


# Effects of a Translational Community-Based Multimodal Exercise Program on Quality of Life and the Influence of Start Delay on Physical Function and Quality of Life in Breast Cancer Survivors: A Pilot Study

Integrative Cancer Therapies  
2018, Vol. 17(2) 337–349  
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DOI: 10.1177/1534735417731514  
journals.sagepub.com/home/ict  


Michael Paul Foley, PhD, PT<sup>1</sup>, Scott Michael Hasson, EdD, PT<sup>2</sup>,  
and Eydie Kendall, PT, PhD<sup>1</sup>

## Abstract

The purpose of this investigation was 2-fold: (1) to investigate the effects of a translational 12-week community-based multimodal exercise program on quality of life (QoL) in breast cancer survivors (BCS) and (2) to examine the influence of a start delay on physical function and QoL in BCS. Fifty-two female BCS completed a 12-week program consisting of 90-minute supervised exercise sessions at a frequency of 2 supervised sessions per week. Exercise sessions consisted of three 30-minute components: (1) aerobic conditioning, (2) resistance exercise training, and (3) balance and flexibility training. Significant ( $P < .05$ ) improvements in QoL were identified post-program completion. Cohort stratification comparison between the early start (<1 year since completion of oncologic treatment) and late start (>1 year since completion of oncologic treatment) revealed no significant ( $P > .05$ ) differences between the early start and late start groups on improvements in physical function. Regarding the influence of start delay on QoL, the early start group showed significant ( $P < .05$ ) improvement in emotional well-being. No other significant differences in improvement in QoL were detected between the early start and late start groups. Regardless of start delay, meaningful improvements in physical function and QoL were found after completing the community-based multimodal exercise program. Early participation in community-based exercise programming may benefit BCS' emotional well-being compared to later participation.

## Keywords

breast cancer survivors, community-based exercise, quality of life, physical function, start delay

Submitted January 30, 2017; revised July 6, 2017; accepted August 12, 2017

## Introduction

Breast cancer is the leading cause of cancer-related death among females worldwide.<sup>1</sup> In 2012, there were an estimated 1.7 million new cases of breast cancer and 521 900 deaths occurred.<sup>1</sup> Among females, breast cancer is the most common cancer in North America, Europe, and Oceania.<sup>2</sup> In 2012 there were an estimated 2.97 million breast cancer survivors (BCS) living in the United States.<sup>3</sup> According to the National Cancer Institute: Surveillance, Epidemiology, and End Results, the 5-year survival rate for breast cancer is 89.4%.<sup>3</sup> Research suggests frailty and prefrailty may be more common in BCS as compared to women with no history of cancer.<sup>4</sup> In a prospective cohort study, functional limitations subsequent to breast cancer

and oncologic treatment were associated with reduction in all-cause and competing cause survival, irrespective of clinical, lifestyle, and sociodemographic factors.<sup>5</sup>

Breast cancer and oncologic treatment can have significant negative effects on physical function<sup>5</sup> and quality of life (QoL).<sup>6</sup> Physical function<sup>5</sup> and QoL<sup>6</sup> are both predictors of breast cancer survival. Modifiable risk factors for reducing breast cancer risk include maintaining a healthy weight,

<sup>1</sup>Idaho State University, Pocatello, ID, USA

<sup>2</sup>Augusta University, Augusta, GA, USA

### Corresponding Author:

Michael Paul Foley, Idaho State University, Campus Stop 8045, Pocatello, ID 83209-8045, USA.

Email: folemich@isu.edu



avoiding alcohol consumption, and being physically active.<sup>2</sup> Physical activity is recommended for primary prevention of certain types of cancers, including breast cancer, many chronic diseases, and for prevention of premature mortality.<sup>7-13</sup> Strong scientific evidence exists supporting physical activity for secondary prevention of breast cancer recurrence and tertiary prevention of cancer-related comorbidities.<sup>14,15</sup> Physical activity is generally recommended for patients with cancer to improve function, reduce fatigue, and increase QoL.<sup>16-20</sup> However, most cancer survivors experience declines in physical activity, do not engage in regular physical activity, and are no more likely to follow physical activity guidelines than the general population.<sup>21,22</sup> The result is that many cancer survivors do not regain their prediagnosis physical activity levels.<sup>23</sup> Despite evidence supporting physical activity and exercise as a countermeasure for breast cancer morbidity and mortality, many BCS do not regularly engage in physical exercise. Participating in regular physical exercise continues to be a challenge for many cancer survivors. There is a growing body of recent research illuminating the need and benefit of community-based exercise programs for cancer survivors.<sup>24-31</sup> Exercise interventions for cancer survivors may include walking, cycling, resistance exercise training, and yoga at moderate to vigorous intensities and have shown significant improvement in health-related QoL and physical functioning.<sup>32</sup> Even though there are clear beneficial associations between physical exercise and cancer, specific exercise recommendations including exercise frequency, intensity, time, type, and volume progression (FITT-VP) are often not reported in many research studies.<sup>33</sup> An additional question for BCS is when to begin an exercise program in the post-cancer diagnosis trajectory? Milne et al studied the effects of a combined aerobic and resistance exercise program in BCS in a randomized control trial.<sup>34</sup> These researchers reported QoL at 12 weeks was significantly ( $P < .001$ ) increased in an immediate exercise group (20.8 points) compared to a delayed exercise group (decreased by 5.3 points). Furthermore, once the delayed group received the exercise intervention they did not reach the same level of improvement as the immediate intervention group. These results support early exercise intervention for BCS. However, the duration of start delays for exercise intervention in BCS can vary infinitely.

