

# THE GROUP PSYCHOTHERAPY AND HOME-BASED PHYSICAL EXERCISE (GROUP-HOPE) TRIAL IN CANCER SURVIVORS: PHYSICAL FITNESS AND QUALITY OF LIFE OUTCOMES

KERRY S. COURNEYA<sup>a\*</sup>, CHRISTINE M. FRIEDENREICH<sup>b</sup>, RAMI A. SELA<sup>a</sup>, H. ARTHUR QUINNEY<sup>a</sup>,  
RYAN. E. RHODES<sup>c</sup>, and MICHAEL HANDMAN<sup>a</sup>

<sup>a</sup> Faculty of Physical Education, University of Alberta, Alberta, Canada T6G 2H9

<sup>b</sup> Alberta Cancer Board, Alberta, Canada

<sup>c</sup> University of Victoria, Canada

## SUMMARY

Physical exercise has been shown to enhance quality of life (QOL) in cancer survivors using pretest–posttest designs and compared to usual care (i.e. no intervention). In the present study, we conducted a randomized controlled trial to determine if exercise could improve QOL in cancer survivors beyond the known benefits of group psychotherapy (GP). We matched 22 GP classes ( $N = 108$ ) on content and then randomly assigned 11 ( $n = 48$ ) to GP alone and 11 ( $n = 60$ ) to GP plus home-based, moderate-intensity exercise (GP + EX). Participants completed a physical fitness test and QOL measures (e.g. Functional Assessment of Cancer Therapy scales) at the beginning and end of GP classes (about 10 weeks). We had excellent recruitment (81%), retention (89%), and adherence (84%) rates and a modest contamination (22%) rate. Using intention-to-treat repeated measures analyses of variance, we found significant Time by Condition interactions for functional well-being, fatigue, and sum of skinfolds. We also found borderline significant interactions for physical well-being, satisfaction with life, and flexibility. All interactions favored the GP + EX condition. We conclude that a home-based, moderate intensity exercise program may improve QOL in cancer survivors beyond the benefits of GP, particularly in relation to physical and functional well-being. Copyright © 2003 John Wiley & Sons, Ltd.

## INTRODUCTION

Cancer and its treatments (e.g. surgery, radiation therapy, and chemotherapy) often produce significant morbidities that undermine the quality of life (QOL) of cancer survivors<sup>1</sup> both during and after treatment. Psychosocial issues may include depression, anxiety, anger, cognitive decline, low self-esteem, loneliness, and loss of a sense of control (e.g. Cleeland *et al.*, 2000; Spiegel, 1997; Zabora *et al.*, 2001). Physical and functional problems may include diminished cardiovascular

function, decreased strength, deterioration of lean body tissue, weight gain/loss, reduced range of motion, difficulty sleeping, fatigue, nausea, and pain (e.g. Baracos *et al.*, 1994; Cleeland *et al.*, 2000; Dimeo *et al.*, 1997; Ringdal *et al.*, 1994; Winningham *et al.*, 1989). Although these side effects tend to peak during treatment, they may persist for many months or even years after treatment (Spiegel, 1997).

Numerous interventions are available to assist cancer survivors in coping with, and recovering from, their disease and treatments including cognitive-behavioral therapies (e.g. relaxation training, meditation, hypnotherapy), informational and educational strategies (e.g. procedural, medical), counseling or psychotherapy (e.g. psychodynamic, existential), peer and professional support groups, and other alternative treatments

\*Correspondence to: Faculty of Physical Education, University of Alberta, E-424 Van Vliet Center, Edmonton, Alberta, Canada T6G 2H9. E-mail: kerry.courneya@ualberta.ca

(e.g. aromatherapy, art therapy). The effectiveness of these interventions has been documented in both narrative and quantitative reviews (Fawzy *et al.*, 1995; Meyer and Mark, 1995; Trijsburg *et al.*, 1992). Arguably, group psychotherapy (GP) is the 'gold standard' for this genre of interventions because it possesses unique advantages over individual interventions such as the opportunity for social support, social comparison, and modeling (Posluszny *et al.*, 1998; Spiegel *et al.*, 1999). A recent review of this literature concluded that there is compelling evidence that GP improves the QOL of cancer survivors (Blake-Mortimer *et al.*, 1999).

One limitation of this genre of interventions, however, is that they are largely psychosocial in nature and are geared mainly towards the emotional and social well-being of cancer survivors (e.g. Posluszny *et al.*, 1998; Spiegel *et al.*, 1999; Trijsburg *et al.*, 1992). Such interventions are less likely to address the physical and functional problems encountered by cancer survivors such as reduced cardiovascular function, loss of muscle strength, and fatigue (Courneya and Friedenreich, 1997a, b). Physical and functional well-being are essential dimensions for overall QOL (Cella and Tulskey, 1990) and may, in part, underlie some of the psychological distress experienced by cancer survivors (Williamson and Schulz, 1992). Moreover, some recent research has shown that functional well-being may be the least possessed but most important dimension underlying satisfaction with life in cancer survivors both during (Courneya *et al.*, 1999, 2000a) and after (Courneya and Friedenreich, 1997a, b) treatments.

To address this limitation, researchers have begun to examine the utility of physical exercise in improving the QOL of cancer survivors. There are now over 40 published studies on this topic and the evidence shows consistent improvements in exercise capacity, muscular endurance, flexibility, body composition, fatigue, treatment side effects, sense of control, anxiety, depression, self-esteem, and satisfaction with life (see Courneya *et al.*, 2000b for a review). As might be expected, however, these early studies either did not include a control condition (i.e. used one group pretest–posttest designs) or employed a usual care condition (i.e. no intervention). Consequently, what we know from these studies is that an exercise intervention is better at improving QOL than no intervention at all. Ultimately, however, a novel intervention therapy should demonstrate that it can improve QOL beyond the best currently

available interventions rather than simply providing an alternative to them. Such a comparison provides the most challenging and rigorous test of the usefulness of a new intervention therapy.

To this end, we conducted the Group Psychotherapy and Home-Based Physical Exercise (GROUP-HOPE) trial. The GROUP-HOPE trial is a randomized controlled trial comparing the effects of GP alone to GP plus home-based exercise (GP+EX). We have previously reported the correlates of exercise adherence and contamination in the two trial arms of this study (Courneya *et al.*, 2002a). In the present paper, we report the results for the physical fitness and QOL outcomes. The primary hypothesis of the study was that the GP+EX condition would demonstrate deeper and broader improvements in QOL than the GP condition. More specifically, we expected the GP condition to demonstrate significant improvements in emotional and social well-being, but not physical and functional well-being. In comparison, we hypothesized that the GP+EX condition would demonstrate even greater improvements in emotional and social well-being (i.e. the 'deeper' hypothesis) and would also demonstrate significant improvements in physical and functional well-being (i.e. the 'broader' hypothesis).

