

# Change in Exercise Tolerance, Activity and Sleep Patterns, and Quality of Life in Patients With Cancer Participating in a Structured Exercise Program

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**Purpose/Objectives:** To investigate the feasibility of an exercise program patterned after a phase II cardiac rehabilitation program to improve selected physiologic and psychological parameters of health in patients with cancer.

**Design:** Prospective, repeated measures study.

**Setting:** Two major military medical centers in the southwestern United States.

**Sample:** 62 patients diagnosed with cancer within the previous two years. Ages ranged from 24–83 ( $\bar{X} = 59$ ). Half of the participants were male and half were female. Minorities made up 29% of the sample. Participants had a wide range of cancer diagnoses and all stages of cancer. Fifteen subjects were undergoing treatment when they enrolled in the study. More than half of the subjects exercised prior to their cancer diagnoses, but fewer than half were able to resume an exercise routine following their cancer diagnoses.

**Methods:** Subjects met two days each week for 12 weeks for exercise and education.

**Main Research Variables:** Exercise tolerance as measured with a graded exercise test, activity and sleep patterns as measured with a wrist actigraph, and quality of life (QOL) as measured with the Cancer Rehabilitation Evaluation System–Short Form.

**Findings:** Significant improvements were observed over time in exercise tolerance, selected activity and sleep patterns, and QOL among the 46 (74%) subjects who completed the program.

**Conclusions:** Patients with various types and stages of cancer can safely exercise using a cardiac rehabilitation model and can realize significant improvements in exercise tolerance, selected activity and sleep patterns, and QOL.

**Implications for Nursing:** Most people are aware that regular exercise is part of a healthy lifestyle. After cancer diagnosis and treatment, patients experience uncertainty regarding how to resume exercise or how to begin an exercise program as part of their rehabilitation. Participation in a structured exercise program can provide patients with a safe environment within which to exercise at an intensity appropriate to their individual needs.

### Key Points . . .

- More than 40 studies published since 1980 have demonstrated that physical activity in patients with cancer improves functional capacity and quality of life.
- Structured cardiac rehabilitation programs have been offered for more than 60 years and are the best developed and tested of the exercise rehabilitation models for chronically ill patients.
- Between 44% and 75% of patients with cancer experience difficulty sleeping. Exercise improves sleep in the general population, but the effect in patients with cancer is unknown.
- Outcomes in patients with various types of cancer at all stages can be improved by participation in a 12-week exercise program patterned after a phase II cardiac rehabilitation program.

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In the United States today, almost nine million people have a history of cancer (American Cancer Society, 2003). The majority are survivors, but approximately four million people are living with cancer (American Cancer Society). Medical care for people with cancer has concentrated almost exclusively on diagnosis and treatment until the past decade, when rehabilitation and health promotion

also have been recognized as essential components of care (Association of Rehabilitation Nurses & Oncology Nursing Society, 1999; Courneya, 2001; Friedenreich & Courneya, 1996).

For chronically ill patient populations, exercise can play a prominent role in maintaining health. Exercise has proven to be beneficial in the management of arthritis (Neuberger et al., 1997; Neuberger, Kasal, Smith, Hassanein, & DeViney, 1994), cardiovascular disease (Balady et al., 2000; Dafoe & Huston, 1997; Wenger et al., 1995), diabetes mellitus (Barnard, Jung, & Inkeles, 1994; Khan & Rupp, 1995; Maynard, 1991), pulmonary disease (Cambach, Chadwick-Straver, Wagenaar, van Keimpema, & Kemper, 1997; Lacasse, Guyatt, & Goldstein, 1997; Tiep, 1997), renal disease (Boyce et al., 1997; Painter, 1994), HIV (Baigis-Smith, Coombs, & Larson, 1994), and psychological stress (Weyerer & Kupfer, 1994). In the growing number of studies that have investigated exercise rehabilitation in patients with cancer, dramatic improvements in physiologic and psychological functioning have been documented in patients participating in aerobic exercise programs. A meta-analysis of 24 studies published from 1980–1997 (Courneya & Friedenreich, 1999) indicated that physical activity in patients with cancer resulted in improvements in functional capacity (Dimeo et al., 1996; Dimeo, Fetscher, Lange, Mertelsmann, & Keul, 1997; Dimeo, Tilmann, et al., 1997; MacVicar, Winningham, & Nickel, 1989; Mock et al., 1994, 1997; Winningham, MacVicar, Bondoc, Anderson, & Minton, 1989) and quality of life (QOL) (Courneya & Friedenreich, 1997a, 1997b; Young-McCaughan & Sexton, 1991), as well as relief from fatigue (Mock et al., 1994, 1997). Research published in the past five years has continued to support these findings (Blanchard, Courneya, & Laing, 2001; Courneya, Friedenreich, Arthur, & Bobick, 1999; Dimeo, Stieglitz, et al., 1997; Dimeo, Stieglitz, Novelli-Fischer, Fetscher, & Keul, 1999; Mock et al., 2001; Porock, Kristjanson, Tinnelly, Duke, & Blight, 2000; Schwartz, 1998, 1999, 2000a, 2000b; Schwartz, Mori, Gao, Nail, & King, 2001; Segal et al., 2001; Segar et al., 1998).

One outcome that has not been systematically investigated as being affected by exercise in patients with cancer is sleep. Various studies have reported that 44%–75% of patients with cancer experience difficulty sleeping (Andrykowski et al., 1997; Engstrom, Strohl, Rose, Lewandowski, & Stefanek, 1999; Miaskowski & Lee, 1999). Changes in activity levels and sleep disturbances often occur simultaneously. Many patients report extreme fatigue during the day but an inability to sleep at night. In women with breast cancer undergoing chemotherapy, the effects of daytime inactivity and nighttime awakenings have been associated with higher cancer-related fatigue (Berger, 1998; Berger & Farr, 1999; Berger & Higginbotham, 2000). Exercise has been shown to improve sleep in the general population (Horne, 1981; Youngstedt, O'Connor, & Dishman, 1997), and anecdotal evidence suggests that some patients find that regular exercise improves their overall energy level and that they sleep better at night. The mechanism for how exercise might relieve fatigue, improve energy, or improve sleep is unknown.

Studies evaluating an exercise intervention in patients with cancer have employed both clinic-based (Dimeo et al., 1996; Dimeo, Fetscher, et al., 1997; Dimeo, Tilmann, et al., 1997, 1999; Segal et al., 2001; Winningham & MacVicar, 1988) and home-based exercise programs (Mock et al., 1994, 1997, 2001; Porock et al., 2000; Schwartz, 1999, 2000a, 2000b; Schwartz et al., 2001; Segal et al., 2001; Segar et al., 1998). However, ex-

cept in one study that used a cardiac rehabilitation program to improve exercise tolerance in 12 survivors of a childhood malignancy (Sharkey, Carey, Heise, & Barber, 1993), no published studies have used a cardiac rehabilitation model for patients with cancer. Cardiac rehabilitation programs are the best developed and tested of the exercise rehabilitation models for chronically ill patients. Outcomes of these programs for patients with cardiac disease include improvement in functional capacity, lessening of symptoms, reduced disability, and improved psychosocial well-being (American Association of Cardiovascular and Pulmonary Rehabilitation, 1999).