There is a great need for translating the benefits of exercise for cancer survivors and establishing community-based exercise programs.<sup>35</sup> Cancer-specific community-based exercise programs provide opportunity for cancer survivors to exercise with other cancer survivors while receiving appropriate exercise supervision. In a previously published study on BCS, physical function was significantly ( $P < .05$ ) improved after participation in a community-based multimodal exercise program.<sup>27</sup> However, the effects on QoL and the effects of a start delay were not assessed. Due to the overall adverse effects of breast cancer and oncologic treatment on physical function and QoL, we have examined the

effects of a translational community-based multimodal exercise program on QoL and the influence of a start delay on physical function and QoL in BCS.

### Purpose

The purpose of this investigation was 2-fold: (1) to investigate the effects of a translational 12-week community-based multimodal exercise program on QoL in BCS and (2) to examine the influence of a start delay on physical function and QoL in BCS.

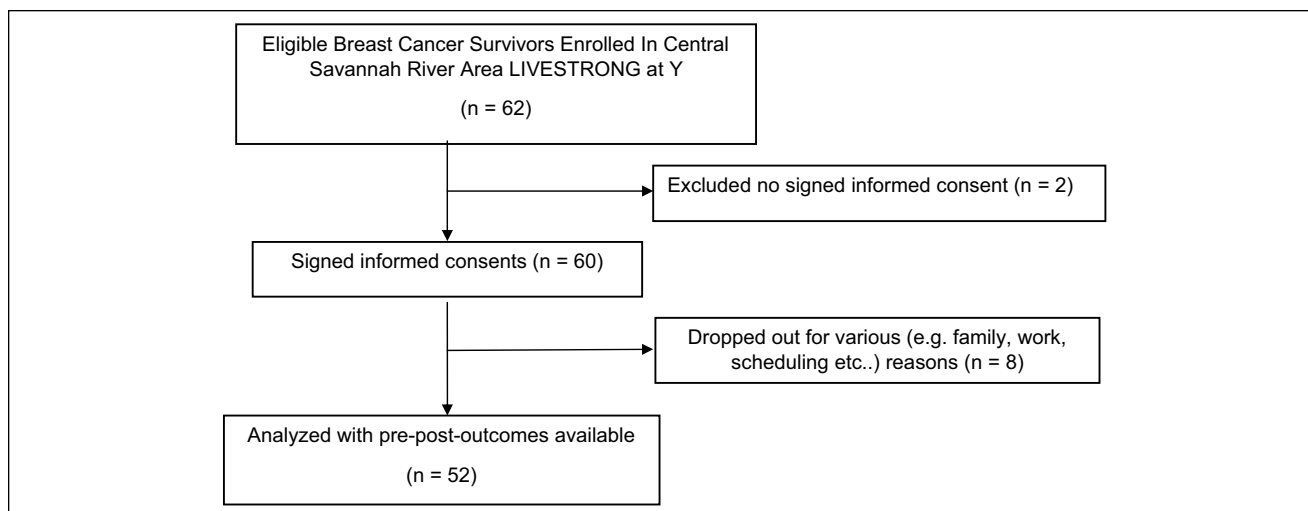
## Methods

### Study Design

For the primary analysis, QoL was assessed pre- and post-participation in a 12-week community-based multimodal exercise program for cancer survivors. Secondary analysis consisted of examining the influence of a start delay on physical function and QoL. For the secondary analysis, BCS were stratified into 2 groups by time following oncologic treatment (ie, surgery, chemotherapy, and/or radiation therapy) completion. Group 1 (early start) consisted of BCS who were within 1 year or less of active oncologic treatment. Group 2 (late start) consisted of BCS who were over 1 year since active oncologic treatment, excluding adjuvant hormonal deprivation therapy. We chose 1 year stratification for many reasons: (1) research has shown that BCS decrease physical activity and exercise levels at cancer diagnosis and during treatment and do not regain their previous levels after cancer treatment<sup>21,23</sup>; (2) many BCS may not be aware that exercising during oncologic treatment is recommended and can be safely tolerated<sup>15</sup>; (3) oncologic treatment of more involved breast cancer can last for the better part of 1 year; (4) 1 year stratification allowed for one cohort that was either still undergoing or recently completed oncologic treatment (acute effects); (5) the cohort over 1 year may be experiencing later effects; and (6) we believe that the 1 year stratification has translational merit for BCS considering community-based exercise programming.

### Participant Population

This study was approved by Augusta University institutional review board and was conducted through a community partnership with the Central Savannah River Area (CSRA) YMCAs. BCS at CSRA YMCAs were approached by the researchers for voluntary participation in this study. Inclusion criteria for this study were (1) consenting adult BCS, (2) signed physician approval for participation, and (3) BCS regardless of treatment/recovery phase. Minors (<18 years of age) were excluded from participation in this study. Written informed consent was obtained from all participants. Study participants were enrolled over a 17-month period. All BCS were female.



**Figure 1.** Study flow diagram.

### Description of the Multimodal Exercise Program

The multimodal exercise program was a free voluntary program that met twice weekly for 90-minute exercise classes for 12 weeks. Each exercise class was divided into three 30-minute components: (1) aerobic conditioning, (2) resistance exercise training, and (3) balance and flexibility training. All sessions were limited to a maximum of 10 participants and were supervised by 2 LIVESTRONG Foundation certified instructors who were also trained YMCA fitness instructors. A licensed physical therapist and certified lymphedema therapist with several years of oncology rehabilitation experience assisted in the program development, implementation, and assessment. Physical function assessments and participant-reported QoL assessments were completed prior to and after completion of the exercise program by the trained YMCA fitness instructors and the licensed physical therapist. The trained individuals performing the assessments did not have any knowledge that the BCS would be later stratified into early start and late start groups for subsequent analysis.