## METHODS

### *Participants*

The methods of the GROUP-HOPE trial have been reported elsewhere (Courneya *et al.*, 2002a). Briefly, we recruited 108 cancer survivors from 22 GP classes offered at the Cross Cancer Institute (CCI) in Edmonton, Alberta, Canada (Figure 1). Eligibility criteria for participation in the study were: (1) a diagnosis of cancer, (2) voluntary participation in one of the GP classes offered at the CCI, (3) ability to answer questions written in English, (4) passing the revised Physical Activity Readiness Questionnaire (rPAR-Q; Thomas *et al.*, 1992), which is a screening tool to determine the need to consult a physician before increasing exercise levels, and (5) no contraindications to moderate intensity exercise based on a submaximal fitness assessment. We did not exclude participants based on any demographic (e.g. age) or medical (e.g. disease stage, treatments status, time since diagnosis) variables. Our primary goal was to have

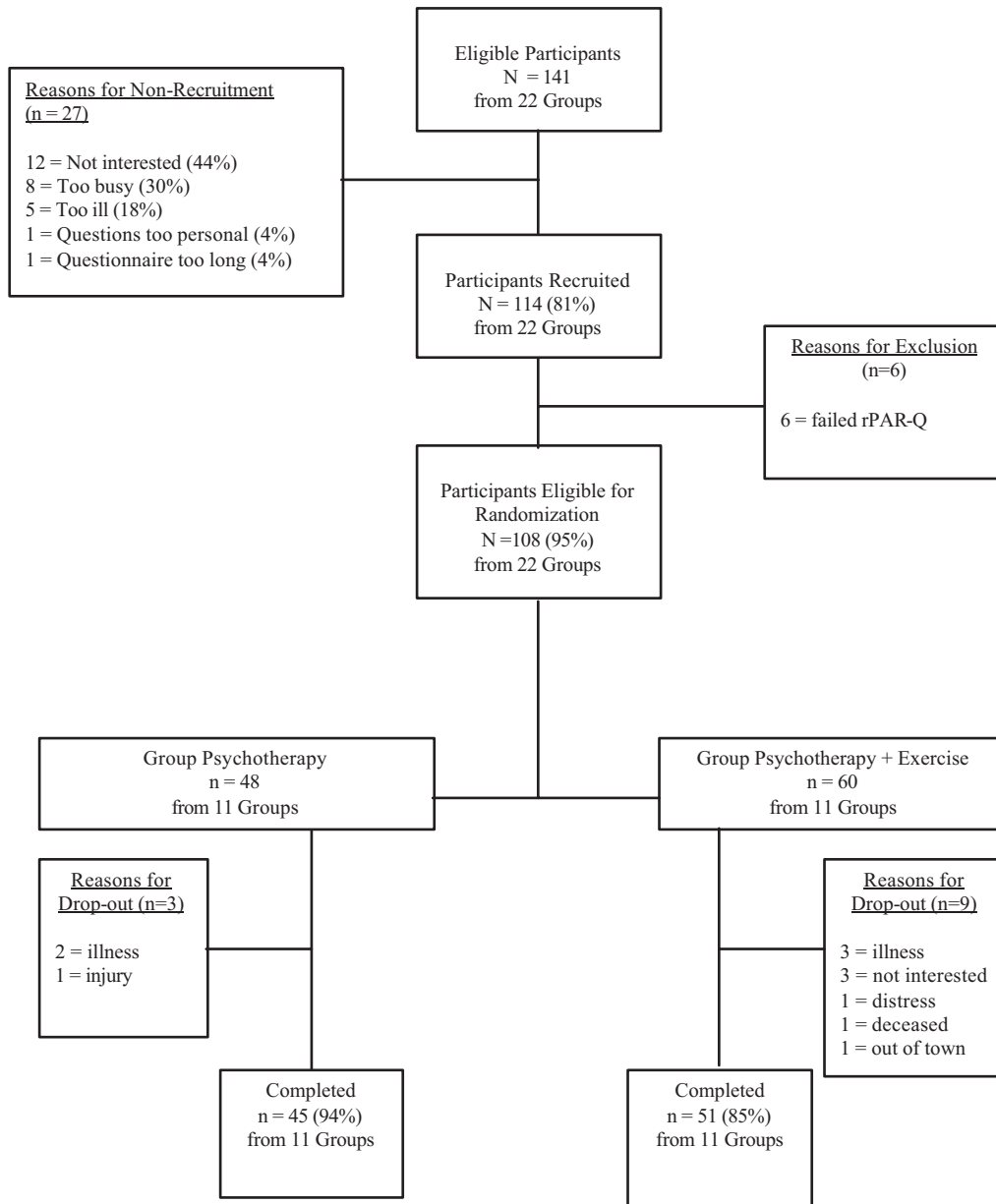


Figure 1. Flow of participants through the study.

participants representative of those who voluntarily join GP classes.

#### *Design and procedures*

The GP classes were conducted between the fall of 1998 and the winter of 2001. The project

director attended the first meeting of each GP class and described the study to prospective participants. Those who were interested in participating in the study were asked to provide their names and telephone numbers and were given a package containing an informed consent, the rPARQ, and a QOL questionnaire. Prospective participants

were telephoned that evening to schedule a physical fitness test as soon as possible and reminded to bring their completed informed consent, rPARQ, and QOL questionnaire to the fitness test.

Prior to the fitness test, GP classes were randomized to experimental conditions using a random numbers table. We randomized *GP classes* to conditions rather than *individuals* because of concerns of possible contamination between the experimental conditions. The GP classes were stratified on content (i.e. stress management versus expressive-supportive therapy) prior to randomization to ensure equal representation in both experimental conditions.

The fitness test was conducted by a certified fitness appraiser (blinded to the experimental condition) under the supervision of the project director (not blinded to the experimental condition). Height and weight were measured followed by the tests of flexibility, body composition, and cardiovascular endurance. After completion of the physical fitness test, the fitness appraiser provided the results to the project director and left the testing facility.

At that time, participants in both experimental conditions received feedback on their test results (i.e. age and sex-matched norms). Participants assigned to the GP condition were then asked not to begin an exercise program and were not given an exercise prescription. They were reminded, however, that they would be given an exercise prescription at the end of the study (in about 10 weeks). Participants assigned to the GP+EX condition received a fitness consultation lasting about 30 min that included a personalized exercise prescription to follow for the length of the GP classes (about 10 weeks). The fitness consultation was based on a booklet developed by the authors entitled 'Guide to Physical Exercise Following a Cancer Diagnosis'. This booklet contained basic information under the headings of 'Exercise Program Guidelines', 'Your Personal Exercise Prescription', 'Rating Your Level of Effort', 'Proper Warm-up and Cool-down', 'Stretching Exercises', 'Signs to Watch Out for When Exercising', and 'Tips for Sticking With Your Exercise Program'.

The project director met all participants just prior to the start of each GP class to have them report their exercise for the previous week. Moreover, modifications were made to the prescribed exercise programs at that time for those in the

GP+EX condition based on their response to the exercise and any acute treatment effects. A minimal amount of encouragement was also provided to those in the GP+EX condition. Participants who did not attend a given GP class were telephoned that evening to report their exercise. We used these weekly exercise reports to determine the adherence and contamination rates for the GP+EX and GP conditions, respectively. At the final GP class (week 10), participants were given the same QOL questionnaire and had a second fitness test scheduled. Participants who were absent at the final GP class was mailed the questionnaire and telephoned to schedule a fitness test.

