I, Wipasiri Naraphong, hereby submit this original work as part of the requirements for the degree of Doctor of Philosophy in Nursing - Doctoral Program.

It is entitled:
Effects of a Culturally Sensitive Exercise Program on Fatigue, Sleep, Mood, and Symptom Distress among Thai Women with Breast Cancer Receiving Adjuvant Chemotherapy: A Pilot Randomized Controlled Trial

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Effects of a Culturally Sensitive Exercise Program on Fatigue, Sleep, Mood, and Symptom Distress among Thai Women with Breast Cancer Receiving Adjuvant Chemotherapy:

A Pilot Randomized Controlled Trial

A dissertation submitted to the

Graduate School

of the University of Cincinnati

in partial fulfillment of the

requirements for the degree of

Doctor of Philosophy

The College of Nursing

by

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December 2012

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ABSTRACT

Breast cancer is a disease with a global burden for women. In Thailand, a Southeast Asian country, the total number of Thai women with newly diagnosed breast cancer patients makes up 47.8% of all new cancer patients (National Cancer Institute - Thailand, 2011). Cancer-related fatigue is a distressing multidimensional symptom associated with cancer diagnosis and treatment. Fatigue, sleep disturbance, mood disturbance, and symptom distress were chosen for evaluation in the present study.

In Western culture, evidence has shown that exercise decreases fatigue for women with breast cancer during adjuvant chemotherapy. Unique Thai cultural beliefs and health practices affect symptom management. The purpose of this pilot study was to develop a 12-week culturally sensitive exercise program (CSEP) and to preliminarily examine the program’s effects on fatigue, sleep disturbance, mood disturbance, and symptom distress at baseline, 4, 7 and 10 weeks in Thai women with breast cancer during active adjuvant chemotherapy.

Twenty-three eligible women from the oncology outpatient clinic of a cancer center in Thailand were randomly assigned to either an experimental group (n = 11), which received the CSEP, or to a control group (n = 12), which received equal care and attention without the CSEP. Data from individual interviews indicated that the CSEP developed in this study was feasible and relevant to their lifestyle. Walking was reported as the preferred exercise for Thai women being treated for early-stage breast cancer. Educational information presented in an exercise booklet format was appropriate in the context of educational level and Thai cultural background.

Participants in the CSEP group reported adherence to daily steps walked with an average of 5,920 steps (SD = 1,523) from baseline to post intervention and showed a trend toward improving symptoms with mean change scores. Participants in the CSEP had a significantly
greater increase in physical fitness measured by a 12-minute walk test than participants in the control group at post intervention. Participants in the CSEP group also had lower levels of fatigue, mood disturbance, and symptom distress. Using generalized estimating equation analyses revealed that a significant group difference was found for the trajectory of mood disturbance. No group differences were found in the changing scores over time in fatigue, sleep disturbance, and symptom distress.

Preliminary results suggest that the CSEP was culturally sensitive and successfully increased physical activity in Thai women. The CSEP can be replicated in a large population of Thai women during active adjuvant chemotherapy. Nurses need to be aware that physical activity may be an effective intervention for managing multidimensional symptoms in women with breast cancer actively receiving adjuvant chemotherapy. Nurses can encourage and establish an exercise intervention to decrease severity of fatigue and women’s distress from its related symptoms.
ACKNOWLEDGEMENTS

The accomplishment of my dissertation and completion of my doctoral study have been achieved due to the great guidance and support of Dr. Adrianne J. Lane, my advisor and dissertation committee chair, who dedicated her invaluable insight, time, and patience in supervising me. With Dr. Lane’s excellent mentoring, I learned to write proposals submitted for grants in the real-life world and to establish research networks. The experiences could not be learned in the usual classroom.

My special thanks and acknowledgements go to the members of my committee: Dr. Kyra Whitmer, Dr. John Schafer, both faculty at the College of Nursing, and Dr. Bradley R. A. Wilson, a Professor of Health Promotion and Education and the director of Graduate Studies and Research at the College of Education, Criminal Justice, and Human Services. I am truly grateful for the wealth of knowledge and wisdom that the dissertation committee members imparted to me. They are like my “academic parents.” I also am grateful for all PhD faculty in the University of Cincinnati from whom I learned throughout my doctoral studies.

My dissertation could not have been completed without the full cooperation of 23 Thai women with early-stage breast cancer and their families. Their participation and openness about their thoughts and perceptions allowed me to gain knowledge and better understanding in the study. I would like to thank the oncologists and nurses of the outpatient chemotherapy clinic at the Lopburi Cancer Center, Thailand, for facilitating the dissertation data collection.

I would like to thank my fellow graduate nursing classmates and Thai friends who assisted me in surviving while I was in Cincinnati. I would like to thank my colleagues at
Boromarajonani College of Nursing, Saraburi, Thailand, for their support to complete my doctoral program at the University of Cincinnati.

I am truly grateful to the Royal Thai Government for financially supporting my study in the United States. I would like to acknowledge the University of Cincinnati: the Graduate Student Governance Association for funding travel support to Thailand for data collection, and the College of Nursing for awarded scholarship.

Lastly, my deepest thanks go to my friend and sister, Suree Jinruang, who greatly helped me with taking care of my mother at the end of her life and fully supported my family in that time. This dissertation is dedicated to my wonderful mother, Sathit Naraphong, who passed away during the first year of my studies; my father, Pradit Naraphong; and two younger sisters, Wimonrat Naraphong, and Wanwirai Naraphong, for their love and support.
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CHAPTER ONE
INTRODUCTION

Statement of Problem

Breast cancer is a disease with a global burden for women. According to a recent World Health Organization (WHO) report, it is the most common cause of cancer mortality, accounting for 16% of cancer deaths in adult women (Jemal et al., 2011). In addition, it is estimated that 1.7 million women worldwide will be diagnosed with breast cancer in 2020. This is due predominantly to a projected increase of 26% in developing countries. In Southeast Asian women, breast cancer is currently the leading form of cancer (Coughlin & Ekwueme, 2009; Editorial, 2009).

Thailand, a developing nation, is one of many Southeast Asian countries faced with this important and growing health concern. Breast cancer has become a prominent health concern in Thailand, resulting in both substantial morbidity and mortality for Thai women. The total number of women with newly diagnosed breast cancer makes up 47.8% of all new cancer patients (National Cancer Institute - Thailand, 2011). Breast cancer has risen each year in Thailand since 2008. Advances in cancer treatments continue to improve patient survival. The impacts of the physical and psychological symptoms of the sequelae of disease and/or treatment vary in severity, ranging from mild to life-threatening.

Adjuvant therapy, such as, chemotherapy and radiotherapy, is commonly prescribed after surgery for women with early-stage breast cancer (stages I, IIA, IIB, and IIIA), in an attempt to increase the disease-free survival (Berger, 1998). These treatments can cause serious side effects in patients. Most cancer patients experience multiple symptoms associated with treatment.
Fatigue is the most frequent cancer- and/or treatment-related symptom reported by patients (Iop, Manfredi, & Bonura, 2004; Redeker, Lev, & Ruggiero, 2000; Wagner & Cella, 2004).

Many patients with cancer experience a variety of potential causes of fatigue, such as direct effects of cancer, symptoms related to cancer, or effects of cancer treatment (Mustian et al., 2007; Winningham et al., 1994). Seventy to 100% of cancer patients report that fatigue affects them at every stage of the disease and report that fatigue is associated with all treatment modalities (Berger, 1998; Irvine, Vincent, Graydon, Bubela, & Thompson, 1994; Richardson, Ream, & Wilson-Barnett, 1998; Stasi, Abriani, Beccaglia, Terzoli, & Amadori, 2003).

Fatigue is reported in a number of recent studies. Cancer patients during anticancer therapy reported experiencing fatigue over 90% of the time since initial diagnosis. This fatigue persisted for days, months, or even years after completion of treatment and was deemed a direct consequence of the treatment for cancer (Can, Durna, & Aydiner, 2004; Dagnelie et al., 2006; Gaston-Johansson, Fall-Dickson, Bakos, & Kennedy, 1999; Hofman, Ryan, Figueroa-Moseley, Jean-Pierre, & Morrow, 2007; Iop et al., 2004; Newton & Smith, 2001; Respini, Jacobsen, Thors, Tralongo, & Balducci, 2003). Further, cancer-related fatigue can be caused by the disease.

Fatigue is a common presenting symptom of cancer.

Studies have shown that the impact of cancer-related fatigue can be divided into four categories. First, physical impacts were commonly cited as a diminished energy level resulting in low levels of daily activities. In this case, decreased physical activity was a natural response to feeling fatigued and depressed (Courneya & Friedenreich, 1997; Courneya et al., 2003; Macvicar, Winningham, & Nickel, 1989). Second, psychological impacts were presented in terms of decreased motivation, anxiety, or depression. Sleep disturbance was also another problem experienced by breast cancer patients (Koopman et al., 2002). Third, as a result of
cancer-related fatigue, participation in social activities also became more difficult. Fourth, fatigue had a tremendous negative impact on economic or employment status (Chan & Molassiotis, 2001; Curt et al., 2000; Magnusson, Möller, Ekman, & Wallgren, 1999).

Nurses and other health care professionals are challenged to help patients manage cancer-related fatigue and remain as fully engaged in life as possible. Cancer-related fatigue can be alleviated by non-pharmacological interventions. Physical activity is recognized as an effective intervention for this symptom in cancer patients undergoing treatment (Berger et al., 2010; Dimeo, 2001; Stevinson & Fox, 2006). A rationale for exercise as an adjunct therapy is that the combined effects of toxic cancer treatments with associated decreased levels of patient activities during treatment diminish the capacity of physical performance. Most cancer patients expend greater effort relative to maximal ability to perform usual activities, thus leading to higher levels of fatigue. Exercise training can reduce the loss of, and even increase, functional capacity (Courneya et al., 2003). Various benefits from exercise programs have been reported for breast cancer patients, including reduced fatigue (Daley et al., 2007; Rabin, Pinto, Dunsiger, Nash, & Trask, 2009), increased functional capacity (Mock et al., 2005), decreased depression (Daley et al., 2007; Rabin et al., 2009), improved sleep patterns (Daley et al., 2007; Rabin et al., 2009), and improved overall quality of life (Campbell, Mutrie, White, McGuire, & Kearney, 2005; Headley, Ownby, & John, 2004).

Overall, exercise is a cornerstone of cancer symptom management (e.g., fatigue, depression, sleep disturbance). No standardized exercise program has been reported for cancer symptom management. To promote and maintain health in general, the American College of Sports Medicine (ACSM) recommends that adults aged 18 to 65 years engage in moderate-intensity aerobic physical activity for a minimum of 30 minutes on five days per week or
vigorou

s-intensity physical activity for a minimum of 20 minutes on three days per week (Haskell et al., 2007). A variety of physical exercise modalities were employed to achieve exercise goals following these recommendations in different types of studies. Most studies focused on the training modality of aerobic exercise (Campbell et al., 2005; Daley et al., 2007; Headley et al., 2004; Mock et al., 2005; Payne, Held, Thorpe, & Shaw, 2008; Pinto, Frierson, Rabin, Trunzo, & Marcus, 2005; Rabin et al., 2009). Only one study (Battaglini et al., 2008) reported that breast cancer patients received both aerobic and resistance training. Two studies reported the use of yoga as a relaxing form of exercise (Carson et al., 2007; Culos-Reed, Carlson, Daroux, & Hately-Aldous, 2006). In most studies, the duration of physical activity was 30 to 60 minutes, and the participants were advised to increase the intensity gradually. General recommendations about how much exercise is needed for patients with cancer are difficult to prescribe and depend upon physical inactivity as a result of pain, weakness, and therapy-related exercise limitation. Up to 70% of patients with cancer do not meet U.S. national exercise recommendations (Jones, Eves, Haykowsky, Freedland, & Mackey, 2009).