Individualized exercise prescriptions were developed for each participant using American College of Sports Medicine exercise guidelines and position statements.<sup>15,36,37</sup> Aerobic conditioning exercises initially (1-2 weeks) consisted of treadmill walking for 10 to 20 minutes working up to an intensity of 70% to 85% heart rate maximum, as tolerated, and “moderate” to “hard” (3 to 5) rating of perceived exertion (RPE) on the Borg scale (0-10).<sup>38</sup> The duration of aerobic conditioning exercises was progressed to 30 minutes for the remainder of the 12 weeks during which participants were encouraged to try other aerobic exercise machines with the instructors’ assistance (eg, cycle ergometers, elliptical trainers, and recumbent stepping trainers). The

resistance exercise training generally consisted of 1 to 2 sets of 8 to 12 repetitions at 60% to 70% of 1 repetition maximum for the major muscle groups.<sup>36</sup> The resistance exercise training was progressed by approximately 5% to 10% when participants were able to perform more than 12 repetitions for a given exercise.<sup>36</sup> Balance and flexibility training mostly consisted of seated and standing static and dynamic balance exercises (eg, balance ball exercises, ball and balloon tosses, reaches, bends, dance exercises, yoga poses) and stretching exercises. Deep diaphragmatic breathing techniques were also performed to encourage relaxation during the balance and flexibility training sessions.

**Participant Baseline Characteristics.** A diagram of study flow is provided in Figure 1. Sixty female BCS signed informed consent for participation in this study, and 52 survivors completed the 12-week multimodal exercise program (86.7%). The most frequently reported reason for dropping out was scheduling/employment conflicts and family scheduling conflicts. Average attendance for the participants over the 12-week program was 80.5%. Baseline participant demographics and anthropometrics for all BCS are presented in Table 1. All participants had breast cancer surgery, 85% received chemotherapy, 75% received radiation therapy, and 39.5% reported they were taking hormonal deprivation therapy. Prior to initiation of the exercise program, participants were asked about their current exercise activity. Participant exercise levels were later categorized as 0 = no regular physical exercise, 1 = some exercise (<2 times per week), and 2 = exercise regularly (>3 times per week). Mean  $\pm$  standard deviation for exercise level was  $0.65 \pm 0.82$ , and the median was 0. Baseline comparison for early and late start groups for physical function and QoL (well-being) outcome measures are presented in Tables 2 and 3, respectively.

**Table 1.** Baseline Demographic and Anthropometric Measures for All Breast Cancer Survivors and the Early Start and Late Start Groups<sup>a</sup>.

	All BCS	Early Start	Late Start
<b>Age (years)</b>			
Mean ± SD	59.7 ± 10.4	59.2 ± 10.8	60.1 ± 10.2
Range	46-82	36-47	36-82
n	52	21	31
<b>Weight (kg)</b>			
Mean ± SD	81.0 ± 16.1	85.9 ± 16.0	77.6 ± 16.3
Range	76.7-127.1	52.2-113.5	50.4-127.1
n	44	18	26
<b>Height (cm)</b>			
Mean ± SD	164 ± 5	165 ± 5	163 ± 5
Range	152-178	152-177	152-178
n	44	18	26
<b>BMI (kg/m<sup>2</sup>)</b>			
Mean ± SD	30.11 ± 2.78	31.71 ± 5.53	27.80 ± 0.89
Range	28.5-47.2	19.8-40.4	25.5-29.8
n	44	18	26
<b>Resting heart rate (beats/min)</b>			
Mean ± SD	76 ± 9.1	79 ± 8.8	74 ± 9.4
Range	60-100	60-96	60-100
n	44	18	26
<b>Resting systolic blood pressure (mm Hg)</b>			
Mean ± SD	128 ± 15	126 ± 15	129 ± 15
Range	100-158	100-158	48-152
N	44	18	26
<b>Resting diastolic blood pressure (mm Hg)</b>			
Mean ± SD	80 ± 8	79 ± 10	80 ± 8
Range	60-96	60-96	64-90
n	44	18	26
<b>Years since medical treatment</b>			
Mean ± SD	4.96 ± 6.30	0.41 ± 0.39	8.04 ± 6.57
Range	0-24	0-0.99	1.50-23.99
n	52	21	31

Abbreviations: BCS, breast cancer survivors; BMI, body mass index.

<sup>a</sup>Medical treatment (surgery, chemotherapy, and/or radiation therapy), all female breast cancer survivors. Early Start = less than 1 year since oncologic treatment completion; Late Start, over 1 year since oncologic treatment completion.

Participants were monitored throughout the exercise program for any signs and symptoms of exercise intolerance and appropriate adjustments were made accordingly on an individualized basis. Participants were also monitored for major adverse events. No significant major adverse events were reported.

### Outcome Measures

**Outcome Measures of Quality of Life.** Participant reported outcome measure of QoL was assessed by completion of a Functional Assessment of Cancer Treatment (FACT-G) survey. The FACT-G (Version 4) is a 26-item cancer-specific, patient-reported QoL outcome measurement tool in which well-being is assessed in 4 domains: (1) Physical

Well-Being (PWB; 7 items with range of possible scores from 0 to 28); (2) Social/Family Well-Being (SWB; 6 items with range of possible scores from 0 to 24); (3) Emotional Well-Being (EWB; 6 items with range of possible scores from 0 to 24); and (4) Functional Well-Being (FWB; 7 items with range of possible scores from 0 to 28). The total of all the domains are represented as Total Well-Being (TWB; 26 items with range of possible scores from 0 to 104). The FACT-G is a widely used patient-reported outcome measure with established reliability and validity.<sup>39</sup> Test-retest reliability for patients (n = 466) in various stages of cancer treatment was determined for the 4 domains of well-being and TWB: (1) PWB = 0.88; (2) SWB = 0.82; (3) EWB = 0.82; (4) FWB = 0.84; and (5) TWB = 0.92.<sup>39</sup> Validity of the FACT-G has been determined in patients with