### *Interventions*

*Group psychotherapy (GP)*: The GP classes conducted at the CCI are offered at three different times during the year (winter, spring, and fall) and led by a clinical psychologist (R.A.S) with over 10 years experience in conducting GP classes with cancer survivors. The classes meet once per week for 10 weeks and last approximately 90 min. The two basic types of classes offered at the CCI are stress management and relaxation training (SMART) and expressive-supportive therapy (EST). The SMART class consists of a psycho-educational experiential modality. The therapeutic goal is to induce relaxation and calmness through three basic methods (Sela, 1998): (1) brief methods which include paced respiration and deep breathing, (2) deep methods which include progressive muscle relaxation, autogenic training, and meditation, and (3) hypnotic techniques which include self-hypnosis and guided enhanced imagery. The EST class is modeled after Spiegel and Classen (2000) and its objectives are to: (1) provide participants with the opportunity to become part of a psychosocial support network, and to interact openly, honestly, and meaningfully with other cancer survivors, (2) expand their repertoire of effective coping skills by learning from each other how to best utilize limited resources of time, energy, and functioning capabilities, and (3) foster realistic hope and optimism, and enhance well-being. The GP classes at the CCI are often organized around demographic and/or medical variables (e.g. breast cancer only, female cancers only, metastatic disease only). These classes are available to all cancer survivors free of charge.

Attendance at the GP classes was taken each week by the clinical psychologist.

*Physical exercise:* Details of the exercise intervention have been presented elsewhere (Courneya *et al.*, 2002a). Briefly, the exercise intervention was a home-based, personalized exercise program taking into account the baseline fitness test results, exercise history, performance status, response to adjuvant chemotherapy or radiation therapy, and personal preferences of the participant. The focus of the program was on improving functional well-being through cardiovascular and flexibility exercises. Individuals were prescribed walking although they were allowed to choose an alternative mode of exercise if they preferred (e.g. swimming, cycling). The goal was to have participants exercising at least 3–5 times per week, for 20–30 min, at 65–75% of their estimated heart rate maximum as soon as was safely possible (American College of Sports Medicine, 1998). Progression towards this goal varied, however, depending on individual motivation and capabilities. There were no exercise meetings or exercise group activities and all costs of the exercise program were covered for the participants (e.g. fitness testing, parking).

### Measures

*Quality of life* was assessed by the Functional Assessment of Cancer Therapy-General (FACT-G) scale developed specifically for cancer survivors (Cella *et al.*, 1993). The FACT-G (Version 4) includes subscales for physical (7 items), functional (7 items), emotional (6 items), social/family (6 items), and spiritual (12 items) well-being. Each item is rated on a five-point scale (0–4) and each subscale receives a summed score (e.g. functional well-being can range from 0–28). Higher scores indicate higher well-being. The FACT-G has been tested in a large sample of cancer survivors and been found to be reliable, valid, responsive, brief, and easy to administer (Cella *et al.*, 1993). Internal consistencies in the present study at baseline and posttest, respectively, were as follows: physical well-being ( $\alpha = 0.77$  and  $0.80$ ), functional well-being ( $\alpha = 0.81$  and  $0.86$ ), emotional well-being ( $\alpha = 0.83$  and  $0.83$ ), social/family well-being ( $\alpha = 0.84$  and  $0.86$ ), and spiritual well-being ( $\alpha = 0.86$  and  $0.90$ ).

*Satisfaction with life* was assessed by the Satisfaction With Life Scale (SWLS) developed

by Diener *et al.* (1985). The SWLS allows individuals to assess the quality of their lives based on their own unique set of criteria without reference to a specific domain. The SWLS contains five items rated on seven point scales and summed for an overall score (i.e. 5–35). Higher scores indicate greater satisfaction with life. The SWLS has been shown to be a highly reliable, valid, and responsive measure of overall QOL (Pavot and Diener, 1993). Internal consistencies in the present study were  $\alpha = 0.89$  (baseline) and  $\alpha = 0.91$  (posttest).

*Depression* was assessed by the Centre for Epidemiological Studies Depression (CES-D) scale which is a well-validated, 20 item scale that measures the frequency of depressive symptoms over the past week (Radloff, 1977). Items are scored from 0 (<1 day) to 3 (5–7 days) and summed for an overall score (i.e. 0–60). Higher scores indicate greater depression. Internal consistencies for the CES-D in the present study were  $\alpha = 0.92$  (baseline) and  $\alpha = 0.94$  (posttest).

*Anxiety* was assessed by the State-Trait Anxiety Inventory (STAI) developed by Spielberger *et al.* (1970). Each scale has 20 items that are rated on a 1 (not at all) to 4 (very much so) scale with an overall range of 20–80. Higher scores indicate higher levels of anxiety. The version used in the present study asked participants how they felt 'during the past week'. The STAI has been widely used in research on clinical and medical populations and has good psychometric properties. Internal consistencies for the STAI in the present study were  $\alpha = 0.93$  (baseline) and  $\alpha = 0.95$  (posttest).

*Fatigue* was assessed by the 13 item Fatigue Scale (FS) of the FACT measurement system developed specifically for cancer survivors (Yellen *et al.*, 1997). The FS includes items concerning the consequences of fatigue as well as symptom expression. It possesses excellent internal consistency, test–retest reliability, and convergent and discriminant validity (Yellen *et al.*, 1997). The scores can range from 0 to 52 with higher scores indicating greater fatigue. Internal consistencies for the FS in the present study were  $\alpha = 0.93$  (baseline) and  $\alpha = 0.94$  (posttest).

*Physical fitness* measurements were made for cardiovascular endurance, body composition, and flexibility.

*Cardiovascular endurance* was assessed by the Modified Balke Treadmill Test (MBTT). The test is terminated when participants reach 70% of their

age-predicted maximum or when they voluntarily terminate the test. The score is the number of seconds to reach 70% of age-predicted maximum heart rate. This test has been shown to have a high correlation with predicted oxygen uptake (American College of Sports Medicine, 2000). A sub-maximal treadmill test was selected over a maximal test for this population because of safety and motivational concerns and because fitness was not the primary outcome of the study. *Body composition* was assessed using Harpenden calipers (British Indicators LTD, London) to measure skinfolds at five standard sites (triceps, biceps, subscapula, suprailiac, and medial calf). The five sites were summed for an overall score with higher scores indicating more body fat. This method for body fat determination has predicted values within 3–5% of those obtained by hydrostatic weighing (McArdle *et al.*, 1991).

*Flexibility* of the lower back and posterior thighs (hamstrings) was assessed with the sit-and-reach test. This test requires participants to extend forward to push a measuring scale that is on top of a box and hold this position for 1 s. The score is the farthest point reached in centimeters out of two trials. The validity and reliability of this test have been established (Baumgartner and Jackson, 1995).

*Physical Exercise* was assessed by the leisure score index (LSI) of the Godin Leisure-Time Exercise Questionnaire (Godin *et al.*, 1986; Godin and Shephard, 1985). The LSI contains three questions that assess the average frequency of mild, moderate, and strenuous exercise during free time in a typical week. We modified the LSI so that average duration was also provided. An independent evaluation of this measure found its reliability and validity to compare favorably to nine other self-report measures of exercise (Jacobs *et al.*, 1993). In the present study, participants completed the LSI at baseline for the past month and then on a weekly basis over the GP classes for the past week.

*Demographic and medical information* were collected using self-report. The demographic variables included age, sex, marital status, education, income, and employment status. The medical variables consisted of date of cancer diagnosis, cancer site, stage of cancer, and dates and types of cancer treatments.

### Statistical analyses

To detect a medium standardized effect size  $d$  (0.50) with a power of 0.80 and an  $\alpha$  of 0.05

(one-tailed), we required 49 participants in each condition. We used a one-tailed test for our outcomes analyses because previous research has consistently documented that exercise has positive effects on both physical and psychological health in a wide variety of populations, including cancer survivors (Courneya *et al.*, 2000b). Our question in the present study was whether or not exercise could *improve* QOL beyond the expected benefits of GP. All analysis were conducted on an intention-to-treat basis (i.e. all randomized participants with posttest data were analyzed according to their assigned conditions regardless of adherence or contamination rates).

