), and knee flexion (9.8; 95% CI 4.5 to 14.4). In all cases, Hispanic BCS exhibited greater improvements compared with non-Hispanic BCS. At 28-week follow-up, all physical fitness variables remained significantly improved for both ethnic groups assigned to the exercise arm when compared with baseline values ($p < 0.001$).

**Patient-reported outcomes** Tables 3 and 4 show the baseline to post-intervention changes in patient-reported outcomes and the interaction by ethnicity. Ethnicity moderated the effect of the exercise intervention on breast cancer–specific quality of life (FACT-Breast 54.1; 95% CI 34.5 to 74.4), physical (24.2; 95% CI 11.5 to 44.4) and mental health (38.1; 95% CI 15.5 to 65.9; assessed by the SF-36), fatigue (3.4; 95% CI 0.5 to 7.4; assessed by the BFI), and depression (4.7; 95% CI 1.5 to 9.4; assessed by the CES-D). At 28-week follow-up, all patient-reported outcomes remained significantly improved for both ethnic groups assigned to exercise compared with baseline ($p < 0.001$).

## Discussion

To our knowledge, this is the first study in exercise oncology to explore differential racial/ethnic responses in physical fitness and quality-of-life between Hispanic BCS and non-Hispanic BCS. At baseline, Hispanic BCS were significantly less fit with poorer quality of life when compared with non-Hispanic BCS. Ethnicity moderated the effects of the 16-week supervised aerobic and resistance exercise intervention on $V0_{2max}$, muscular strength, and all domains of quality of life, including breast cancer–specific quality of life, health status, fatigue, and depression.

To date, there have been few studies that have reported on minority cancer survivors and exercise, despite substantial research documenting prolific disparities in minority participation in physical activity [30–32]. This includes exercise interventions for Black BCS [33–36], Hispanic BCS [31], and Black prostate cancer survivors [37] with positive effects of exercise observed for increasing moderate-to-vigorous physical activity [31, 34]; improving physical function [33], physical fitness [34], and muscle strength [37]; and reducing in blood pressure and depression [35]. Further, there is little evidence that explores differences in response to a targeted exercise intervention aimed to attenuate outcomes related to physical fitness in Hispanic BCS versus non-Hispanic BCS. Recently, Ortiz et al. [38] reported that Hispanic BCS have significantly lower muscular strength and aerobic capacity when compared with normative age-referenced population-based scores [31]. These findings demonstrate the critical need for an exercise intervention that may attenuate long-term differences in physical fitness that may extend into survivorship. The present study serves to fill this gap in the literature regarding exercise interventions in ethnically diverse breast cancer survivors.

Following our intervention, the Hispanic BCS experienced a greater increase in estimated $VO_{2max}$ (8.4 ml/kg/min) when compared with the non-Hispanic BCS. Profound differences were also noted for the four strength measures with the Hispanic BCS experiencing greater strength gains (ranging from ~ 2 to 12 kg) when compared with the non-Hispanic BCS. There are no studies with which we can directly

