BRIEF REPORT

A PILOT STUDY OF GROUP EXERCISE TRAINING (GET) FOR WOMEN WITH PRIMARY BREAST CANCER: FEASIBILITY AND HEALTH BENEFITS

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SUMMARY

Evidence is accumulating for physical activity as an effective, well-tolerated, highly rewarding complementary behavioral intervention for enhancing quality of life (QOL) as well as fitness among individuals with chronic and even terminal illnesses. However, relatively few studies have examined the feasibility and potential health benefits of supervised, structured exercise programs for sedentary women with primary breast cancer. Forty women over the age of 45 with primary breast cancer participated in a course of group exercise training (GET) delivered in a structured format three times per week for 16 weeks. GET emphasizes physical activities that promote aerobic fitness, strength, and flexibility. Assessments of fitness/vigor and QOL were conducted prior to, during, and upon completion of the program. Results demonstrated that GET was feasible, safe, and well-tolerated. Moreover, the participants experienced significant health benefits over the course of the intervention in multiple dimensions of fitness/vigor (aerobic capacity, strength, flexibility) as well as QOL (increased positive affect, decreased distress, enhanced well-being, and improved functioning). Discussion highlights the need for inclusion of physical activity programs in comprehensive, complementary treatment regimes for breast cancer patients. Copyright © 2002 John Wiley & Sons, Ltd.

INTRODUCTION

A diagnosis of breast cancer is a catastrophic life event for most women. Surgery, chemotherapy, radiation therapy, and hormone therapy directly address the biological, disease-related facets of this disease. Yet, psychosocial effects of breast cancer and its treatment can exact an enormous toll on quality of life (QOL). Behavioral interventions can enhance QOL and in some cases appear to increase disease-free intervals and reduce mortality (e.g. Fawzy et al., 1993; Fawzy, 2001; Spiegel et al., 1989). Furthermore, even if mortality cannot be reduced, complementary behavioral interventions can play a significant QOL-enhancing role in cancer care.

Complementary behavioral interventions involving physical activity have emerged in recent years as a component of care for a variety of medical conditions. It is a central feature of cardiac rehabilitation (Froelicher, 1990) as well as an important element in physical therapy following injuries, burns, strokes, and other forms of chronic disability such as arthritis, diabetes, and

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respiratory disorders (Sluis et al., 1993). Physical activity is clearly associated with health and mood (LaFontaine et al., 1992). Moreover, it can help modify risk factors for chronic disease and promote healing, thereby potentiating treatments and optimizing health (Blair and Broadney, 1999; Sallis and Owen, 1999).

The significance of physical activity in disease prevention is highlighted in Healthy People 2000, in which its promotion was identified as the number one priority, yet only 40% of American adults engage in more than occasional moderate exercise (American College of Sports Medicine, 1991). Furthermore, women tend to participate less frequently in vigorous physical activity in comparison to men, particularly among older age groups (United States Centers for Disease Control and Prevention, 1993). Surprisingly, despite relatively wide acceptance within the medical and scientific communities of the benefits of physical activity for a broad range of conditions, little attention has been given to promoting it in cancer care.

EXERCISE AS A SURVIVORSHIP-ENHANCING BEHAVIORAL INTERVENTION FOR BREAST CANCER

To date, we have identified 15 published studies and three dissertations examining exercise interventions in breast cancer patients (Courneya and Friedenriech, 1997; MacVicar and Winningham, 1986; MacVicar et al., 1989; Mock et al., 1994, 1997; Nelson, 1991; Pinto et al., 1998; Schwartz, 1998, 1999, 2000; Schwartz et al., 2001; Segal et al., 2001, 1998; Winningham, 1983; Winningham and MacVicar, 1988; Winningham et al., 1989; Young-McCaughan and Sexton, 1991). As can be seen, five of these studies came out of Winningham’s research program in the 1980s.

This corpus of research provides evidence that physical activity is of both biological and psychosocial benefit for breast cancer survivors. Exercise participation led to increased functional capacity, improved mood, decreased nausea and somatization, increased self-esteem, increased natural killer cell activity, better adjustment to illness and decreased distress, improved body image, decreased fatigue and emotional distress during radiation therapy, and reduced depression and anxiety.