For the primary analysis, we used a 2 (Time)  $\times$  2 (Condition) doubly multivariate repeated measures analysis of variance (RM-MANOVA) with Time as the within subjects factor (baseline and posttest), Condition as the between subjects factor (GP and GP + EX), and our 13 outcome measures as the dependent variables (physical well-being, functional well-being, emotional well-being, social/family well-being, spiritual well-being, satisfaction with life, anxiety, depression, fatigue, treadmill time, sum of skinfolds, weight, and flexibility). The RM-MANOVA is considered the most appropriate and conservative statistical test of an interaction effect in a repeated measures design (Algina and Keselman, 1997). Follow-up univariate  $F$  tests were reported after significant multivariate effects. Significant univariate  $F$  tests for an interaction effect were deconstructed using dependent and independent  $t$ -tests.

We also report effects sizes for all our analyses based on Cohen's (1988, 1992) guidelines for univariate  $F$  tests [ $\eta^2 = 0.01$  (small), 0.06 (medium), and 0.14 (large)] and for  $t$ -tests [ $d = 0.20$  (small), 0.50 (medium), and 0.80 (large)]. In calculating effect size  $d$ , we used (a) the pooled S.D. at baseline when comparing baseline means, (b) the S.D. of the GP condition at posttest when comparing posttest means, and (c) the respective baseline S.D.'s when comparing pre-post means within experimental conditions.

## RESULTS

Overall retention for our study was excellent (89%) and was not significantly different between the GP (94%) and GP + EX (85%) conditions ( $p = 0.150$ ). Moreover, the study participants who

dropped out of our study were not significantly different from those who completed the study in terms of demographics, medical variables, past exercise, or baseline QOL. All remaining analyses are based on the 96 participants who were randomized and provided posttest data.

#### Baseline characteristics

The age of participants ranged from 25 to 74 with a mean of 51.55 (S.D. = 10.15), 84.4% were female, 73.1% were married/common law, 58.7% had completed university, 43.5% were currently employed, and 66.7% had a family income of greater than \$40,000 per year. Medical information indicated that months since diagnosis ranged from 1 to 93 with a mean of 16.28 (S.D. = 17.55). Moreover, 62.9% were within one year of diagnosis, 80.9% were within two years, and 97.8% were within five years. In terms of cancers, 40.6% were diagnosed with breast cancer, 9.4% colon cancer, 5.2% ovarian cancer, 4.2% each with stomach cancer and melanoma, 3.1% each with

Hodgkin's disease, non-Hodgkin's lymphoma, brain, and lung cancer, 15.6% with other cancers, and 8.3% missing. Cancer stage data indicated that 50% were stage I/II and 50% were stage III/IV. In terms of individual treatments, 79.5% had surgery, 50.0% received radiation therapy, and 68.2% received chemotherapy. At the time of the intervention, 34.1% were currently on chemotherapy, 19.3% were currently on radiation therapy, and 44.3% were currently on at least one treatment (9.1% were on both). We compared experimental conditions on all demographic and medical variables and found only one difference (data presented in Courneya *et al.*, 2002a). The GP condition contained a higher percentage of married persons (88 versus 61%).

Table 1 details the past exercise and group psychotherapy variables at baseline. There were no differences between experimental conditions on these variables.

Baseline QOL scores indicated significant psychological distress, as might be expected in a sample of GP participants. Specifically, 58.3% of participants scored 16 or above on the CES-D

Table 1. Comparison of experimental conditions on past physical exercise and group psychotherapy variables at baseline

	Overall	GP	GP + EX	<i>p</i> <sup>a</sup>	<i>d</i>
<i>Past physical exercise</i>					
Mild minutes	105.08 (145.50)	88.38 (93.88)	119.82 (178.87)	0.276	0.22
Moderate minutes	45.66 (73.93)	33.78 (59.14)	56.14 (84.07)	0.132	0.30
Strenuous minutes	16.08 (46.83)	15.52 (51.53)	16.57 (42.78)	0.914	0.02
Moderate/strenuous Minutes combined	61.74 (93.17)	49.30 (86.52)	72.71 (98.20)	0.221	0.25
Total minutes	166.82 (185.48)	137.68 (117.76)	192.53 (227.43)	0.149	0.30
% > 60 min of moderate/strenuous	40.6 (49.4)	33.3 (47.7)	47.1 (50.4)	0.174	0.28
<i>Group psychotherapy</i>					
% SMART classes	54.5	54.5	54.5	1.000	0.00
% Participants from SMART classes	63.5 (48.4)	71.1 (45.8)	56.9 (50.0)	0.149	0.29

GP = Group Psychotherapy; GP + EX = Group Psychotherapy plus Exercise; SMART = Stress Management and Relaxation Training.  
<sup>a</sup>*p* level is two-tailed.

(i.e. in need of diagnostic follow up for clinical depression) and the mean STAI (past week) of the group was 48.95 (S.D. = 12.18), which places participants at about the 97th percentile for anxiety compared to age- and sex-based norms. Moreover, baseline fitness test results indicated below average scores for age and sex-based norms. More specifically, the mean for flexibility places the group in the 'fair' category and the mean for sum of skinfolds falls well outside the acceptable level for health benefits (Canadian Society of Exercise Physiology, 2000).

We compared experimental conditions at baseline on our 13 outcome measures and found only one significant difference. The GP condition had significantly higher satisfaction with life [ $t(94) = 2.46$ ,  $p = 0.016$ , two-tailed;  $d = 0.49$ ]. Differences in baseline QOL measures were accounted for in our repeated measures analyses.

#### Fidelity of participants to experimental conditions

Table 2 presents data on the fidelity of participants to their assigned experimental conditions. Over 95% of participants chose walking as their mode of exercise. As expected, the GP+EX condition performed significantly more moderate and strenuous exercise but not more mild exercise. A cut-point of 60 min of moderate/strenuous exercise per week was achieved by 84.4% (43/51) in the GP+EX condition (i.e. the adherence rate) compared to 22.2% (10/45) in the GP condition (i.e. the contamination rate). There were no differences in GP attendance between experimental condition or within GP class type (i.e. SMART versus EST). These data indicate that the exercise intervention was successfully implemented without adversely affecting the GP comparison condition.

Table 2. Fidelity of participants to experimental conditions

	Overall	GP	GP+EX	$p^a$	$d$
<i>Intervention exercise</i>					
Mild minutes	58.42 (64.36)	61.67 (73.54)	55.55 (55.61)	0.645	0.08
Moderate minutes	69.34 (79.90)	30.21 (43.13)	103.86 (83.69)	0.000	1.71
Strenuous minutes	24.02 (63.67)	9.03 (41.29)	37.24 (76.30)	0.030	0.68
Moderate/strenuous Minutes combined	93.35 (118.15)	39.24 (74.30)	141.10 (129.25)	0.000	1.37
Total minutes	151.77 (138.24)	100.91 (104.24)	196.65 (149.56)	0.001	0.92
% > 60 min of moderate/strenuous	55.2 (50.0)	22.2 (42.0)	84.3 (36.7)	0.000	1.48
<i>Group psychotherapy</i>					
Group psychotherapy attendance	6.45 (2.35)	6.01 (2.30)	6.84 (2.34)	0.083	0.36
% Attending 5+ classes	81.3 (39.2)	77.8 (42.0)	84.3 (36.7)	0.418	0.15
Days between testing	73.68 (15.26)	72.22 (17.60)	74.96 (12.89)	0.374	0.16

GP = Group Psychotherapy; GP+EX = Group Psychotherapy plus Exercise. Exercise means and standard deviations are based on weekly exercise reports.

