

# Can Counseling Add Value to an Exercise Intervention for Improving Quality of Life in Breast Cancer Survivors? A Feasibility Study

Fiona Naumann, PhD; Eric Martin, Masters; Martin Philpott, PhD; Cathie Smith, Masters; Diane Groff, PhD; and Claudio Battaglini, PhD

**B**reast cancer is the most common cancer experienced by women.<sup>1</sup> Advances in breast cancer detection and targeted treatment have resulted in an increased number of women surviving the disease, with a 5 year survival rate of 89%.<sup>1</sup> Unfortunately, survival can be associated with lingering physiological and psychological side effects that can persist for many years, compromising the survivors' overall quality of life (QOL).<sup>2-6</sup>

Exercise is known to be beneficial to the recovery of women with cancer by reducing treatment-related side effects and improving the physical and emotional aspects of well-being.<sup>7-18</sup> There is extensive research examining the benefits of exercise in the breast cancer population, including improved physical fitness, improved QOL, reduced depression and trait anxiety over time, reduced fatigue, and lessening of other side effects associated with treatment.<sup>7-14</sup> Further-

**Author Affiliations:** The School of Medical Sciences, Faculty of Medicine, The University of New South Wales, Randwick, Australia (Dr Naumann); School of Health Science (Mr Martin), School of Arts, Science and Counselling (Dr Philpott and Ms Smith), The University of Notre Dame Australia, Fremantle Campus, Fremantle, Australia (Mr Martin); the Department of Exercise and Sport Science (Drs Groff and Battaglini) and the Lineberger Comprehensive Cancer Center (Dr Battaglini), University of North Carolina at Chapel Hill, Chapel Hill, North Carolina.

**Submitted for Publication:** January 25, 2011; accepted September 1, 2011.

**Published Online:** Dec 13, 2011 (doi: 10.1016/j.suponc.2011.09.004)

**Correspondence Author:** Fiona Naumann, PhD, The University of New South Wales, Level 1, South Wing, Edmund Blackett Building, Prince of Wales Hospital, Randwick, NSW, Australia, 2031 (f.naumann@unsw.edu.au).

J Support Oncol 2012;10:188-194 © 2012 Elsevier Inc. All rights reserved. doi:10.1016/j.suponc.2011.09.004

## ABSTRACT

**Background:** Improved survivorship has led to increased recognition of the need to manage the side effects of cancer and its treatment. Exercise and psychological interventions benefit survivors; however, it is unknown if additional benefits can be gained by combining these two modalities.

**Objective:** Our purpose was to examine the feasibility of delivering an exercise and counseling intervention to 43 breast cancer survivors, to determine if counseling can add value to an exercise intervention for improving quality of life (QOL) in terms of physical and psychological function.

**Methods:** We compared exercise only (Ex), counseling only (C), exercise and counseling (ExC), and usual care (UsC) over an 8 week intervention.

**Results:** In all, 93% of participants completed the interventions, with no adverse effects documented. There were significant improvements in VO<sub>2</sub>max as well as upper body and lower body strength in the ExC and Ex groups compared to the C and UsC groups ( $P < .05$ ). Significant improvements on the Beck Depression Inventory were observed in the ExC and Ex groups, compared with UsC ( $P < .04$ ), with significant reduction in fatigue for the ExC group, compared with UsC, and no significant differences in QOL change between groups, although the ExC group had significant clinical improvement.

**Limitations:** Limitations included small subject number and study of only breast cancer survivors.

**Conclusions:** These preliminary results suggest that a combined exercise and psychological counseling program is both feasible and acceptable for breast cancer survivors and may improve QOL more than would a single-entity intervention.

more, evidence from recent longitudinal cohort studies has demonstrated positive associations between posttreatment physical activity and additional breast cancer events and survival, as well as significantly lower mortality in survivors who engaged in moderate to high physical activity levels (8-9 metabolic equivalent

[MET] hours/week) compared with low activity or no activity.<sup>15–19</sup>

However, exercise may not assist in all survivors' needs, particularly fear of recurrence and uncertainty for the future. Psychological interventions may be more appropriate to meet these needs. Various psychological interventions and a recent meta-analysis have examined the effectiveness of various psychosocial interventions in breast cancer patients. These findings concluded that interventions improved coping or control skills, lessened depressive and anxiety symptoms, improved emotional well-being, increased fighting spirit, and improved health and well-being.<sup>18–21</sup>