In designing an exercise program for patients with cancer, the first consideration is patient safety. A simple and culturally sensitive exercise program should motivate participation. A walking-based exercise is an aerobic type of moderate physical activity that can serve as a natural choice because it relates to all activities of daily living that cancer patients do during and after cancer treatment (Hoffman, 2006). Although numerous study results have indicated that walking-based exercise results to relieved symptoms of fatigue and improved psychosocial outcomes in breast cancer patients and survivors. These findings have not been consistently reported in the literature: some studies have (Battaglini et al., 2008; Mock et al., 2005; Rabin et al., 2009), while others have not (Campbell et al., 2005; Payne et al., 2008). The variability in
these results may be attributed to differences in research designs to test the effects of exercises; using quasi-experimental design with the absence of comparison group, overall sample size, or sample characteristics. Some studies focused on patients undergoing treatment participating in supervised, on-site exercise training and included specific behavioral skills relevant to exercise (Battaglini et al., 2008; Campbell et al., 2005; Carson et al., 2007; Culos-Reed et al., 2006; Daley et al., 2007; Headley et al., 2004; Payne et al., 2008). In addition, the majority of studies on walking use a treadmill as standard training equipment. Based on the literature review, the samples in these previous studies were predominantly highly educated Caucasian women from higher income levels; thus, additional research is warranted in diverse populations such as Asians, Latinos, and African Americans with lower income or less education.

In Thailand, the use of exercises is not associated with routine cancer care. Further, the use of treadmill exercises is not a common form of therapy, possibly related to a decreased access to exercise facilities. Because of this, these findings related to use of treadmills cannot be generalized to patients who have limited access to exercise facilities. A home-based exercise program is an alternative for such patients to improve their well-being and has the advantages of being low in cost and high in accessibility. A literature review from available studies in Thailand reveals only one study by Srisuksrirphan and colleagues (2008), which examined the effect of the home-based walking exercise on fatigue in breast cancer patients receiving adjuvant chemotherapy. This study was limited by the quasi-experimental design, small sample size, and use of only subjective measures. Regardless of these limitations, patients that were in the exercise group demonstrated significantly decreased fatigue after 10 weeks. Even though exercise programs have been provided for cancer patients by several researchers, getting Thai women with cancer to maintain walking exercise is not without challenge. Such programs may
be insensitive to special culturally based concerns. Understanding how culture affects illness behavior is one key to cultural sensitivity. Particularly, understanding the patient’s culture helps the health professional to influence health behavior in positive ways.

In traditional Thai cultural beliefs related to sickness, ill people are thought to lack energy. Obtaining additional rest and avoiding activities are believed to preserve energy; therefore, exercise is commonly not encouraged for patients undergoing cancer treatment. Additionally, for Thai women and their families, cancer is recognized as a life-threatening disease. Seventy-seven percent of women with cancer reported the most common way of coping with their treatment was “rest” to maintain health and help recovery (Lundberg & Trichorb, 2001). Predominantly, in Thai culture, the family is the smallest unit of identity and decision making. Whenever one member of the family is facing a serious problem, all family members share the responsibility for the problem (Cooper & Cooper, 1990). According to cultural belief and demographic characteristics (e.g., education level, income level), the concept that exercise would help Thai women with breast cancer to relieve symptoms may be a rather counterintuitive idea. Therefore, this proposed study includes family involvement in the recruitment and adherence strategies. Literacy-level appropriateness and cultural values are used to develop appropriate materials and instruments for Thai women with breast cancer.

Although the benefits of body movement have been reported in the literature, most Thai women with breast cancer are unaware of such findings and do not increase their physical activity. To begin, an exercise program should be simple and motivating. Walking may be an acceptable and easily implemented program that Thai women with breast cancer can adopt to decrease adjuvant therapy-induced fatigue. Designing an exercise program to be part of their normal routine may increase adherence. In Thai society, women have the expected duties of
taking care of their families and doing household chores. Including household tasks when designing a culturally sensitive exercise program will strengthen the opportunity for Thai women to participate in an exercise program. Providing information related to exercise should be articulated in creative ways to turn everyday chores into a workout, encouraging a change to a structured exercise program.

To close the gaps identified above, a need exists to develop and pilot test the effects of a culturally sensitive walking-based exercise program on cancer-related fatigue and other symptoms—sleep disturbance, mood disturbance, and symptom distress—in Thai women with breast cancer.

**Significance for Nursing**

Cancer-related fatigue has been recognized as the “sixth vital sign” in patients undergoing cancer therapy and in cancer survivors (Given, 2008; Mayer, 2008). As discussed above, women suffering from breast cancer can experience a wide range of cancer-related fatigue and distressful symptoms that are associated with the disease and its treatment modalities. Current research evidence suggests that exercise could ameliorate cancer-related fatigue; however, there are no evidence-based guidelines for nursing regarding the standard for the exercise intervention and evaluation for the woman with breast cancer receiving adjuvant treatment.

About 44% of nurses used exercise as a strategy to manage cancer-related fatigue (Given, 2008). In a literature review from 2000-2010, 17 studies evaluated the effect of an exercise intervention on reducing cancer-related fatigue in women with breast cancer. Of the 17 studies, five (29%) focused on home-based exercise in women with breast cancer receiving adjuvant chemotherapy and radiotherapy.
Cancer-related fatigue is considered to be a multidimensional symptom. In addition, little research has explored the efficacy of exercise intervention for multiple symptoms. The focus of this proposed study is on cancer-related fatigue and concurrent symptoms. In order to advance nursing practice, it is critical to develop effective interventions and symptom management strategies that are evidence-based. The preliminary findings of this pilot study have the potential to help health care providers enhance the effectiveness of nursing interventions for women with breast cancer who are in diverse cultural environments.

**Purpose/Research Questions**

Designed to overcome some of the limitations of prior investigations, the primary purpose of the pilot study was to develop a clinically feasible, culturally sensitive home-based exercise program that will significantly improve cancer-related fatigue in Thai women with breast cancer receiving adjuvant chemotherapy with and without radiotherapy. In addition, the secondary purpose was to conduct a preliminary data analysis to examine the effects of the culturally sensitive exercise program on the levels of sleep disturbance, mood disturbance, and symptom distress. To inform the effect size calculation for a larger trial, the observed effect size and confidence interval (CI) were calculated and reported. The following research questions and specific aims guided the study:

*Research Question 1:* Are there slope differences in the levels of cancer-related fatigue between the group using the culturally sensitive exercise program (CSEP) as an intervention and the comparison group?

*Specific Aim 1:* To examine the effect of the CSEP on the levels of cancer-related fatigue measured by the Piper Fatigue Scale-Revised (PFS-R) at 4, 7, and 10 weeks in Thai women with breast cancer during adjuvant chemotherapy.
Hypothesis 1: Compared to Thai women with breast cancer in the usual care group, women in the CSEP group will report lower levels of cancer-related fatigue at 4, 7, and 10 weeks during adjuvant chemotherapy.

Research Question 2: Are there slope differences in the levels of sleep disturbance between the group using the CSEP as an intervention and the comparison group?

Specific Aim 2: To examine the effect of the CSEP on the levels of sleep disturbance measured by the Modified General Sleep Disturbance Scale (MGSDS) at 4, 7, and 10 weeks in Thai women with breast cancer during adjuvant chemotherapy.

Hypothesis 2: Compared to Thai women with breast cancer in the usual care group, women in the CSEP group will report lower levels of sleep disturbance at 4, 7, and 10 weeks during adjuvant chemotherapy.

Research Question 3: Are there slope differences in the levels of mood disturbance between the group using the CSEP as an intervention and the comparison group?

Specific Aim 3: To examine the effect of the CSEP on the levels of the mood disturbance measured by the Profile of Mood States-Brief Form (POMS-BF) at 4, 7, and 10 weeks in Thai women with breast cancer during adjuvant chemotherapy.

Hypothesis 3: Compared to Thai women with breast cancer in the usual care group, women in the CSEP group will report lower levels of mood disturbance at 4, 7, and 10 weeks during adjuvant chemotherapy.

Research Question 4: Are there slope differences in the levels of symptom distress between the group using the CSEP as an intervention and the comparison group?
Specific Aim 4: To examine the effect of the CSEP on the levels of symptom distress measured by the Memorial Symptom Assessment Scale (MSAS) at 4, 7, and 10 weeks in Thai women with breast cancer during adjuvant chemotherapy.

Hypothesis 4: Compared to Thai women with breast cancer in the usual care group, women in the CSEP group will report lower levels of symptom distress at 4, 7, and 10 weeks during adjuvant chemotherapy.

Theoretical Framework

The theoretical framework for this study was based on the Theory of Unpleasant Symptoms (TOUS) developed by Lenz, Pugh, Milligan, Gift, and Suppe (1997). The TOUS provided the overall framework for organizing and structuring this study with identified symptoms as central concepts. Symptoms can occur alone or in isolation from one another, more often, multiple symptoms are experienced simultaneously. The nature of a symptom can be truly known and described only by the individual experiencing it. It is asserted that all symptoms vary in intensity, degree of associated distress, timing, and quality.

Three factors are identified as influencing the symptom experience: physiological factors, psychological factors, and situational factors. Physiological factors are considered pathologic processes, disease stages, and treatments and are often interrelated and reflected in unpleasant symptoms. Psychological factors include both affective and cognitive responses. That is, the individual’s mental state, mood, or knowledge about the symptoms can contribute to intensifying the symptom. Situational factors are associated with the individual’s environments, both social and physical, that affect the individual’s experience and reporting of symptoms. Culture, a component of social environments, can influence the experience of symptoms. Performance is the final concept of the TOUS. It is conceptualized to represent the consequences of the
symptom experience. It includes functional and cognitive activities. A number of different performance outcomes may occur simultaneously but also can be time-ordered.