<sup>a</sup> $p$  level is two-tailed.

*Effect of experimental conditions on quality of life*

As hypothesized, results of the RM-MANOVA indicated a significant Time by Condition interaction [Wilk's Lambda = 0.79;  $F(13, 82) = 1.69$ ,  $p = 0.040$ , one-tailed;  $\eta^2 = 0.211$ ]. Follow-up univariate  $F$  tests revealed significant interactions for functional well-being (Figure 2), fatigue (Figure 3), and sum of skin folds (Figure 4). Moreover, we also found borderline significant interactions for physical well-being (Figure 5), satisfaction with life, and flexibility. Descriptive data and complete statistical results for these analyses are presented in Table 3.

We deconstructed the univariate interactions with dependent and independent  $t$ -tests. For functional well-being, the significant interaction was caused by a non significant decrease in the GP condition [ $t(44) = 0.94$ ,  $p = 0.353$ , two-tailed;  $d = 0.11$ ] compared to a significant increase in the GP+EX condition [ $t(50) = 2.17$ ,  $p = 0.018$ , one-tailed;  $d = 0.27$ ]. The significant interaction changed a borderline significant difference in favor of the GP condition at baseline [ $t(94) = 1.69$ ,  $p = 0.094$ , two-tailed;  $d = 0.34$ ] into a nonsignificant difference in favor of the GP+EX condition at posttest [ $t(94) = 0.17$ ,  $p = 0.431$ , one-tailed;  $d = 0.03$ ]. For fatigue, the significant interaction

was caused by a nonsignificant increase in the GP condition [ $t(44) = 0.55$ ,  $p = 0.587$ , two-tailed;  $d = 0.08$ ] compared to a significant decrease in the GP+EX condition [ $t(50) = 1.83$ ,  $p = 0.037$ , one-tailed;  $d = 0.28$ ]. The significant interaction changed a nonsignificant difference in favor of the GP condition at baseline [ $t(94) = 0.49$ ,  $p = 0.626$ , two-tailed;  $d = 0.10$ ] into a nonsignificant difference in favor of the GP+EX condition at posttest [ $t(94) = 1.24$ ,  $p = 0.109$ , one-tailed;  $d = 0.27$ ]. For sum of skinfolds, the significant interaction was caused by a significant increase in the GP condition [ $t(44) = 2.16$ ,  $p = 0.037$ , two-tailed;  $d = 0.14$ ] and a significant decrease in the GP+EX condition [ $t(50) = 2.47$ ,  $p = 0.009$ , one-tailed;  $d = 0.14$ ]. The significant interaction changed a nonsignificant difference in favor of the GP+EX condition at baseline [ $t(94) = 0.54$ ,  $p = 0.591$ , two-tailed;  $d = 0.11$ ] into a significant difference at posttest [ $t(94) = 1.93$ ,  $p = 0.028$ , one-tailed;  $d = 0.37$ ].

For physical well-being, the borderline significant interaction was caused by a nonsignificant increase in the GP condition [ $t(44) = 0.26$ ,  $p = 0.793$ , two-tailed;  $d = 0.04$ ] compared to a significant increase in the GP+EX condition [ $t(50) = 2.16$ ,  $p = 0.018$ , one-tailed;  $d = 0.34$ ]. The borderline interaction changed a nonsignificant

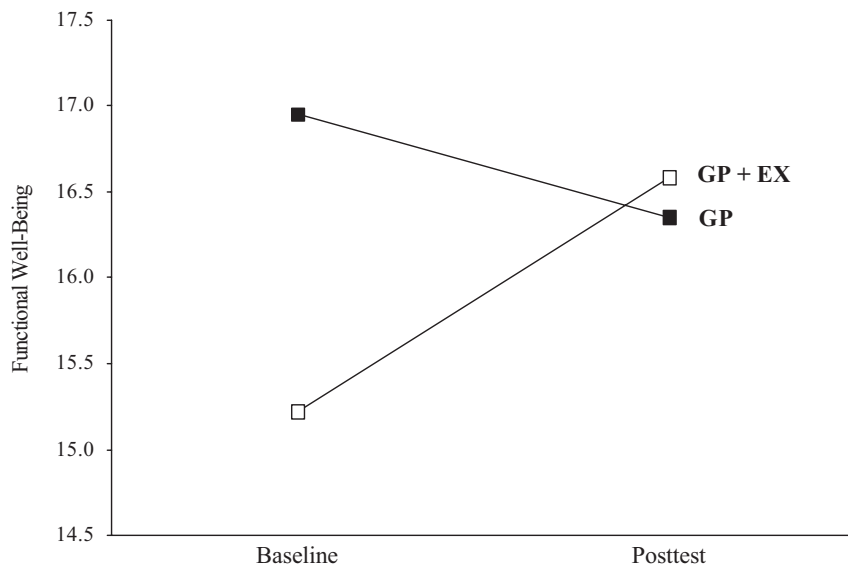


Figure 2. Significant Time by Condition interaction for functional well-being. GP=Group Psychotherapy; GP+EX=Group Psychotherapy plus Exercise.

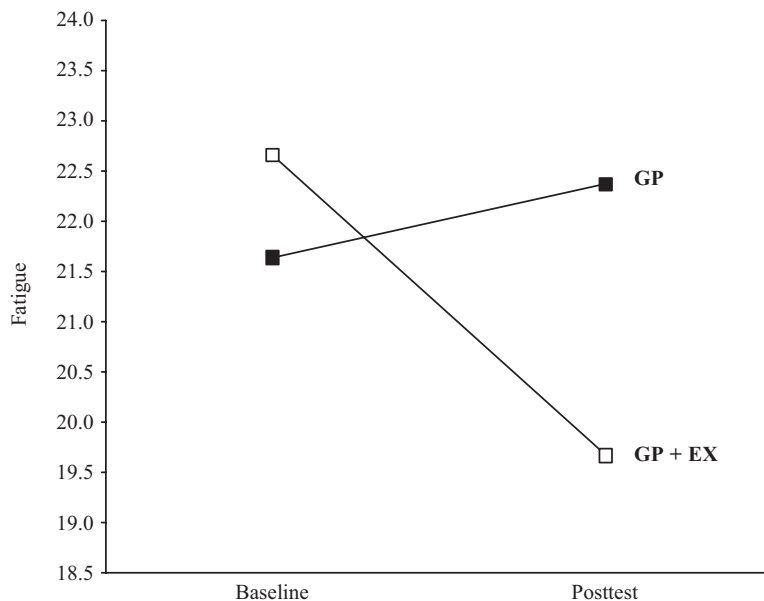


Figure 3. Significant Time by Condition interaction for fatigue. GP=Group Psychotherapy; GP + EX=Group Psychotherapy plus Exercise.