These findings must be approached with some caution, however, due to possible methodological and statistical-power limitations. It is also important to note that patient samples in these studies were typically heterogeneous with regard to age, stage of disease, and pre-intervention level of activity; participants were generally not concurrently undergoing adjuvant therapies; the exercise interventions involved prescriptions for unsupervised, individual aerobic activity (walking or cycle ergometry); and outcome measures were unidimensional.

Exercise promotion among women with breast cancer is a public health concern that must not be neglected. Unfortunately, the research data base from which to develop clinical recommendations regarding physical activity in breast cancer care is limited. Therefore, it is critical to demonstrate that women with breast cancer can in fact safely participate in, as well as benefit from, appropriately tailored exercise programs.

We recently conducted a pilot study to determine the feasibility, safety, and benefits of a comprehensive group exercise intervention, group exercise training (GET), for women with primary breast cancer. We were guided in designing the group exercise intervention by concepts and training strategies used in cardiac rehabilitation with similar aged populations.

METHODS

Subjects

Participants were 40 sedentary women, age 45 or older (mean age 55.3, S.D. = 8.4, range = 45–76), who had been diagnosed and surgically treated for Stage I 13 (32%), Stage II 22 (55%), or Stage III 5 (13%) breast cancer. The staging schema of the American Joint Committee on Cancer and the International Union Against Cancer was used, and the distribution obtained is representative of national trends for women with regional breast disease (American Cancer Society, 2000). Most women were within 12 months of diagnosis (83%) and all were postsurgery. Surgery type was distributed as follows: 18 (45%) received a modified radical mastectomy (unilateral or bilateral) and 24 (60%) received lumpectomy or breast-conserving therapy (a few received both, hence the percentages sum to greater than 100). Most were
concurrently undergoing adjuvant therapies. Adjuvant therapy combinations were distributed as follows: 24 (60%) received radiotherapy, 26 (65%) received chemotherapy, and 20 (50%) received hormonal therapy (Tamoxifen).

Participants were recruited primarily through local support groups and newspaper advertisements. Fifty-one women provided informed consent to enter the protocol and 40 completed the 16-week intervention. All participants received standard care breast cancer treatment as determined by their oncologists.

Exercise intervention

GET participants met three days a week for a period of 16 weeks in keeping with American College of Sports Medicine (1991) guidelines. Participants entered the group as they were recruited (i.e. a rolling admission policy) so that group size was allowed to vary from four (minimum) to ten (maximum). One-hour sessions were run by two exercise physiologists and were structured to include a check-in, a warm-up period, aerobic training, resistance training and a cool-down.

Vital signs were evaluated (e.g. blood pressure and heart rate) during check-in. The warm-up period lasted 10–15 min and included slow rhythmic activities, range of motion, and stretching. The aerobic training phase lasted 20 min and included walking, cycling, step and dance movements, and other aerobic activities. Exercise intensity and duration was prescribed on an individual basis using the results from baseline fitness assessments. Initial intensity levels were set at 40–60% of estimated maximal aerobic capacity, which increases to 70% over the 16-week period. Progression was based on functional capacity and health status. The resistance training and cool down phase lasted 20 min and emphasized stretching and resistance training with the use of resistance bands, dumbbells, and variable resistance machines.

Instruments

**Fitness/vigor.**

Resting blood pressure (BP) and heart rate (HR). BP was measured after the subject had been sitting quietly for 5 min, using American Heart Association guidelines (1981). HR was counted by palpation for two 30-s periods after the BP measurements had been completed and averaged.

**Height and weight.** Height was measured to the nearest centimeter and weight was recorded to the nearest quarter pound.

**Body fat.** Skinfold fat thickness was measured to the nearest 0.5 mm at three sites (triceps, suprailium and thigh) with a Lange skinfold caliper using standardized techniques (Lohman et al., 1988). Body density was calculated from the sum of three skinfolds using the formula of Jackson et al. (1980). Percent fat was calculated by the formula of Siri (1961).

**Aerobic capacity.** A single-stage submaximal treadmill walking test (Ebbeling et al., 1991) was used to estimate aerobic capacity.

**Flexibility.** Flexibility was measured using a standard Sit-And-Reach Test (Wells and Dillon, 1952).

**Strength.** Estimated one-repetition maximum tests on the bench press and leg press (Cybex variable resistance equipment) was used to assess upper and lower body strength.