In this study, the TOUS provided perspectives from which to conceptualize the phenomenon that describes cancer-related fatigue as an energy deficit and relates fatigue to disease, treatment, activity, rest, and symptoms. Fatigue can precede and may result in sleep disturbance, mood disturbance, and symptom distress. The TOUS embodies the assertion that multiple symptoms can occur concurrently. Consequently, for a woman with breast cancer, experiencing the symptom of fatigue can negatively impact her mood state and sleep quality. The experience of fatigue can limit a cancer patient’s physical activity, and inactivity may reciprocally increase the intensity of fatigue and symptom distress. That is, physical performance can have a reciprocal relationship to cancer-related fatigue. Additionally, it can impair desire to interact with others. Increased interaction can be received from one’s social environment (e.g., employment status, marital and family status, and social support); thus, situational influencing factors have a positive impact in mitigating the negative impact of the symptom experience of physical illness. The three influencing factors are hypothesized to produce variation in the symptom experience. The TOUS also helps highlight certain aspects of the symptom experience and potential strategies for symptom management. Exercise or physical activity as a potential intervention can improve physical performance and in turn physical performance can mitigate cancer-related fatigue. With regard to the three influencing factors and translation to women with breast cancer in racial/ethnic groups, incorporating cultural sensitivity considerations will enhance the efficacy of a designed exercise program.

In summary, this pilot study was aimed to examine the hypothesis proposed by the theoretical framework that a culturally sensitive exercise program as an intervention would
ameliorate fatigue as a primary outcome and improve overall sleep disturbance, mood disturbance and symptom distress. The synthesis of the TOUS was depicted in a model (Figure 1-1) that was explored among the variables in this study. According to the model, the intervention (CSEP) is developed by appraising the three influential factors after reviewing the relevant literature. There is research evidence to support relationships among these influential factors directly influence the symptoms. In the framework for this study, the influential factors will have a direct effect on the CSEP. As a result, the CSEP is proposed to mediate the interaction between influencing factors (physiological, psychological, and situational factors), and outcomes (fatigue, sleep disturbance, mood disturbance, and symptom distress). Therefore, the framework can be used to develop the intervention, and evaluate changes in symptoms depending on these influential factors.

![Figure 1-1. Theoretical framework.](image-url)
**Definition of Terms**

*Culturally Sensitive Exercise Program* refers to a structured guideline primarily designed for gradually progressive home-based aerobic exercise combining routine household physical activities with structured walking targeting Thai women with breast cancer undergoing adjuvant chemotherapy with or without radiotherapy regimens. Exercise outcomes will be measured by an estimate of total physical activity energy expenditure in kilocalories per day and 12-minute walk test (12-MWT) in meters.

*Fatigue* refers to the perception of breast cancer patients undergoing adjuvant chemotherapy with and without radiotherapy as being tired, weak, or lethargic, unable to perform normal daily activities, and having decreased work efficiency. These influences will be measured by the Piper Fatigue Scale-Revised, which has been translated into Thai by Pritsanapanurungsie (2000).

*Sleep Disturbance* is defined as a subjective experience of sleep quantity and quality in the past week. It will be measured by the Modified General Sleep Disturbance, which has been translated and back-translated into Thai by Hanprasitkam and colleagues (2007).

*Mood Disturbance* is defined as a subjective experience of mood disturbances including tension, depression, anger, vigor, fatigue, and confusion. It will be measured by the Profile of Mood States-Brief Form, which has been translated into Thai by Petpichetchian (2001).

*Symptom Distress* is defined as the degree of discomfort reported by patients receiving chemotherapy or radiotherapy. It will be measured by the Memorial Symptom Assessment Scale, which has been translated into Thai by Suwisith and colleagues (2008).

*Adjuvant Chemotherapy* is defined as the use of chemotherapy regimens with or without radiotherapy in addition to surgical treatment for breast cancer. Adjuvant chemotherapy may
include CMF (cyclophosphamide/methotrexate/fluorouracil), CEF (cyclophosphamide/epirubicin/fluorouracil), AC or AC + paclitaxel (doxorubicin/cyclophosphamide/followed by paclitaxel), CAF (cyclophosphamide/doxorubicin/fluorouracil), TAC (docetaxel/doxorubicin/cyclophosphamide), FEC100 or FEC100 + docetaxel (fluorouracil/epirubicin/cyclophosphamide/followed by docetaxel).
CANCER-RELATED FATIGUE

Definition of cancer-related fatigue. Fatigue is a subjective phenomenon. Generally, fatigue is a universal symptom that occurs in healthy individuals and persons with acute/chronic illness. In healthy persons, fatigue is a normal protective mechanism that helps maintain physical and psychological equilibrium and is easily relieved by rest; whereas, fatigue in cancer patients is more difficult to solely remedy by rest (Prue, Rankin, Allen, Gracey, & Cramp, 2006; Romanelli, Bozzone, Magrone, Pascoli, & Sterzi, 2004).

There are several definitions used in the literature to describe cancer-related fatigue. Aistars (1987) stated that fatigue is a situation caused by prolonged stress that results from direct or indirect attributions to the disease process and contributes to subjective feelings of generalized weariness, weakness, exhaustion, and lack of energy. Nail and King (1987) described fatigue as a human response to the experience of having cancer and to undergoing treatment for cancer. Fatigue is a self-recognized phenomenon involving how the individual feels and how this feeling influences the activities in which one chooses to engage.

To date, the National Comprehensive Cancer Network (NCCN) defines cancer-related fatigue as “a distressing persistent, subjective sense of physical, emotional, and/or cognitive tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning” (Berger et al., 2010). These characteristics are consistent with a qualitative study by Holley (2000). The study indicated that compared with typical fatigue, cancer-related fatigue was more rapid in onset, more intense with no relationship
to physical exertion, more energy-draining for performing activities, longer lasting, and unrelieved by sleep and rest, often unexpected, and tended to increase the feelings being disconcerted and anxiety.

Therefore, cancer-related fatigue has been defined as a subjective and multifaceted phenomenon influenced by various factors (e.g., physical, psychological, and other potential causes). Most patients with cancer experience a variety of potential causes of fatigue as follows: direct effects of cancer, symptoms related to cancer, effects of cancer treatment (Mustian et al., 2007; Winningham et al., 1994).

**Prevalence of cancer-related fatigue and adjuvant therapy.** The prevalence of cancer-related fatigue has been reported in many studies concerning treatment. Particularly, fatigue is reported in a number of recent studies in which cancer patients during anti-cancer therapy experienced fatigue over 90% of the time and the fatigue persisted for days, months, or even years after completion of treatment. Thus, by implication, fatigue is a direct consequence of treatment for cancer (Can et al., 2004; Dagnelie et al., 2006; Gaston-Johansson et al., 1999; Hofman et al., 2007; Iop et al., 2004; Newton & Smith, 2001; Respini et al., 2003). According to many studies, results consistently showed that the prevalence of fatigue in women with breast cancer receiving adjuvant chemotherapy was approximately 70-94% (Greene, Nail, Fieler, Dudgeon, & Jones, 1994; Longman, Braden, & Mishel, 1999; Molassiotis & Chan, 2004).

In addition, the fatigue associated with radiation has been investigated both during a course of treatment and after completion of the course. Evidence of persistence of fatigue comes from several studies. A study by Rucinska and Langkjer (2006) found that for 85% of women with breast cancer, fatigue was the most commonly reported symptom and it persisted during and after adjuvant postoperative radiotherapy. This is consistent with recent findings by Sjövall,
Strömbeck, Löfgren, Bendahl, and Gunnars (2010) that fatigue was the most prevalent side effect of a total sample of 171 women with breast cancer treated with adjuvant postsurgical radiotherapy.

Similarly, the prevalence of cancer-related fatigue and adjuvant therapy in Thailand has been documented. Moderate fatigue has been reported among various types of cancer patients receiving cancer therapy (Buranaruangrote, 2006; Jantaramanee, 2006; Kongsaktrakul, 2004; Pritsanapanurungsie, 2000; Saejew, 2001). A recent Thai study described cancer therapy-related symptoms in Thai patients with cancer receiving chemotherapy, radiation therapy, and combined chemotherapy and radiation therapy. Fatigue symptoms were consistently reported for more than 50% of various types of cancer therapy (Piamjariyakul et al., 2010). As a result of the disease or the side effects of treatments for the disease, cancer patients suffer from fatigue.

**Assessing and measuring cancer-related fatigue.** Fatigue is common for patients with cancer to mention that they face in their life but, unlike pain, the assessment of fatigue is not routinely performed in clinical settings. However, like pain, fatigue is a subjective experience. Fatigue is a multifaceted symptom and is observed as a component of symptom clusters (e.g., pain, mood and sleep disturbance, and deconditioning) (Mitchell & Berger, 2006). Thus, accurate assessment of fatigue is the first critical part of providing appropriate and effective management (Scruggs, 2009).

As mentioned previously, since fatigue is primarily a subjectively experienced symptom, the most commonly described types of instruments for measuring fatigue are self-report measures. Three formats are predominantly used to evaluate cancer-related fatigue in the literature (Jean-Pierre et al., 2007; Minton & Stone, 2009). First, using unidimensional questions measures the occurrence and severity of cancer-related fatigue. Second, multidimensional
instruments are designed specifically to evaluate the effect of cancer-related fatigue across several domains of physical, socio-psychological, and cognitive functioning. Third, single items and subscales have been drawn from measures of related aspects (e.g., quality of life, mood state, and health status). Because of differing formats, the several instruments that have been used to measure cancer-related fatigue also vary by psychometric properties, domains and dimensions, and methods of administration. Use of each format should be considered when measuring the symptom of fatigue.

Time in a fatigue assessment is an important consideration. Fatigue may vary in intensity and duration according to the time at which fatigue was measured. Particularly, there have been studies focusing on patterns of fatigue during cancer adjuvant therapy (Berger, 1998; Berger, Lockhart, & Agrawal, 2009; Molassiotis & Chan, 2004). For adjuvant chemotherapy, timing of measurements is relative to the different cycles of chemotherapy as well as the administration of chemotherapy. The study results revealed that cancer-related fatigue increased over the course of treatment. Cancer-related fatigue peaked 2-5 days after treatment and remained elevated the week after each cycle of chemotherapy (Schwartz et al., 2000). Additionally, chemotherapy regimens and fatigue were found to significantly change over time. The pattern of fatigue was primarily mild, rose to moderate, and then dropped back down to mild. Fatigue levels did not return to baseline and did not differ based on regimens (Berger et al., 2009).

In terms of adjuvant radiotherapy, several studies have also investigated changes in fatigue in patients with cancer during the course of treatment. Multiple measures of radiation therapy-related fatigue demonstrate a pattern of fatigue that gradually accumulated over time, with the greatest fatigue observed 1 day after treatment ended. Recovery after treatment slowly returned to near baseline levels in 2 weeks (Schwartz et al., 2000). In addition, a recent study by
Dhruva and colleagues (2010) investigated the trajectories of evening and morning fatigue in women with breast cancer who underwent adjuvant radiotherapy over 25 weeks. The study revealed that evening fatigue increased over the course of adjuvant radiotherapy and then declined after the completion of the treatment. Morning fatigue decreased over the course of the treatment and then plateaued after the completion of the treatment. Interestingly, with hierarchical linear modeling (HLM), this study also explored the effects of predictors on patients’ trajectories of evening and morning fatigue. Three variables that predicted interindividual differences for evening fatigue were taking care of children, working, and baseline level of depressive symptoms. Meanwhile, morning fatigue was predicted by six variables: age, body mass index (BMI), trait anxiety, sleep disturbance, number of comorbidities, and stage of disease (Dhruva et al., 2010). These data may guide development of intervention studies for cancer-related fatigue.