**Table 1** Baseline participant characteristics

| Variable | HBCS $n = 56$ Mean (SD) | NHBCS $n = 41$ Mean (SD) | *P* value |
|---|---|---|---|
| Age (year) | 46.8 (10.2) | 55.7 (10.5) | < 0.001 |
| Postmenopausal, *n* (%) | 27 (48) | 25 (61) | 0.01 |
| Weight (kg) | 87.0 (13.5) | 84.0 (13.8) | 0.11 |
| Height (cm) | 157.2 (6.0) | 159.8 (6.1) | 0.36 |
| BMI (kg/m$^2$) | 35.1 (6.1) | 33.1 (5.4) | 0.49 |
| BMI category, *n* (%) | | | |
| Overweight, BMI < 30 | 19 (34) | 28 (68) | < 0.001 |
| Obese, BMI ≥ 30 | 37 (66) | 13 (32) | < 0.001 |
| Education, *n* (%) | | | |
| High school degree | 43 (76) | 13 (32) | < 0.001 |
| Some college/college degree | 13 (24) | 28 (68) | < 0.001 |
| Marital status, *n* (%) | | | |
| Married | 50 (89) | 35 (85) | 0.73 |
| Unmarried | 6 (11) | 6 (15) | 0.82 |
| Time since diagnosis (mo) | 6.1 (2.0) | 6.4 (2.1) | 0.42 |
| Disease stage, *n* (%) | | | |
| I | 24 (43) | 22 (52) | 0.09 |
| II | 15 (27) | 18 (43) | 0.08 |
| III | 17 (30) | 1 (5) | < 0.001 |
| ER+, and or PR+, HER2/neu− | | | |
| Yes | 40 (71) | 35 (85) | < 0.001 |
| No | 16 (29) | 6 (15) | < 0.001 |
| ER−, and or PR−, HER2/neu− | | | |
| Yes | 16 (29) | 6 (15) | < 0.001 |
| No | 40 (71) | 35 (85) | < 0.001 |
| Surgery protocol, *n* (%) | | | |
| Lumpectomy | 5 (10) | 6 (15) | 0.71 |
| Mastectomy | 51 (90) | 35 (85) | 0.76 |
| Treatment in addition to surgery, *n* (%) | | | |
| Radiation only | 5 (6) | 5 (16) | 0.55 |
| Chemotherapy only | 8 (14) | 11 (26) | 0.21 |
| Radiation and chemotherapy | 43 (80) | 24 (58) | < 0.001 |
| Chemotherapy protocol, *n* (%) | | | |
| No taxane | 6 (12) | 4 (10) | 0.84 |
| Taxane | 50 (82) | 36 (90) | 0.44 |
| Duration of chemotherapy (weeks) | | | |
| < 16 | 20 (35) | 16 (40) | 0.35 |
| ≥ 16 | 36 (65) | 25 (60) | 0.19 |
| Current endocrine therapy, *n* (%) | | | |
| None | 6 (12) | 3 (10) | 0.66 |
| Tamoxifen | 26 (46) | 21 (45) | 0.80 |
| Aromatase inhibitor | 24 (42) | 19 (45) | 0.78 |
| Recent physical activity (min/week of moderate to vigorous intensity recreational activity) | 7.4 (5.3) | 9.5 (7.4) | < 0.001 |

*Abbreviations*: *HBCS* Hispanic breast cancer survivors, *NHBCS* non-Hispanic breast cancer survivors, *BMI* body mass index, *SD* standard deviation