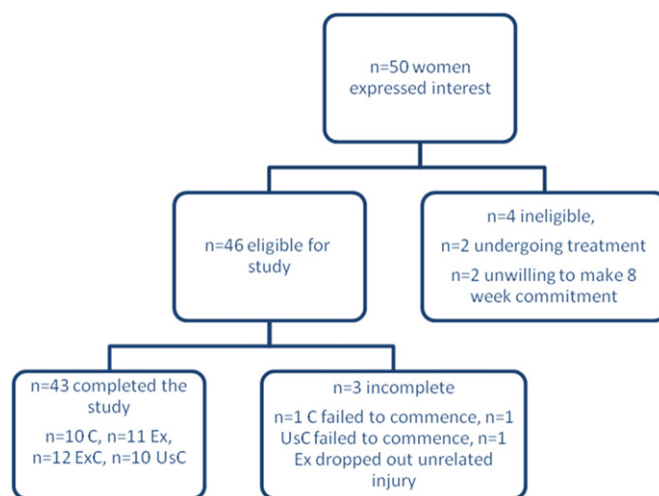
Despite the evidence showing the efficacy of both modes of intervention, the majority of the research has examined the benefits of a single modality.<sup>7–14</sup> Research is needed to identify if a multimodal approach can further enhance recovery from breast cancer and its treatment. The aim of this research was to examine if a multimodal approach to cancer rehabilitation is well tolerated by breast cancer survivors and effective at improving QOL and other physical and psychological parameters in breast cancer survivors than either single modality approach.

## METHODS

This study utilized a randomized 4 group design consisting of a psychological counseling-only group (C; n = 10), an exercise-only group (Ex; n = 11), a combined exercise and psychological counseling group (ExC; n = 12) and a usual care group (UsC; n = 10) of breast cancer survivors. Participants were randomized to each group on a rolling enrollment basis. The study was approved by the Human Ethics Committee of the University of Notre Dame, South Bend, Ind., and all participants provided written informed consent.

Feasibility was assessed through recruitment and retention rates, session attendance, and adherence to the exercise and counseling program. Adherence was monitored by the exercise trainers and counselors in the patient training log. An exit interview was also utilized to record patient satisfaction with the program and to capture qualitative data.

Eligibility criteria included females with confirmed stage I–III invasive breast cancer who were within 12 months of treatment completion (except hormone therapy), were aged 35–70 years, were sufficiently fluent in English, and were either not participating in structured regular exercise or nutrition programs in the last 6 months or currently not meeting the American College of Sports Medicine guidelines for adequate physical activity (< 150 min per wk). Exclusion criteria included acute or chronic bone, joint, or muscular abnormalities that would compromise the patient's ability to participate in exercise; immune deficiency that would compromise the patient's ability to participate in exercise; failure of the Physical Activity Readiness Questionnaire;<sup>22</sup> or presence of metastatic disease. Baseline data collection included demographic data, precancer physical activity levels, cancer treatment, current medication, and a battery of psychological



**Figure** Consort Diagram Illustrating Subject Recruitment, Eligibility, Study Completion, and Dropouts

and physiological protocols. The outcome measures were assessed at baseline and postintervention at 8 weeks.

The psychological measures included Functional Assessment of Cancer Therapy–Breast (FACT-B) quality of life scale,<sup>23,24</sup> Piper Fatigue Scale (PFS),<sup>25</sup> and Beck Depression Inventory (BDI).<sup>26,27</sup> Increases in FACT-B scores of 7–8 points represent a clinically significant change. Total scores on the PFS of less than 3 represent no or mild fatigue, scores of 3–6 represent moderate fatigue, and scores greater than 6 represent severe levels of fatigue. A change of 3–4 points in the fatigue score represents a clinically significant change in fatigue.<sup>27</sup> Total BDI scores are 0–13 (minimal range), 14–19 (mild), 20–28 (moderate), and 29–63 (severe symptoms).<sup>27</sup> A 5-point difference corresponded to a minimally important clinical difference.<sup>28</sup>

The physiological assessments included height (wall-mounted stadiometer), weight (A&D Weighing, San Jose, CA), body mass index (BMI) utilizing the equation weight kg/height<sup>2</sup> (m<sup>2</sup>), and body composition via a 7-site skinfold measurement (triceps, chest, subscapular, midaxilla, abdomen, suprailiac, and thigh).<sup>29</sup> Cardiorespiratory endurance was assessed using the Modified Bruce Treadmill Protocol, a multistage, variable speed and elevation treadmill test used to estimate VO<sub>2</sub>max.<sup>30</sup> The YMCA bench press test was utilized to estimate upper-body muscular strength, and a one-repetition maximum (1-RM) leg press test was utilized to assess lower-body dynamic strength, using a seated leg press set at a 45-degree angle.<sup>31</sup>

Subjects in the exercise group participated in 8 weeks of individualized exercise training, three times per week, for 45–60 minutes. The target goal for each participant was 150 minutes per week of moderate-intensity physical activity, that met the American College of Sports Medicine guidelines.<sup>31</sup> Each exercise program was individualized according to baseline health and fitness levels and personal goals. An accredited exercise physiologist delivered the exercise sessions, including car-

**Table 1**

Baseline Demographic Characteristics, Diagnosis, and Treatment According to Group (n = 43)