Selecting a fatigue measure for research use can be a challenge. To measure cancer-related fatigue, 3 unidimensional and 37 multidimensional self-assessment tools have been developed (Seyidova-Khoshknabi, Davis, & Walsh, 2010). Jacobsen (2004) suggested four practical considerations to help researchers evaluate which measure is appropriate. First, some measures are suitable for use with individuals who are currently experiencing fatigue but are unsuitable for use with individuals who may not currently be experiencing fatigue. The time frame covered by the assessment is the second consideration. Some measures are keyed primarily to different time frames (e.g., past 24 hours, past week). The third consideration is the measure’s psychometric properties. Although there has been accumulating evidence of measures’ validity and reliability, the strength of evidence should be composed of the quality of methods used to develop the measures' multidimensional format and the population on which the
psychometric data are validated. The fourth consideration is whether or not the research questions being asked correspond to the various multidimensional measures.

In addition to the described considerations, minimizing response burden is a concern for researchers. Shortening a measure is one of the most common modifications. When selecting modified measures, substantial psychometric work is needed to determine whether the measure supports the full breadth of the original constructs. At a minimum, the full range of reliability and content validity may need to be assessed for a modified measure after the original psychometric work was conducted (Switzer, Wisniewski, Belle, Dew, & Schultz, 1999).

Cultural appropriateness of a research instrument for a study population is an important consideration. For cross-cultural research in which quantitative measures will be used, to save time and effort, previously developed instruments with good psychometrics properties are often used (Cha, Kim, & Erlen, 2007). Thus, instrument translation is employed to be both culturally acceptable and appropriately and validly translated. The process of translation into the language of the culture being studied becomes an important part of these measures. Four techniques have been recommended: back-translation, bilingual techniques, committee approach, and pretest (Brislin, 1970). Further, each of these techniques was analyzed, and the strengths and weaknesses were classified into six categories by Maneesriwongul and Dixon (2004). The categories were: forward-only translation, forward translation with testing, back-translation, back-translation and monolingual test, back-translation and bilingual test, and back-translation and monolingual and bilingual tests.

Since there is no consensus among researchers about which of these techniques might be the ideal translation technique, recommended minimum standards for applying an instrument developed in another language are that it should combine back-translation with an acceptable
internal consistency reliability testing among monolingual subjects. In back-translation, if words and concepts have no clear equivalence in the target language version, modification can be allowed. Strengthened internal consistency reliability enhances the credibility of the findings because reliability and validity of the source language version cannot be assumed for the target language version (Maneesriwongul & Dixon, 2004).

In conclusion, cancer-related fatigue can be measured effectively in research, if the selection of a cancer-related fatigue measure is closely examined to determine which is the most valid, reliable, and feasible to use given the setting, research goals, and whether the intervention is designed to reduce the symptom of cancer-related fatigue (Mortimer et al., 2010).

**Concurrent Symptoms of Cancer-Related Fatigue**

According to the theory of unpleasant symptoms (TOUS) (Lenz et al., 1997), patients with cancer often experience several concurrent symptoms as a result of the disease and its treatment. One symptom may influence the severity of other symptoms. Fatigue is reported as one of several symptoms that frequently occur in clusters (Barsevick, Whitmer, Nail, Beck, & Dudley, 2006). There is growing evidence of studies in breast cancer that examined the association between cancer-related fatigue and multiple symptoms, such as, pain, insomnia, and depressed mood (Bender, Ergyn, Rosenzweig, Cohen, & Sereika, 2005; H.-J. Kim, Barsevick, Tulman, & McDermott, 2008).

Research in cancer symptom management has typically focused on the alleviation of single symptoms. Future research is needed to further explore the efficacy of intervention for multiple symptoms (Barsevick et al., 2010). As a result, in the research being presented here, the secondary purpose of this study is to determine whether the intervention intended for cancer-
related fatigue will influence the severity of other symptoms. Sleep disturbance, mood disturbance, and symptom distress are selected for observation.

**Sleep disturbance.** Sleep disturbance is one of the most frequent and disturbing complaint of patients with cancer (L. Liu & Ancoli-Israel, 2008). Like fatigue and pain, sleep disturbance is often defined subjectively as insomnia, poor sleep quality, and short sleep duration. Compared to healthy patients, cancer patients had poorer subjective sleep quality (Owen, Parker, & McGuire, 1999).

Several integrative reviews of the literature indicated that self-reported changes in sleep are frequently reported by patients with cancer (Ancoli-Israel, Moore, & Jones, 2001; L. Liu & Ancoli-Israel, 2008; Roscoe et al., 2007). The prevalence of sleep disturbances has mostly been investigated in cross-sectional studies and has been reported with rates ranging from 30% to 75% of newly diagnosed and recently treated cancer patients (L. Liu & Ancoli-Israel, 2008).

Among patients with different types of cancer, sleep complaints have varied at different treatment phases. Fortner and colleagues (2002) studied the characteristics of sleep in breast cancer patients whether or not they were receiving chemotherapy or radiation therapy, in comparison to patients with general medical conditions. It was found that 61% of breast cancer patients had significant sleep problems. More recently, the prevalence of insomnia among 823 breast cancer patients undergoing chemotherapy was reported by Palesh and colleagues (2010). The amount of insomnia in patients with breast cancer was 60% and remained unchanged during cycle 1 and cycle 2 of chemotherapy (Palesh et al., 2010).

A study by Savard and colleagues (2001) studied the prevalence of insomnia in 300 breast cancer patients treated with radiotherapy and found that approximately 51% of the sample reported insomnia symptoms (e.g., sleep difficulties, night-time awakenings, using a sleep-
promoting substance). One variable that was found to increase the relative risk (odds ratio; OR) to report insomnia symptoms was to be treated by a combination of radiotherapy and chemotherapy for an early-stage breast cancer (OR = 4.3, 95% CI [1.70, 10.70]).

In addition, with the increasing numbers of breast cancer cases in women aged 50 years or older, sleep variables (i.e., subjective sleep quality, objective sleep quality, nocturnal sleep time, sleep-onset latency, nocturnal awakenings, day sleep time, daytime sleepiness, and insomnia) were described in a metasynthesis of sleep studies at different points in chemotherapy treatment (Enderlin et al., 2010). The major findings were as follows: subjective sleep quality was reported as poor in days 8-9 of a 21-day third cycle; objective sleep quality measured by actigraphy was poor during the third chemotherapy cycle; nocturnal sleep time was 6-6.6 hours, characterized as below average for normal adult range (7-9 hours), during the first two days of the first chemotherapy cycle and during the third cycle of treatment; sleep-onset latency was reported as exceeding 30 minutes during the active chemotherapy treatment; nocturnal awakenings were found to be frequent (2-22 times per night) prior to and over the course of adjuvant chemotherapy cycles; day sleep time was 66 minutes, within normal adult range (5-120 minutes); daytime sleepiness (i.e., difficulty waking and getting up) was significantly more reported during active chemotherapy treatment (days 8-9); and insomnia symptoms were reported by 33% of women with breast cancer within six months of breast cancer diagnosis, by 60% during chemotherapy treatment, and by 33%-50% four years after chemotherapy treatment.

In summary, in patients with breast cancer, insufficient sleep may lead to increased fatigue. Exercise has been classified as an effective nonpharmacological intervention optimizing sleep quality and decreasing fatigue (Berger & Mitchell, 2008; Erickson & Berger, 2011). Two
exercise studies were primarily tested to decrease fatigue and then improve sleep in patients with breast cancer (Mock et al., 1997; Wang, Boehmke, Wu, Dickerson, & Fisher, 2011).

**Mood disturbance.** Generally, mood disturbance is defined as “a transient feeling, emotional tone, or general attitude. As a temporary emotional state, mood fluctuates depending upon one’s circumstances” (Von Ah, Kang, & Carpenter, 2008). Mood disturbance (e.g., anxiety, depression, and lack of motivation) is a coexisting psychological symptom reported by patients with cancer. The prevalence of feeling depressed was the third symptom reported in 51% of the cancer patients (Curt et al., 2000).

Because cancer is a serious and potentially life-threatening illness, researchers have shown that women with breast cancer are more vulnerable to mood disturbance than women without cancer. Nearly 50% of the women with early breast cancer had clinical depression and anxiety or both in the year after diagnosis. Furthermore, 15%-25% of women with breast cancer reported these ongoing symptoms for five years after diagnosis (Burgess et al., 2005). Similar findings were reported by Lueboonthavatchai, who studied the prevalence of anxiety and depression in 300 Thai women with breast cancer using the Thai Hospital Anxiety and Depression Scale and found that 16% had anxiety disorder, 19% had anxiety symptoms, 9% had depressive disorder, and 16.7% had depressive symptoms (Lueboonthavatchai, 2007).

In addition, mood disturbance in women with breast cancer varies prior to, during, and after adjuvant therapy. A recent longitudinal study by Von Ah and Kang (2007) examined mood disturbance over an 18-month period measured by The Profile of Mood States-Short Form (POMS-SF) in women newly diagnosed with breast cancer. Although the overall mean scores on the POMS-SF were generally low prior to adjuvant therapy, mood disturbance remained
stable during and near the completion of adjuvant therapy. Thus, mood disturbance among women living with breast cancer may play a significant role in predicting cancer-related fatigue.

It has been found empirically that mood disturbance influences cancer-related fatigue in women with breast cancer. Von Ah and colleagues (2008) studied mood disturbance as a potential psychological predictor in 44 women with breast cancer to determine whether it predicted concurrent cancer-related fatigue before, during, and after adjuvant therapy. Multiple regression results revealed that the most significant predictor of cancer-related fatigue at each time point was mood disturbance. Higher cancer-related fatigue was significantly associated with more mood disturbance at all three time points. Although the sample size in this study is relatively small, it makes sense to examine mood disturbance in the context of a cancer-related fatigue reduction. Also, the findings have some implication to optimize the delivery of exercise intervention to combat cancer-related fatigue in patients with breast cancer.

Symptom distress. Symptom distress is a subjective experience and is a threat to patients with cancer. The importance of symptom distress is that it is related to various aspects of health and illness (i.e., quality of life, treatment tolerance, and survival) in patients with cancer and other illnesses (Goodell & Nail, 2005). A review of literature indicated that operational definitions and measurements of symptom distress in adult patients with cancer have been studied, and reviewed by nursing scholars (Goodell & Nail, 2005; McClement, Woodgate, & Degner, 1997; Rhodes & Watson, 1987; Tang, Wang, Hung, & Lin, 2011; Tishelman, Taube, & Sachs, 1991). To date, a lack of consensus exists regarding how symptom distress is operationally defined and how it should be accurately measured.

In the TOUS, four dimensions of a symptom are: intensity, distress, quality, and timing. Distress reflects the degree to which the person is bothered by the symptom (Lenz et al., 1997).
A recent analysis of the research literature revealed that symptom distress refers to “the degree of physical or mental suffering, discomfort, or bother reported by individuals in relation to their perceptions of the symptom” (Fu, LeMone, & McDaniel, 2004). In addition, symptom distress in cancer patients is affected by various factors such as age, gender, culture, family role, educational level, types of treatment, health knowledge, values, beliefs, and past experiences (Fu et al., 2004; McClement et al., 1997; Tishelman et al., 1991). Self-reported symptom distress and associated factors in Asian cancer patients before and after radiotherapy was assessed by Tang and colleagues (2011). Findings from that study supported other studies, in that 35.9% of cancer patients reported an increase in the overall figures of symptom distress. Patients aged 20 to 39 years had a greater increase in symptom distress than those in different age groups, which reached statistical significance ($p < .001$).