**Table 2** Ethnicity as a moderator of exercise effects on physical fitness in breast cancer survivors

| | Number | Baseline mean (SD) | Number | Post-intervention Mean (SD) | Adjusted mean change Mean (95% CI)^ | Adjusted subgroup difference in mean change Mean (95% CI); *P*^ | Adjusted Interaction effect Mean (95% CI); *P*^ |
|---|---|---|---|---|---|---|---|
| $VO^2_{max}$ (ml/kg/min) | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 18.5 (4.1) | 28 | 35.3 (7.9) | 16.8 (6.7 to 20.5) | 17.4 (6.5 to 22.1) | 8.4 (3.2 to 13.4) |
| Usual care | 27 | 18.0 (4.5) | 24 | 17.4 (4.0) | − 0.6 (− 1.7 to 1.3) | < 0.001 | 0.002 |
| NHBCS | | | | | | | |
| Exercise | 19 | 26. 1 (6.1) | 19 | 34.8 (8.0) | 8.6 (5.0 to 12.3) | 9.0 (2.6 to 15.1) | |
| Usual care | 22 | 26.4 (6.5) | 22 | 26.0 (6.7) | − 0.4 (− 1.8 to 1.0) | 0.003 | |
| Chest press (kg) | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 6.2 (1.5) | 28 | 20.6 (5.1) | 14.4 (7.1 to 21.9) | 14.2 (6.5 to 20.0) | 2.1 (0.5 to 3.6) |
| Usual care | 27 | 6.0 (1.0) | 24 | 5.8 (1.4) | − 0.2 (− 1.3 to 1.5) | < 0.001 | 0.01 |
| NHBCS | | | | | | | |
| Exercise | 19 | 11.0 (2.2) | 19 | 21.8 (5.9) | 10.8 (4.3 to 15.9) | 12.1 (4.4 to 17.1) | |
| Usual care | 22 | 11.2 (2.4) | 22 | 9.9 (2.7) | − 1.3 (− 2.0 to 1.9) | 0.002 | |
| Latissimus pulldown (kg) | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 22.1 (4.3) | 28 | 39.3 (5.7) | 17.2 (8.9 to 23.5) | 18.4 (9.3 to 24.6) | 6.4 (1.9 to 15.5) |
| Usual care | 27 | 22.6 (4.0) | 24 | 21.4 (3.9) | − 1.2 (− 2.4 to 0.4) | < 0.001 | 0.008 |
| NHBCS | | | | | | | |
| Exercise | 19 | 34.3 (4.5) | 19 | 40.1 (6.0) | 5.8 (3.1 to 13.9) | 12.0 (4.2 to 18.2) | |
| Usual care | 22 | 34.2 (4.8) | 22 | 28.0 (4.0) | − 6.2 (− 9.1 to − 1.0) | < 0.001 | |
| Knee extension (kg) | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 35.1 (9.0) | 28 | 72.1 (11.3) | 37.0 (21.7 to 46.9) | 40.5 (25.9 to 51.6) | 10.5 (5.6 to 15.4) |
| Usual care | 27 | 35.6 (9.2) | 24 | 32.1 (8.7) | − 3.5 (− 5.1 to − 1.2) | < 0.001 | 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 50.1 (10.3) | 19 | 75.6 (12.3) | 25.5 (17.2 to 35.6) | 30.0 (18.2 to 41.5) | |
| Usual care | 22 | 49.5 (10.6) | 22 | 49.0 (105) | − 0.5 (− 1.4 to 2.2) | < 0.001 | |
| Knee flexion (kg) | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 35.4 (11.6) | 28 | 63.7 (11.8) | 28.3 (12.8 to 50.0) | 36.3 (18.0 to 53.6) | 12.7 (4.5 to 24.4) |
| Usual care | 27 | 35.6 (11.7) | 24 | 27.5 (9.9) | − 8.1 (− 14.5 to − 2.4) | < 0.001 | < 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 45.5 (10.9) | 19 | 65.1 (11.9) | 19.6 (11.6 to 41.5) | 23.6 (16.0 to 33.6) | |
| Usual care | 22 | 45.9 (11.3) | 22 | 41.9 (11.5) | − 4.0 (− 8.7 to − 0.9) | < 0.001 | |

*Abbreviations*: *HBCS* Hispanic breast cancer survivors, *NHBCS* non-Hispanic breast cancer survivors, *SD* standard deviation, *CI* confidence interval, *ml* millimeter, *kg* kilogram, *min* minute, *P P* value

^Estimated based on mixed model analysis and adjusted for baseline value of the outcome, age, and recent physical activity

**Table 3** Ethnicity as a moderator of exercise effects on breast cancer–specific quality of life in breast cancer survivors