Cardiac rehabilitation programs typically have trained personnel and a variety of exercise equipment. Patients with cancer could be enrolled in these same programs, making use of existing space and equipment. Recruiting patients with cancer into existing cardiac rehabilitation programs could provide an environment for patients with cancer to safely exercise and could facilitate research investigating the use of aerobic exercise in the rehabilitation of this patient population.

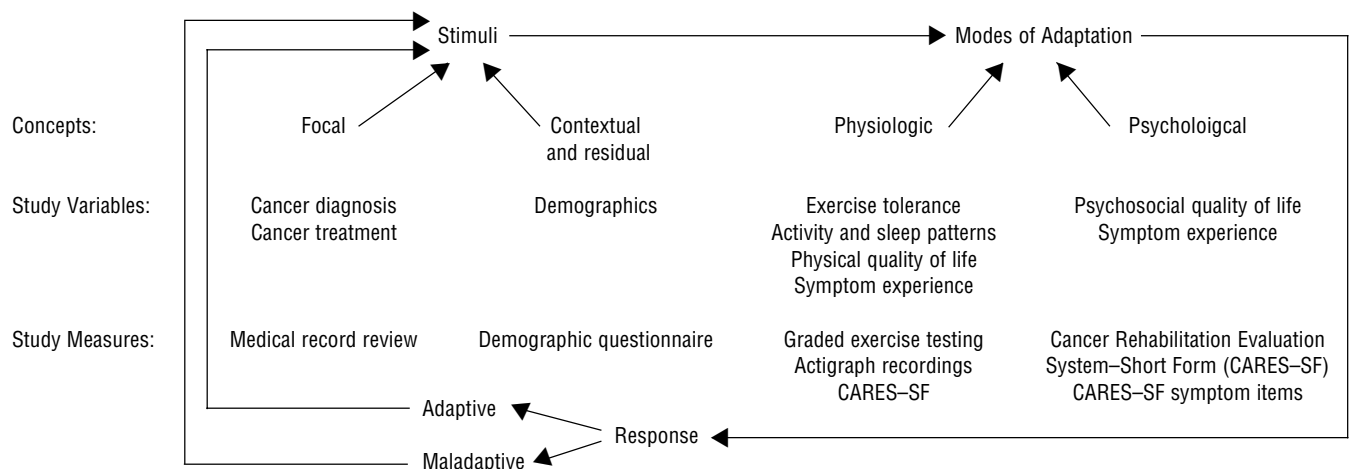
The purpose of this study was to investigate the feasibility of an exercise intervention program patterned after a phase II cardiac rehabilitation program to positively influence selected physiologic and psychological parameters of health in patients with cancer. The following research questions were posed.

1. What are the changes in exercise tolerance, activity and sleep patterns, and QOL experienced by patients with cancer while they participate in a 12-week, phase II cardiac rehabilitation program?
2. Do certain demographic, cancer-related, treatment-related, physiologic, or psychological variables either encourage or prevent patients with cancer from participating in a 12-week, phase II cardiac rehabilitation program?

## Framework

The Roy Adaptation Model (Roy & Andrews, 1991) guided the design of this study. The model is based on the assumption that people are in constant interaction with a changing environment. To cope with a changing world, people use various biologic, psychological, and social mechanisms. Incoming stimuli activate coping mechanisms. Focal stimuli are those most immediately confronting a person (e.g., cancer diagnosis, treatment). Contextual stimuli are all other stimuli present in the situation that contribute to the effect of focal stimuli (e.g., age, socioeconomic status, social support, family responsibilities). Residual stimuli are environmental factors that may affect the situation (e.g., previous experience with cancer, previous experience with exercise). A person's modes of adaptation elicit either an adaptive or maladaptive response. The response then serves as feedback that affects the perception and processing of incoming stimuli. Adaptive responses promote the integrity and wholeness of the person. The goal of nursing is to promote adaptation and thereby contribute to health and QOL.

The Roy Adaptation Model has proven useful in the study of various aspects of cancer care (Maxwell, Givant, & Kowalski, 2001; Nuamah, Cooley, Fawcett, & McCorkle, 1999; Tulman & Fawcett, 1990; Young-McCaughan, 1996), including the use of exercise in patients with cancer (Mock et al., 1994, 1997). Figure 1 illustrates the relationship between the components of the Roy Adaptation Model and this study's variables. The focal stimuli are the diagnosis and treatment of cancer. Contextual and residual stimuli all affect coping



**Figure 1. Investigating the Ability of an Exercise Intervention Program to Positively Influence Selected Physiologic and Psychological Parameters of Health in Patients With Cancer Using the Roy Adaptation Model**

mechanisms and, in turn, modes of adaptation. Responses to previous stimuli modulate the processing of new stimuli affecting adaptation. In this study, exercise was tested as an intervention to facilitate positive adaptation.

## Methods

### Sample and Setting

Subjects were recruited from the oncology clinics of two major military medical centers in the southwestern United States. All study subjects had a biopsy-proven cancer diagnosis within the previous two years, were at least 18 years old, were able to read and speak English, and had a medical statement from either the patient's primary care provider or the primary oncologist indicating that participation in the program was not medically contraindicated. Patients with bone or joint destruction that could have been aggravated with exercise and those who had severe cognitive impairment, identified by either the patient's medical care provider or by the study team, were excluded from the study.

During the course of the study, 3,139 medical records were screened, identifying 500 patients who were eligible. The study team contacted 323 patients, and 62 (19%) consented to participate. The primary reasons patients gave for not being able to join the study were living out of town and not being able to commute to the hospital twice a week to exercise ( $n = 74$ , 23%), not being able to make the exercise and education times because of scheduling conflicts with work and home responsibilities ( $n = 62$ , 19%), wanting to wait until treatment was completed to make a decision ( $n = 34$ , 11%), and currently exercising and not needing or wanting to join a structured program ( $n = 19$ , 6%).

### Study Design and Main Research Variables

This was a prospective, repeated-measures study. The independent variable was a 12-week exercise program modeled after an existing phase II cardiac rehabilitation program. The dependent variables were changes over time in exercise tolerance, activity and sleep patterns, and QOL.

**Exercise intervention program:** The hospital's ongoing Cardiac Rehabilitation Program is a three-phase program be-

ginning in the hospital. Phase II is an outpatient program beginning when the patient is discharged from the hospital. It is designed to increase exercise tolerance, provide education for cardiac risk factor behavior modification, and enhance psychological status. In this study, patients with cancer were enrolled into an exercise program similar to the existing phase II cardiac rehabilitation program. Just as with the existing program, subjects were instructed to exercise at a prescribed "step" ranging from 1–18. Each step outlined walking duration, speed, and grade; number and duration of stair step exercises; and arm exercises with progressive increases in intensity. Patients met twice a week for supervised exercise as prescribed by an exercise physiologist. As with the existing phase II cardiac rehabilitation program, subjects were expected to exercise an additional three to five times per week and record the type, duration, and intensity of their exercise in an exercise log. Exercise logs were reviewed with patients each week by a member of the research team to encourage maximum participation and assess whether a subject's exercise prescription needed to be modified. In addition to the classes on the anatomy and physiology of exercise, nutrition, stress management, and decision making given to cardiac patients, classes for patients with cancer included cancer and cancer therapies, drug review, sleep, spiritual health, QOL, and health evaluation and assessment.

