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on Fatigue in Breast Cancer Patients Following Clinical
Treatment

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13. ABSTRACT (Maximum 200 Words) This study will test the effect of low-moderate intensity exercise on fatigue and physical functioning in women who have completed treatment for breast cancer. Sample: Subjects are 10-40 women, ages 20-80. Methods: Participants are randomly assigned to an exercise or control group. The exercise group participates in an exercise program 3 times a week for 10 weeks. Physical functioning is measured by aerobic capacity. Both groups record their weekly level of fatigue using a Linear Analogue Self-Assessment Scale (LASA) and the Schwartz Cancer Fatigue Scale (SCFS). Data Analysis: Aerobic capacity data is analyzed with the paired t-test. A repeated measures ANOVA will be used to analyze the fatigue data. An alpha level of <0.05 will be considered statistically significant. Preliminary Results: Aerobic capacity increased significantly (37%) in the exercise group while the control group remained the same. Fatigue reported with the LASA scale decreased in the exercise group and increased in the control group but the differences were not statistically significant ($p = .387$). Fatigue reported with the Schwartz scale decreased in the exercise group and increased in the control group. This change was statistically significant between the groups ($p = .0004$) but not statistically significant within the groups ($p = .446$).				
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I. INTRODUCTION

Fatigue is the most common symptom resulting from cancer and the treatments following diagnosis. Published reports suggest that more than 70% of patients receiving chemotherapy or radiation reported fatigue symptoms (Courneya et al. 2000). These symptoms included such things as tired legs, whole body tiredness, and feelings of wanting to lie down (Mock et al. 2001). Additionally, fatigue increases with the number of radiation or chemotherapy cycles (Mock et al. 1997).

Several studies have investigated the effect of exercise on fatigue in cancer patients (Dimeo, F.C., et al., 1997, Mock, V., et al. 1997, Schwartz, A.L., et al. 2001).

Data is being collected that suggests exercise can reduce fatigue in people surviving cancer. Little data however exists as to the appropriate intensity of exercise to reduce fatigue. Burnham et al. (2001) found that low intensity exercise was equally as effective as moderate intensity exercise in reducing fatigue in exercising cancer survivors. If this result holds true, it may be that lower levels of exercise intensity may be as effective and better tolerated by patients who are suffering from extreme fatigue.

The purpose of this study is to investigate the effects of low to moderate intensity exercise on fatigue and physical function in cancer survivors.

II. BODY OF RESEARCH

Specific Aims

- The specific aims of this study are to test the effect of low to moderate intensity aerobic exercise treatment on self-reported fatigue and physical functioning for women who have completed therapy for breast cancer.

Sample

- To be included in this study women must be: a) 20-80 years of age, b) have stage I or II breast cancer for which treatment concluded one to twelve months prior to enrolling in this study, and c) have been cleared to participate by their primary care provider. Women will be excluded if they have are being treated for other chronic diseases which would contribute to their fatigue such as congestive heart failure.

Tools

- A modified Linear Analogue Self-Assessment Scale (LASA) and the Schwartz Cancer Fatigue Scale (SCFS) are used to measure self-reported fatigue levels. The LASA anchors, on a 100 mm line, for fatigue are "not at all fatigued" and "extremely fatigued;" for energy levels they are "not at all energetic" and "extremely energetic." The score is determined by measuring the placement of the mark on the line. Scores range from 0 to 100. Test-retest reliability of the scale was tested 12 weeks apart in 60 cancer patients (Sutherland, 1989). Test-retest of the LASA averaged $r = .79$, which the researchers concluded, was a feasible, reliable and valid measure of emotional distress for cancer patients. The SCFS asks participants to rate: tired, difficulty thinking, overcome, worn out, and listless from 1 being "not at all," 2 a little, 3 moderately, 4 quite a bit and 5 extremely. The SCFS demonstrated strong internal consistency reliability exceeding Cronbach alpha $> .85$ (Schwartz, 2002).
- Physical functioning is determined by measuring aerobic capacity during treadmill testing. The aerobic exercise will be preformed on treadmills, stationary bicycles, and stair climbing machines. The subjects will be started at 25-35% of their heart rate reserve increasing to 40-60% by week 10.