CHARACTERISTIC	COUNSELING (n = 10)		EXERCISE (n = 11)		EXERCISE & COUNSELING (n = 12)		USUAL CARE (n = 10)		P
Age (years)	55.1	±7.5	49.0	±10.0	49.0	±8.2	51.8	±11.5	.402
Height (cm)	164.2	±6.7	167.4	±5.4	163.3	±4.2	164.2	±7.7	.417
Cancer stage	2.20	±0.63	1.91	±0.83	1.83	±0.39	2.00	±0.67	.592
Months posttreatment	2.30	±2.11	5.36	±5.01	8.75	±6.58	7.6	±5.40	.032
Chemotherapy	9	90%	8	73%	9	75%	6	60%	.507
Radiation	5	62.5%	9	90%	9	75%	5	50%	.197
Surgery									.360
Mastectomy	2	25%	5	50%	7	58%	4	40%	
Lumpectomy	6	75%	4	40%	4	33%	6	60%	
No Treatment	0	0%	1	10%	1	8%	0	0%	
Hormones									.143
Tam	8	80%	9	82%	9	75%	5	50%	
AI	1	10%	2	18%	3	25%	5	50%	
None	1	10%	0	0%	0	0%	0	0%	
8-week exercise compliance	NA	—	86.0%	±8.9	80.6%	±16.3	NA	—	.362
8-week counseling compliance	84.6%	±10.9	NA	—	88.3%	±9.8	NA	—	.440

ANOVA difference between groups for age, height, cancer stage, months posttreatment, 8-week exercise compliance, and 8-week counseling compliance.

Chi squares were used to test difference in chemotherapy, radiation, surgery, and hormone therapy.

Months post treatment Tukey post hoc analysis: ExC significantly longer out than C ( $P < .028$ ).

diovascular training, strength training, patient-specific rehabilitation, core training, and flexibility.

Participants who underwent psychological counseling met with an accredited counselor for a 1 hour session once a week for 8 weeks. The counselor employed a client centered therapy approach based on the individual needs of each participant, whereby they facilitated disclosure of feelings and anxieties, clarified issues, and provided reassurance and support for the women as required. The general themes covered were: having cancer and the implications, stress, distress, uncertainty, fear and anxiety, body image, family relationships, intimacy, hopefulness, and future focus. Subjects in the UsC group did not participate in any exercise or counseling during the 8 weeks.

At the completion of the intervention, all subjects participated in an exit interview with the program manager. The exit interview allowed the staff to provide feedback to participants on their progress, gain feedback from the participants on the program, and help identify if they would need and want to seek further professional help.

### Statistical Analysis

This study used intention-to-treat analyses to include baseline characteristics of subjects who dropped out. For demographic and medical characteristics, analyses of variance (ANOVAs) were used to assess differences between groups for age, height, cancer stage, months posttreatment, and exercise and counseling compliance rates. Chi-squared tests were used to assess if there were significant differences between groups in frequency of treatment use. An ANOVA revealed a significant difference between groups on months posttreatment.

This factor was used as a covariate when comparing baseline outcome measures and change in outcome measures. Additionally, due to the small sample size in this pilot study, baseline values were used as covariates for all change scores. Analyses of covariance (ANCOVAs) were used to assess change in outcome measures, with post hoc analyses conducted via Bonferroni tests that were adjusted for multiple comparisons. All statistical analyses were done on the computer program SPSS (v18) (SPSS, Inc., Chicago, IL), and all statistical significance was carried out at  $P < .05$ .

### RESULTS

In all, 50 participants were recruited from oncology specialists and cancer support groups, as illustrated in Figure. An aspect of feasibility is attrition. Of the 46 women who enrolled in the study, 43 completed the study, representing a 7% attrition rate or, conversely, a 93% rate of retention. The three women who dropped out after randomization had their baseline data included in the intention-to-treat analysis.

At baseline, no significant differences existed among groups for demographic characteristics, cancer stage, cancer treatment, and exercise or counseling compliance (Table 1). Participants completed an average of 84% of all scheduled exercise sessions and 87% of all scheduled counseling sessions, with no significant differences among groups. There were no adverse reactions to participation in the exercise or counseling intervention.

There was no significant difference at baseline among groups for height, weight, BMI, or percent body fat (Table 2). There was no significant difference among groups for change in weight, BMI, or percentage of body fat across the intervention.

**Table 2**

Change in Body Composition at 8 Weeks (n = 43)

CHARACTERISTIC	GROUP	BASELINE		8-WEEK CHANGE	
		ADJUSTED MEAN	STANDARD ERROR	ADJUSTED MEAN	STANDARD ERROR
Body weight (kg)	C	67.1	4.45	0.12	0.48
	Ex	76.0	3.98	0.45	0.40
	ExC	74.0	3.95	-0.54	0.38
	UsC	73.6	4.21	0.23	0.45
<i>P</i>		.521		.607	
BMI (kg/m <sup>2</sup> )	C	24.9	1.68	-0.1	0.18
	Ex	27.3	1.50	0.1	0.15
	ExC	27.5	1.49	-0.2	0.14
	UsC	27.4	1.59	0.1	0.17
<i>P</i>		.579		.208	
Body fat (%)	C	33.4	2.52	0.8	0.87
	Ex	32.2	2.12	-0.3	0.73
	ExC	32.9	2.11	-1.3	0.69
	UsC	33.1	2.51	0.6	0.82
<i>P</i>		.918		.116	

All baseline scores were compared via ANCOVA, factoring in months post treatment as a covariate, with months adjusted to 6.12 for all groups.