### Demographic Information

Demographic, cancer diagnosis, and cancer treatment information was collected at the beginning of the study by a questionnaire completed by each subject and a medical record review completed by a member of the research team.

### Exercise Tolerance

Exercise tolerance was measured with maximal graded exercise testing before and after the 12-week exercise program. American College of Sports Medicine guidelines for exercise testing (American College of Sports Medicine, 2000) were followed using the Bruce protocol which dictated the speed, grade, and duration of the test (Bruce, Kusumi, & Hosmer, 1973). Estimated maximal oxygen uptake ( $VO_{2MAX}$ ) was calculated using a validated equation for the protocol

(McConnell & Clark, 1987). All estimated  $\text{VO}_{2\text{MAX}}$  units were converted into metabolic equivalents (METs) (American College of Sports Medicine). Exercise capacity commonly is calculated in METs; one MET is equal to 3.5 ml/kg per minute, or the average oxygen uptake of a person at rest (American College of Sports Medicine). As exercise capacity increases, so do the METs a patient can comfortably expend during graded exercise testing. METs were used in this study to describe the change in exercise tolerance from baseline to week 12.

**Activity and sleep patterns:** Activity and sleep data were collected four times during the study from a wrist-worn Motionlogger™ Actigraph (Ambulatory Monitoring, Inc., Ardsley, NY). An actigraph is a microcomputer that measures movement in three dimensions. The displacement of a sensor beam in the actigraph generates a voltage proportional to the deflection (Leidy, Abbott, & Fedenko, 1997; Mason & Redeker, 1993; Tryon, 1991). These changes in voltage are recorded by the actigraph as activity counts per epoch of time.

The actigraph has proven to be a valid and reliable measure of both activity and sleep. The actigraph differentiates between physical activity and sedentary activity and is highly correlated with oxygen uptake and heart rate during sedentary and physical activity (Leidy et al., 1997; Patterson et al., 1993). Actigraph algorithms for characterizing sleep periods and sleep stages correlate highly with electroencephalograph recordings (Cole, Kripke, Gruen, Mullaney, & Gillin, 1992). The actigraph has been used in a wide variety of populations, including healthy, elderly people (Evans & Rogers, 1994); women after coronary artery bypass surgery (Redeker, Mason, Wykpisz, Glica, & Miner, 1994); patients with chronic congestive heart failure (Davies, Jordan, & Lipkin, 1992); and patients with cancer (Berger, 1998; Berger & Farr, 1999; Berger & Higginbotham, 2000; Sarna & Conde, 2001).

Actigraphs were initiated to collect data in one-minute epochs. Data were retrieved from the actigraphs using ACT (version 7.66) computer software (Ambulatory Monitoring, Inc.). Participants in the study wore an actigraph for 72 hours at baseline and during weeks 4, 8, and 12 of the study. Watches began collecting data as they were donned (typically from 10 am–3 pm on Tuesday) and continued until they were returned (typically from 10 am–3 pm on Friday). ActionW (version 1.38) computer software (Ambulatory Monitoring, Inc.) was used to produce linear actigrams, score sleep, and calculate summary statistics. To provide a consistent and complete record across all participants and all weeks, actigrams were trimmed to a single 48-hour record. Records began at 9:01 am on Wednesday and ended at 9 am on Friday. Brief periods of time when the watch was not worn (e.g., during showering or bathing) were marked as nonscored intervals. Each 48-hour record included two “up” (active) periods and two “down” (rest) periods. Sleep periods during the 48 hours were scored using the Cole-Kripke (with rescore) algorithm (Action3, 1995). Two measures of daytime activity and four measures of sleep were used to characterize the activity and sleep patterns of the participants. Definitions of these six measures are described in Figure 2.

**QOL:** The Cancer Rehabilitation Evaluation System–Short Form (CARES–SF) was used to measure QOL four times during the study. CARES–SF is a self-administered

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### Daytime Activity Measures

**Activity level:** The actigraph determined “activity count” for each one-minute epoch of the up-interval summed across epochs in the up-interval divided by the number of epochs, thereby providing a mean level of activity during the up-interval. The mean activity level for the two up-intervals was averaged to provide a single value for “activity level” in a typical minute of each day.

**Percentage of napping:** The sum of the number of one-minute epochs during the up-interval scored as sleep, divided by the total number of one-minute epochs during the up-interval, multiplied by 100. The percentage of napping for the two up-intervals was averaged to provide a single value for “percentage of napping” in a typical day. A person normally might nap only 1% of the time he or she is up during the day.

### Sleep Measures

**Duration of sleep:** The sum of the number of one-minute epochs that were scored as sleep during the down-interval. The duration of sleep for the two down-intervals was averaged to provide a single value for the “duration of sleep” in a typical night. A person normally attempts to sleep seven to nine hours (420–540 minutes) in 24 hours (Rechtschaffen & Siegel, 2000).

**Percentage of sleep:** The sum of the number of one-minute epochs during the down-interval that were scored as sleep, divided by the total number of one-minute epochs during the down interval, multiplied by 100. The percentage of sleep for the two down intervals was averaged to provide a single value for “percentage of sleep” in a typical night; 95% indicates a good night’s sleep, 90%–95% indicates a good night’s sleep with some tossing and turning, 85%–90% indicates a problematic night’s sleep, and less than 85% indicates a bad night’s sleep (Miaskowski & Lee, 1999).

**Number of awakenings:** The number of epochs in a down-interval in which the participant changed from asleep to awake. The number of awakenings for the two down-intervals was averaged to provide a single value for the “number of awakenings” in a typical night. A person normally awakens two to six times during a typical night’s sleep of 420 minutes (Rechtschaffen & Siegel, 2000).

**Sleep episode length:** The sum of the number of one-minute epochs during each episode of sleep during the down-interval divided by the total number of sleep episodes during the down-interval. The sleep episode length for the two down-intervals was averaged to provide a single value for the “sleep episode length” in a typical night. A person normally has sleeping episodes lasting 90–110 minutes) in 24 hours (Rechtschaffen & Siegel, 2000).

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### Figure 2. Measures of Daytime Activity and Sleep Obtained From the Actigraph for This Study

questionnaire designed to measure QOL in people with cancer (Ganz, Schag, & Cheng, 1990; Schag, Ganz, & Heinrich, 1991). Subjects respond to statements indicating how much a particular problem applies to them by using a five-point rating scale that ranges from “not at all” to “very much.” CARES–SF produces scores for overall QOL as well as scores for five domains of QOL (Schag, Heinrich, Aadland, & Ganz, 1990). The five domains addressed are physical functioning, psychosocial functioning, medical interaction, marital, and sexual (Schag et al., 1990). Of particular interest in this study were the overall QOL score and the physical and psychosocial functioning domain scores. Lower scores indicate better QOL.

A long version of CARES originally was developed using a competency-based model of coping with cancer. CARES has undergone extensive psychometric testing to establish the instrument’s reliability and validity (Schag et al., 1990, 1991). From the original version of the CARES, a shorter version was developed, CARES–SF (Schag et al., 1991). CARES–SF still assesses patients in five domains of QOL but takes the

patient much less time to complete. Data previously collected from 1,760 patients in four different samples of patients with cancer were used to demonstrate that CARES-SF is highly related to CARES ( $r = 0.98$ ). CARES-SF has excellent test-retest reliability (86% agreement), concurrent validity with related measures, and acceptable internal consistency of summary scales ( $\alpha = 0.61\text{--}0.85$ ) (Schag et al., 1991). From selected single items on CARES-SF, energy and sleeplessness were assessed over time.