Symptom distress is an individual’s perception that determines the initiation, continuation, and discontinuation of the activities to relieve, decrease, or prevent a single symptom or multiple symptoms experienced simultaneously. Also, symptom distress is a major indicator in evaluating symptom status as an outcome of symptom management (Dodd et al., 2001; Fu et al., 2004; Lenz et al., 1997).

Therefore, the degree of symptom distress is an indicator variable for effective symptom management in patients with cancer (Berger, 1998; Dodd et al., 2001; Fu et al., 2004; Maevicar et al., 1989). Only a few exercise intervention studies have examined symptom distress as a concurrent predictor of cancer-related fatigue (van Weert et al., 2006). The overlap of the simultaneous occurrence of more than one symptom measured by symptom distress offers direction for effective exercise intervention programs to manage cancer-related fatigue in future research.
Cultural Sensitivity in Exercise for Managing Cancer-Related Fatigue

Accumulating evidence supports the idea that exercise is considered to be safe and have potential benefits during cancer treatment. Such exercise programs may not be appropriate for women who perceive that cancer patients should get more rest and gently exercise. The exercise interventions in previous studies for managing cancer-related fatigue or other cancer-related symptoms were only designed and guided by formative research. Because complex health behaviors vary with ethnic variations and cultural differences the diversity of cultural constructs should be considered when designing exercise interventions to increase the involvement in exercise for ethnic subgroups.

**Definition of cultural sensitivity.** Culture is a central theoretical concept in anthropology and is multidimensional. An important aspect is that the influence of culture on behavior is not always conscious. It is a system of learned patterns of behavior through the socialization process. It is shared by the individual and other people of a group. The different dimensions of culture refer to common patterns held by a region, community, family, and individual. To use culture in practical ways, culture can be considered at these different levels (Krefting, 1991). Understanding how culture affects illness behavior is one key to cultural sensitivity. Particularly, understanding the patient’s culture helps the health professional to influence health behavior in positive ways. There is no one way to help all cultures or all individuals within a similar cultural background.

Cultural sensitivity is the term used across multiple disciplines. The following definition is widely accepted in public health and based on the work of Resnicow and colleagues (1999). “Cultural sensitivity is the extent to which ethnic/cultural characteristics, experiences, norms, values, behavioral patterns, and beliefs of a target population as well as relevant historical,
environmental, and social forces are incorporated in the design, delivery, and evaluation of targeted health promotion materials and programs” (Resnicow et al., 1999). In addition, cultural sensitivity is defined by two primary dimensions: surface structure and deep structure. Surface structure refers to the extent to which interventions fit culture, experience, and behavioral patterns of a target population. Social and behavioral characteristics of a target population are applied to intervention material and messages. Channels and settings are also identified to properly deliver messages and programs. Deep structure is the second dimension of intervention sensitivity. It requires understanding how cultural, social, psychological, environmental, and historical factors influence health behaviors in the proposed target population, as well as understanding how individual persons of the target population perceive the cause, course, and treatment of illnesses (Resnicow et al., 1999).

To summarize, implications for exercise programs across racial, ethnic, and culturally diverse groups should have two-dimensional cultural sensitivity. That means the exercise program should have surface structure, which involves how interventions enhance receptivity, comprehension, or acceptance of messages (also called feasibility), and have deep structure which conveys salience. Applying two-dimensional cultural sensitivity has more effect on the effectiveness of programs. Culture profoundly affects the way people define and experience health and disease. A need exists for health interventions to be designed to be more culturally sensitive (Nazarea, 1999).

From a literature review, a variety of ways have been employed in providing culturally sensitive practice by health care professions. To improve understanding the term “culture” as described within the nursing field, a concept analysis was performed. The following concepts emerged as attributes of cultural sensitivity by Foronda (2008). Knowledge is the first attribute
of cultural sensitivity. It is important for one to have adequate knowledge of cultural differences in a variety of contexts. A second attribute is consideration, defined as having concern for one’s background in approaching patients (i.e., language, beliefs, values, diet, customs, and traditions). Understanding, defined as perceiving and comprehending the meaning upon observations, is a third essential attribute to provide cultural sensitivity. The effects and significance of another’s values and experiences must be paid attention to for cultural sensitivity. The fourth attribute, respect, is a fundamental component of cultural sensitivity. Respect is defined as having appreciation or regard for one’s cultural beliefs and values. To address one’s needs and display cultural sensitivity, tailoring is the final attribute, defined as altering or adapting one’s own perspective first, then selecting tailored interventions next.

A practice guideline was developed for providing culturally sensitive interventions (College of Nurses of Ontario, 2009). There are four elements for providing culturally sensitive care. Self-reflection is a first element to assist nurses in clarifying her/his values and biases associated with her/his approach. A second element is acquiring cultural knowledge. Nurses should obtain a broad understanding of how cultures can affect the way people (i.e., patients/clients and caregivers) view and respond to their behaviors. An important role of nurses is to help the patient reach her/his specific health goal. Facilitating patient choice is a third element, if the desired patient choice does not pose negative consequences. Communication is a fourth element. This means nurses can include verbal and nonverbal approaches to communicate with patients. Working with interpreters is a concern in situations where a language barrier exists between the nurse and the patient. Also, nonverbal communication can be very helpful (e.g., demonstration, gestures, pictures or symbols, written information) in communicating with the patient.
Likewise, the American Cancer Society (ACS) set a goal of overcoming barriers to cancer care through culturally tailored programs by the year 2015. Sociocultural factors need to be considered to direct the mechanism for cancer prevention and control in future research (Nguyen & Kagawa-Singer, 2008). Oncology nurses are urged to develop cultural competence and deliver culturally sensitive care because cultural beliefs and norms are known to profoundly influence patients’ health beliefs and practices toward cancer, early detection and screening service, and compliance with treatments (Navon, 1999).

Developing culturally sensitive interventions is a challenging process. Resnicow and colleagues (2000) stated that the process of developing culturally sensitive interventions should begin with an analysis of data obtained from quantitative and qualitative techniques. Quantitative approaches may be composed of surveys, secondary analysis of existing datasets, or archival information. Either focus groups or pretesting methods are potentially valuable qualitative means to elucidate thoughts, feelings, experiences, and environmental enabling and constraining factors. When conducting focus groups, materials and messages can be shown to the target population and then can be used to provide an opportunity to examine the messages’ possible culturally-based format and content. Pretesting can be useful to obtain feedback involving feasibility of the intervention delivery process. In addition, the sensitivity of the materials and messages can also be typically asked as "How appropriate are these materials for patients like you?" As mentioned above, surface and deep structure can be increased and then interventions do become culturally sensitive.

**Thai women and cultural context.** Thailand is located in Southeast Asia and nearly 94% of the population of approximately 63 million is devoutly Buddhist. Thai culture as an Asian culture encompasses a wide range of cultures, languages, and religious practices.
Distinctly, Thai has a strong family hierarchy, with the elderly being held in great regard. It is a common societal value and practice among Thais to refuse something when offered the first time. Even though Thais have concerns or feelings, Thais rarely share their feelings and thoughts with others (Pinyuchon & Gray, 1997).

For Thai women, cancer is recognized as a life-threatening disease. One published descriptive study in Thailand showed that women’s most common feeling was of “anxiety” and “fright/fear” when they knew that they would be treated (42% and 26%, respectively). For 67% of women with cancer, the most common way of coping with their treatment was “rest” to maintain health and help recovery (Lundberg & Trichorb, 2001). Additionally, most are midlife women aged 40-59 years (Li, Holm, Gulanick, Lanuza, & Penckofer, 1999). The first primary cancer was diagnosed at an age over 35 years of age. The peak incidence for breast cancer diagnosis in Thai women was 40-59 years of age (66%). This age group was mostly married (National Cancer Institute - Thailand, 2010).

Midlife in Thai society is a time of shifting roles for women, as well as a time of biological, psychological, and sociocultural changes. Midlife experiences of Thai women were explored by Arpanantikul (2004). The findings indicated that physical and mental health problems produced the expected and unexpected changes; thus, midlife women were vulnerable to poor health. However, midlife women adapted themselves to changes as follows: acknowledging midlife change, dealing with change, and seeking social support. Thai midlife women thought about their future—wishing to live with children, be healthy, own property, and practice religion for the next life. With regard to cancer nursing implications, nurses can support women with cancer by helping them to think ahead about how to participate in cancer symptom management.
As in many other Asian cultures, a family is a cultural context that directly influences how Thai women with breast cancer define and manage their cancer. The family is the smallest unit of identity and decision making in Thai culture. Many of the problems faced were coped with because of support from husband, family, and neighbors. Whenever one of its members is facing a serious problem, all family members share the responsibility for the problem (Cooper & Cooper, 1990). Similar results were found in the study by Ratanasiri and colleagues (2000) of the illness experience and coping with cancer among Thai female patients. Family reaction to the patient was found to be sympathetic and supportive—taking the patient to see doctor, encouraging the patient to rest and taking over household tasks. Fear of death was the most common problem relating to the resolution and coping mechanisms. Particularly, family support was an important factor leading to reduced fear of death. Thai patients get support from their spouse, children, and friends. Such support is very important and helps women feel better. A nursing implication is that nurses need to realize and try to respond appropriately to Thai cancer patients’ cultural beliefs in order to effectively develop strategies and to adopt the behavioral interventions that focus on exercise.

Rural and urban considerations have a great cultural influence on the daily living of Thai people. Rapid socioeconomic change has had a great impact on both rural and urban Thai communities. Thai society gradually has become less agricultural and more industrialized and urbanized. Due to economic demands, particularly for women living in low-income families, women living in both urban and rural areas go to work. In urban areas in Thailand, traffic congestion is an obstacle for Thai women who spend more time traveling and feel very tired. In rural Thailand, women help their husbands plough and harvest in the fields (Pinyuchon & Gray, 1997). Most Thai women with chronic illness, during and after treatment, try to balance working
outside the home as well as doing the work of the household (Puavilai & Stuifbergen, 2000). As a result, Thai women do not formally exercise on a regular basis. In addition, Lundberg and Rattanasuwan (2007) studied experiences of fatigue in Thai cancer patients undergoing radiation therapy. The results showed that a long commute to the hospital due to a long distance and/or heavy traffic was a main cause of their fatigue. Thus, providing a home-based exercise program may more easily apply to either physically inactive or less physically active women diagnosed with breast cancer who have limited access to supervised-based exercise interventions due to transportation or scheduling difficulties.