All delta scores were compared via ANCOVA, factoring in the baseline score and months post treatment as covariates, with months adjusted to 6.12 for all groups.

At baseline, there was no significant difference between groups for upper body strength, lower body strength, and estimated VO<sub>2</sub>max (Table 3). At the completion of the intervention, there was a significant difference between groups for change in upper body strength, lower body strength, and VO<sub>2</sub>max. Bonferroni post hoc analyses revealed that the Ex group significantly improved their upper body strength compared to the C ( $P < .000$ ) and UsC ( $P < .000$ ) groups as well as their estimated VO<sub>2</sub>max compared to C ( $P < .002$ ). The ExC group significantly improved upper body strength compared to C ( $P < .000$ ) and UsC ( $P < .001$ ) and their VO<sub>2</sub>max compared to C ( $P < .003$ ).

At baseline, no significant differences existed between groups for depressive symptoms (Table 4). After 8 weeks, ANCOVA indicated significant differences for change in BDI between groups. Reductions in BDI were observed in the Ex group (3.6 points) and the ExC group (3.9 points). Minimal changes in BDI were observed in the C group, with the BDI increasing in the UsC group. Bonferroni post hoc analyses indicated a significantly greater reduction in depression profiles in the Ex group compared to UsC ( $P < .045$ ) and in the ExC group compared to UsC ( $P < .048$ ).

At baseline, there was a significant baseline difference in PFS total score. Bonferroni post hoc analyses revealed significant differences for total PFS score between the C and Ex groups ( $P < .025$ ). Changes in overall fatigue scores were analyzed via ANCOVA, indicating significant differences in change in overall fatigue levels. Bonferroni post hoc indicated there was only a significant difference between ExC and UsC on overall fatigue ( $P < .003$ ).

**Table 3**

Change in Aerobic Fitness and Strength in Response to the Interventions at 8 Weeks (n = 43)

CHARACTERISTIC	GROUP	BASELINE		8-WEEK CHANGE	
		ADJUSTED MEAN	STANDARD ERROR	ADJUSTED MEAN	STANDARD ERROR
Bench press (kg)	C	15.6	4.34	-4.3	1.76
	Ex	14.3	3.67	7.9	1.47
	ExC	16.2	3.65	7.1	1.39
	UsC	14.5	4.33	-1.8	1.66
<i>P</i>		.996		.000	
Leg press (kg)	C	72.5	6.80	1.3	4.6
	Ex	71.7	5.74	7.7	3.8
	ExC	85.6	5.71	17.0	3.8
	UsC	66.6	6.78	3.5	4.4
<i>P</i>		.260		.019	
VO <sub>2</sub> max (mL · kg <sup>-1</sup> · min <sup>-1</sup> )	C	29.1	2.00	-2.2	1.02
	Ex	31.9	1.68	3.1	0.86
	ExC	33.0	1.68	3.2	0.82
	UsC	28.4	2.00	-0.1	0.98
<i>P</i>		.338		.001	

All baseline scores were compared via ANCOVA, factoring in months posttreatment as a covariate, with months adjusted to 6.12 for all groups.

All delta scores were compared via ANCOVA, factoring in the baseline score and months posttreatment as covariates, with months adjusted to 6.12 for all groups.

ΔBench press at 8 weeks ( $P < .000$ ); Bonferroni post hoc: Ex vs C ( $P < .000$ ); Ex vs UsC ( $P < .000$ ); ExC vs C ( $P < .000$ ); ExC vs UsC ( $P < .001$ ).

ΔLeg press at 8 weeks ( $P < .019$ ); Bonferroni post hoc: no pairwise comparison significant; ΔVO<sub>2</sub> at 8 weeks ( $P < .001$ ); Bonferroni post hoc: Ex vs C ( $P < .002$ ); ExC vs C ( $P < .003$ ).

At baseline, no significant differences existed for QOL profiles between groups (Table 5). At the completion of the intervention, ANCOVA revealed significant differences in change in overall QOL ( $P < .004$ ) and in the Physical ( $P < .000$ ), Emotional ( $P < .000$ ), and Functional ( $P < .000$ ) Well-Being scales between groups. The ExC group reported the greatest improvement in QOL compared to the single modalities, with more than twice the increase compared to the Ex group and more than 7 times that of the UsC and C groups. Bonferroni post hoc analysis revealed that the overall QOL difference between the ExC and C groups ( $P < .063$ ) did not reach significance but there was a significant difference in the emotional well-being subscale between the ExC and UsC groups ( $P < .006$ ), and the ExC and C groups ( $P < .001$ ).