**Table 2.** Baseline and Post-Measurements of Physical Function Comparing the Early Start and Late Start Groups.

	Baseline (Pre)			Post		
	Early Start	Late Start	P Value (2-Tail); t Value	Early Start	Late Start	P Value (2-Tail); t Value
<b>TUG (seconds)</b>						
Mean ± SD	8.3 ± 2.7	7.9 ± 2.2	P = .513; t = 2.028	6.6 ± 1.8	6.7 ± 2.3	P = .994; t = 2.013
Median	8.05	6.89		6.8	6	
Range	10.6	7.9		6.3	9.5	
95% CI	7.05-9.55	6.05-7.73		6.01-7.66	5.77-7.51	
n	20	29		20	29	
<b>6MWT (meter)</b>						
Mean ± SD	399.2 ± 69.1	426.9 ± 87.3	P = .258; t = 2.019	473.4 ± 90.1	478.9 ± 103.6	P = .852; t = 2.021
Median	405.0	426.7		468	503	
Range	328	330		304	375	
95% CI	370-440	392.3-461.4		428-518	473.9-519.7	
n	18	28		18	28	
<b>Leg Press (kg)</b>						
Mean ± SD	56.8 ± 32.1	62.4 ± 35.4	P = .504; t = 2.019	81.0 ± 32.6	77.0 ± 36.4	P = .902; t = 2.010
Median	47.7	95.4		79.5	85.2	
Range	125	118.2		120.5	127.3	
95% CI	41.4-72.4	80.3-110.1		65.5-96.9	65.5-95.4	
n	19	28		19	28	
<b>Chest Press (kg)</b>						
Mean ± SD	17.6 ± 12.4	19.8 ± 12.9	P = .551; t = 2.022	26.7 ± 12.1	26.6 ± 12.2	P = .963; t = 2.019
Median	15.9	21.6		22.7	4.5	
Range	43.2	38.6		43.2	31.8	
95% CI	11.6-23.6	15.0-24.8		20.96-32.62	3.92-9.55	
n	19	27		19	27	
<b>Back Scratch (cm)</b>						
Mean ± SD	-10.6 ± 10.7	-12.2 ± 12.6	P = .436; t = 2.026	-5.9 ± 12.9	-7.0 ± 10.9	P = .763; t = 2.039
Median	-11.3	-14.0		-10.8	-6.4	
Range	45	48.6		47	44.5	
95% CI	-15.9 to -5.3	-17.4 to 8.9		-12.3 to 0.5	-11.1 to 2.97	
n	18	29		18	29	
<b>Functional Reach (cm)</b>						
Mean ± SD	29.6 ± 8.5	29.5 ± 6.8	P = .971; t = 2.048	35.6 ± 8.0	35.0 ± 6.9	P = .837; t = 2.051
Median	30.5	30.5		36.8	3.8	
Range	38.1	24.1		25.4	26.7	
95% CI	25.1-34.2	26.7-32.7		30.79-40.33	2.30-8.33	
n	16	22		16	22	
<b>SLST (seconds)</b>						
Mean ± SD	26.8 ± 22.2	26.1 ± 20.4	P = .999; t = 2.032	33.7 ± 20.6	32.3 ± 22.4	P = .877; t = 2.024
Median	22.2	20.5		32.7	30.0	
Range	58.0	58		58.1	58.2	
95% CI	15.78-37.88	19.07-34.59		23.44-43.94	24.29-41.10	
n	18	29		18	29	

Abbreviations: CI, confidence interval; TUG, Timed Up and Go Test; 6MWT, Six-Minute Walk Test; SLST, Single Leg Stance Test; Early Start, less than 1 year diagnosis and treatment; Late Start, over 1 year since diagnosis and treatment.

cancer (n = 437) by comparing known ECOG Performance Status scores to FACT-G scores using one-way analysis of variance.<sup>39</sup> The FACT-G scores were significantly higher for patients with better ECOG Performance Status scores.<sup>39</sup>

**Outcome Measures of Physical Function.** In this study, the outcome measures of physical function were thoughtfully chosen because they were believed to likely represent performance outcomes related to common impairments

**Table 3.** Baseline and Post-Measurements of QoL (Well-Being) Comparing the Early Start and Late Start Groups.

	Baseline (Pre)			Post		
	Early Start	Late Start	P Value (2-Tail)	Early Start	Late Start	P Value (2-Tail)
<b>PWB</b>						
Mean ± SD	19.8 ± 5.8	21.1 ± 4.8	P = .617	24.2 ± 4.5	24.1 ± 3.4	P = .555
Median	21	21.5		25	24.5	
Range	18	17		18	16	
95% CI	16.62-23.04	19.26-23.01		21.70-26.69	22.73-25.39	
n	15	28		15	28	
<b>SWB</b>						
	22.7 ± 4.3	22.3 ± 5.7	P = .848	22.0 ± 5.0	23.2 ± 4.5	P = .868
	23	24		24	24	
	16	21		17	16.3	
	20.35-25.11	20.13-24.54		20.22-25.72	21.51-24.97	
	15	28		15	28	
<b>EWB</b>						
	17.3 ± 3.3	19.9 ± 2.9	P = .017	20.2 ± 2.4	20.5 ± 2.9	P = .456
	16	20		19.2	21	
	11	10.8		8	11	
	15.50-19.16	18.78-21.01		18.79-21.50	19.41-21.66	
	15	28		15	28	
<b>FWB</b>						
	16.9 ± 6.5	20.1 ± 4.7	P = .119	20.1 ± 4.9	21.8 ± 5.0	P = .350
	15.4	20		20	21	
	23	22		17	16	
	13.37-20.51	18.26-21.91		17.41-22.85	19.81-23.69	
	15	28		15	28	
<b>TWB</b>						
	77.2 ± 16.1	83.4 ± 13.0	P = .168	87.4 ± 14.4	90.3 ± 10.9	P = .693
	78	86		92	90.65	
	54	55		53	40.3	
	68.30-86.15	78.42-88.50		79.51-95.40	86.09-94.54	
	15	28		15	28	

Abbreviations: QoL, quality of life; CI, confidence interval; PWB, physical well-being; SWB, social well-being; EWB, emotional well-being; FWB, functional well-being; TVB, total well-being; Early Start, less than 1 year diagnosis and treatment; Late Start, over 1 year since diagnosis and treatment; P value, independent-samples Kruskal-Wallis test.

specifically related to breast cancer and oncologic treatment morbidity (ie, mobility, muscular strength, upper extremity flexibility, and balance).