## Study Procedure

The study proposal was reviewed and approved by the hospitals' institutional review boards and human use committees. Subjects were recruited through weekly reviews of clinic schedules for eligible patients and with flyers throughout the hospitals. A letter was sent to the subjects' primary care providers requesting medical clearance for patients to participate. The study physician also reviewed subjects' research files for any indication that they should not participate. Subjects were screened, enrolled, and started on the exercise program as they presented. After baseline testing (with the demographic questionnaire, CARES-SF, graded exercise test, and wrist actigraphy), CARES-SF and wrist actigraph data were collected again at weeks 4, 8, and 12. At the completion of the 12-week exercise rehabilitation program, patients again underwent graded exercise testing.

## Analytical Approach

The design of this study was based on a body of research demonstrating that patients who engage in exercise show improvements in physiologic and psychological parameters of health (Courneya & Friedenreich, 1999). Consequently, data from this study were analyzed to evaluate the statistical significance of changes from baseline to the end of the program in exercise tolerance, activity and sleep patterns, and QOL. Data were analyzed using the SPSS® statistical computer package (SPSS Inc., Chicago, IL). Descriptive statistics were used to summarize sample characteristics. Mixed and repeated measures rank tests,  $t$  tests, and analyses of covariance were used as appropriate to the comparison. Chi square tests were used with categorical data to evaluate differences between subgroups of the sample.

# Findings

## Demographics

The 62 subjects ranged in age from 24–83 ( $\bar{X} = 59$ ,  $SD = 13$ , median = 62). The majority ( $n = 44$ , 71%) were older than 55. Gender was evenly distributed in the sample, with 50% men ( $n = 31$ ) and 50% women ( $n = 31$ ). Minorities were well represented ( $n = 18$ , 29%), with 13% of the sample reporting being African American ( $n = 8$ ), 11% Hispanic or Latino ( $n = 7$ ), and 5% of mixed heritage ( $n = 3$ ). Body mass index (BMI) for subjects ranged from 19–44 ( $\bar{X} = 29.1$ ,  $SD = 5.5$ , median = 30.2). All educational levels were represented equally. The majority of the participants were retired ( $n = 32$ , 52%), although 22 (35%) still were working either full-time or part-time (see Table 1).

## Cancer History

Subjects enrolled in the study had been treated for one of 16 different cancers. However, breast and prostate cancer

**Table 1. Demographics**

Variable	n	%
<b>Age (years)</b>		
Range = 24–83	–	–
$\bar{X} = 59.1$	–	–
Median = 62	–	–
$SD = 13.5$	–	–
<b>Body mass index</b>		
Range = 19–44	–	–
$\bar{X} = 29.1$	–	–
Median = 30	–	–
$SD = 5.5$	–	–
<b>Gender</b>		
Male	31	50
Female	31	50
<b>Ethnicity</b>		
Caucasian	44	71
African American	8	13
Hispanic or Latino	7	11
Mixed heritage	3	5
<b>Marital status</b>		
Single, never married	2	3
Married	53	85
Widowed	6	10
Divorced	1	2
<b>Education</b>		
Some high school	2	3
High school	15	24
Associate's degree	15	24
Bachelor's degree	16	26
Graduate degree	14	23
<b>Employment</b>		
Retired	32	52
Full-time	14	23
Part-time	8	13
Homemaker	4	6
Unemployed	4	6

N = 62

were the most frequent diagnoses. All stages of cancer were represented. Subjects received all types of primary cancer therapy, including surgery ( $n = 51$ , 82%), chemotherapy ( $n = 26$ , 42%), radiation therapy ( $n = 25$ , 40%), endocrine therapy ( $n = 14$ , 23%), and immunotherapy ( $n = 3$ , 5%). At enrollment into the study, 15 subjects (24%) were undergoing cancer treatment; the remaining 47 had completed treatment (see Table 2).

## Exercise History and Frequency of Exercise During the Study

Thirty-six subjects reported exercising prior to being diagnosed with cancer, and exercise was characterized as engaging in an aerobic activity for at least three 20-minute sessions per week. However, only 13 of the 36 subjects (36%) who exercised prior to their cancer diagnoses continued an exercise program afterwards. Interestingly, 7 of 26 subjects who had not exercised prior to their cancer diagnosis (27%) reported beginning an exercise program on their own after being diagnosed with cancer.

**Table 2. Cancer History**

Variable	n	%
<b>Type of cancer</b>		
Breast	14	22
Prostate	12	19
Ovarian	6	9
Colorectal	5	8
Endometrial	4	6
Cervical	3	5
Kidney	3	5
Non-Hodgkin's lymphoma	3	5
Skin	3	5
Lung	2	3
Testicular	2	3
Bladder	1	2
Bone	1	2
Hodgkin's disease	1	2
Leukemia	1	2
Sarcoma	1	2
<b>Stage of disease</b>		
0	2	3
I	17	27
II	24	39
III	11	18
IV	7	11
Not staged	1	2
<b>Cancer treatment</b>		
Surgery	51	82
Chemotherapy	26	42
Radiation therapy	25	40
Endocrine therapy	14	23
Biologic response modifiers (as therapeutic treatment)	3	5
Biologic response modifiers (as supportive treatment)	9	15
Bone marrow transplant or peripheral blood stem cell transplant	2	3
<b>Time course in treatment</b>		
Undergoing cancer treatment	15	24
Completed cancer treatment within the previous six months	23	37
Completed cancer treatment more than six months prior to enrolling in the study	24	39

N = 62

Note. Some patients received more than one type of cancer treatment.

Forty-six subjects (74%) were able to complete the 12-week exercise protocol, attending almost 80% of the exercise sessions offered. In addition to the classes, participants who completed the study reported exercising an additional two to three days per week at home (see Table 3). No adverse events related to exercise occurred.

### Exercise Tolerance

Baseline and week 12 data are available on only 44–45 of the 46 subjects who completed the study. A significant improvement ( $p < 0.001$ ) was found in estimated maximum METs among subjects who completed the program (see Table 4). Of the 45 subjects who completed both baseline and week 12 treadmill tests, 31 (69%) showed an increase in estimated maximum METs from baseline to week 12. The increase from baseline ranged from 8%–73%. An additional 8 subjects (18%) were able to sustain their baseline performance at week 12.

**Table 3. Exercise Participation by Program Finishers**

Variable	$\bar{X}$	SD	Days Per Week	Range
Number of days exercised in clinic (out of 24 sessions offered during the 12-week program)	19.0	3.7	1.6	8–24
Number of days exercised at home (out of 60 during the 12-week program)	25.5	17.0	2.1	0–55
Total number of days exercised during study (out of 84 during the 12-week program)	44.5	18.4	3.7	10–78

N = 46

Perhaps more indicative of exercise tolerance than a single-session exercise test is the change in exercise prescription over the course of the study. A significant improvement ( $p < 0.001$ ) occurred in the duration and intensity subjects were exercising when comparing their baseline exercise prescriptions to their week 12 exercise prescriptions (see Table 4). Of the 44 subjects who completed both baseline and week 12 testing, 41 (93%) increased their level of exercise approximately five steps. This indicates that although most subjects were walking approximately three-quarters of a mile in 15 minutes on a level surface at the start of the study, they were walking twice as far in 30 minutes at a 5% grade at the end of 12 weeks. Increases ranged from one to nine steps ( $\bar{X} = 4.6$ ,  $SD = 2.37$ , median = 5).