Major findings from the exit interview were that the program provided the participants with support, that the intervention was delivered with the utmost professionalism, and that the participants particularly liked the individual nature of the program. All participants either agreed or strongly agreed that they derived physical and emotional benefits from the program, including feeling fitter, stronger, more organized, and they had regained control in their life. One important description revealed by some of the women in the exit interviews was that undergoing the counseling made them realize

**Table 4**

Change in Beck Depression Inventory (BDI) and Piper Fatigue Scale (PFS) at 8 Weeks for All Groups (n = 43)

CHARACTERISTIC	GROUP	BASELINE		8-WEEK CHANGE	
		ADJUSTED MEAN	STANDARD ERROR	ADJUSTED MEAN	STANDARD ERROR
BDI	C	15.3	3.10	-0.3	1.51
	Ex	11.7	2.71	-3.6	1.31
	ExC	15.0	3.03	-4.0	1.48
	UsC	8.91	2.89	2.0	1.44
<i>P</i>		.360		.017	
PFS	C	5.80	0.64	-1.43	0.47
	Ex	3.30	0.54	-0.69	0.40
	ExC	5.06	0.53	-1.90	0.36
	UsC	3.90	0.60	0.26	0.43
<i>P</i>		.031		.000	

Baseline scores were compared via ANCOVA, factoring in months post treatment as a covariate, with months adjusted to 6.12 for all groups.  
 ANCOVA baseline PFS (*P* < .031); Bonferroni post hoc: C vs Ex (*P* < .025).  
 Delta scores were compared via ANCOVA, factoring in the baseline score and months posttreatment as covariates, with months adjusted to 6.12 for all groups.  
 ΔBDI at 8 weeks (*P* < .017); Bonferroni post hoc: Ex vs UsC (*P* < .045); ExC vs UsC (*P* < .048).  
 ΔPFS at 8 weeks (*P* < .000); Bonferroni post hoc: ExC vs UsC (*P* < .003).

that they had been avoiding and blocking out some of their unresolved feelings that lingered after treatment completion.

**DISCUSSION**

This pilot study provided preliminary information on the feasibility and effectiveness of a multimodal rehabilitation program for breast cancer survivors, incorporating both exercise and psychological counseling, for improving physiological function, QOL, depressive symptoms, and fatigue. Overall, exercise plus counseling was an acceptable and feasible intervention for this breast cancer population, with the exercise program adherence averaging 80% and the psychological counseling intervention averaging 83% adherence. Objective data further supported its feasibility, with 89% of the participants completing the program.

Albeit small, the ExC group improved body composition, losing an average of 1.3% of body fat in 8 weeks. In contrast, those in the C and UsC groups gained a small amount of body fat. Although the changes in percentage of fat were not significant, the gain was worth noting in relationship to possible longer-term trends that were identified by Caan et al.<sup>32</sup> Weight gain after breast cancer diagnosis has been associated with earlier recurrence and shorter survival.<sup>33</sup> Obesity appears to double the risk of recurrence and death among breast cancer survivors, and this adverse association remains, irrespective of menopausal status and adjustment for stage of treatment.<sup>34</sup>

At the completion of the intervention, the exercise training groups improved their upper body strength compared to the C/UsC groups. Surprisingly, for lower body strength, despite the overall ANCOVA suggesting a significant difference

**Table 5**

Change in Functional Assessment of Cancer Therapy-Breast (FACT-B) and Subscales at 8 Weeks for All Groups (n = 43)

CHARACTERISTIC	GROUP	BASELINE		8-WEEK CHANGE	
		ADJUSTED MEAN	STANDARD ERROR	ADJUSTED MEAN	STANDARD ERROR
FACT-B total	C	92.7	8.12	-0.03	4.03
	Ex	102.5	6.85	6.8	3.37
	ExC	97.9	6.80	14.5	3.20
	UsC	104.5	7.64	3.1	3.60
<i>P</i>		.746		.004	
Physical Well-Being (PWB)	C	18.7	2.00	0.8	1.18
	Ex	21.5	1.68	1.9	0.99
	ExC	19.4	1.67	4.2	0.94
	UsC	22.9	1.88	0.8	1.07
<i>P</i>		.365		.000	
Emotional Well-Being (EWB)	C	15.4	1.88	-1.5	0.97
	Ex	18.5	1.59	1.0	0.81
	ExC	17.1	1.58	4.1	0.76
	UsC	18.8	1.77	-0.1	0.86
<i>P</i>		.673		.000	
Social Well-Being (SWB)	C	20.2	2.22	0.8	1.19
	Ex	20.2	1.87	0.9	1.00
	ExC	20.9	1.85	-0.01	0.94
	UsC	22.3	2.08	-0.2	1.05
<i>P</i>		.934		.600	
Functional Well-Being (FWB)	C	16.4	2.78	-0.8	1.60
	Ex	18.8	2.34	1.5	1.33
	ExC	19.9	2.32	2.0	1.26
	UsC	19.6	2.61	0.5	1.42
<i>P</i>		.908		.000	
Additional Concerns (AC)	C	21.7	2.12	-1.0	1.38
	Ex	24.2	1.79	1.6	1.16
	ExC	20.9	1.78	2.7	1.10
	UsC	20.8	2.00	2.3	1.22
<i>P</i>		.408		.055	