**Mobility.** The Timed Up and Go (TUG) was performed according to the procedures originally described by Mathias et al.<sup>40</sup> Test-retest reliability has been reported as high (intraclass correlation coefficient [ICC] = 0.97) in elderly populations.<sup>41</sup> The Six-Minute Walk Test (6MWT) was administered according to the original procedures described in the American Thoracic Society guidelines.<sup>42</sup> High test-retest reliability (0.93) has been reported in patients with cancer.<sup>43</sup>

**Muscular strength.** Lower and upper body strength were assessed by 1 repetition maximum (1RM) using leg press

and chest press machines, respectively. The protocol for testing 1RM consisted of general warmup exercises for upper and lower extremities (3-4 minutes) followed by a demonstration of the chest and leg press. Each participant performed a low load chest press to verify correct position and technique. An initial load (20% to 30% body weight for chest press and 40% to 50% body weight for leg press) was performed for several repetitions. Participants then rated perceived exertion using the modified Borg scale (0-10). After 2 minutes of rest additional load was added based on RPE rating (lower rating = more load). This procedure was repeated until 1RM volitional maximum was achieved. A similar procedure was used to determine 1RM for leg press. High test-retest reliability of 1RM for leg press (0.99) and chest press (0.98) has been reported in untrained middle-aged individuals.<sup>44</sup>

**Upper extremity flexibility.** The back scratch test was used to assess upper extremity flexibility. It was performed in standing position by having participants reach over their head (arm external rotation and flexion) with their right hand and then reaching downward (fingers extended and palm facing toward their back) along their back toward the left hand (fingers extended and facing away from their back while reaching upwards toward the right hand), attempting to touch or overlap their fingers. The distance of overlap or space between the 2 middle fingers was measured as positive or negative, respectively. Participants performed this procedure 2 times, and the best measurement (greatest overlap = +; or least gap = -) of the 2 measurements was utilized as right back scratch. Similarly, participants performed the back scratch again this time using the left hand for reaching over their head and the right hand reaching around their back. This test was identified as the left back scratch. Right and left upper extremity flexibility values were then averaged for respective pre- and post-upper extremity flexibility values. Intraclass correlation coefficient for the back scratch test in female patients with fibromyalgia has been reported as 0.96.<sup>45</sup>

**Balance.** A Functional Reach test (FR) was performed as an assessment of balance according to procedures outlined by Duncan et al.<sup>46</sup> Excellent test-retest reliability has been reported for the FR in community-dwelling elderly (ICC = 0.92).<sup>46</sup> Single Leg Stance Time (SLST) was also used as a proxy measure of balance and was assessed by having each participant stand barefoot on a hard surface in a relaxed posture with their weight evenly distributed between their feet. Each participant then stood on their right leg, without using any assistance, for up to 60 seconds or until they placed their left foot back on the floor. Participants completed 2 trials unless their first trial was 60 seconds. The best time of the 2 trials was identified as right single leg stance time. Similarly, the single leg stance was performed again standing on the contralateral foot. Right and left single leg stance times were then averaged for respective pre- and post-single leg stance times. Clinically, the single leg stance has shown good reproducibility and reliability (ICC = 0.95) in elderly populations.<sup>47</sup>

### Statistical Analysis

Analyses were performed using SPSS version 23.0. Analyses of outcome measures were performed on all outcome measures where we had both pre- and post-assessments. In some cases participants did not complete a pre- or post-assessment and thus were excluded from analysis. For the primary analysis, the pre- and post-domains of QoL (PWB, SWB, EWB, FWB, and TWB) were tested for skewness and kurtosis using *z* tests. A *z* score was calculated by dividing the skew values and the excess kurtosis values by their respective standard

errors.<sup>48</sup> *Z* scores for either skewness or excessive kurtosis greater than 1.96 (0.05  $\alpha$  level) warranted rejection of the null hypothesis, and that the alternative hypotheses was accepted: the sample was not normally distributed.<sup>48</sup> Results from this analysis revealed that some of the pre- or post-well-being scores were either skewed or kurtotic. Therefore, related-samples Wilcoxon signed rank tests were used for pre- and post-comparisons to test the effects of the translational exercise program on QoL. Post hoc power and effects sizes (ES) were calculated using *G\*Power*.<sup>49</sup> Compensation for the use of nonparametric testing was performed by adjusting the number of subjects (determined by multiplying the actual number by 0.85) and using the resultant number of participants to calculate power.<sup>50</sup> Interpretation of ES was performed according to the original scales described by Cohen: 0.20 to 0.50 = "small to moderate"; 0.51 to 0.80 = "moderate to large"; and greater than 0.80 = "large."<sup>51</sup> Minimal clinically important differences (MCIDs) were determined for FACT-G scores based on published research by Eton et al, whereas a combination of distribution- and anchor-based approaches for endpoints in BC were used to determine other dependent variables MCIDs.<sup>52</sup> Eton et al reported a difference of 5 to 6 points as the range for the MCID for the total FACT-G score.<sup>52</sup> Also, Eton et al suggested the MCIDs for the well-being domains can be calculated by dividing the MCID estimates (5-6 points) by the total possible points in the FACT-G (104) to determine percentage range for MCIDs (5/104 = 4.8% and 6/104 = 5.8%).<sup>52</sup> The percentage range values (4.8% to 5.8%) can then be multiplied by the possible score for each FACT-G domain (PWB = 28 possible points; SWB = 24 possible points; EWB = 24 possible points; and FWB = 28 possible points) to represent domain-specific MCID ranges.<sup>52</sup>