- Demographic, cancer, and exercise characteristics are determined by asking participants to fill out a detailed form. Questions include their age, address, list of allergies, medications, previous medical history, level of education, and ethnic affiliation. Cancer characteristics include a short history of the onset of cancer, assessment, and treatment. Exercise characteristics include current and past exercise programs, frequency of exercise and duration, types of work and physical activities.

Design and Procedures

- Subjects are being recruited from local medical centers, clinics, and hospitals in both Central and North Central Washington State. Recruitment is done through advertising with flyers, posters, letters, and word of mouth. Initial screening is conducted by phone interview. Each subject is informed both verbally and in writing as to the purpose and admission criteria of this study. Subjects who meet admission criteria sign and receive a copy of the informed consent. The subjects are then randomly assigned to an exercise or control group at the time demographics and baseline measures are obtained. The exercise group will report for a controlled exercise program 3 times a week for 10 weeks. All subjects have aerobic capacity measured at the beginning and end of 10 weeks. Fatigue is being measured weekly for 10 weeks.

Exercise Intervention

- All participants spend the first 3-5 minutes doing aerobic warm-up exercises. They then spend 5 minutes stretching. The following 14 minutes consists aerobic exercise on treadmills, stationary bicycles, stair-climbing machines, and aerobic dance. This is followed by an aerobic cool-down (3-5 minutes) and stretching (5-8 minutes) for a total of 30-37 minutes per session.
- The aerobic exercise period, in accordance to the ACSM's recommendation (American College of Sports Medicine Position Stand, 1998), is increased by 2 minutes per week to total 32 minutes by week 10. The subjects exercise 30-37 minutes initially and increase to 50-59 minutes duration by the end of 10 weeks. Detailed instruction of the exercise program and equipment used is provided to each participant. Results of the study, when available, will also be provided to each of the participants at the conclusion for those who are interested.
- Heart rate is monitored using a Polar heart rate monitor (Target model). Aerobic capacity testing will be conducted on a treadmill. Subjects will establish a comfortable walking pace of 1.5 to 4 mph. The grade of the treadmill is increased 1% each minute and continues till the subjects report volitional exhaustion. Heart rate is monitored during treadmill testing with an electrocardiogram. Oxygen consumption is being measured using an open circuit indirect calorimetry technique. The metabolic cart is calibrated to known concentrations of oxygen and carbon dioxide prior to each test. The subjects breath into a 2-way valve system during the test, which is connected to the metabolic cart. The subjects inhale room air while their exhaled gases go directly into the metabolic cart. This process permits quantification of expiratory volumes, O₂ concentrations, and carbon dioxide concentrations.

Data Analysis

- Demographic data is measured by descriptive statistics (measures of central tendency and dispersion). Aerobic capacity data is being analyzed with a paired t-test. A repeated measures ANOVA is used to determine if the changes to the self-reported fatigue levels are statistically significant. All values are reported as means and standard errors. An alpha level of <0.05 is considered statistically significant.

III. KEY RESEARCH ACCOMPLISHMENTS

A. Experiential Learning

Study Title: The Effects of Low to Moderate Intensity Aerobic Exercise on Fatigue in Breast Cancer Patients Following Clinical Treatment

1. Recruitment of Subjects for the project (ongoing).

- Assisted with posters development and placed in appropriate sites for subject recruitment.
- Assisted with newspaper advertisements that have been placed in local newspapers for subject recruitment.
- Radio advertisements were developed and played on local radio stations for subject recruitment.
- The principal and co-investigator have contacted local medical groups and hospitals to recruit subjects.
- The principal and co-investigator contacted local support groups for subject recruitment.

2. Initial Data Collection Period and Randomization into Groups (ongoing).

- Subjects are contacted and scheduled for the initial data collection test at the Central Washington University Exercise Science Laboratory.
- Subjects read and sign the informed consent document.
- Demographic and medical information is collected.
- Maximal aerobic capacity tests are conducted on the treadmill at the Exercise Science Laboratory.
- The fatigue scales are explained to the subjects and the initial fatigue measures are collected.
- Subjects are randomly assigned to either the exercise or control groups.
- Subjects are contacted and informed of their group status.