All baseline scores compared via ANCOVA, factoring in months posttreatment as a covariate, with months adjusted to 6.12 for all groups.  
 All delta scores compared via ANCOVA, factoring in the baseline score and months post-treatment as covariates, with months adjusted to 6.12 for all groups.  
 ΔFACT-B at 8 weeks (*P* < .004), Bonferroni post hoc: no pairwise comparison significant; trend toward difference in C vs ExC (*P* < .06).  
 ΔPWB at 8 weeks (*P* < .000), Bonferroni post hoc: no pairwise comparison significant.  
 ΔEWB at 8 weeks (*P* < .000), Bonferroni post hoc: ExC vs C (*P* < .001), ExC vs UsC (*P* < .006).  
 ΔFWB at 8 weeks (*P* < .000), Bonferroni post hoc: no pairwise comparison significant.

among groups (*P* < .019), Bonferroni post hoc tests revealed no significant differences. This is likely due to the large, though nonsignificant (*P* < .260), baseline difference among the groups, which was factored in as a covariate. The exercise training groups also improved predicted maximum oxygen consumption of a magnitude of 3.1 to 3.2 mL · kg · min<sup>-1</sup>,

equivalent to about 10%. This finding was in contrast to the C or UsC group, which reported slight declines in cardiorespiratory fitness. These findings are consistent with a meta-analysis of other exercise intervention studies,<sup>14</sup> which reported a mean increase of  $3.39 \text{ mL} \cdot \text{kg} \cdot \text{min}^{-1}$  in response to exercise, equivalent to almost one MET improvement in fitness. Improvement in cardiorespiratory fitness was a positive finding from this study, especially as aerobic fitness is an established predictor of disease risk and mortality.<sup>35</sup>

Reductions in depressive symptoms favored the two exercise groups (Ex, ExC), with BDI scores decreasing 3.6 and 4.0 points, respectively. This reduction in depressive symptoms approached the 5-point difference, corresponding to a minimally important clinical difference.<sup>28</sup>

The ExC group reduced their depression symptom inventory scores from 15.0 (mild depression) to 11 (normal range). Although the scores were not significantly different at baseline, the ExC group did commence the study with the highest depression inventory, with mild depression symptoms and possibly more to gain from the intervention than did those groups starting with lower depressive symptom scores. Surprisingly, the C group exhibited minimal changes in depressive scores. One possible explanation was raised in the exit interviews: The counseling process brought up issues that many women were possibly suppressing to protect themselves and those around them. A main focus of the counseling was reframing and developing better coping strategies. However, a focus on the women's problems, even with the aim of relieving the anxiety and depression associated with them, may have increased the women's awareness of their psychological and emotional struggles. This self-confrontation may have led to greater feelings of depression in the short term, which could have been alleviated after continued practice of coping strategies taught to the women by the counselor throughout the intervention. A notable finding from this study was that the greatest reduction in depressive symptoms was observed in the multimodal group that engaged in both exercise and counseling, which would certainly be recommended as a more comprehensive approach. The improvement seen in the ExC group may indicate that simultaneously participating in exercise plus counseling provides a coping mechanism for the women, with the exercise acting as an outlet to relieve depression and increase levels of dopamine and serotonin, hormones that are associated with depression.

The intervention also revealed reductions in self-reported fatigue in the C, Ex, and ExC groups compared, with those in UsC, with significant reductions reported in ExC, compared with UsC. The current study provides evidence that incorporating exercise and counseling after treatment was conducive to reducing fatigue, and addressed both the mental and physical aspects of fatigue. It should be noted that while the ExC group had the greatest reduction in overall fatigue, the C group had a greater reduction than did the Ex group. While these differences were nonsignificant, the trends may indicate that psychological counseling makes important contributions to fatigue reduction.

As hypothesized, the greatest improvement in QOL was observed in the multimodal group, with more than double the

improvement of the Ex group. In response to the intervention, both the Ex and ExC groups exceeded the 5-point minimally important difference identified for the FACT-B scale,<sup>23,24</sup> with adjusted improvements of 6.8 and 14.5 points in the Ex and ExC groups, respectively. The Ex group's findings were consistent with the meta-analysis,<sup>14</sup> whereby pooled data from three randomized, controlled trials demonstrated a significant increase of 6.62 on the FACT-B scale in breast cancer survivors in response to exercise. In contrast, C and UsC group scores remained relatively unchanged. The ExC group improved more than twice as much as the Ex group, which improved more than twice as much as the UsC group. In raw changes, the C group improved 2.0 points, the Ex group improved 6.5 points, and the ExC group improved 15.0 points. Even with the raw data, the sum of the C and Ex groups is only slightly greater than half the improvement when the interventions were delivered simultaneously. These results indicate that there is some interaction between these two modalities that allows for more than additive gains in QOL.