### Activity and Sleep Patterns

Actigraph data were available on 44 of the 46 subjects (96%) who completed the study. A substantial amount of actigraph data were lost as a result of equipment malfunction or participant discomfort. Therefore, analysis of sleep and activity data was confined to a comparison of baseline and week 12 data. Activity data from both baseline and week 12 were available on 30–42 of the 46 subjects (67%–91%) who completed the study. Sleep data from both baseline and week 12 were available on only 34–42 of the 46 subjects (74%–91%) who completed the study.

**Activity patterns:** Subjects followed conventional diurnal cycles, getting out of bed between 5 am and 9 am and returning to bed between 9 pm and 1 am. No significant change was found in either activity level or percentage of

**Table 4. Change in Exercise Tolerance Over the 12-Week Rehabilitation Program**

Variable	N	Baseline $\bar{X}$ (SD)	Week 12 $\bar{X}$ (SD)	p
Estimated maximum metabolic equivalents	45	7.25 (2.06)	8.36 (2.11)	< 0.001
Exercise prescription (18-step protocol)	44	3.8 (3.05)	8.4 (3.90)	< 0.001

napping among subjects who completed the rehabilitation program. However, a significant improvement was found in subjects' self-report of energy ( $p = 0.004$ ) (see Table 5). Controlling for gender, age, and BMI did not change the outcome of this analysis.

**Sleep patterns:** Subjects who completed the rehabilitation program slept an average of 6.5 hours per night at baseline. However, their sleep was quite fragmented; average sleep episodes lasted less than 50 minutes, and they awakened 14 times per night on average. Thus, subjects spent an average of only 78% of the night asleep. No significant improvement was found in objective measures of sleep during the course of the rehabilitation program. Despite this, a significant improvement occurred in the subjects' self-reports of difficulty sleeping ( $p = 0.03$ ) (see Table 6). Controlling for gender, age, and BMI did not change the outcome of this analysis.

### Quality of Life

Baseline and week 4, 8, and 12 data were available on 41–42 of the 46 patients (89%–91%) who completed the study. Significant improvement was found in the CARES–SF Global Score among subjects who completed the program ( $p = 0.03$ ). Pairwise comparisons of means indicated that week 12 scores were significantly lower than baseline scores ( $p = 0.01$ ). (Remember, lower scores indicate better QOL.) Significant improvements also were found from baseline to week 12 on the physical ( $p = 0.002$ ) and psychological ( $p = 0.09$ ) subscales (see Table 7).

A mixed analysis of covariance was conducted to assess the influence of gender, age, and BMI on improvement in QOL. None was a significant covariate ( $p > 0.10$ ), and none significantly interacted with the main effect of time ( $p > 0.10$ ). These results make clear that the improvement in QOL was independent of gender, age, and BMI.

### Characteristics of Subjects Who Completed the Exercise Protocol

The secondary aim of this feasibility study was to identify the characteristics of patients who would be able to com-

**Table 5. Change in Activity Level Over the 12-Week Rehabilitation Program**

Variable	N	Baseline $\bar{X}$ (SD)	Week 12 $\bar{X}$ (SD)	p
Activity level (average activity count per minute during the day)	31	199.32 (24.74)	197.31 (30.89)	$> 0.10$
Percentage of napping (per- centage of day spent sleeping)	31	4.00% (5.78)	5.10% (8.65)	$> 0.10$
CARES–SF (response to, “I do not have the energy I used to.” Lower values indicate more energy.)	42	1.74 (1.27)	1.17 (1.32)	0.004

CARES–SF—Cancer Rehabilitation Evaluation System–Short Form

**Table 6. Change in Sleep Patterns Over the 12-Week Rehabilitation Program**

Variable	N	Baseline $\bar{X}$ (SD)	Week 12 $\bar{X}$ (SD)	p
Duration of sleep (in minutes)	34	388.3 (85.45)	375.8 (94.98)	$> 0.10$
Percentage of night spent sleeping	34	77.8% (16.99)	76.5% (17.97)	$> 0.10$
Average length of a sleep episode (in minutes)	34	48.5 (51.67)	65.2 ( 99.04)	$> 0.10$
Number of awakenings	34	14.0 (7.29)	13.9 (6.54)	$> 0.10$
CARES–SF (response to, “I have difficulty sleeping.” Higher values indicate more difficulty.)	42	1.36 (1.36)	1.02 (1.28)	0.03

CARES–SF—Cancer Rehabilitation Evaluation System–Short Form

plete a rehabilitation program. A quarter of the sample ( $n = 16$ ) was unable to complete the 12-week exercise program. Reasons provided included treatment side effects ( $n = 5$ ), medical factors ( $n = 5$ ), and work or personal factors ( $n = 5$ ). One subject did not give a reason. Other investigators have reported similar attrition rates ranging from 8%–27% (Courneya, 2001; Mock et al., 1994, 1997; Schwartz, 1999; Segal et al., 2001; Winningham & MacVicar, 1988). In an effort to better understand why some subjects were able to complete the program (completers) and others could not (non-completers), a series of analyses were done comparing the two groups (see Table 8). Subjects most likely to complete the program were older, male, Caucasian, and retired, although only the age difference was statistically significant ( $t(60) = 2.17$ ,  $p = 0.03$ ). The small number of subjects with the same cancer diagnosis precludes an analysis of the difference between completers and noncompleters by diagnosis; however, the time course of treatment significantly influenced completion rates ( $\chi^2[1] = 12.08$ ,  $p = 0.001$ ). That is, of the subjects who had completed treatment, 85% (40 of 47) completed the exercise program, but only 40% (6 of 15) of those in treatment completed the program. As shown in Figure 3, stage of cancer also significantly influenced completion rates; subjects with early-stage cancer completed the program at higher rates (Kruskal-Wallis(1) = 4.97,  $p = 0.03$ ).

### Other Significant Findings

The subjects were overwhelmingly positive about participating in the study. Patients and their healthcare providers have received this exercise rehabilitation program enthusiastically.

Many participants have said that since their cancer diagnoses they have found engaging in physical activities difficult. The availability of a structured, supervised program has enhanced their return to normal routines. Following are three of their stories, in their own words.