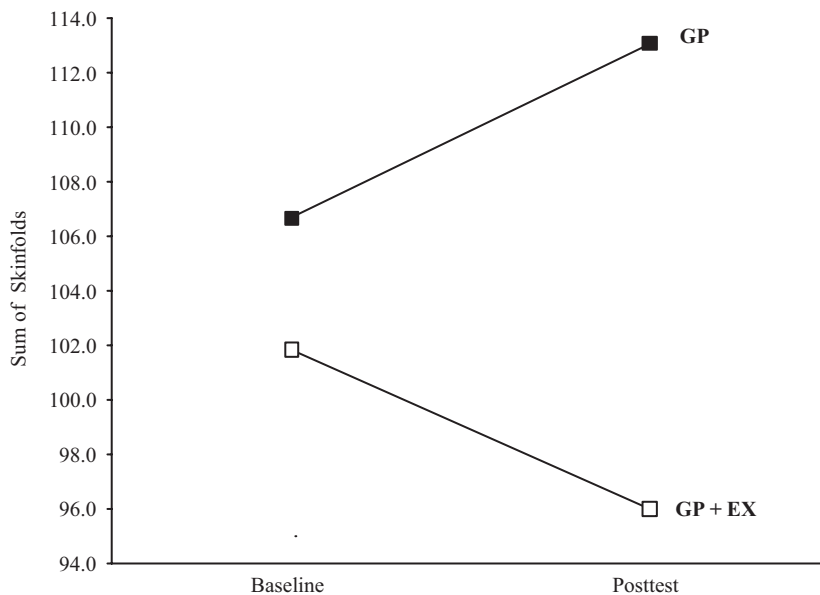


Figure 4. Significant Time by Condition interaction for sum of Skinfolde. GP=Group Psychotherapy; GP + EX=Group Psychotherapy plus Exercise.

difference in favor of the GP condition at baseline [ $t(94) = 0.52$ ,  $p = 0.608$ , two-tailed;  $d = 0.11$ ] into a nonsignificant difference in favor of the GP + EX

condition at posttest [ $t(94) = 0.90$ ,  $p = 0.186$ , one-tailed;  $d = 0.18$ ]. For satisfaction with life, the borderline significant interaction was caused by a

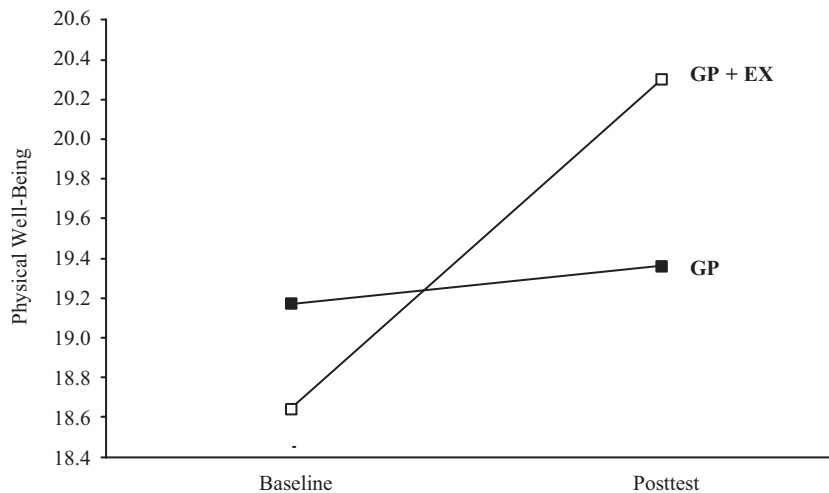


Figure 5. Borderline significant time by Condition interaction for physical well-being. GP = Group Psychotherapy; GP + EX = Group Psychotherapy plus Exercise.

nonsignificant decrease in the GP condition [ $t(44) = 0.70$ ,  $p = 0.488$ , two-tailed;  $d = 0.07$ ] compared to a borderline significant increase in the GP + EX condition [ $t(50) = 1.58$ ,  $p = 0.061$ , one-tailed;  $d = 0.16$ ]. The borderline interaction changed a significant difference in favor of the GP condition at baseline [ $t(94) = 2.46$ ,  $p = 0.016$ , two-tailed;  $d = 0.49$ ] into a nonsignificant difference in favor of the GP condition at posttest [ $t(94) = 1.31$ ,  $p = 0.194$ , two-tailed;  $d = 0.29$ ]. Lastly, for flexibility, the borderline significant interaction was caused by a nonsignificant increase in the GP condition [ $t(44) = 1.22$ ,  $p = 0.229$ , two-tailed;  $d = 0.06$ ] compared to a significant increase in the GP + EX condition [ $t(50) = 2.66$ ,  $p = 0.006$ , one-tailed;  $d = 0.20$ ]. The borderline interaction maintained a nonsignificant difference in favor of the GP + EX condition at baseline [ $t(94) = 0.48$ ,  $p = 0.630$ , two-tailed;  $d = 0.10$ ] into the posttest [ $t(94) = 1.24$ ,  $p = 0.109$ , one-tailed;  $d = 0.23$ ].

We also found a significant main effect for Time [Wilk's Lambda = 0.62;  $F(13, 82) = 3.91$ ,  $p < 0.001$ , two-tailed;  $\eta^2 = 0.382$ ] but not Condition [Wilk's Lambda = 0.82;  $F(13, 82) = 1.35$ ,  $p = 0.205$ , two-tailed;  $\eta^2 = 0.176$ ]. Follow-up univariate  $F$  tests for the Time main effect revealed significant overall improvements in emotional well-being [ $F(1, 94) = 10.26$ ,  $p = 0.002$ , two-tailed;  $\eta^2 = 0.098$ ], spiritual well-being [ $F(1, 94) = 11.28$ ,

$p = 0.001$ , two-tailed;  $\eta^2 = 0.107$ ], anxiety [ $F(1, 94) = 14.94$ ,  $p < 0.001$ , two-tailed;  $\eta^2 = 0.137$ ], treadmill time [ $F(1, 94) = 6.52$ ,  $p = 0.012$ , two-tailed;  $\eta^2 = 0.065$ ], and flexibility [ $F(1, 94) = 7.89$ ,  $p = 0.006$ , two-tailed;  $\eta^2 = 0.077$ ].

#### Ancillary analysis

Although our study was not powered to examine potential moderating factors, we explored this possibility as a hypothesis-generating endeavor for future research. The *a priori* moderators we chose to examine were treatment status (active treatment versus posttreatment), cancer site (breast versus other), and GP class content (SMART versus EST). For each of these analysis, we repeated the RM-MANOVA with each of the moderator variables as an additional between-subjects factor. No significant interactions emerged involving any of the potential moderating variables. We also conducted a 'per protocol' analysis of GP class attendance using only participants who attended at least five GP sessions. These participants (81.3%) averaged 7.26 (S.D. = 1.73) out of the 10 sessions. The results remained unchanged indicating that the superiority of the GP + EX condition over the GP condition is not likely due to a poorly implemented GP intervention.