**Quality of life: Mood/Distress.**

**Beck Depression Inventory** (BDI; 21 items; Beck et al., 1961). The BDI measured current depressive symptomatology. This measure demonstrates solid reliability; reported split-half reliability coefficients have ranged from 0.58 to 0.93 and test–retest reliability has ranged from 0.69 to 0.90 (Beck et al. 1988).

**State-Trait Anxiety Inventory** (STAI; 40 items; Spielberger, 1983). The STAI was used to measure state anxiety only (subject to transitory change) in the present study. Coefficient alphas for the state anxiety subscale have ranged from 0.90 to 0.92.

**Positive and Negative Affect Schedule** (PANAS; 20 items; Watson et al., 1988). The PANAS measured two primary and independent dimensions of mood, positive affect and negative affect.
The alpha coefficients ranged from 0.86 to 0.90 for positive affect and 0.84 to 0.87 for negative affect.

Hamilton Rating Scale for Depression (HRSD; 27-item version; Hamilton, 1967). The HRSD is an interviewer-rated measure of the severity of the current depressed state. Ratings are made based on information obtained in a focused clinical interview. Inter-rater reliability for the HRSD has been documented to range from 0.84 and above (Rabkin and Klein, 1987). The HRSD was used to assess change in symptomatic distress during the course of the exercise training.

Quality of life: Well-being.

Functional Assessment of Cancer Treatment (FACT; 28 items; Cella et al., 1993). The FACT includes 6 well-being subscales: physical, social/family, relationship with doctor, emotional, functional, and miscellaneous. Test–retest reliability for the subscales and global scale had been observed to range from 0.82 to 0.92.

Quality of life: Functioning.

Cancer Rehabilitation Evaluation System (CARES; 59 items; Ganz et al., 1992). The CARES includes 5 functioning subscales: physical, psychosocial, medical interaction, marital interaction, and sexual. Test–retest reliability for each of the 5 subscales and the global scale ranges from 0.69 to 0.92.

The Global Assessment Scale (GAS; Endicott et al., 1976). The GAS is a single rating of a patient’s level of current functioning using a continuum of mental health-illness ranging from 0 to 100 anchored at 5-point intervals. As such, it measures severity of psychopathology on the basis of a global rating as opposed to multidimensional assessment of symptoms. Ratings are made based on information obtained in a focused clinical interview. Several studies have shown the reliability of the GAS to be quite acceptable, with test–retest reliabilities ranging from 0.69 to 0.91 (Endicott et al., 1976; Clark and Friedman, 1983; Skodal et al., 1988).

The Life Functioning Scales (LFS; Howard et al., 1992). The LFS assesses the patient’s status in six domains of life functioning: self-management; work, school, or household functioning; intimate relationships; social functioning; family functioning; and, health and grooming. Analogous to the GAS, each of the six domains of the Life Functioning Scales is rated on a continuum ranging from 0 to 100 anchored at 5-point intervals and are made based on information obtained in a focused clinical interview. A reliability analysis of the sum of the six scales resulted in a coefficient alpha of 0.84. Corrected item-total correlations ranged from 0.55 to 0.66 pointing to the presence of an overall dimension of functioning, but also indicative of meaningful content heterogeneity across the six domains.

RESULTS

Feasibility

Recruitment and retention. Recruitment into the project began in early January 1997. The first exercise class began on 2/10/97. We have demonstrated the ability to successfully recruit women with primary breast cancer to participate in a group exercise intervention. We have been able to recruit 51 women with primary breast cancer; of these, 40 (including seven women over the age of 65) have completed the 16-week GET intervention.

Another element of feasibility for any intervention research protocol is that of attrition. Once recruited, are subjects compliant in completing the protocol? Eleven of the women who entered the protocol dropped out (all by the 3rd week of the exercise program). This represents a 21.6% attrition rate or, conversely, a 78.4% rate of retention. Among the 11 who did not continue, 4 dropped out due to non-cancer-related physical problems (e.g. arthritis), 3 were unable to continue due to travel or scheduling constraints, 1 discontinued because she felt the exercise was “not strenuous enough”, and 3 declined to return follow-up phone calls to ascertain the reasons for discontinuing.