| | Number | Baseline Mean (SD) | Number | Post-intervention Mean (SD) | Adjusted mean change Mean (95% CI)^ | Adjusted subgroup difference in mean change Mean (95% CI); *P*^ | Adjusted Interaction effect Mean (95% CI); *P*^ |
|---|---|---|---|---|---|---|---|
| Physical well-being | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 14.0 (2.1) | 28 | 27.3 (4.9) | 13.3 (6.0 to 21.2) | 15.4 (8.5 to 24.1) | 12.3 (4.2 to 18.4) |
| Usual care | 27 | 14.5 (2.5) | 24 | 12.4 (2.0) | − 2.1 (− 3.7 to 1.3) | < 0.001 | 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 21. 1 (3.0) | 19 | 23.8 (3.0) | 2.7 (1.3 to 5.3) | 3.1 (0.6 to 5.1) | |
| Usual care | 22 | 21.8 (3.4) | 22 | 21.0 (2.7) | − 0.4 (− 1.3 to 1.0) | 0.01 | |
| Social well-being | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 13.2 (2.5) | 28 | 26.9 (5.1) | 13.7 (7.1 to 21.6) | 13.9 (5.8 to 19.0) | 9.8 (3.5 to 13.6) |
| Usual care | 27 | 13.0 (2.0) | 24 | 12.8 (1.9) | − 0.2 (− 1.3 to 1.0) | < 0.001 | 0.002 |
| NHBCS | | | | | | | |
| Exercise | 19 | 20.0 (2.2) | 19 | 23.8 (5.0) | 3.8 (2.3 to 8.9) | 4.1 (1.4 to 7.1) | |
| Usual care | 22 | 20.2 (2.4) | 22 | 19.9 (2.0) | − 0.3 (− 1.0 to 0.9) | 0.002 | |
| Emotional well-being | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 12.1 (2.3) | 28 | 25.3 (5.7) | 13.2 (6.9 to 18.5) | 14.4 (9.3 to 22.6) | 11.4 (5.9 to 15.5) |
| Usual care | 27 | 12.6 (2.0) | 24 | 11.4 (2.9) | − 1.2 (− 2.4 to 0.5) | < 0.001 | 0.002 |
| NHBCS | | | | | | | |
| Exercise | 19 | 20.3 (2.5) | 19 | 22.1 (6.0) | 1.8 (0.3 to 4.9) | 3.0 (1.2 to 7.2) | |
| Usual care | 22 | 20.2 (2.8) | 22 | 19.0 (4.0) | − 1.2 (− 2.1 to 2.0) | 0.01 | |
| Functional well-being | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 13.1 (2.4) | 28 | 27.9 (5.1) | 14.8 (7.5 to 22.5) | 15.1 (7.8 to 21.0) | 11.4 (4.5 to 14.7) |
| Usual care | 27 | 13.0 (2.0) | 24 | 12.7 (1.8) | − 0.3 (− 1.2 to 1.0) | < 0.001 | 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 20.0 (2.2) | 19 | 23.4 (5.0) | 3.4 (2.1 to 8.7) | 3.7 (1.4 to 6.2) | |
| Usual care | 22 | 20.2 (2.4) | 22 | 19.9 (2.1) | − 0.3 (− 1.0 to 1.1) | 0.002 | |