Table 3. Descriptive statistics and univariate *F* tests for the Time by Condition interaction

	Baseline	Posttest	Time × Condition		
	<i>M</i> (S.D.)	<i>M</i> (S.D.)	F(1,94)	<i>p</i> -Level <sup>a</sup>	$\eta^2$
<i>Physical well-being</i>					
GP	19.17 (5.14)	19.36 (5.11)	1.94	0.084	0.020
GP + EX	18.64 (4.89)	20.30 (5.14)			
Overall	18.89 (4.99)	19.86 (5.12)			
<i>Functional well-being</i>					
GP	16.95 (5.04)	16.39 (5.45)	4.85	0.015	0.049
GP + EX	15.23 (4.96)	16.58 (5.30)			
Overall	16.04 (5.04)	16.49 (5.34)			
<i>Emotional well-being</i>					
GP	14.87 (4.60)	16.60 (4.19)	0.05	0.416	0.000
GP + EX	15.58 (5.02)	17.09 (4.66)			
Overall	15.25 (4.82)	16.86 (4.43)			
<i>Social/family well-being</i>					
GP	18.26 (5.02)	18.59 (4.62)	0.48	0.246	0.005
GP + EX	16.98 (5.36)	17.85 (4.13)			
Overall	17.58 (5.21)	18.20 (4.36)			
<i>Spiritual well-being</i>					
GP	30.87 (6.44)	32.78 (7.02)	0.02	0.447	0.000
GP + EX	28.13 (9.21)	30.20 (9.01)			
Overall	29.42 (8.11)	31.41 (8.20)			
<i>Life satisfaction</i>					
GP	23.13 (6.42)	22.68 (6.68)	2.68	0.053	0.028
GP + EX	19.51 (7.82)	20.76 (7.59)			
Overall	21.21 (7.39)	21.66 (7.21)			
<i>Anxiety</i>					
GP	49.48 (12.02)	44.34 (8.98)	0.03	0.428	0.000
GP + EX	48.49 (11.08)	43.81 (11.97)			
Overall	48.95 (11.48)	44.06 (10.62)			
<i>Depression</i>					
GP	18.57 (11.84)	18.31 (11.37)	0.50	0.242	0.005
GP + EX	21.51 (11.45)	19.65 (13.28)			
Overall	20.13 (11.66)	19.02 (12.38)			
<i>Fatigue</i>					
GP	21.64 (9.69)	22.37 (9.84)	3.03	0.043	0.031
GP + EX	22.66 (10.57)	19.67 (11.31)			
Overall	22.18 (10.13)	20.93 (10.68)			
<i>Treadmill time</i>					
GP	430.56 (333.43)	485.82 (345.71)	0.00	0.483	0.000
GP + EX	475.33 (336.69)	528.80 (362.44)			
Overall	454.34 (334.16)	508.66 (353.49)			
<i>Sum of skinfolds</i>					
GP	106.69 (47.13)	113.09 (46.57)	10.61	0.001	0.101
GP + EX	101.85 (40.86)	96.02 (40.02)			

Table 3 (continued)

	Baseline	Posttest	Time × Condition		
	<i>M</i> (S.D.)	<i>M</i> (S.D.)	<i>F</i> (1,94)	<i>p</i> -Level <sup>a</sup>	$\eta^2$
Overall	104.12 (43.74)	104.02 (43.83)			
<i>Weight</i>					
GP	74.49 (15.72)	74.65 (15.91)	0.05	0.413	0.001
GP + EX	69.10 (13.38)	69.15 (12.99)			
Overall	71.63 (14.70)	71.73 (14.62)			
<i>Flexibility</i>					
GP	25.32 (11.78)	26.01 (12.08)	2.28	0.068	0.024
GP + EX	26.45 (11.24)	28.75 (9.50)			
Overall	25.92 (11.45)	27.46 (10.82)			

GP = Group Psychotherapy; GP + EX = Group Psychotherapy plus Exercise.

<sup>a</sup>*p* level one-tailed.

## DISCUSSION

The primary finding of our study was that a 10 week, home-based, moderate intensity exercise program improved QOL in cancer survivors beyond GP alone. More specifically, we found significant beneficial effects for functional well-being, fatigue, and sum of skinfolds. We also found borderline significant effects for physical well-being, satisfaction with life, and flexibility. The overall multivariate effect of our exercise intervention on QOL was very large ( $\eta^2 = 0.211$ ) and the individual effects were mainly in the small to medium range. The magnitude of these effects are slightly higher than those reported in a meta-analysis of cognitive-behavioral, informational/educational, psychotherapy, and social support interventions for cancer survivors (Meyer and Mark, 1995). Moreover, we consider these effects to be meaningful considering that they are above and beyond the benefits of GP.

The pattern of results appears to support our hypothesis that exercise would have a broader effect on QOL because five of the six affected outcomes are related to physical and functional well-being. There were no changes in any of the specific indicators of emotional or social well-being. The effect on satisfaction with life may be considered to support both the 'deeper' and 'broader' hypotheses because it is likely a summary measure of physical and functional well-being as well as emotional and social well-being (Courneya and Friedenreich, 1997a, b). Notwithstanding the limited effects of our intervention on emotional

and social well-being, the beneficial effects on physical and functional well-being are noteworthy.

The improvement in functional well-being is consistent with a recent randomized trial of 122 breast cancer survivors (Segal *et al.*, 2001). This finding is particularly important because very few extant interventions are designed to address functional well-being in cancer survivors. Yet, previous research has shown that functional well-being may be the least possessed but most important dimension underlying overall satisfaction with life in cancer survivors both during (Courneya *et al.*, 1999, 2000a) and after (Courneya and Friedenreich, 1997a, b) treatments. Exercise may be one of the few interventions that can enhance functional well-being in cancer survivors and, consequently, its incorporation into coping and rehabilitation programs for cancer survivors may be essential.

The salutary effect of our intervention on fatigue is also noteworthy. Fatigue is considered one of the most common and distressing symptoms of the cancer experience (e.g. Irvine *et al.*, 1998, 1994; Kurt *et al.*, 1999) and can persist for months or even years after cancer treatments (Jacobsen and Stein, 2000). Moreover, very few interventions have been proven to reduce fatigue (Crawford and Gabrilove, 2001) and it is often treated inappropriately with rest (Kurt *et al.*, 1999). For example, a recent survey reported that when cancer survivors asked their physicians what they recommended to reduce fatigue, 40% said nothing, 37% said rest or relaxation, and only 5% said exercise (Kurt *et al.*, 1999). Our finding is

consistent with a growing body of literature showing that exercise can help manage fatigue in cancer survivors (Dimeo *et al.*, 1999; MacVicar and Winningham, 1986; Mock *et al.*, 1994, 1997). Consequently, exercise may merit recognition as a primary treatment of fatigue in cancer survivors. Interestingly, the fact that our GP intervention did not reduce fatigue is consistent with a recent large scale GP intervention in metastatic breast cancer survivors (Goodwin *et al.*, 2001).

A third major finding of the present study was the differential changes in skinfold measures over the intervention. We found a significant increase in the GP condition and a significant decrease in the GP + EX condition. Previous exercise research has shown that exercise can produce weight loss (Segal *et al.*, 2001; Schwartz, 1999), prevent weight gain (Schwartz, 2000), and improve body composition in breast cancer survivors (Winningham *et al.*, 1989). Weight gain is a common problem for women treated for breast cancer and may be a prognostic factor for survival (Camoriano *et al.*, 1990). Moreover, on the primary prevention side, obesity is a strong risk factor for various cancers including endometrial, kidney, gallbladder, breast, and colon (Bergstrom *et al.*, 2001). Improvements in body composition in cancer survivors, therefore, may be even more etiologically relevant for prognosis than improvements in fitness.

The borderline significant interactions for physical well-being, flexibility, and satisfaction with life provide further support for the effectiveness of our intervention. Satisfaction with life is arguably the most clinically relevant outcome because it represents an overall evaluation of life rather than of a specific symptom or function. Proportionately, it may be the most difficult to change. No previous exercise intervention studies in cancer survivors have shown changes in such a overarching outcome, although descriptive studies have reported positive correlations between exercise and satisfaction with life (Courneya and Friedenreich, 1997b; Courneya *et al.*, 1999, 2000a).