In Thailand, there is still limited research regarding the exercise preferences of Thai cancer patients. Only one published survey showed the factors affecting physical activity of 642 rural Thai women (Laosupap, Sota, & Laopaiboon, 2008). The results indicated that the prevalence of physical activity of the women was 46.9%. Beliefs and knowledge in physical activity of the women seemed to be new information. They did not know the health benefits of exercise and how much exercise is enough (intensity, duration, and frequency). Health care providers were important contributors to their decision to engage in physical activity as well. At this point, it may be implicitly concluded that most Thai women with cancer are not or are less physically active. The associated factors of knowledge and perceived benefits of physical activity may be beneficial information for promoting further research related to culturally sensitive exercise programs in Thai women with cancer.

Physical activity is a complex behavior. It is difficult to fully understand why one does not have, nor how to get one to initiate, a physically active lifestyle. This difficulty is compounded by cancer. Although exercise is one of the cornerstones of cancer symptom management (e.g., fatigue, depression, sleep disturbance), exercising during illness seems
counterintuitive to the cancer patients (Ingram, Wessel, & Courneya, 2010). An individual’s exercise preferences may influence the success of an exercise intervention. It is necessary to mention studies assessing preferences in cancer patients before designing interventions. The results have demonstrated that there are more preferences for moderate-intensity exercise (usually walking), exercise outdoors or at home, and exercise alone or with a family member or friend (Demark-Wahnefried, Peterson, McBride, Lipkus, & Clipp, 2000; Jones & Courneya, 2002; Rogers, Courneya, Shah, Dunnington, & Hopkins-Price, 2007; Rogers, Courneya, Verhulst, Markwell, & McAuley, 2008). Recently, similar results were found in the study by Roger and colleagues (2009). Rural breast cancer survivors preferred home-based exercise (63%) and also moderate-intensity exercise (65%). Exercise preference is further complicated for women with breast cancer by their adjuvant treatment side effects. To better understand how women with breast cancer perceive the benefits of and challenges to exercising during adjuvant treatment in which they are engaged, Ingram and colleagues (2010) qualitatively examined women’s perceptions of a home-based exercise program while receiving adjuvant chemotherapy for breast cancer. Feasibility and acceptability were evaluated by using content analysis. The results were categorized into two themes: exercise challenges and exercise facilitators and strategies. Exercise challenges were factors that these women had to overcome to continue their exercising. Treatment-related factors (e.g., the side effects of chemotherapy, medications prescribed to correct side effects [antiemetic]) were the major exercise challenges. Adaptations, internal motivations, and external supports were exercise facilitators and strategies that helped women maintain or resume exercising. Time to exercise was frequently adjusted. A few days after chemotherapy treatments, women did report less exercise. As a result, women adapted to perform their full exercise program either by exercising early in the morning or by exercising in
multiple shorter sessions throughout the day. Women also mentioned that the emotional and physical benefits of exercising and a feeling of personal achievement became further sources of internal motivation to keep moving. Finally, use of external supports (e.g., exercise instruction manuals, exercise DVDs, and telephone check-ups by the research team) was frequently noted to increase confidence to carry out their exercise.

In conclusion, cultural contexts mentioned previously will be used to guide the development and implementation of a culturally sensitive exercise program in order to grasp the possible constraints on behavior change and thus the scope for intervention.

**Exercise for Managing Cancer-Related Fatigue**

Cancer symptom management is recognized as a major goal to help patients with cancer. Cancer-related fatigue is a difficult symptom to directly treat with pharmacological therapies. Non-pharmacologic behavioral interventions emerge as an approach to mitigate fatigue effectively. Behavioral techniques may include exercise, psychosocial support, stress management, energy conservation, nutrition therapy, sleep therapy, and restorative therapy (Mustian et al., 2007).

For many cancer patients, decreasing physical activity is a natural response to feeling fatigued. Over time, physical inactivity has a negative impact on performing activities of normal daily living (Courneya & Friedenreich, 1999; Macvicar et al., 1989). Exercise-based interventions have become increasingly recognized as beneficial for cancer patients during and following treatments.

**Definition of terms related to exercise interventions.** Two terms were defined in studies focusing on the effect of exercise on cancer-related fatigue. Theoretically, physical activity is defined as any movement of skeletal muscles that results in increasing energy
Expenditure; whereas, exercise is aimed at improving or maintaining physical fitness (cardiovascular, muscle strength, endurance, flexibility, and body composition). In addition, a dose of exercise is concerned with intensity and duration; exercise is specifically delineated as a subset of physical activity (Thompson et al., 2003). An exercise training program consists of a mode or type of exercise, volume (i.e., frequency, intensity, and duration), setting, and progression (McNeely & Courneya, 2010).

**Exercise physiology and cancer-related fatigue.** Though interest in administering exercise interventions across post-diagnosis periods (i.e., pretreatment, treatment, survivorship, and end of life) is increasing, the potential mechanisms of exercise on cancer-related fatigue remain unknown (McNeely & Courneya, 2010). According to specialists of exercise physiology, cancer-related fatigue is originated from physical and physiological fatigue. Physical fatigue is defined as the decline in muscle tension or force capacity with repeated stimulation. The specific test during submaximal or maximal exercise tasks can be used to quantify the physical fatigue. Physiological fatigue is defined as interactive events between the central nervous system (CNS) and the skeletal muscle fiber. At the CNS level, neuromodulators, such as ammonia or cytokines, generally act on the CNS to alter the psychic or perceptual state and decrease ability to exercise. The concentration of cytokines increases in cancer patients as a result from side effects of anticancer drugs on the CNS and the interaction between the tumor and the host defense system (McAdle, Katch, & Katch, 2010).

In addition, several review articles have been published giving perspective on how exercise physiology may contribute to cancer-related fatigue. According to Lucía, Earnest, and Pérez (2003), insufficient oxygen transport to muscles can help explain fatigue in patients with cancer. Anemia (a hemoglobin concentration of less than 12 g/dl) is one of several specific
problems that make oxygen supply insufficient to meet the oxygen demands of working muscles. Anemia is further aggravated with progressive disease and treatment. Chemotherapy and radiotherapy can damage bone marrow and produce renal toxicity. Only a few studies have tested the effect of exercise on hemoglobin concentration in patients with cancer (Dimeo et al., 1997; Dolan et al., 2010; Drouin et al., 2006).

Loss of lung volume caused by advancing stage of disease or treatment also reduces the ventilation/perfusion ratio and further decreases arterial blood oxygenation and oxygen supply to the working muscles. Particularly, lung toxicity occurs after chest irradiation. Cough and dyspnea are common symptoms found in acute radiation pneumonitis, depending on the dose and volume of the lung irradiated. Pulmonary fibrosis can develop as a consequence of tissue repair after ionizing radiation in late radiation pneumonitis. Consequently, a decrease in the arterial oxygen saturation is severely compromised by alveolar capillary membrane damage, decreased lung perfusion, and lower lung compliance. Insufficient blood pumping due to decrease in central cardiac dynamics occurs as a result of cancer treatment. Mediastinal radiation and several antineoplastic agents can induce myocardial damage which leads to decreased cardiac output. In cancer patients, cardiac atrophy further reduces cardiac output due to prolonged bed rest (Dimeo, 2001; Lucía et al., 2003).

Skeletal muscle wasting is reported to be a physiological factor contributing to cancer-related fatigue. Decreased skeletal muscle mass and muscle strength in cancer result from sedentary habits, long-term bed rest, decreased food intake, and an imbalance in the rates of muscle protein synthesis and degradation (Al-Majid & McCarthy, 2001; Lucía et al., 2003). This problem is furthered by tumors that elicit an inflammatory response (prostaglandin E2) and by the subsequent negative effects of immunosuppressive drugs. These effects result from
decreased mitochondrial volume or mitochondrial myopathy (Lucía et al., 2003). Because cancer patients often describe cancer-related fatigue as feeling tired, weak, exhausted, and lack of energy, a hypothesis to explain this aspect is depletion of substrates in muscle fibers. Depletion of phosphocreatine reflects a mismatch between ATP synthesis and degradation inside muscle fibers (Lucía et al., 2003; Ryan et al., 2007).

Finally, cancer-related fatigue may be caused by a failure of the excitation-contraction (EC) coupling process. EC coupling is a signaling cellular process by which the electrical discharge on muscle fiber membrane results in the contraction of a muscle fiber. Calcium release from the sarcoplasmic reticulum is the signal for coupling (contraction) and uncoupling (relaxation) that continuously operates during any type of exercise or physical activity. Metabolically active molecules such as tumor necrosis factor α (TNFα; a side effect of treatment such as ionizing radiation) can impair EC coupling (Lucía et al., 2003). Exercise could be thought of as an effective means for managing cancer-related fatigue through preserving muscle strength or endurance by preventing deterioration of function (Ng, 2010).

**Exercise recommendations and women with breast cancer.** The benefits of exercise or physically active lifestyle for cancer symptom management have been supported by numerous randomized, controlled clinical trials evaluating during and after treatment in patients with various types of cancer. Consequently, there is an increasing body of literature available on exercise-based interventions which purport to alleviate the burden of cancer-related fatigue for cancer patients and survivors (Cramp & Daniel, 2008; de Nijs, 2008; Kirshbaum, 2007, 2010; Knols, 2005; Stricker, Drake, Hoyer, & Mock, 2004; Wanchai, Armer, & Stewart, 2011). The existing research findings have been used to develop evidence-based guidelines or prescriptions
for exercise in cancer patients and survivors during and after cancer treatments (Schmitz et al., 2010).

In women diagnosed with early-stage breast cancer (stage I-IIIa), the types of exercise that may be beneficial and should be carefully considered for managing cancer-related fatigue is questionable. Currently, no direct specific evidence is available about the best type, frequency, duration, or intensity of exercise. There are existing guidelines and recommendations developed for exercise from the American College of Sport Medicine (ACSM), the American Heart Association (AHA), the American Cancer Society (ACS), the United States Department of Health and Human Services (US DHHS), and the position stand of the Australian Association of Exercise and Sport Science (AAES) (Hayes, Spence, Galvão, & Newton, 2009; Schmitz et al., 2010). Previous studies follow the guidelines for the general population by the ACSM. That is, physical activity in adults aged 18 to 65 years should be moderate-intensity aerobic activity for a minimum of 30 minutes on five days per week or vigorous-intensity activity for a minimum of 20 minutes on three days per week (Haskell et al., 2007). Up to 70% of patients with cancer do not meet U.S. national exercise recommendations (Jones et al., 2009).

Recently, the ACSM released guidelines in implementing physical activity programs for cancer survivors both during and after cancer treatment (Schmitz et al., 2010). For the guidelines, cancer survivor is defined as from the time of diagnosis until the end of life. The ACSM guidelines focus on adult cancers and sites (i.e., breast, prostate, colon, hematologic with hematopoietic stem cell transplantation (HSCT) and without HSCT, and gynecologic cancer), where most evidence had been assembled for multiple outcomes. The guidelines broadly recommend at least 150 minutes of moderate-intensity aerobic exercise each week. Moderate-intensity aerobic, such as walking, is safe for most patients with cancer. A routine physical and
stress test, such as a treadmill stress test, is not required before beginning a moderate-intensity exercise program. Resistance and flexibility exercises are also recommended for most patients with cancer but should be cautiously prescribed among those with the potential for elevated risk. Particularly, women with breast cancer and at risk for lymphedema should be cautious.