As hypothesized, the largest improvement in QOL was observed in the multimodal group that utilized both exercise and counseling, highlighting the importance and magnitude of combining the two modalities and showing that the interaction is more than additive. Possible explanations for the large increase in QOL for the ExC group were twofold: the effectiveness of dealing with the physical and mental aspects of recovery and the fact that the initial scores of this group were the lowest and possibly had the most potential to improve. These findings show that while addressing only one dimension of QOL may improve a breast cancer survivor's overall well-being, attention must be given to multiple dimensions to fully improve global QOL. Anecdotally, many of the women indicated they were keen to join an exercise program but not a counseling program after their breast cancer treatment. However, all stated that they gained enormous benefit from the counseling sessions and enjoyed the multimodal approach to their rehabilitation.

Limitations of this study include the small sample size and subsequent limited power, and the fact that correcting for months post treatment and baseline factors allowed for more conservative results. Data from this study indicate that further research is warranted to determine what effects a multimodal exercise and counseling program may have for physiological and psychological well-being in breast cancer survivors, incorporating a larger cohort study and longer duration. Further research is also warranted to determine if a multimodal exercise and counseling program can elicit similar physiological and psychological well-being benefits for other cancer survivor populations.

## CONCLUSIONS

Conclusions should be taken with care, and further randomized, controlled research would be needed to confirm these physical and psychological improvements in response to the exercise and psychological counseling intervention. However, this trial provides preliminary evidence that a multimodal exercise and counseling program is feasible, has good adherence, and was

effective for improving physiological function, QOL, fatigue, and depression symptoms in breast cancer survivors. It also suggests that after breast cancer, survivors need help addressing all dimensions of their QOL, and that a holistic approach will be more beneficial and meaningful than would only a physically or psychologically focused intervention.

Future research needs to determine what exact form of intervention will best improve each dimension of QOL for breast cancer survivors. For example, to address the physical dimension, possibilities range for exercise programs to deliver hydrotherapy, Pilates, resistance training, and any combination or permutation of other fitness activities. Likewise, various psychological interventions exist, from analytic psychotherapy to group discussion counseling. In addition to clinical effectiveness, these modes

need to be tested for what combinations are most acceptable for patients and what can feasibly be delivered in different circumstances. For example, the availability of trained professionals is likely to differ from an urban to a rural setting; it would be advantageous to identify the most effective interventions that can also be delivered across any setting.

**Acknowledgments:** This work was funded by a Foggarty grant and Health Benefits Funds, through the University of Notre Dame Australia.

**Conflict of Interest Disclosures:** All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr. Naumann's institution has received a grant from Health Benefits Fund. Professor Philpott's and Dr. Smith's institution has received a grant as well as fees for consulting from Health Benefits Fund. Dr. Groff, Professor Martin and Associate Professor Battaglini have nothing to disclose.