It was disappointing that our exercise intervention did not produce additional improvements in emotional and social well-being. Previous exercise research has clearly demonstrated such improvements in cancer survivors, however, as mentioned earlier, these studies have either compared exercise to a usual care control condition or did not include a control condition. The obvious explanation for our null findings, therefore, is the quality of our comparison condition. GP alone was sufficient to

improve anxiety, emotional well-being, and spiritual well-being and perhaps it is unreasonable to expect further improvements in these parameters from exercise. Nevertheless, there was certainly room for further improvements given the high level of distress in our sample, even after the intervention was over. An understanding of the mechanisms by which GP and exercise improve emotional well-being in cancer survivors may help to determine their potential overlapping or complementary nature.

One perplexing finding of the present study is that both conditions improved equally and significantly in cardiovascular endurance despite the fact that the GP + EX condition reported 3.6 times the amount of moderate/strenuous exercise. The significant improvement in fitness we found in the GP + EX condition is consistent with previous research in cancer survivors (Dimeo *et al.*, 1999; Winningham and MacVicar, 1986; Segal *et al.*, 2001). It is possible that participants in the GP condition were so deconditioned that even the mild exercise they performed (about 60 min), or the modest amount of moderate/strenuous exercise they performed (40 min), resulted in fitness improvements. It is also possible that participants in the GP + EX condition may have overestimated the intensity of their exercise in the self-report measure. This possibility would explain why there were significant differences in body composition between the experimental conditions (which is dependent on the total volume of exercise) but not cardiovascular endurance (which is more dependent on intensity). Lastly, the MBTT is a submaximal measure of aerobic capacity based on heart rate response, which may vary dramatically based on disease and treatment status. Unfortunately, there are no submaximal measures of aerobic capacity that have been validated with cancer survivors.

Interestingly, we found that cancer site (breast versus other), treatment status (active versus completed), and GP class content (SMART versus EST) did not moderate the effectiveness of our intervention. The majority of the 40 published studies on exercise in cancer survivors have examined breast cancer survivors, with a smaller number examining bone marrow transplant survivors. Very little research has examined other major cancers (e.g. colorectal, prostate, lung) and research with these other groups of cancer survivors is warranted. The fact that treatment status did not modify our intervention effect is consistent

with research that has found exercise useful both during and after adjuvant therapy (See Courneya *et al.*, 2002b, in press a, for reviews). It is important to note, however, that our study was not powered to examine these moderators and future research on these issues is warranted.

Several biopsychosocial mechanisms may explain the QOL improvements in cancer survivors that result from exercise training. The most common explanations relate to improvements in cardiovascular fitness, muscular endurance, body composition, endorphins, psychological distraction, mastery achievements, positive feedback from others, and social interaction. Few studies, however, have examined mechanisms of change (Courneya, 2001). In the present study, we found effects on body composition and flexibility but not on cardiovascular endurance or social well-being. Other possible mediating mechanisms for the present findings were not measured. Further studies designed specifically to examine mediating mechanisms between exercise and QOL in cancer survivors are needed.

Importantly, it is unlikely that the results of our study can be explained by a poor implementation of the GP intervention. First, attendance at the GP classes averaged 65%, which is comparable to other studies on the effectiveness of GP interventions (e.g. Goodwin *et al.*, 2001; Helgeson *et al.*, 1999; Spiegel *et al.*, 1999). Second, when we restricted our analyses to only those participants who attended at least 50% of the GP classes (and averaged 73% attendance), we still found significant effects for our exercise intervention. Finally, and perhaps most importantly, we observed significant improvements in the GP condition over time (e.g. anxiety, emotional well-being, spiritual well-being) consistent with previous literature on GP and QOL (Blake-Mortimer *et al.*, 1999). These findings indicate that we compared our exercise intervention to an effective GP condition.

Still, there are limitations in our study that need to be taken into consideration when interpreting the findings and planning future research. First, we did not use a full factorial design (i.e. usual care controls, EX alone, GP alone, and GP+EX). Consequently, we cannot comment on the relative utility of EX alone versus GP alone, or of GP+EX versus EX alone. We restricted our study to the GP and GP+EX conditions because we felt that this was an ecologically valid question. That is, there are many cancer survivors who voluntarily join GP classes around the world. Moreover,

the participants who voluntarily join GP classes may be different than participants who would agree to be randomized to a GP condition. A full factorial design would not likely attract participants who felt they should seek psychotherapy and, consequently, it would be a different sample and a different study question. Our study generalizes to cancer survivors who voluntarily seek GP counseling. Still, further research using a full factorial design may provide important additional information on the combined effects of EX and GP.

Second, our exercise intervention was not supervised. Consequently, we were unable to tightly regulate the frequency, intensity, and duration of the exercise and had to rely on self-report measures of exercise. Of course, supervised exercise programs incur problems of their own including uncontrolled social interaction during the exercise bout, low cost-effectiveness, and limited generalizability. The home-based exercise program implemented in the present study has greater ecological validity because it is cost-effective and the majority of cancer survivors prefer unsupervised exercise at home (Jones and Courneya, 2002). Nevertheless, future research might use objective activity monitors or supervised fitness programs to verify levels of exercise behavior.

Third, our exercise program was only 10 weeks in length and we did not provide any long-term follow-up because of the cross-over design (i.e. controls received the intervention at the end of the study). Consequently, our conclusions are restricted to the short term effects of exercise in GP participants. Studies providing longer term follow-up are needed to determine if the intervention effects are short lived or, alternatively, if there are any late-appearing benefits of exercise. Fourth, we recruited participants from two types of GP classes led by one clinical psychologist from one cancer center. Our results may not generalize to other types of GP classes led by different clinical psychologists from other cancer centers. Replication of our results elsewhere is needed to document the generalizability of our findings.

Fifth, we did experience some exercise adherence and contamination problems. About 20% of participants in the exercise condition failed to meet our minimum cut-point of averaging 60 min of moderate/strenuous exercise per week whereas 20% in the control condition did meet this cut-point. Some of the contamination problem may

have resulted from having the control condition monitor and report their exercise on a weekly basis or because we allowed previous exercisers into the study. Correlates of adherence and contamination in this study are presented elsewhere (Courneya *et al.*, 2002a) and the information may help with the implementation of future trials in this population. Importantly, the adherence and contamination problems likely reduced the effect of our intervention. Lastly, our participants were mostly white, well-educated, middle-to-upper class women, which are common biases among participants in cancer support groups (Taylor *et al.*, 1986).

In summary, the GROUP-HOPE trial is the first randomized controlled trial to compare exercise to another validated QOL intervention in cancer survivors. Thus, it provided the most rigorous and useful test of a novel intervention by comparing it to the current gold standard. We had excellent recruitment and retention rates. Our randomization to experimental conditions was successful and fidelity to our experimental conditions was very good. We included fitness testing and used QOL measures that assessed clinically meaningful outcomes and possessed excellent psychometric properties. Lastly, the exercise intervention we evaluated is easily transferable to other clinic-based or community-based psychosocial oncology practices. Our results indicate that exercise improves QOL in cancer survivors beyond GP, especially for physical and functional outcomes. If our findings are replicated, practitioners who offer GP classes to cancer survivors may consider exercise as possible adjunct therapy, primarily to enhance physical and functional well-being.

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#### NOTE

1. As suggested by the National Coalition for Cancer Survivorship (<http://www.cansurvivorship.org/>) we use the term cancer survivor to refer to 'Any individual that has been diagnosed with cancer, from the time of discovery and for the balance of life'. Our sample contains both cancer survivors on active treatment and those who have completed treatment.

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