Safety and tolerability. There were no adverse reactions to participation in the exercise intervention. Participants completed an average of 88% of sessions (S.D. = 4.5%). More importantly, the participants uniformly and enthusiastically endorsed the program.
The following variables were assessed at baseline, Week 8, and Week 16: weight, percent body fat (based on skinfold measurements), resting heart rate, resting systolic and diastolic blood pressure, flexibility (sit-and-reach), aerobic capacity (estimated VO2 maximum), and strength (estimated sub-maximum bench press and leg press). We observed significant improvement over 16 weeks on 5 of the 9 measures using repeated-measures analyses of variance: resting systolic blood pressure, *F*(2,37)=5.87, *p*<0.05; flexibility (sit-and-reach), *F*(2,37)=31.99, *p*<0.001; aerobic capacity (estimated VO2 maximum), *F*(2,37)=62.79, *p*<0.001; strength (bench press), *F*(2,37)=61.87, *p*<0.001; and strength (leg press), *F*(2,37)=101.57, *p*<0.001. Results are summarized in Table 1.

### Health benefits: Quality of life

#### Mood/Distress

The following instruments were administered at baseline, Week 8, and Week 16: BDI, STAI, PANAS, and HRSD. As was evident from baseline scores, participants on average were not experiencing high levels of distress at the start of the study. Nonetheless, we observed significant improvement from baseline to Week 16 (*p*<0.05) on 4 of the 5 measures using repeated-measures analyses of variance: BDI, *F*(2,37)=12.39, *p*<0.01; PANAS positive affect, *F*(2,37)=12.40, *p*<0.01; PANAS negative affect, *F*(2,37)=9.26, *p*<0.01; HRSD, *F*(2,37)=15.59, *p*<0.001. Results are summarized in Table 2.

### Well-Being

The FACT, which assesses well-being in five domains, was administered at baseline, Week 8, and Week 16. We observed significant improvement from baseline to Week 16 (*p*<0.05) on the FACT global score, *F*(2,37)=10.19, *p*<0.01 and functional well-being *F*(2,37)=4.59, *p*<0.05. In addition, statistical trends (*p*<0.10) for improvement were apparent on 2 of the remaining 3 FACT subscales: relationship with physician, *F*(2,37)=2.99, *p*<0.10 and emotional well-being, *F*(2,37)=4.06, *p*<0.10. Results are summarized in Table 3.

### Functioning

Three instruments were administered at baseline, Week 8, and Week 16 to assess broad domains of current life functioning: CARES, GAS, and LFS. As was evident from baseline scores, participants on average were functioning reasonably well at the start of the study. Nonetheless, we observed significant improvement from baseline to Week 16 on scores of global functioning for all three measures using repeated-measures analyses of variance; CARES global score, *F*(2,37)=9.43, *p*<0.01; GAS, *F*(2,37)=6.64, *p*<0.05; and LFS global score, *F*(2,37)=7.13, *p*<0.05.

The CARES scales assess functioning in five domains. We observed significant improvement from baseline to Week 16 (*p*<0.05) on 3 of the 5 CARES subscales: medical interaction, *F*(2,37)=7.49, *p*<0.01; physical functioning, *F*(2,37)=9.24, *p*<0.01; and psychosocial functioning, *F*(2,37)=7.29, *p*<0.05.
The Life Functioning Scales assess the patient's status in six domains. We observed significant improvement from baseline to Week 16 ($p < 0.05$) on 2 of the 6 Life Functioning subscales: self-management, $F (2,37) = 20.12, p < 0.001$ and health and grooming, $F (2,37) = 13.64, p < 0.01$. Results for functioning are summarized in Table 4.

**DISCUSSION**

This study provides useful data concerning the feasibility, safety, and tolerability of GET with primary breast cancer patients. Furthermore, it makes specific contributions to the growing literature on physical activity in breast cancer. The study focused on a more homogeneous sample.
of patients, sedentary women 45 or older with primary breast cancer, rather than a group more heterogeneous with regard to preintervention activity level, age and disease stage. Moreover, the majority of the participants were concurrently undergoing adjuvant therapies (i.e. chemotherapy, radiation, and/or hormone therapy) while engaging in GET. GET is a supervised, comprehensive group physical activity program of 16 week duration that involves aerobic as well as strength and flexibility training, whereas previous published studies have typically involved unmonitored individual aerobic activity (e.g. walking, cycle ergometry) of shorter duration. Methodologically, outcome was assessed comprehensively, both fitness/vigor (aerobic capacity, strength, and flexibility) and QOL (mood/distress, well-being, functioning) were conceptualized and measured multidimensionally rather than unidimensionally (e.g. aerobic capacity or mood/distress only).