However, given the recent general recommendations about how much exercise is needed, patients with cancer are less likely to engage in physical activity because physical inactivity is a result of pain, weakness, or therapy-related exercise limitation. Based on accumulating evidence, although previous studies have shown the safety and potential benefits of aerobic exercise during adjuvant treatments for breast cancer, to encourage regular participation in moderate-intensity physical activity in breast cancer patients, more research is needed.

**Aerobic exercise programming and cancer-related fatigue.** An exercise program is being developed herein to help women maintain and increase physical activity after breast cancer diagnosis and through their cancer treatments. This could lead to improvements in fatigue, sleep, mood, and symptom distress relief. Physical activity has shown additional benefits for chronic conditions in observational studies. The most classic study of Paffenbarger and colleagues (1993) has shown in those who expend only 1000 kcal (4200 kJ) per week, all-cause mortality can be reduced 20-30%. For the frail person or sedentary patient, at least 500 kcal (2100 kJ) per week may provide a fitness benefit (Pearce, 2008). Recently, prospective studies have similarly shown that women who engaged in at least 9 metabolic equivalent task (MET) hours per week of physical activity after being diagnosed with stage I through stage IIIa breast cancer have a 50% improved rate of breast cancer recurrence, breast cancer death, and all-cause mortality (Ligibel, 2011). Therefore, these findings will be extended to develop an exercise program to help less-active women diagnosed with early-stage breast cancer increase activity.
Aerobic exercise is regarded as an effective method to improve cancer-related fatigue. It is difficult to motivate patients and to determine aerobic exercise parameters (i.e., duration, intensity, and frequency). Church, Earnest, Skinner, and Blair (2007) stated that just 10 minutes each day of some activity improves fitness levels for sedentary women. A fitness benefit was reported with an expenditure of as little as 150 kcal per day, six days of the week (Pearce, 2008). Such simple ideas may result in moving from inactivity to activity. Flexibility exercises (i.e., stretching, and range-of-motion) may be used to prepare participants for the next phase of exercise training.

A recent article provided an overview of exercise programs for cancer-related fatigue based on the research literature and the authors’ clinical experience (McNeely & Courneya, 2010). The authors summarized aerobic exercise prescription considerations for cancer survivors with different cancer-related fatigue levels (Table 2-1).

Table 2-1
Aerobic Exercise Prescription Considerations

<table>
<thead>
<tr>
<th>Fatigue level</th>
<th>Frequency (days/week)</th>
<th>Duration (min/session)</th>
<th>Intensity</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild fatigue &lt; 3/10 VAS</td>
<td>3-5</td>
<td>20-30</td>
<td>60%-80% HR max</td>
<td>Progressive aerobic exercise program</td>
</tr>
<tr>
<td>Moderate fatigue 4-6/10 VAS</td>
<td>3-5</td>
<td>Repeated bouts of 5-10</td>
<td>60%-80% HR max</td>
<td>Gradual increase in exercise frequency</td>
</tr>
<tr>
<td>Severe fatigue ≤ 7/10 VAS</td>
<td>Throughout the day</td>
<td>5-10</td>
<td>Low intensity</td>
<td>Frequent sessions of low intensity</td>
</tr>
</tbody>
</table>

A meta-analysis further indicated the potential benefits of aerobic exercise during and after cancer adjuvant therapy; 1) improving cardiopulmonary function (peak oxygen consumption [$\text{VO}_{2\text{peak}}$] and 12-minute walk test [12-MWT]) and 2) decreasing body composition (lean body mass and total body fat) (C.-J. Kim, Kang, & Park, 2009). The improvement of these benefits could mediate mechanisms of the phenomenon of cancer-related fatigue (McNeely & Courneya, 2010).

A major goal of various exercise training is to mitigate side effects. In designing an exercise program for sedentary patients, the first step is patient safety. Exercise tolerance should also be used to guide effective exercise training programs to improve clinical outcomes (Jones et al., 2009). To assess potential contraindications, obtaining oncologist approval for preexercise medical assessments and exercise testing is important before exercise training. Cardiorespiratory fitness needs to be measured to ensure that an individual can perform activities for extended periods (McNeely & Courneya, 2010). Cardiorespiratory fitness can be directly and indirectly measured in several ways. Maximal exercise tests have been accepted as the gold standard for determining fitness. Submaximal exercise tests (i.e., age-predicted maximal heart rate, 6 or 12-MWT, and constant load test) can also be used as objective determination of cardiorespiratory fitness in adult cancer patients. Compared to maximal tests, submaximal tests may be more feasible, reasonable, and inexpensive in non-clinical settings. Additionally, submaximal tests are useful for exercise oncology studies. Such tests provide complementary, objective data on change in cardiorespiratory fitness or functional capacity associated with change in exercise behavior assessed by self-report or other tools (Jones, 2010).

In aerobic exercise training, exercise intensity is the most important factor affecting increases in cardiorespiratory fitness (American College of Sports Medicine, 2010). The exact
level of intensity is not yet known, especially for patients receiving adjuvant therapy with cancer or women with early-stage breast cancer. In most previous studies, aerobic exercise programs for women with breast cancer had the median frequency at three sessions per week and the median duration at 30 to 40 minutes per session. The intensity of exercise was low to moderate at 40% to 75% of oxygen uptake or at the perceived exertion (RPE) rate of 11 to 13 out of 20 maximum (C.-J. Kim et al., 2009).

If intensity exceeds the optimal range, individuals may be sore, or get injured. Conversely, if intensity is below the optimal range, they will not improve in health and fitness benefits. Intensity-monitoring methods should be used. Traditionally, two basic categories of measuring intensity of physical activity have been used: laboratory methods (requiring equipment) and field methods (requiring minimal or no equipment) (Webster & Aznar-Laín, 2008). In home-based aerobic exercise programs, field methods (i.e., heart rate, METs, RPE, talk testing) are more practically and easily measured. Heart rate and METs are objective; while, RPE and talk test are subjective. Each method has its own advantages and limitations. Applying these methods for monitoring exercise intensity should be combined to get a better picture of how intensely patients are exercising (Janot, 2005).

The RPE is a valid tool in monitoring exercise intensity because it correlates well with physiological and metabolic responses during exercise—blood lactate accumulation, heart rate, pulmonary ventilation, and oxygen uptake. It takes advantage of situations, such as an inappropriate heart rate response to exercise, lack of equipment, or inability to measure heart rate manually (Webster & Aznar-Laín, 2008). The talk test may be one of the most effective methods to individualize exercise intensity. The premise behind this method is that if an individual is unable to talk comfortably during exercise, the exercise intensity is likely to be hard
or vigorous (Jeans, Foster, Porcari, Gibson, & Doberstein, 2011; Persinger, Foster, Gibson, Fater, & Porcari, 2004). For individual exercise training, the most effective way is to combine heart rate, RPE, and talk test to set and monitor intensity properly (Janot, 2005; Webster & Aznar-Lain, 2008).

To improve and maintain aerobic fitness, a factor that is potentially important is the preferred method of selecting exercise the intensity of the exercisers. A survey study indicated that 86% of adult women involved in aerobic exercise primarily used RPE to gauge exercise intensity. The adult women were unaware of heart rate or RPE as a method of checking their exercise intensity (Johnson & Phipps, 2006). Therefore, increasing patient education in the use of heart rate and RPE or other methods for monitoring the exercise intensity level is needed for successful exercise programming.

Interval training is an alternative method that takes advantage of improvements in cardiorespiratory fitness and early fatigue of continuous exercise. Interval training is important to increase likelihood of long-term adherence in cancer patients who need a slow progression of exercise (McNeely & Courneya, 2010). The length of exercise intervention may make a significant difference on end points. The ACSM recommends that an effective exercise intervention should last at least 12 weeks in order to get adequate benefits for cardiorespiratory fitness. Similarly, a recent meta-analysis of aerobic exercise for women with breast cancer indicated that compared with an exercise intervention less than 12 weeks, an exercise intervention of more than 12 weeks showed a larger effect size on VO$_2$peak, 12-MWT, and total body fat ($d = 1.50, 0.44, -0.94$, respectively) (C.-J. Kim et al., 2009).

**Exercise intervention studies for fatigue management in women with breast cancer.**

Interest in exercise programs to manage cancer treatment-related fatigue has been indicated by a
growing number of randomized controlled trials (RCTs). This literature review only focuses on exercise studies in women with breast cancer during adjuvant cancer therapy. Gaps are identified in directing research activity in the cancer-related fatigue management of breast cancer.

Exercise programs offered exercise training in different settings: on-site with supervision (e.g., hospital, outpatient clinic) and home-based exercise. Four studies were conducted on-site by providing classes to teach behavioral skills relevant to exercise (Campbell et al., 2005; Courneya et al., 2007; Drouin et al., 2005; Payne et al., 2008). Five studies involved home-based walking programs (Dodd et al., 2010; Mock et al., 2005; Schwartz, Mori, Gao, Nail, & King, 2001; Wang et al., 2011; Yang, Tsai, Huang, & Lin, 2010).

A variety of physical exercise modalities were employed to achieve exercise goals following physical activity recommendations. Most studies focused on training different aerobic exercise modalities. Walking is the most aerobic type of moderate physical activity which was chosen for improving cancer-related fatigue and other outcomes of interest (Campbell et al., 2005; Drouin et al., 2005; Mock et al., 2005; Payne et al., 2008; Wang et al., 2011; Yang et al., 2010). Additionally, these studies followed the guidelines for the general population by the ACSM. The exercise frequency was three to five times per week. The duration was 30 to 60 minutes, and the participants were advised to increase the intensity gradually. No standardized exercise program has been identified in the literature.

To maximize the effectiveness of exercise programs, the length of these programs showed variability ranging from 6 weeks to 6 months of the participant’s adjuvant therapy. Exercise adherence is an important component of the ability to reach a clinically significant intervention effect. Two studies reported adherence rates (Campbell et al., 2005; Mock et al.,
Exercise adherence in the on-site supervised exercise program was 70% (Campbell et al., 2005). The home-based exercise program reported adherence rate as 72%. The definitions of exercise adherence were not consistent from study to study. Delivery methods may be an impact factor on the dose of intervention; nevertheless, it should be clear and carefully assessed to determine whether different modes of delivery generate different outcomes (Aranda, 2008; Conn, Rantz, Wipke-Tevis, & Maas, 2001).

Most interventions were delivered face-to-face to individual patients; however, ongoing advances in information technology provide useful opportunities for interventions to be delivered by telephone, videotapes, CDs, etc. A study looked at different modes of delivery (Mock et al., 2005).

In terms of the methodological rigor, determining the sample size for any research project, particularly a quantitative research study, is essential. The majority of studies did not present sample size calculation based on power calculation. Three studies had unusually small sample sizes because of being in the pilot phase, thus resulting in underpowered studies (Campbell et al., 2005; Drouin et al., 2005; Payne et al., 2008).