| Additional concerns | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 13.9 (2.6) | 28 | 26.8 (3.8) | 12.9 (7.8 to 20.0) | 13.4 (6.0 to 18.6) | 9.5 (4.3 to 15.4) |
| Usual care | 27 | 13.6 (2.7) | 24 | 13.0 (2.9) | − 0.5 (− 1.5 to 1.0) | < 0.001 | 0.003 |
| NHBCS | | | | | | | |
| Exercise | 19 | 21.2 (4.9) | 19 | 24.5 (4.1) | 3.3 (1.2 to 5.5) | 3.9 (1.0 to 6.6) | |

**Table 3** (continued)

| | Number | Baseline Mean (SD) | Number | Post-intervention Mean (SD) | Adjusted mean change Mean (95% CI)^ | Adjusted subgroup difference in mean change Mean (95% CI); *P*^ | Adjusted Interaction effect Mean (95% CI); *P*^ |
|---|---|---|---|---|---|---|---|
| Usual care | 22 | 21.5 (4.3) | 22 | 20.9 (4.5) | − 0.6 (− 1.5 to 1.2) | 0.002 | |
| FACT-General | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 52.4 (7.6) | 28 | 107.4 (11.9) | 55.0 (32.7 to 72.0) | 58.8 (35.0 to 79.0) | 44.5 (27.1 to 70.4) |
| Usual care | 27 | 53.1 (7.7) | 24 | 49.3 (9.9) | − 3.8 (− 5.5 to − 1.4) | < 0.001 | < 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 81.4 (11.9) | 19 | 93.1 (9.9) | 11.7 (5.6 to 18.5) | 14.3 (8.0 to 21.6) | |
| Usual care | 22 | 82.4 (11.3) | 22 | 79.8 (11.5) | − 2.6 (− 3.7 to 1.9) | < 0.001 | |
| FACT-Breast | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 66.3 (8.6) | 28 | 134.2 (15.8) | 67.9 (41.1 to 88.2) | 72.3 (48.9 to 95.3) | 54.1 (34.5 to 74.4) |
| Usual care | 27 | 66.7 (8.7) | 24 | 62.3 (9.9) | − 4.4 (− 6.5 to − 1.6) | < 0.001 | < 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 102.6 (13.9) | 19 | 117.6 (12.9) | 15.0 (7.6 to 21.5) | 18.2 (11.3 to 23.6) | |
| Usual care | 22 | 103.9 (13.3) | 22 | 100.7 (13.5) | − 3.2 (− 5.7 to − 1.0) | < 0.001 | |
| Trial outcome index | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 41.0 (7.6) | 28 | 82.0 (9.8) | 41.0 (20.1 to 62.0) | 43.0 (20.0 to 66.6) | 31.9 (18.5 to 54.4) |
| Usual care | 27 | 41.1 (7.7) | 24 | 38.1 (7.9) | − 2.0 (− 4.5 to 1.4) | < 0.001 | < 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 62.3 (8.9) | 19 | 71.7 (9.0) | 9.4 (5.6 to 14.5) | 11.1 (6.0 to 18.6) | |
| Usual care | 22 | 63.5 (8.3) | 22 | 61.8 (8.5) | − 1.7 (− 3.0 to 1.1) | < 0.001 | |