## REFERENCES

PubMed ID in brackets

- Jemal A, Siegel R, Xu J, et al. Cancer statistics 2010. *CA Cancer J Clin* 2010;60:277-300.
- Bower JE, Ganz PA, Desmond KA, et al. Fatigue in breast cancer survivors: occurrence, correlates and impact on quality of life. *J Clin Oncol* 2000;18:743-753.
- Burgess C, Cornelius V, Love S, et al. Depression and anxiety in women with early breast cancer: five-year observational cohort data. *BMJ* 2005;330:702-705.
- Glanz K, Lerman C. Psychosocial impact of breast cancer: five year observational cohort data: a critical review. *Ann Behav Med* 1992;14:204-210.
- Jefford M, Karahalios E, Pollard A, et al. Survivorship issues following treatment completion—results from focus groups with Australian cancer survivors and health professionals. *J Cancer Surviv* 2008;2:20-32.
- Girgis A, Boyes A, Hansen V. What are the unmet needs of breast cancer survivors 5-6 years post-diagnosis? *Clin Updates Breast Cancer* 2008;3(2):15-17.
- Schmitz KH, Ahmed RL, Hannan PJ, et al. Safety and efficacy of weight training in recent breast cancer survivors to alter body composition, insulin, and insulin-like growth factor axis proteins. *Cancer Epidemiol Biomarkers Prev* 2005;14(7):9.
- Battaglini C, Bottaro M, Dennehy C, et al. The effects of an individualized exercise intervention on body composition in breast cancer patients undergoing treatment. *Sao Paulo Med J* 2007;125(1):22-28.
- Courneya KS, Segal RJ, Mackey JR, et al. Effects of aerobic and resistance exercise in breast cancer patients receiving adjuvant chemotherapy: a multicenter randomized controlled trial. *J Clin Oncol* 2007;25(28):4396-4404.
- Milne HM, Wallman KE, Gordon S, et al. Effects of a combined aerobic and resistance exercise program in breast cancer survivors: a randomized controlled trial. *Breast Cancer Res Treat* 2008;108:279-288.
- Galvao D, Newton R. Review of exercise intervention studies in cancer patients. *J Clin Oncol* 2005;23(4):899-909.
- Kirshbaum MN. A review of the benefits of whole body exercise during and after treatment for breast cancer. *J Clin Nurs* 2007;16(1):104-121.
- Courneya KS, Mackey JR, Bell GJ, et al. Randomized controlled trial of exercise training in postmenopausal breast cancer survivors: cardiopulmonary and quality of life outcomes. *J Clin Oncol* 2003;21:1660-1668.
- McNeely ML, Campbell KL, Rowe BH, et al. Effects of exercise on breast cancer patients and survivors; a systematic review and meta-analysis. *Can Med Assoc J* 2006;175:34-41.
- Irwin ML. Physical activity interventions for cancer survivors. *Br J Sports Med* 2009;43:32-38.
- Holmes MD, Chen WY, Feskanich D, et al. Physical activity and survival after breast cancer. *JAMA* 2005;293(20):2479-2486.
- Holick CN, Newcomb PA, Trentham-Dietz A, et al. Physical activity and survival after diagnosis of invasive breast cancer. *Cancer Epidemiol Biomarkers Prev* 2008;17(2):379-386.
- Bertrum LAC, Stefanick ML, Saquib N, et al. Physical activity, additional breast cancer events, and mortality among early stage breast cancer survivors: findings from the WHEL Study. *Cancer Causes Control* 2011;22:427-435.
- Irwin ML, McTiernan A, Manson JE, et al. Physical activity and survival in postmenopausal women with breast cancer: results from the Women's Health Initiative. *Cancer Prev Res* 2011;4:522-529.
- Zimmerman T, Heinrichs N, Baucom DH. "Does one size fit all?" Moderators in psychosocial interventions for breast cancer patients: a meta-analysis. *Ann Behav Med* 2007;34(3):225-239.
- Ross L, Boesen EH, Dalton SO, et al. Mind and cancer. Does psychological intervention improve survival and psychological well-being? *Eur J Cancer* 2002;38(11):1447-1457.
- Canadian Society for Exercise Physiology. PAR-Q and You. Glouster, Canada: Canadian Society for Exercise Physiology; 1994.
- Cella DF, Tulsy DS, Gray G, et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. *J Clin Oncol* 1993;11:570-579.
- Brady MJ, Cella DF, Mo F, et al. Reliability and validity of the Functional Assessment of Cancer Therapy—Breast quality-of-life instrument. *J Clin Oncol* 1997;15:974-986.
- Piper BF, Dibble SL, Dodd MJ, et al. The revised Piper Fatigue Scale: psychometric evaluation in women with breast cancer. *Oncol Nurs Forum* 1989;25:677-684.
- Beck AT, Ward CH, Mendelson M, et al. An inventory for measuring depression. *Arch Gen Psychiatry* 1961;4:561-571.
- Salkind MR. Beck Depression Inventory in general practice. *J R Coll Gen Pract* 1969;18:267-271.
- Hiroe T, Kojima M, Yamamoto I, et al. Gradations of clinical severity and sensitivity to change assessed with the Beck Depression Inventory-II in Japanese patients with depression. *Psychiatry Res* 2005;135(3):229-235.
- Jackson AS, Pollock ML, Ward A. Generalized equations for predicting body density of women. *Med Sci Sports Exerc* 1980;12(3):175-181.
- Heyward VH. *Advanced Fitness Assessment and Exercise Prescription*, 5th ed. Champaign, IL: Human Kinetics; 2006.
- American College of Sports Medicine. *ACSM's Guidelines for Exercise Testing and Prescription*, 7th ed. Philadelphia: Lippincott, Williams & Wilkins; 2006.
- Caan B, Sternfeld B, Gunderson E, et al. Life After Cancer Epidemiology (LACE) study: a cohort of early stage breast cancer survivors (United States). *Cancer Causes Control* 2005;16:545-556.
- Kroenke CH, Chen WC, Rosner B, et al. Weight, weight gain and survival after breast cancer diagnosis. *J Clin Oncol* 2005;23(7):1370-1378.
- Ingram C, Courneya KS, Kingston D. Effects of exercise on body weight and composition in breast cancer in breast cancer survivors: an integrative systematic review. *Oncol Nurs Forum* 2006;33:937-947.
- Myers J, Prakash M, Froelicher V, et al. Exercise capacity and mortality among men referred for exercise testing. *N Engl J Med* 2002;346(11):793-801.