3. Ten-Week Training Program (ongoing).

- The subjects in the exercise group perform supervised aerobic exercise three times a week for the ten-week study period.
- The initial exercise duration is 14 minutes of aerobic exercise. Exercise duration increases two minutes a week throughout the study. Exercise duration is recorded for each subject by the principle investigator.
- The initial exercise intensity is 25-35% of heart rate reserve. Intensity will increase to approximately 40-60% of heart rate reserve by week ten. The principal and co-investigator calculate exercise intensity increases for each subject. Exercise intensity is measured during exercise with a Polar heart rate monitor.
- The control group performs their normal activities during this period with the exception of performing any new exercise programs.
- A modified Linear Analogue Self-Assessment Scale (LASA) and the Schwartz Cancer Fatigue Scale (SCFS) is used to measure self-reported fatigue levels. These

scales are given to all participants (exercise and control groups) weekly. The subjects return the scales to the principal investigator in stamped self-addressed envelope.

- The principal and co-investigator score and record all fatigue scales weekly.
- 4. Data Collection Period (ongoing).**
- Subjects are contacted after the 10 weeks time period is concluded and scheduled for the final data collection test at the Central Washington University Exercise Science Laboratory.
 - Maximal aerobic capacity tests are conducted on the treadmill at the Exercise Science Laboratory.
 - The two fatigue scales are administered for the final time.
- 5. Statistical Analysis and Report Writing.**
- Final statistical analyses will be performed on the fatigue and maximal aerobic capacity data at the close of the study in April 2005.
 - Findings will be summarized into a final report.
 - An initial manuscript will be prepared for publication.
 - **Results of research will be presented in poster format during the fourth ERA of Hope meeting sponsored by the DOD BCRP on June 8-11, 2005, at the Pennsylvania Convention Center, Philadelphia, Pennsylvania. Hopefully, from the many submitted abstracts, the results of this research will be selected for a platform presentation**
- 6. Summary (trainee's) Role in the Research Project**
- Scientific design of the project
 - Recruitment of subjects
 - Initial data collection including medical and demographic information, maximal aerobic capacity testing, and fatigue measures.
 - Randomization of subjects into exercise control group
 - To supervise the ten-week training period.
 - To collect weekly fatigue data.
 - Conduct the final data collection period.
 - Perform statistical analysis.
 - Summarize findings into final report for Master's thesis
 - Preparing initial manuscript for publication.
- 7. Value to Date**
- The training so far has been very valuable! I've enhanced my skills in the use of exercise as a rehabilitative tool for the reduction of fatigue in breast cancer survivors. This is important as few medical professionals are trained in this field. I've been able to apply these new research skills to establish additional exercise programs for breast cancer survivors and to continue to explore this much-needed area of research.

B. Didactic Learning (on going till August 2005)

Completed Courses to Date - Cumulative GPA 3.81

- Research Methods (5 credits) – Nursing Methods
- Health Promotion (3 credits) - Nursing
- Pain Management (3 credits) – Nursing
- Loss, Grief, Death, and Dying in Clinical Practice (4 credits) - Nursing
- Biological Aspects of Cancer: Implications for Care (3 credits) – Nursing
- Cancer Symptom Management (3 credits) – Nursing
- Cellular and Molecular Immunology (3 credits) – Nursing
- Seminar in Cardiovascular Nursing (3 credits) – Nursing
- Pharmacotherapeutics for Acute/Critical Illness (3 credits) – Pharmacology
- Cancer Pharmacotherapeutics (2 credits) – Pharmacology
- Human Physiology (4 credits) – Department of Physiology
- Masters Thesis – on going

C. Initiation of Exercise Program

- Researched exercise programs offered specifically for breast cancer patients and learned about the *Lebed Method: Focus on Healing through Movement and Dance*. The Lebed Method is a therapeutic exercise program for women who have had breast surgery, node dissection, radiation, chemotherapy, or suffer from chronic fatigue. The program was created to help breast cancer survivors live a better quality of life.
- Enrolled exercise rehabilitation interns from Central Washington University in training programs offered in Seattle Washington to learn the *Lebed Method*.
- Networked with medical centers in Central and North Central Washington (Yakima, Wenatchee, and Omak) to secure site for exercise classes to take place.
- Developed partnership with *The Wellness Place*, a cancer resource center located in Wenatchee, Washington, to assist with sponsoring the programs. Facilitated training for some of their personnel to teach the classes.
- Started ongoing 10-week exercise programs in September 2003. These exercise programs are now well established and will continue in North Central Washington after the study concludes.