*Abbreviations*: *HBCS* Hispanic breast cancer survivors, *NHBCS* non-Hispanic breast cancer survivors, *SD* standard deviation, *CI* confidence interval, *FACT* Functional Assessment of Cancer Therapy, *P P* value

^Estimated based on mixed model analysis and adjusted for baseline value of the outcome, age, and recent physical activity

**Table 4** Ethnicity as a moderator of exercise effects on health status, fatigue, and depression in breast cancer survivors

| | Number | Baseline Mean (SD) | Number | Post-intervention Mean (SD) | Adjusted mean change Mean (95% CI)^ | Adjusted subgroup difference in mean change Mean (95% CI); *P*^ | Adjusted Interaction effect Mean (95% CI); *P*^ |
|---|---|---|---|---|---|---|---|
| SF-36 Subscores | | | | | | | |
| Physical functioning | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 44.0 (8.1) | 28 | 77.3 (14.9) | 33.3 (16.0 to 61.2) | 41.8 (18.5 to 64.1) | 31.5 (14.2 to 68.4) |
| Usual care | 27 | 44.5 (8.5) | 24 | 36.4 (8.0) | − 8.5 (− 13.7 to − 1.3) | < 0.001 | < 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 71.1 (13.0) | 19 | 76.8 (13.0) | 6.7 (1.3 to 9.3) | 10.3 (2.6 to 15.1) | |
| Usual care | 22 | 71.8 (13.4) | 22 | 68.2 (12.7) | − 3.6 (− 7.3 to − 1.0) | < 0.001 | |
| Role-physical | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 53.2 (9.5) | 28 | 76.9 (15.1) | 23.7 (7.1 to 41.6) | 29.9 (15.8 to 59.0) | 18.8 (5.5 to 33.6) |
| Usual care | 27 | 53.0 (9.0) | 24 | 46.8 (9.9) | − 6.2 (− 13.3 to − 1.0) | < 0.001 | < 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 70.0 (12.2) | 19 | 78.8 (15.0) | 8.8 (2.3 to 18.9) | 11.1 (1.4 to 17.1) | |
| Usual care | 22 | 72.2 (12.4) | 22 | 69.9 (12.0) | − 2.3 (− 4.0 to 0.9) | 0.002 | |
| Bodily pain | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 32.1 (4.3) | 28 | 65.3 (9.7) | 33.2 (16.9 to 58.5) | 42.4 (19.3 to 62.6) | 26.4 (5.9 to 45.5) |
| Usual care | 27 | 32.6 (4.0) | 24 | 23.4 (3.9) | − 9.2 (− 22.4 to − 2.5) | < 0.001 | < 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 50.3 (9.5) | 19 | 62.1 (9.0) | 11.8 (0.3 to 18.9) | 16.0 (4.2 to 27.2) | |
| Usual care | 22 | 50.2 (9.8) | 22 | 46.0 (6.0) | − 4.2 (− 8.1 to − 0.2) | 0.003 | |
| General health | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 43.1 (5.4) | 28 | 70.9 (9.1) | 27.8 (7.5 to 42.5) | 32.1 (17.8 to 61.0) | 19.4 (8.5 to 34.7) |
| Usual care | 27 | 43.0 (5.0) | 24 | 38.7 (4.8) | − 4.3 (− 9.2 to − 1.0) | < 0.001 | < 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 60.0 (9.2) | 19 | 67.4 (9.0) | 7.4 (1.1 to 18.7) | 12.7 (1.4 to 20.2) | |
| Usual care | 22 | 60.2 (9.4) | 22 | 54.9 (9.1) | − 5.3 (− 10.0 to − 0.1) | 0.002 | |
| Mental health | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 52.9 (5.6) | 28 | 76.8 (13.8) | 23.9 (7.8 to 40.0) | 34.5 (16.0 to 58.6) | 19.6 (4.3 to 35.4) |
| Usual care | 27 | 53.6 (5.7) | 24 | 43.0 (4.9) | − 10.6 (− 19.5 to − 2.0) | < 0.001 | < 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 69.2 (9.9) | 19 | 79.5 (11.1) | 10.3 (1.2 to 15.5) | 14.9 (6.0 to 26.6) | |
| Usual care | 22 | 69.5 (9.3) | 22 | 65.9 (9.5) | − 4.6 (− 8.5 to − 0.2) | 0.002 | |
| Role-emotional | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 52.4 (7.6) | 28 | 107.4 (11.9) | 55.0 (32.7 to 72.0) | 58.8 (35.0 to 79.0) | 44.5 (27.1 to 70.4) |
| Usual care | 27 | 53.1 (7.7) | 24 | 49.3 (9.9) | − 3.8 (− 5.5 to − 1.4) | < 0.001 | < 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 81.4 (11.9) | 19 | 93.1 (9.9) | 11.7 (5.6 to 18.5) | 14.3 (8.0 to 21.6) | |
| Usual care | 22 | 82.4 (11.3) | 22 | 79.8 (11.5) | − 2.6 (− 3.7 to 1.9) | < 0.001 | |
| Social functioning | | | | | | | |