To analyze whether start delay had an influence on physical function or QoL, normality testing for the early and late start groups were performed according to the same *z*-score procedure described above.<sup>48</sup> If the outcome measures were normally distributed, we performed independent *t* tests. If outcome measures were not normally distributed, we performed independent samples Kruskal-Wallis tests. We used null hypothesis testing (2-tailed) for all outcome measures. All data were tested for differences at an  $\alpha$  level of .05.

Summary of the data analyses are as follows: (1) to test for baseline differences in early versus late start, independent *t* tests or independent samples Kruskal-Wallis tests were performed; (2) within-group (pre/post) changes in QoL outcomes for all participants combined were analyzed using Wilcoxon signed rank tests (physical function not reported for all combined because previously those results have been published<sup>27</sup>); (3) the effect of early versus late start change was tested by stratifying early versus late start and then performing within-group tests (Wilcoxon signed rank tests or dependent *t* tests); and (4) difference scores were calculated for the pre/post assessments, which were

**Table 4.** Measurements of QoL (Well-Being) Pre- and Post-Community-Based Multimodal Exercise Program.

Measure	Pre	Post	Change	Power	P Value (2-Tail)	ES	MCID
<b>PWB</b>							
Mean ± SD	20.7 ± 5.2	24.1 ± 3.8	3.43 ± 4.3	1.00	P = .001	0.66	1.34-1.62
Median	21	28					
Range	19	18					
95% CI	19.09-22.27	22.94-25.28	2.09-4.77				
n	43	43	43				
<b>SWB</b>							
Mean ± SD	22.5 ± 5.2	23.2 ± 4.6	0.7 ± 6.2	0.20	P = .462	0.12	1.15-1.39
Median	23	24					
Range	21	17					
95% CI	20.88-24.07	21.74-24.56	1.25-2.59				
n	43	43	43				
<b>EWB</b>							
Mean ± SD	19.0 ± 3.2	20.4 ± 2.7	1.4 ± 3.2	0.83	P = .002	0.44	1.15-1.39
Median	20	21					
Range	11	11					
95% CI	18.00-19.99	19.56-21.24	0.40-2.40				
n	43	43	43				
<b>FWB</b>							
Mean ± SD	18.0 ± 5.5	21.2 ± 5.0	2.2 ± 4.0	0.94	P = .001	0.40	1.34-1.62
Median	20	21					
Range	24	17					
95% CI	17.29-20.69	19.64-22.72	0.96-3.43				
n	43	43	43				
<b>TWB</b>							
Mean ± SD	81.3 ± 14.3	89.3 ± 12.1	8.0 ± 9.8	1.00	P = .001	0.56	5.0-6.0
Median	85	92					
Range	57	56					
95% CI	76.88-85.68	85.59-93.04	5.03-11.04				
n	43	43	43				

Abbreviations: QoL, quality of life; ES, effect size; MCID, minimal clinically important difference; CI, confidence interval; PWB, physical well-being; SWB, social well-being; EWB, emotional well-being; FWB, functional well-being; TWB, total well-being; P value, Wilcoxon signed rank test for related samples.

then used to compare the early versus late start groups (using independent *t* tests or independent samples Kruskal-Wallis tests).

## Results

### Effects of the Community-Based Exercise on QoL

Primary analysis of QoL for all participants revealed there were statistically significant ( $P < .05$ ) differences in pre- and post-measurements for PWB, EWB, FWB, and TWB (Table 4). No significant ( $P > .05$ ) difference in SWB was detected. “Moderate to large” effect size improvements were found for PWB and TWB, while “small to moderate” effect sizes were found for EWB and FWB. The mean differences in PWB, EWB, FWB, and TWB were greater than their respective MCID ranges, which indicated the changes were clinically important.

### Influence of Start Delay on Physical Function and QoL

For the secondary analyses, examination of the influence of start delay on physical function showed there were no significant differences in pre- (baseline) and post-physical function between the early start and late start groups (Table 2). Analysis between the early start and late start groups for QoL indicated no significant group differences in either baseline or post-comparisons for the following well-being domains: PWB, SWB, FWB, and TWB (Table 3). However, the early start group had significantly ( $P < .05$ ) lower pre-EWB (17.3) compared to the late start group (19.9). There was no significant difference in post-EWB between the early start (20.2) and late start (20.5) groups.

Analyses for postintervention changes in physical function between the early start and late start groups revealed that no significant changes were detected between the groups (Table 5). No significant changes in PWB, SWB,