D. Development of Oncology Team in North Central Washington

- Assessed community needs for rehabilitation programs for cancer survivors.
- Researched regional cancer treatment centers in Oregon and Washington and programs offered for patients going through cancer treatment and rehabilitation.
- Visited sites and observed programs offered for cancer patients and determined feasibility for implementation in North Central Washington.
- Networked with director of St. Charles Cancer Treatment Center in Central Oregon to observe development of some of their cancer programs and to assist with initiation of exercise program in Central Oregon. The medical centers in both Central Oregon and North Central Washington are very similar in size and area of service to rural and underserved communities.

- Discussed findings with medical director and administrative staff at regional medical center in North Central Washington in spring 2004.
- Placed on Cancer Care Committee in North Central Washington in July 2004 as a result of being supported by this award and starting the study and exercise program. Nominated as chair for new subcommittee to develop and package oncology team for North Central Washington incorporating exercise as rehabilitative tool.
- Identified personnel in North Central Washington providing care to cancer patients and asked them to be part of an oncology team to include rehabilitative services.
- Established goals for team and facilitated and coordinated first “team” meeting July 2004. Gave PowerPoint presentation at meeting.
- Facilitated implementation of exercise program (used in study) as rehabilitative tool for cancer patients with oncology team members, which is still ongoing in process.

IV. REPORTABLE OUTCOMES

This is a preliminary report for this ongoing study, therefore these results may change as more subjects are enrolled. To date, 16 breast cancer patients (8 exercise and 8 control) have completed data collection. Five additional subjects have been added to the study but are not yet through the study period. The preliminary results for aerobic capacity, LASA fatigue scale and Schwartz fatigue scale are reported below.

- **Aerobic Capacity**

Means and standard errors for the aerobic capacity appear below. Aerobic capacity increased in the exercise group by 37%. The control values decreased by .7%. Statistical analysis showed a significant difference between the groups ($p = .0001$). These results suggest that the exercise group improved its fitness level while the control group did not.

Group	Pre VO2 in ml/kg/min $\pm$ SE	Post VO2 in ml/kg/min $\pm$ SE
Exercise	13.02 $\pm$ 1.79	17.88 $\pm$ 1.75
Control	16.08 $\pm$ 1.55	15.97 $\pm$ 1.44

- **LASA Fatigue Scale**

Means and standard errors for week one and week ten for the LASA fatigue scale appear below. With this scale, the lower score reflects a lower fatigue rating and a higher score reflects a higher fatigue rating. Repeated measures ANOVA results indicate no statistically significant change over time ($p = .297$) and no significant differences between the groups ($p = .387$). A closer look at the data suggests that fatigue is lower in the exercise group (lower score) and greater in the control group (higher score) over the study period. However the high degree of variance around the scores leads to a non-significant difference. This might change as more subjects are added to the study.

Group	LASA score Week 1	LASA score Week 10
Exercise	37.50 $\pm$ 9.63	24.80 $\pm$ 10.19
Control	30.14 $\pm$ 6.65	35.85 $\pm$ 14.58

- **Schwartz Fatigue Scale**

Means and standard errors for week one and week ten for the Schwartz fatigue scale appear below. With this scale, the lower score reflects a lower fatigue rating and a higher score reflects a higher fatigue rating. Repeated measures ANOVA results indicate no statistically significant change over time ($p = .446$) for the groups however there was a statistically significant interaction between the groups ($p = .0004$). These results suggest that the groups are behaving differently. The Schwartz graph in the appendix section A clearly shows a decrease in fatigue in the exercise group and an increase in fatigue in the control group. A closer look at this graph shows an increase in the fatigue measure at week 8 in the exercise group. This coincides with an incident that occurred at one of the training facilities. A whooping cough contamination occurred at this facility causing the subjects there to be treated with a medication that caused fatigue and nausea as a side effect. This is reflected in week eight on the graph and contributes to the non-significant result over time. It is hoped that with the addition of more subjects the negative side effect will be diluted.

Group	Schwartz score Week 1	Schwartz score Week 10
Exercise	19.62 $\pm$ 2.12	8.37 $\pm$ 1.43
Control	12.42 $\pm$ 1.96	17.71 $\pm$ 3.09

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Appendix A
Swartz Fatigue Scale