Feasibility

Recruitment and retention. We were able to successfully recruit older women with primary breast cancer to participate in a group exercise intervention. This is significant because when we began this study it was not clear that we would be able to successfully recruit this subject population into an exercise protocol, let alone effectively retain them through completion of a demanding 16-week regimen. Retention/attrition is an important element of feasibility in any intervention study. Not only did breast cancer patients enter our protocol, they completed it in spite of the dosage of the intervention: duration (16 weeks) and intensity (1 h, 3 times per week). These data are comparable to retention/attrition rates for clinical intervention studies (for exercise as well as psychosocial treatments) of lesser dosage with comparable medically ill populations (e.g. Dimeo et al., 1997; Fawzy et al., 1993; Mock et al., 1994, 1997; Segar et al., 1998).

Safety and tolerability. In terms of safety, we note that no participant experienced adverse reactions to the GET program. This provides strong support for the assertion that GET is safe for women undergoing treatment for primary breast cancer. Moreover, it addresses the concerns voiced by many that exercise in breast cancer patients might initiate and/or exacerbate lymphedema, which occurs in 25–28% of patients following treatment and has been thought to be associated with upper extremity activity (Logan, 1995). In fact, exercise is beginning to be studied as an intervention for this condition (Kalda and McKenzie, 2000; McKenzie and Jespersen, 2000).

Health benefits: fitness/vigor

Statistically significant improvements in fitness/vigor were observed by the end of the 16-week program. As hypothesized, this group of women—most of whom had not exercised regularly in many years—manifested substantial increases in strength, flexibility, and aerobic capacity by the end of the intervention period. These improvements are comparable to results observed in studies of healthy women in this age group (Drinkwater, 1984). Moreover, participants on average maintained weight as well as percent body fat. This is not a trivial observation; breast cancer patients typically lose weight during adjuvant therapies and then gain weight beyond their baseline in the time period following cessation of adjuvant treatments. Our findings demonstrate that, contrary to traditional expectations, physical activity in this population does not lead to iatrogenic complications such as lymphedema, nor is it contraindicated due to fatigue or other treatment-related side effects. Just as important, primary breast cancer patients were willing and able to participate in GET and reported that this physical activity results in greater vigor (i.e. less fatigue and other treatment-related side effects).

Health benefits: quality of life

As a group, even though our GET participants were not experiencing high levels of distress or major life difficulties, they reported improved QOL in terms of reduced distress, enhanced well-being, and improved functioning in multiple domains by the end of the program. Not only did the GET participants experience reduced negative affect, they simultaneously noted increased positive affect. This finding reminds us that positive affect and negative affect are relatively independent dimensions of emotional experience (Watson et al., 1988). In terms of well-being, we observed both decreases in perceptions...
of physical illness and increases in perceptions of agency and the capacity to cope with illness. Moreover, not only were patients feeling better after completion of the GET regimen, but they report functioning more effectively as well in multiple domains including personal self-care, interactions with health care providers, and interchanges with family and friends.

**Limitations**

The limitations of the pilot study also should be noted. First, our participants were highly self-motivated and therefore not necessarily representative of all women with breast cancer. Second, participants served as their own 'controls', so efficacy data are necessarily preliminary. Third, because follow-up data are only beginning to accumulate, the long-term impact of the intervention remains to be determined. Finally, the present findings do not address potential mechanisms of action by which health benefits are derived from participation in physical activity.

Nonetheless, we find these preliminary data to be encouraging as part of a growing literature supporting the use of physical activity programs in comprehensive, complementary treatment regimes for breast cancer patients. Future research is needed to establish the efficacy of physical activity in randomized, controlled trials. In addition, studies are needed that examine mechanisms of action (mediators and moderators of change) as well as intermediate and longer-term health benefits (i.e. health behavior, disease free interval, and survival time).

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**REFERENCES**