**Table 7. Change in Quality of Life Over the 12-Week Rehabilitation Program**

Cancer Rehabilitation Evaluation System-Short Form <sup>a</sup>	N	Baseline $\bar{X}$ (SD)	Week 4 $\bar{X}$ (SD)	Week 8 $\bar{X}$ (SD)	Week 12 $\bar{X}$ (SD)	Test Results
Global score	42	46.8 (8.62)	45.6 (9.18)	45.1 (9.89)	44.3 (10.12)	$F(1,41) = 7.21^b$ $p = 0.01$ $F(2,7, 100.1) = 3.38^c$ $p = 0.03$
Physical	42	49.0 (6.81)	46.9 (7.24)	47.6 (7.88)	46.1 (8.10)	$F(1,41) = 12.74$ $p = 0.001$ $F(3,0,121.2) = 5.19^c$ $p = 0.002$
Psychological	41	47.8 (7.17)	46.6 (7.66)	46.1 (8.28)	45.6 (7.96)	$F(1,40) = 5.32$ $p = 0.03$ $F(2,5,100.9) = 2.29^c$ $p = 0.09$

<sup>a</sup> The range of scores is 0–100, with lower scores indicating a better quality of life.

<sup>b</sup> Tukey LSD Test: baseline to week 4,  $p = 0.10$ ; week 4 to week 8,  $p > 0.10$ ; week 8 to week 12,  $p > 0.10$ ; baseline to week 12,  $p = 0.01$ .

<sup>c</sup> Greenhouse-Geiser correction for repeated measures.

I am an active-duty staff sergeant. After my treatment for cancer, I was concerned about my ability to pass the Army physical fitness test. At the recommendation of my physician, I was enrolled in the exercise intervention study, which provided me a program to rebuild my stamina, the supervision to exercise safely, and the confidence to exercise without fear of violating my profile.

I am a 61-year-old woman who had surgery for stage I ovarian cancer. Two months after surgery, I started the exercise program and feel it was the best thing I could have done. . . . Since taking part in this study, my blood pressure has become much more stable, I am sleeping a lot better at night and not napping during the day, and I am gaining energy. And, most important to me, I no longer feel depressed. . . . I now know that exercise is something I can't do without and will continue to incorporate in my life.

I was in the latter stages of chemotherapy and radiation treatments for lung cancer when approached to join the exercise intervention study. At that time, I would often have to stop and rest while walking from the parking lot to the hospital for treatments. . . . Gradually, through the supervised exercises twice a week in the hospital plus "homework," I was able to improve to the point where I could spend 15, then 25, then 35, and finally 45 minutes on the treadmill. I could not believe how well I was feeling at the end of my active participation in the study.

## Conclusion

### Limitations of the Study

The phase II cardiac rehabilitation intervention program that served as the model for this study included both an exercise component and an education component. Subjects received both components, so determining whether changes in exercise tolerance, activity and sleep patterns, and QOL were a result of the exercise, the education, or a combination of

both is impossible. Although changes in physiologic measures, such as exercise tolerance, likely could not be attributed to education alone, the study design cannot rule out this possibility. Additionally, the study design was not able to isolate the effects of social support during the exercise and education sessions on the outcomes measures of interest.

Another limitation of this study was the lack of a comparison group. Subjects may have improved over time as a function of normal restorative processes, and changes in exercise tolerance, activity and sleep patterns, and QOL may have been unrelated to participation in the rehabilitation program. However, the consistent improvement in each of the dependent variables does not support this notion.

Missing actigraph data resulted in a subsample of subjects that may not have represented the study sample accurately and was too small to provide sufficient statistical power. Idiosyncrasies of the actigraph hardware and software resulted in some data loss. Some subjects found the actigraphs uncomfortable or inconvenient to wear and removed them for prolonged periods during data collection. The actigraphs used for this study were approximately the size and shape of an oversized wristwatch. More recent models of the actigraph have a smaller profile, and patient acceptance of them is greater.

The diversity of the sample in terms of cancer diagnosis, stage of cancer, cancer treatments, and time course of treatment was a significant strength of the study; however, the constraints of the small sample size precluded an in-depth analysis of the role of these factors in determining outcomes.

## Discussion

This feasibility study documented significant improvements in exercise tolerance, activity and sleep patterns, and QOL in patients with various types of cancer at all stages of disease who participated in a 12-week exercise program patterned after a phase II cardiac rehabilitation program. Using the Roy Adaptation Model to guide the study, the exercise program was designed as an intervention to facilitate an adaptive response to the focal stimuli of cancer diagnosis and treatment. The improvements in both physiologic and



**Table 8. Comparisons Between Program Completers and Noncompleters**

	Completers (n = 46)		Noncompleters (n = 16)		p
<b>Age (years)</b>					
Range	24–83		30–67		
$\bar{X}$	61		53		
SD	13		14		0.03
<b>Body mass index</b>					
$\bar{X}$	28.7		30.0		
SD	5.5		5.7		> 0.10
	n	%	n	%	p
<b>Gender</b>					
Male	25	54	6	37	
Female	21	46	10	63	> 0.10
<b>Ethnicity</b>					
Caucasian	35	76	9	56	
Minority	11	24	7	44	> 0.10
<b>Education</b>					
Some high school	1	2	1	6	
High school	11	24	4	25	
Associate's degree	13	28	2	13	
Bachelor's degree	11	24	5	32	
Graduate degree	10	22	4	25	> 0.10
<b>Employment</b>					
Retired	26	57	6	38	
Full-time	11	24	3	18	
Part-time	4	9	4	25	
Homemaker	2	4	2	13	
Unemployed	3	7	1	6	> 0.10
<b>Treatment time course</b>					
Undergoing treatment	6	14	9	56	
Completed treatment	40	86	7	44	0.001

Note. Because of rounding, percentages may not total 100.

psychosocial modes of adaptation (i.e., exercise tolerance, activity and sleep patterns, and QOL) indicate that the exercise program did facilitate an adaptive response. These improvements with exercise are consistent with findings of other studies (Courneya & Friedenreich, 1997a, 1997b, 1999; Courneya et al., 1999; Dimeo et al., 1996, 1999; Dimeo, Fetscher, et al., 1997; Dimeo, Stieglitz, et al., 1997; Dimeo, Tilmann, et al., 1997; MacVicar et al., 1989; Mock et al., 1994, 1997, 2001; Porock et al., 2000; Schwartz, 1998, 1999, 2000a, 2000b; Schwartz et al., 2001; Segal et al., 2001; Segar et al., 1998; Winningham et al., 1989; Young-McCaughan & Sexton, 1991). This study expanded the findings from previous studies by including patients with all types of cancer in every stage. The subjects were overwhelmingly positive about participating in the study. The availability of a structured, supervised program enhanced their return to normal routines.

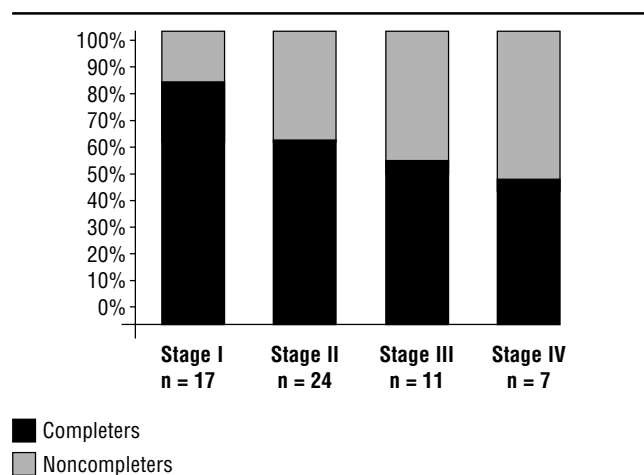
Although most other studies prescribed home-based exercise programs (Mock et al., 1994, 1997, 2001; Porock et al., 2000; Schwartz, 1999, 2000a, 2000b; Schwartz et al., 2001; Segar et al., 1998), this study prescribed an exercise program

patterned after an existing phase II cardiac rehabilitation program. This model worked exceedingly well. The cardiopulmonary rehabilitation clinic was able to dedicate time to the cancer rehabilitation program, maximizing the use of existing space and equipment. The patients with cancer who joined the study benefited from close supervision by experienced staff.