**Table 4** (continued)

| | Number | Baseline Mean (SD) | Number | Post-intervention Mean (SD) | Adjusted mean change Mean (95% CI)^ | Adjusted subgroup difference in mean change Mean (95% CI); *P*^ | Adjusted Interaction effect Mean (95% CI); *P*^ |
|---|---|---|---|---|---|---|---|
| HBCS | | | | | | | |
| Exercise | 29 | 66.3 (8.6) | 28 | 134.2 (15.8) | 67.9 (41.1 to 88.2) | 72.3 (48.9 to 95.3) | 54.1 (34.5 to 74.4) |
| Usual care | 27 | 66.7 (8.7) | 24 | 62.3 (9.9) | − 4.4 (− 6.5 to − 1.6) | < 0.001 | < 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 102.6 (13.9) | 19 | 117.6 (12.9) | 15.0 (7.6 to 21.5) | 18.2 (11.3 to 23.6) | |
| Usual care | 22 | 103.9 (13.3) | 22 | 100.7 (13.5) | − 3.2 (− 5.7 to − 1.0) | < 0.001 | |
| Vitality | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 41.0 (7.6) | 28 | 82.0 (9.8) | 41.0 (20.1 to 62.0) | 43.0 (20.0 to 66.6) | 31.9 (18.5 to 54.4) |
| Usual care | 27 | 41.1 (7.7) | 24 | 38.1 (7.9) | − 2.0 (− 4.5 to 1.4) | < 0.001 | < 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 62.3 (8.9) | 19 | 71.7 (9.0) | 9.4 (5.6 to 14.5) | 11.1 (6.0 to 18.6) | |
| Usual care | 22 | 63.5 (8.3) | 22 | 61.8 (8.5) | − 1.7 (− 3.0 to 1.1) | < 0.001 | |
| Physical component summary | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 43.1 (4.6) | 28 | 72.6 (9.1) | 29.4 (15.1 to 62.8) | 36.4 (13.3 to 66.8) | 24.2 (11.5 to 44.4) |
| Usual care | 27 | 43.3 (4.7) | 24 | 36.3 (3.9) | − 7.0 (− 16.5 to 11.7) | < 0.001 | < 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 62.9 (8.9) | 19 | 71.3 (9.0) | 8.4 (1.6 to 13.5) | 12.2 (2.7 to 20.6) | |
| Usual care | 22 | 63.6 (8.3) | 22 | 59.8 (8.5) | − 3.8 (− 9.0 to − 0.4) | 0.003 | |
| Mental component summary | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 53.1 (7.2) | 28 | 100.1 (14.8) | 47.0 (20.1 to 73.0) | 52.4 (25.5 to 76.6) | 38.1 (15.5 to 65.9) |
| Usual care | 27 | 53.6 (7.7) | 24 | 48.2 (7.9) | − 5.4 (− 11.5 to − 1.7) | < 0.001 | < 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 78.9 (9.9) | 19 | 90.5 (10.8) | 11.6 (3.6 to 22.1) | 14.3 (4.4 to 25.6) | |
| Usual care | 22 | 79.8 (9.3) | 22 | 77.1 (8.9) | − 2.7 (− 7.6 to 1.4) | < 0.001 | |
| BFI | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 9.1 (1.6) | 28 | 3.0 (1.5) | 6.1 (1.1 to 12.0) | 6.3 (2.0 to 14.6) | 3.4 (0.5 to 7.4) |
| Usual care | 27 | 9.3 (1.8) | 24 | 9.1 (1.9) | − 0.2 (− 1.5 to 1.3) | < 0.001 | 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 5.3 (1.9) | 19 | 2.7 (1.0) | 2.6 (0.6 to 6.5) | 2.9 (0.9 to 6.3) | |
| Usual care | 22 | 5.5 (1.7) | 22 | 5.8 (1.5) | − 0.3 (− 1.1 to 1.7) | < 0.001 | |
| CES-D | | | | | | | |
| HBCS | | | | | | | |
| Exercise | 29 | 19.1 (4.6) | 28 | 11.0 (4.8) | 8.1 (3.2 to 14.0) | 8.6 (1.0 to 15.6) | 4.7 (1.5 to 9.4) |
| Usual care | 27 | 19.4 (4.7) | 24 | 19.9 (4.9) | − 0.5 (− 3.6 to 2.4) | < 0.001 | < 0.001 |
| NHBCS | | | | | | | |
| Exercise | 19 | 12.3 (2.9) | 19 | 8.7 (3.0) | 3.6 (0.3 to 6.5) | 3.9 (0.2 to 6.6) | |
| Usual care | 22 | 12.5 (2.3) | 22 | 12.8 (2.5) | − 0.3 (− 1.9 to 1.1) | < 0.001 | |