**Table 5.** Pre- and Post-Change Comparing Physical Function Between the Early Start and Late Start Groups.

	Early Start Change	Late Start Change	P Value (2-Tail); t Value
<b>TUG (seconds)</b>			
Mean ± SD	1.7 ± 1.5	1.2 ± 1.5	<i>P</i> = .274; <i>t</i> = 2.018
Median	1.15	1.0	
Range	6.1	7.04	
95% CI	1.0-2.38	0.63-1.79	
n	20	29	
<b>6MWT (meter)</b>			
Mean ± SD	72.1 ± 70.5	52.0 ± 56.6	<i>P</i> = .319; <i>t</i> = 2.039
Median	64.8	30	
Range	273.8	182	
95% CI	37.01-107.13	29.58-74.32	
n	18	28	
<b>Leg Press (kg)</b>			
Mean ± SD	24.1 ± 21.6	15.6 ± 13.9	<i>P</i> = .168; <i>t</i> = 2.048
Median	22.7	11.4	
Range	90.9	45.4	
95% CI	13.85-34.71	10.82-21.79	
n	19	27	
<b>Chest Press (kg)</b>			
Mean ± SD	9.1 ± 8.9	6.8 ± 7.4	<i>P</i> = .334; <i>t</i> = 2.034
Median	4.5	4.5	
Range	29.5	31.8	
95% CI	4.86-13.44	3.92-9.55	
n	19	27	
<b>Back Scratch (cm)</b>			
Mean ± SD	4.7 ± 11.1	5.2 ± 8.5	<i>P</i> = .294; independent-samples Kruskal-Wallis test
Median	2.22	3.8	
Range	50.8	32.0	
95% CI	0.88-10.19	2.60-7.80	
n	18	29	
<b>Functional Reach (cm)</b>			
Mean ± SD	5.0 ± 10.5	5.5 ± 6.9	<i>P</i> = .832; <i>t</i> = 2.06
Median	5.7	3.8	
Range	43.8	26.67	
95% CI	0.35-11.56	2.30-8.33	
n	16	22	
<b>SLST (seconds)</b>			
Mean ± SD	6.9 ± 12.2	6.2 ± 12.1	<i>P</i> = .787; <i>t</i> = 2.028
Median	2.5	3.65	
Range	58.5	62.7	
95% CI	0.78-12.94	1.31-10.43	
n	18	29	

Abbreviations: CI, confidence interval; TUG, Timed Up and Go Test; 6MWT, Six-Minute Walk Test; SLS, Single Leg Stance Test; Early Start, less than 1 year diagnosis and treatment; Late Start, over 1 year since diagnosis and treatment.

FWB, and TWB were detected between the early start and late start groups (Table 6). However, a statistically significant ( $P < .05$ ) improvement in EWB was detected in the early start group (Table 6). The ES for the improvement in EWB for the early start group was “large” (0.88). The early

start group had a 2.8-point improvement in EWB, which was greater than the calculated MCID range (1.15-1.39), which suggests a clinically important improvement in EWB had occurred in the early start group. No significant change in EWB was detected for the late start group.

**Table 6.** Pre- and Post-Change Comparing QoL (Well-Being) Between the Early Start and Late Start Groups.

	Early Start Change	Late Start Change	P Value (2-Tail)
<b>PWB</b>			
Mean ± SD	4.4 ± 5.4	2.9 ± 3.7	<i>P</i> = .630
Median	3.0	2	
Range	19	16	
95% CI	1.36-7.37	1.51-4.34	
n	15	28	
<b>SWB</b>			
Mean ± SD	0.24 ± 6.4	0.90 ± 4.3	<i>P</i> = .627
Median	0	0	
Range	26	23.9	
95% CI	-3.31 to 3.80	-0.76 to 2.56	
n	15	28	
<b>EWB</b>			
Mean ± SD	2.8 ± 2.4	0.6 ± 3.4	<i>P</i> = .010
Median	3	0.6	
Range	8	16	
95% CI	1.50-4.10	-0.68 to 1.96	
n	15	28	
<b>FWB</b>			
Mean ± SD	3.2 ± 4.1	1.7 ± 3.9	<i>P</i> = .307
Median	3	1.5	
Range	15	17	
95% CI	0.92-5.50	0.142-3.18	
n	15	28	
<b>TWB</b>			
Mean ± SD	10.2 ± 12.9	6.9 ± 7.6	<i>P</i> = .878
Median	4.8	5.4	
Range	42.2	28.2	
95% CI	3.10-17.36	3.90-9.81	
n	15	28	

Abbreviations: QoL, quality of life; CI, confidence interval; PWB, physical well-being; SWB, social well-being; EWB, emotional well-being; FWB, functional well-being; TWB, total well-being; Early Start, less than 1 year diagnosis and treatment; Late Start, over 1 year since diagnosis and treatment; *P* value, independent-samples Kruskal-Wallis test.

## Discussion

The principle findings in this study are the following: (1) for the complete cohort of BCS the post-outcome measures of QoL (PWB, EWB, FWB, and TWB) were significantly ( $P < .05$ ) higher compared to pre-intervention scores; (2) no significant differences ( $P > .05$ ) were detected between the early start and late start groups for physical function (Mobility: TUG, 6MWT; Strength: leg press strength and chest press strength; Upper Extremity Flexibility: back scratch measurement; and Balance: FR and SLST); (3) no significant differences were detected in PWB, FWB, and TWB between the early start and late start groups; and (4) a significant ( $P < .05$ ) improvement in EWB in the early start group was detected.

Although BCS showed significant improvements in QoL after participating in this community-based exercise program, careful interpretation of these results are warranted. Due to this being a community-based cancer survivor exercise program and we studied those BCS who volunteered to participate, we did not have any randomization nor a control group. Therefore, time was the independent variable and may have played a role in the improvements in QoL. This study was a translational investigation and we did not have a control group; therefore, conclusions cannot be made that are directed toward cause and effect. The design of this study was to test change in the outcomes during the intervention, and this design does not determine the effects of the intervention since other factors may have contributed to the change. We can only say that improvements were detected in the post-assessments of QoL.

Closer examination of the domains of well-being revealed that the 17% improvement in post-PWB (3.43) was greater than the MCID range (1.34-1.62); hence, this may be a clinically important improvement (Table 4). Additionally, the ES improvement in PWB was “moderate to large” (0.66). This finding makes sense in that the exercise program primarily focused on physical exercise and not necessarily the other domains of well-being. The improvement in PWB (3.43) is of similar magnitude to the improvement in PWB (2.9) found after participating in a community-based exercise program for any cancer survivor.<sup>26</sup> Statistically significant improvements in EWB (7.4%), FWB (12%), and TWB (10%) were detected, and all of these improvements were greater than their respective MCIDs.