In this study, objective measures of sleep showed a great deal of variability, suggesting that patients with cancer, either receiving treatment or recently completing treatment, may experience minor to profound sleeping problems. Although no significant changes in the actigraph measures of sleep were observed, subjects who completed the 12-week exercise program did report less difficulty sleeping and more energy on the CARES-SF. This is consistent with other research that has shown that exercise can both improve sleep (Mock et al., 1997; Poniatowski & Mock, 2001) and relieve fatigue (Mock, 2001; Mock et al., 1997, 2001; Schwartz, 2000a; Schwartz et al., 2001). Additional research is warranted to investigate the unique sleep issues that arise for people with cancer who are undergoing treatment and those who are recovering, as well as how exercise might relieve sleep problems in this patient population.

Patients rehabilitate from cancer diagnosis and treatment in different ways, and exercise is not a choice all patients make. Only 19% (62 of 326) of patients who were contacted consented to participate in this study. For many, exercise was not a regular part of their lives prior to their cancer diagnoses and was not something they wanted to undertake. Others reported time constraints. Other studies have reported recruitment rates from 33%–91% (Courneya, 2001; Dimeo, Fetscher, et al., 1997; Mock et al., 1997; Porock et al., 2000; Schwartz, 1999, 2000b; Segal et al., 2001; Segar et al., 1998). Recruitment rates for studies of patients with cardiac disease into cardiac rehabilitation programs have been reported to be 33%–50% of eligible patients (Moore, Ruland, Pashkow, & Blackburn, 1998; Oldridge et al., 1991; Parks, Allison, Doughty, Cunningham, & Ellis, 2000). The factors influencing decisions to join an exercise rehabilitation program are not understood completely.

Of the patients who enrolled in this study, a quarter (16 of 62) were unable to complete the 12-week program.

**Figure 3. Influence of Stage of Cancer on Completion Rates**

Other investigators have reported similar attrition rates, ranging from 8%–27%, for reasons similar to those reported in this study, including treatment side effects, medical factors, and work or personal factors (Courneya, 2001; Mock et al., 1994, 1997; Schwartz, 1999; Segal et al., 2001; Winningham & MacVicar, 1988). However, in this study, 60% (n = 9) of subjects who were undergoing treatment could not complete the exercise protocol. In studies of women with breast cancer undergoing treatment, other investigators have reported only an 8%–22% attrition rate (Mock et al., 1994, 1997; Schwartz, 1999, 2000a, 2000b; Schwartz et al., 2001; Segal et al., 2001). The higher attrition rate for those under treatment in this study may have been because of the aggressive treatment protocols subjects in this study were undergoing, including weekly regimens, multiple agents for lymphoma, paclitaxel for ovarian cancer, doxorubicin-containing regimens for breast and bone cancers, and investigational phase I/II drug testing. Berger (1998) found that women with breast cancer receiving doxorubicin-containing protocols experienced lower levels of activity and higher levels of fatigue as compared with women receiving regimens that did not include doxorubicin. Patients undergoing treatment usually experience varying degrees of fatigue that occur unpredictably. These patients commonly already are making several trips to the hospital each week for treatment and monitoring and may find committing to an exercise program that requires additional trips to a treatment facility difficult. A home-based exercise program may be better suited to patients undergoing therapy.

Unique clinical issues arose in this study for which no standards for exercise prescription exist. For example, at the time she joined the study, one woman was experiencing lower extremity lymphedema after radiation therapy for cervical cancer. This challenged the study team to prescribe an exercise regimen that would not exacerbate her lymphedema. Several patients who previously had received paclitaxel were experiencing peripheral neuropathy at the time they wanted to join the study. Patients with severe neuropathy were not allowed to join the study because the study team was not confident they could safely exercise on a treadmill. Others who had milder neuropathy were enrolled into the study and monitored closely. Exercise did not appear to improve or worsen the neuropathy.

## Recommendations for Further Research

Whether participation in this type of program effects any long-term change in health habits or improvement in health is unknown. An ongoing study, “Outcomes of an Exercise Intervention for Cancer Patients” (Young-McCaughan, Uniformed University of the Health Sciences TriService Nursing Research Program N00-017) is examining how patients perform over the 18 months following participation in the 12-week exercise program, capitalizing on valuable lessons learned in the implementation of the current study.

Future research should differentiate the effects of the exercise from the effects of the education in the intervention. A randomized clinical trial design could address this issue; however, noncompliance with a forced exercise or rest program can confound this type of study design. Collaborations with behavioral scientists experienced with exercise interventions are needed to address these perplexing issues.

Questions remain as to the dose of exercise required for benefit and whether certain types of exercise (e.g., strengthening, aerobic) are better suited for certain cancers or cancer treatments. The advantages and disadvantages of clinic-based versus home-based exercise programs for various patient populations should be defined. Additional research also is needed to develop evidence-based clinical standards for exercise prescription in patients with cancer who are experiencing side effects of therapy that may affect their ability to exercise safely.

## Implications for Nursing

These findings indicate that patients with various types and stages of cancer can exercise safely using a cardiac rehabilitation model and that significant improvements in exercise tolerance, activity and sleep patterns, and QOL can be realized in this patient population. Most people are aware that regular exercise is part of a healthy lifestyle. After cancer diagnosis and treatment, patients experience uncertainty regarding how to resume exercise or how to begin an exercise program as part of their rehabilitation. Many do not feel strong enough to exercise and are unsure if they can exercise safely after receiving treatments known to have cardiac, pulmonary, and neurologic toxicities. Participation in a structured exercise program can provide patients with a safe environment in which to exercise at intensities appropriate to their individual needs.

Exercise prescription in patients with cancer is an aspect of cancer rehabilitation that demands the expertise of a multidisciplinary team that includes oncology nurses, exercise physiologists, physical therapists, oncology physicians, and people with cancer. Unlike other patient populations, people with cancer who are beginning an exercise program have much greater variability in their exercise capacity depending on age, history with exercise, type and stage of cancer, type of cancer treatment, and point in the trajectory of cancer diagnosis and treatment. Although standard exercise prescriptions can serve as a baseline, exercise prescriptions for patients with cancer, particularly those undergoing treatment, must be individualized based on history and physical assessment and modified based on patient abilities. Oncology nurses have an important role to play in this emerging field of rehabilitation of patients with cancer.

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## For more information . . .

- Association of Cancer Online Resources: Fatigue Associated With Cancer  
[listserv.acor.org/archives/cancer-fatigue.html](http://listserv.acor.org/archives/cancer-fatigue.html)
- CancerSymptoms.org: Ways to Manage Your Cancer Symptoms  
[www.cancersymptoms.org](http://www.cancersymptoms.org)
- American Council on Exercise  
[www.acefitness.org](http://www.acefitness.org)

Links can be found using ONS Online at [www.ons.org](http://www.ons.org).