*Abbreviations*: *HBCS* Hispanic breast cancer survivors, *NHBCS* non-Hispanic breast cancer survivors, *SD* standard deviation, *CI* confidence interval, *SF-36* Short form-36 Health Status, *BFI* Brief Fatigue Index, *CES-D* Center for Epidemiological Studies Depression, *P P* value

^Estimated based on mixed model analysis and adjusted for baseline value of the outcome, age, and recent physical activity

compare our results, given ethnocentric differences in muscular strength and $VO_{2max}$ in response to an exercise intervention. Still, our results agree with those of Hughes et al. [39] who found significant increases in upper extremity strength and aerobic capacity in a cohort of Hispanic BCS in response to a 10-week home-based exercise intervention. Hughes et al. (2008) observed a 62.74% increase in upper extremity strength, whereas in our study, Hispanic BCS who participated in exercise demonstrated an increase in upper extremity strength by 232% and 77% in chest press and latissimus pulldown, respectively. Our results expand on these findings to include a comparison with non-Hispanic BCS and outcomes of muscular strength across both upper and lower extremities; importantly, we included lower extremity strength in our study as it has been associated with improved health-related quality-of-life [40–43].

Our results suggest that Hispanic BCS may derive greater benefit from participation in a combined aerobic and resistance exercise program than their non-Hispanic BCS counterparts in domains of breast cancer–specific quality of life, health status, fatigue, and depression. For instance, following the exercise intervention the Hispanic BCS experienced a profoundly larger benefit in breast cancer–specific quality of life noted in the overall score of the FACT-B with a mean difference of 54.1 when compared with the non-Hispanic BCS. In a literature review by Yanez et al. [7], across common clinical patient-reported outcomes like quality of life measured by SF-36 and FACT-B, which were utilized in this study, Hispanic BCS were particularly at risk for increased depression, poorer physical health status, and increased fatigue compared with non-Hispanic BCS. Our exercise intervention effectively improved upon the domains of health-related quality-of-life, ones for which Hispanic BCS may have particularly high risk. It is plausible that the profound exercise-induced benefit on patient-reported outcomes experienced by Hispanic BCS was due to lack of participation in self-reported lifetime physical activity making this group potentially more susceptible to positive change as the intervention was entirely novel physically, psychosocially, and physiologically. In addition, given the majority of the Hispanic BCS was Spanish-speaking, a group of bilingual Spanish-speaking exercise trainers delivered the intervention to this sample which differed from the monolingual exercise trainers assigned to supervise the non-Hispanic BCS. This may have allowed for an immediate sense of support and belonging, sense of accomplishment during and upon completion of each session, and subsequently increased self-efficacy in the Hispanic BCS group. Common barriers to lack of participation in clinical trials by Hispanic women include mistrust and lack of access to Spanish-speaking staff [44, 45], which were inherently overcome in the present study by utilization of Spanish-speaking staff.

Furthermore, it is plausible based on greater stage and higher prevalence of triple negative disease that the Hispanic BCS experienced more extensive treatments allowing for superior exercise-induced benefits. Disparities in breast cancer are well documented with Hispanic BCS diagnosed at a younger age, ER-negative tumors, higher tumor grades when compared with non-Hispanic white BCS [46], in concordance with our sample. Notably, additional differences in baseline values between Hispanic and non-Hispanic BCS exist, that while adjusted for in our model, may impact our results. Hispanic BCS were more likely to be younger and premenopausal, obese, physically inactive, and less educated. Our ongoing exercise trial specifically targeting Hispanic BCS seeks to determine the impact of these characteristics on the benefits of exercise (NCT03120390). Nonetheless, our results contribute critical data to the current landscape of exercise oncology literature, as, to our knowledge, there are no other interventional studies that have aimed to improve health-related quality of life in Hispanic BCS. Given that the disparities in outcomes between Hispanic and non-Hispanic BCS are well studied and well accepted in the literature, the results of this study provide an important strategy that could attenuate ethnocentric differences in breast cancer survivor's quality of life and call for future research in this domain. Our findings further support the need to promote aerobic and resistance exercise among minority cancer survivors, in alignment with the 2019 ACSM exercise guidelines for cancer survivors promoting weekly aerobic and resistance exercise [10], and the promotion of a physical activity service for inclusion of survivorship care programs supported by the 2020 Commission on Cancer of the American College of Surgeons [47].

Strengths of this study include the ethnically diverse, high-risk sample of breast cancer survivors, a randomized controlled design, the collection of patient reported outcomes, and an adherence rate of 96%. Adherence rates are particularly relevant in cancer trials involving minority populations as there is a paucity of evidence regarding minority participation and adherence with lifestyle-modifiable interventions [48]. Minority participation in cancer clinical trials is lower than non-Hispanic Caucasians, with several studies highlighting the numerous barriers to recruitment and poorer adherence of ethnic minorities in lifestyle interventions [48, 49]. Historically, Hispanic women have reported more perceived obstacles to exercise participation than Caucasian women [30], thus highlighting the importance of including bilingual exercise trainers with one-on-one supervised training and flexible scheduling, which may have contributed to the high adherence rate and modest loss to follow-up. Limitations include lack of an attention control group and the challenge of reproducing the intervention with high adherence outside of a supervised training environment.

In summary, when compared with non-Hispanic BCS, Hispanic BCS derived significantly greater benefit from our 16-week clinical, supervised aerobic, and resistance exercise intervention in outcomes of physical fitness and health-related

quality of life. The findings of our study, therefore, are a particularly important contribution to the literature on breast cancer and exercise, demonstrating ethnocentric differences between HBCS and NHBCS at baseline, and showing that ethnicity is a moderator of the effects of exercise on physical fitness and quality-of-life. This study requires confirmation and highlights the need for further investigation into disparities and related modifiable lifestyle interventions in improving physical fitness and quality of life across minority populations of breast cancer survivors. Future work should examine ethnically appropriate exercise interventions and culturally tailored patient reported outcomes, to engender better outcomes and effectively bolster physical fitness and related quality-of-life in Hispanic BCS.

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## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical 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 article does not contain any studies with animals performed by any of the authors.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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