Comparison of the changes in QoL in the present investigation with other community-based exercise programs for cancer survivors is difficult due to the diversity of exercise programs and variations of outcome measures for assessing for QoL. Nonetheless, general comparison of the present findings for QoL improvements are in accord with the results from a systematic review and meta-analysis regarding the effects of exercise on improving health-related QoL (HRQoL) in cancer survivors, which reports exercise has a positive impact on HRQoL in cancer survivors.<sup>53</sup>

With respect to the secondary aims to assess the influence of start delay on physical function and QoL, we did not detect any significant differences in any of the baseline outcome measures for physical function between the early start and late start groups (Table 2). Similarly, between-groups comparison did not reveal any significant differences in post-assessments for physical function. Between-groups comparison for changes in physical function revealed there were no significant ( $P > .05$ ) differences detected between the early and late start groups (Table 5). We have already published the significant ( $P < .05$ ) improvements in these physical function outcome measures in these BCS.<sup>27</sup> Considering that these BCS made significant improvements

in physical function as noted in the previously published study and there were no significant ( $P > .05$ ) differences in the improvements for physical function between the early and late start groups in the present study, it can be surmised that improvements in physical function may not be affected by this start delay. Again, we did not utilize a control group so no cause and effects can be determined, only an improvement was detected. Also, the BCS who participated in this community-based exercise program had no major adverse events while exercising. From these results, we advocate support for community-based exercise programming for BCS for improving physical function. Additionally, because we did not detect any significant differences in physical function between the early and late start groups, we propose that this start delay may not have negatively affected improvements in physical function outcome measures related to breast cancer morbidity (mobility, strength, upper extremity flexibility, and balance). Likewise, because we studied volunteer BCS enrolled in a community-based cancer survivor exercise program, these BCS may not represent other BCS. Similarly, because we defined start delay as over 1 year since active oncologic treatment, these results may not represent other start delays.

As to the influence of start delay on QoL, no significant ( $P > .05$ ) differences in baseline assessments of PWB, SWB, FWB, and TWB were detected (Table 3). However, the early start group had significantly ( $P < .05$ ) lower baseline EWB (13%) compared to the late start group. Perhaps this is to be expected as the early start group was earlier in their cancer survivorship. Only the early start group had a significant ( $P < .05$ ) change in EWB (16% improvement). Perhaps explanation of the lack of improvement in EWB for the late start group was they may have experienced a “ceiling effect.” For the early start group, the ES for EWB improvement was “large” (0.88) and the mean change for EWB (2.8) was greater than the MCID range (1.15-1.39). Interpretation of this can be the improvement in EWB for the early start group was clinically important. Again, we cannot attribute the improvement in EWB in the early start group to the exercise program, as we did not have a control group for comparison.

## Clinical Relevance and Conclusions

Cancer survivors are living longer and many have amenable impairments in QoL and physical function. There is strong evidence supporting that exercise training is safe for cancer survivors during and after oncologic treatment and exercise training can positively improve physical function and QoL in cancer survivors.<sup>15,53</sup> There is a call to action for more support toward development of cancer survivorship exercise programming, as well as better program description that includes FITT-VP exercise parameters.<sup>35</sup> We believe that we have adequately described this exercise program

and included FITT-VP parameters to enable better identification of exercise parameters likely to stimulate improvements in QoL and physical function for cancer survivors. Specifically, the types of exercise modes in the present study were chosen specifically to rehabilitate the major likely physical impairments (mobility, strength, upper extremity flexibility, and balance) associated with breast cancer and oncologic treatment. We think the carefully chosen outcome measures in this study can provide field test measurements for assessing likely impairments associated with breast cancer and oncologic treatment morbidity for nonclinical applications. The totality of this should help support “real-world” translational community-based exercise programming for cancer survivors.

The majority of high-quality research in this area is focused on clinical exercise trails; consequently, there is a great need for translational research on “real-world” cancer survivor exercise programming. We believe this investigation describes a community-based exercise program that was developed from applied exercise science and clinical cancer research regarding the benefits of exercise for cancer survivors and attempts to start to bridge a gap between clinical research and community applications for exercise programming for cancer survivors. Additionally, a particular strength of this study is that this investigation is the only study we are aware of that attempts to investigate the influence of a start delay for community-based exercise programming for cancer survivors on physical function and QoL in BCS. However, recognizing the small sample size and no control group, we only propose to encourage BCS to participate in community-based exercise programming regardless of start delay. Future research with cause and effect research designs can better answer whether start delays for participating in community-based exercise programming affects improvement in physical function and QoL in BCS and other cancer survivors with other cancer types.

## Study Limitations

Throughout the discussion, we have attempted to discuss limitations of this study where they were relevant to specific topic discussion. Summary of the limitations are as follows: no control group and no randomization, so results cannot be interpreted as cause and effect and may not apply to all BCS. This was a community-based cancer exercise program and we solicited volunteer cancer survivors for participation from cancer survivors who were going to participate in the exercise program; therefore, this sample may not represent BCS as a whole. Another limitation of this study was the small sample size particularly after start delay stratification and the variability of start delay within the groups. Also, we did not assess potential covariates (eg, race, ethnicity, income, education); therefore, the generalizability of these results is limited. The outcome measures for

assessing QoL and physical function may not be sensitive enough to assess influence of start delay. We did not assess the breast cancer subscale B of the FACT; consequently, we cannot address any subscale domains specific for BCS. Further research may attempt to address some of these limitations. Recognizing the limitations, we propose this study provides translational research support for community-based exercise programming for cancer survivors.

### Authors' Note

Eydie Kendall is now affiliated to Plymouth State University, Plymouth, NH, USA.

### Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

### Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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