A commentary on the preceding article appears on the following pages.

Victoria Mock, DNSc, AOCN®

This is an innovative and exciting research study by Stacey Young-McCaughan, RN, PhD, AOCN®, and her team. The project is novel in that it tests a phase II cardiac rehabilitation program adapted for patients with cancer, an intervention not reported previously in exercise studies in oncology populations. In addition, the sample was a group of patients with a variety of cancer diagnoses and treatments, including radiation therapy, chemotherapy, biotherapy, and surgery. The use of treadmills and actigraphy to objectively measure exercise tolerance and sleep also are innovative strategies and add to the precision of measuring these outcomes.

The study has many other strengths, including the interdisciplinary team, the use of an adaptation model theoretical framework that includes physiologic and psychosocial outcomes, a well-developed intervention protocol, and the use of valid and reliable instruments.

Discussion of several components of the study may enlighten future research in this field. First, the study was a one-group pretest and post-test experimental design. The study might be considered the equivalent of a phase II clinical trial design in that it tested the feasibility as well as safety and efficacy of a specified dose of an intervention in a specific population. However, this study was different from most phase II cancer clinical trials in that it was not a sample of patients with one cancer diagnosis but a mixed sample with a variety of types of cancer and a wide age range. To determine the potential importance of this difference, an examination of the concepts of internal and external validity and the influence of sample variability is useful. External validity is the extent to which findings from a particular research project can be generalized beyond the sample used in the study (Burns & Grove, 2001). The more diverse the study sample is, the broader the generalization, because the sample will reflect a broader range of types of individuals in the population. Internal validity is the extent to which study outcomes can be accurately attributed to the intervention being tested—not to extraneous variables (Burns & Grove). Thus, the ability to see pretest to post-test changes (variability) in study outcomes is strengthened if variability from other factors is controlled or minimized. Therefore, a sample that is homogeneous—that is, similar in terms of age, gender, cancer diagnosis, and exercise at baseline—allows researchers to more easily see pretest to post-test changes in activity, sleep, and quality of life that are effects of the exercise intervention rather than the results of the wide variability naturally present in a heterogeneous sample of men and women of a wide range of ages with different cancer diagnoses. However, the generalizability of findings from a study with a homogeneous sample is limited to one gender, one cancer diagnosis, and a smaller age range. So, strengthening the internal validity with a homogeneous sample has implications for the external validity (generalizability) and strengthening the external validity with a hetero-

geneous sample can influence the internal validity by making differences between groups more difficult to see.

This study had a very diverse sample—men and women ages 20–85 with different cancer diagnoses, cancer treatments, and stages of disease. However, not enough of any one cancer diagnosis or cancer treatment was represented to draw conclusions about safety, efficacy, and effectiveness. The finding of no differences between pretest and post-test scores seen in some outcomes could be related to the sample size in relation to the wide sample variability. As calculated mathematically, the power to see differences when groups are compared is related to the variability between groups (in this case, between testing periods) divided by the variability within groups (plus error variance). Statistically significant differences from pretest to post-test were seen on exercise tolerance and quality-of-life outcomes. Furthermore, differences could have been seen in the sleep outcomes if the sample had been more homogeneous or the sample size larger to offset the wide variability in subjects.

Another aspect of the sample design that warrants discussion is the lack of a control or comparison group. Without a control group that did not receive the intervention, the researchers cannot be certain whether study outcomes were directly related to the intervention or to other factors such as the normal recovery process after completion of cancer treatment.

The intervention is described as a traditional cardiac rehabilitation program that included educational classes on relevant topics such as nutrition, stress management, sleep, and quality of life, as well as an exercise component. The exercise component was twice-weekly supervised laboratory exercise plus a recommended three to five additional sessions weekly at home. The comprehensive nature of the rehabilitation program probably is most effective for patients, but, from a research perspective, it leaves uncertain the relative contributions of each of the components to the study outcomes. Changes in exercise tolerance almost certainly were effects of the exercise, but changes in sleep could have been the result of helpful hints in the classes and quality-of-life improvements could have been related to exercise, education, or group social support. A future study with a four-group design could determine the relative contributions of each of the components if one group were control, one group received exercise only, one group received education only, and the fourth group received the comprehensive rehabilitation program.

Although the subjects had an impressive 74% adherence rate for attendance at 80% of the supervised exercise sessions, no information is available on the percentage of patients who

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participated in a less-than-optimal amount of exercise at home, and no correlations were reported between the dose of exercise and education subjects received and the study outcomes. This would be helpful in linking the intervention to the outcomes as well as determining a minimally effective or optimum dose of the intervention. How many times a week does a patient need to exercise to improve exercise tolerance? Did patients who exercised more have a better sleep quality or a higher quality of life?

The wrist actigraphs were worn for 72 hours at four time periods during the study (baseline and at weeks 4, 8, and 12). However, a significant amount of actigraphy data was missing, so drawing conclusions with confidence is difficult. Also, patients could have experienced a Hawthorne effect and exercised more when wearing the actigraphs because they knew their activity could be observed by the investigators. One way to address this issue would be to have patients wear the actigraphs for longer periods, even if the data were not analyzed or even collected.

So was the rehabilitation program feasible for patients with cancer? With a 74% completion rate, the program clearly was acceptable to patients and manageable for most of them. An exception may be the patients who were in active cancer treatment, of whom only 40% completed the program. This adherence rate is considerably lower than that reported for other home-based exercise programs for patients in active cancer treatment (about 70%–75% adherence [Mock et al., 1997; Schwartz, Mori, Gao, Nail, & King, 2001]) and raises interesting questions about why these patients were unable to complete the program. Completers were more likely to be male, older, Caucasian, and retired—suggesting that the program was difficult to manage for younger, working women in active cancer treatment.

Another important issue in determining feasibility is the extent to which eligible patients were willing to enter the study and be subjects in an exercise study. In this case, of 3,139 records screened, only 500 patients (about one in six) met eligibility criteria for the study (even with its broad inclusion criteria). Of those eligible and contacted, only 19% consented. Most did not consent because of the commute to the

hospital (23%) or lack of time to exercise (19%). So, if 19% of the 500 eligible patients entered the study, they represented only 3% of the accessible population at the site, representing a rather low penetration of the population. A low penetration of the population suggests that the sample may not be representative or the intervention may not be feasible or acceptable to many patients in the population (Clark, 2001). Although this type of assessment of penetration is routine for research reports reviewed in leading medical journals, nurse researchers are just becoming aware of the importance of collecting the data needed for such an assessment. So this team should be highly praised for its recognition of this issue and the inclusion of such data in the study.

Was the rehabilitation program beneficial for patients with cancer? Because significant improvements in exercise tolerance and quality of life were observed, even with the great diversity in the sample, the researchers can be confident that the program was beneficial. The study has made an important contribution to knowledge about rehabilitation for patients with cancer in terms of the effectiveness of a supervised laboratory exercise-plus-education program and in regard to inclusion of a diverse patient sample, particularly in relation to age of subjects (71% were older than 55) and cancer diagnoses. This team has identified very interesting sleep disturbances in this population and has laid the foundation for future research with this promising intervention. Young-McCaughan must be commended for her bold and innovative approach to rehabilitation of patients with cancer.

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