As a result of this review focusing solely on patients with breast cancer, participants in most studies have been largely female. In addition, the studies were conducted with patients at different stages of the disease and undergoing various forms of treatment. Seven studies recruited patients with stage 0 through stage IIIa receiving adjuvant chemotherapy or radiotherapy (Campbell et al., 2005; Courneya et al., 2007; Dodd et al., 2010; Drouin et al., 2005; Mock et al., 2005; Wang et al., 2011; Yang et al., 2010). Most studies have been done with middle-aged participants ranging in age from 35 to 60 years. Only a study by Payne and colleagues (2008) focused specifically on older breast cancer patients (mean aged 64.7 years).
receiving adjuvant hormonal therapy. The populations in these studies were predominantly highly educated Caucasian women from a higher income level. Two very recent studies examined the effects of exercise in Asian women with breast cancer (Wang et al., 2011; Yang et al., 2010).

All of these nine studies did not typically assess cancer-related fatigue as a primary outcome variable. Four studies indicated that exercise had a statistically significant effect on reducing cancer-related fatigue from baseline to post-test (Drouin et al., 2005; Mock et al., 2005; Schwartz et al., 2001; Wang et al., 2011). Results from measures of physical fitness, physical functioning, psychological well-being (e.g., depression, mood states), quality of life, and health-related biomarkers have also reported positive effects from exercise interventions during treatments for breast cancer patients. Most of the studies used a variety of self-report instruments which were previously tested in cancer populations and have been considered valid and reliable fatigue instruments (e.g., the Piper Fatigue Scale, the Profile of Mood States Fatigue Subscale, and the Functional Assessment of Chronic Illness Therapy-Fatigue). When different outcome measures are used, it is difficult to make comparisons about the clinical significance of a given treatment across studies.

Summary

Scientific evidence has clearly presented the benefits of the use of exercise as a non-pharmacological intervention for management of cancer-related fatigue in the breast cancer population. Culture sensitivity is needed to develop effective interventions. Understanding different cultures and how features of each can help find ways to better design studies and create exercise interventions for different ethnic groups is essential.
Methodological limitations of previous studies should be improved in future research. In the case of exercise or physical activity interventions, what types (aerobic, resistance, or both) and doses (duration, frequency, and intensity) of exercise which would be most effectively applied to patients with different stages and treatment regimens of breast cancer have not been determined for clinical practice. Conducting additional studies is still needed, especially in regard to diverse samples of ethnicity and socioeconomic status. Because the main predictor of long-term outcome from exercise is adherence to exercise interventions, future research should pay attention to this. Several strategies and delivery methods need to be studied to verify what the optimal technique and delivery method is for a physical exercise intervention. To strongly support exercise as an effective intervention for fatigue in the breast cancer population, research designs, and sample size should also be considered to assure the quality of research.
CHAPTER THREE

METHODS

Research Design and Methods

Design overview. This study was a pilot, pre-and post-test, two-arm randomized control trial that was conducted to develop a culturally sensitive exercise program (CSEP) and examine the effects of the CSEP on fatigue, sleep disturbance, mood disturbance, and symptom distress in Thai women with breast cancer receiving adjuvant chemotherapy with and without radiotherapy. Table 3-1 presents the time points for pre-and post measurement for the study. All eligible patients in both the control and intervention groups completed a baseline assessment (T1) on the day they started their adjuvant chemotherapy regardless of where they were in their treatment cycle as long as there were at least four cycles remaining. After the first three weeks, three subsequent measurement sessions (T2-T4) were conducted on the day they commenced each chemotherapy cycle in the oncology clinic. For fatigue data only, patients were phoned between 48 and 72 hours post measurement session (T2-T4) to answer questions specific to fatigue. This timeline was designed because it is known that the highest level of fatigue is between 48 to 72 hours following treatment (Battaglini et al., 2008; Meek et al., 2000). Eligible patients were randomly assigned to either the experimental group (CSEP) or the usual care group (UC) after the completion of the baseline assessments. The intervention group received the training intervention session scheduled in the oncology clinic (T1). Three self-directed intervention sessions (X1-X3) were in the home setting during weeks 1-12 of treatment for the experimental group.
Table 3-1

*Schematic of Study Design*

<table>
<thead>
<tr>
<th>Assessment point</th>
<th>Exercise intervention and post-treatment measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T1; Baseline assessment and training</td>
</tr>
<tr>
<td>Point in treatment protocols</td>
<td>CTx # 1</td>
</tr>
<tr>
<td>A. 21 days x 6 cycles (CMF/CEF)</td>
<td></td>
</tr>
<tr>
<td>B. 21 days x 4 cycles (AC)</td>
<td></td>
</tr>
<tr>
<td>C. 21 days x 6 cycles (CAF/FEC100/TAC/FEC100+docetaxel)</td>
<td></td>
</tr>
<tr>
<td>D. 21 days x 8 cycles (AC+paclitaxel)</td>
<td></td>
</tr>
<tr>
<td>Groups</td>
<td>O₁ R O₂ X₁ O₃ X₂ O₄ X₃</td>
</tr>
<tr>
<td>Experimental (CSEP)</td>
<td>O₁ R</td>
</tr>
<tr>
<td>Control (UC)</td>
<td>O₁</td>
</tr>
</tbody>
</table>

Standard adjuvant treatment protocols are used at the research site as follows: CMF (cyclophosphamide/methotrexate/fluorouracil), CEF (cyclophosphamide/epirubicin/fluorouracil), AC or AC + paclitaxel (doxorubicin/cyclophosphamide/followed by paclitaxel), CAF (cyclophosphamide/doxorubicin/fluorouracil), TAC (docetaxel/doxorubicin/cyclophosphamide), FEC100 or FEC100 + docetaxel (fluorouracil/epirubicin/cyclophosphamide/followed by docetaxel).

*Setting.* Participants for the proposed study were recruited from the outpatient oncology clinics at the Lopburi Cancer Center. The research site is situated in the central part of Thailand under the jurisdiction of the Ministry of Public Health, Thailand. The Lopburi Cancer Center, located 75 miles (120 kilometers) outside of the Bangkok metropolitan area, is a provincial branch of National Cancer Center, Thailand, that offers cancer screening, prevention, treatment, research and education. The radiation oncology clinic is open daily from 8:00 a.m. to 4:00 p.m. on Monday to Friday. The chemotherapy clinic is open four weekdays (Monday, Wednesday, Thursday, and Friday) from 8:00 a.m. to 3:00 p.m.
Sample.

Sample size determination. The sample size for the proposed study was calculated according to Diggle et al. (2002). Determination of sample size for longitudinal studies requires the following quantities: type I error rate ($\alpha$), effect size ($d$), power, measurement variation, number of repeated observations per person, non-centrality parameter (NCP) and correlation among the repeated observations.

Ten systematic reviews and meta-analyses have reported on the effects of exercise as an integral part of cancer symptom management (Brown et al., 2011; Conn, Haf Dahl, Porock, McDaniel, & Nielsen, 2006; Cramp & Daniel, 2008; Jacobsen, Donovan, Vadaparampil, & Small, 2007; Kangas, Bovbjerg, & Montgomery, 2008; Markes, Brockow, & Resch, 2006; McNeely et al., 2006; Schmitz et al., 2005; Speck, Courneya, Måsse, Duval, & Schmitz, 2010; Velthuis, Agasi-Idenburg, Aufdemkampe, & Wittink, 2010). The estimated effect sizes were determined by Cohen (1988) as follows. Effect sizes of less than .20 are considered small, those of less than .50 are considered medium, and those of .80 or greater are considered large; however, effect sizes greater than .20 are clinically meaningful (Kangas et al., 2008; Revicki et al., 2006).

These studies revealed that the overall effect sizes for exercise interventions on cancer-related fatigue ranged from .22 to .42. Of 10 studies, three systematic reviews and meta-analyses have been conducted examining the effect of exercise on fatigue in breast cancer patients and survivors (Brown et al., 2011; McNeely et al., 2006; Velthuis et al., 2010). The pooled results showed a small-to-moderate effect (.22-.39). A more recent meta-analysis (Brown et al., 2011) reported the overall effect size of exercise reduced cancer-related fatigue among adult breast cancer patients with an effect size of .39 [95% CI: .27-.51] with homogeneity of distribution for
RCTs studies of a two-group comparison examining the difference between exercise and a control group.

To achieve the above requirements, the optimal sample size of 15 in each group, or a total of 30 subjects, was based on the following assumptions: an effect size of .30 with a one-sided significance level of .05, and power of .80, number of repeated observations per person \( (n) \); \( n = 4 \). Correlation among the repeated observations \( (\rho) \) is also needed to determine a target sample size based on the proposed study design (Diggle, Heagerty, Liang, & Zeger, 2002). In the present study, the pattern of correlation among repeated observations was estimated from the previous study by Dodd et al. (2010); then, \( \rho = .20-.80 \). However, for longitudinal study with repeated measurements over time design, the attrition rate should be known, to estimate the potential dropout when calculating the sample size (Duffy, 2006). A recent systematic review of exercise interventions indicated that a median program completion rate was 87%. Most programs were of 6 to 12 weeks duration (Maddocks, Mockett, & Wilcock, 2009). Therefore, the nurse researcher over-enrolled by 15% (to 17 subjects per group) to control for possible attrition. The total sample size needed for this pilot study should be 34.

As shown in Figure 3-1, a total of 177 women were initially screened, and 86 women were potentially eligible (48.59%). Twenty-three of the eligible women consented to participate (26.74%).

**Participants and eligibility.** Before the recruitment process was launched, this research was reviewed and approved by the Institution Review Boards (IRBs) of the University of Cincinnati, and the Lopburi Cancer Center under the jurisdiction of the Ministry of Public Health, Thailand (Appendix A).
Participants included in this study who met the following eligibility criteria were recruited from the site mentioned above; thus, eligibility criteria are that women:

a) Were diagnosed with postoperative stage I-IIla breast cancer
b) Were 18-60 years of age
c) Had no other concurrent cancer
d) Were scheduled to receive a minimum of four cycles of each chemotherapy protocol during the study period
e) Were able to speak, read and write in Thai and agree to sign consent to participate in the project
f) Could be contacted by phone

Patients were ineligible if they had a history of severe psychiatric illness; had acute or chronic bone, joint, or muscular abnormalities that would increase risk of fall; or use assistive devices for walking as observed during the medical history review and physical examination by an oncologist.

**Recruitment Activities**

The enhancement of recruitment and retention of patients with cancer is important for conducting randomized clinical trials (RCTs) for cancer symptom management. Based on a literature review, the effectiveness of recruitment methods was described to identify and overcome unique challenges of collaborating with sites and participants relevant to cancer symptom management RCTs, and exercise intervention studies, specifically in cancer populations (Berger, Neumark, & Chamberlain, 2007; Pinto et al., 2004). Three appropriate methods that fit into Thai culture traditions were applied in the present study. The first recruitment method was to establish a partnership with oncologists and nurses at the research site
and gain their support to compile a list of their patients meeting initial eligibility criteria. A formal letter approved by the IRBs was sent to oncologists and nurses at the research site requesting Thai women with breast cancer under their care had an opportunity to participate in this study. An abstract of the study was attached for their review, and the researcher met with health care providers through formal and informal meetings to explain the rationale for the study, potential benefits to their patients, eligibility requirements, to answer any questions, and to listen to suggestions. The oncologists and nurses later recommended patients to participate in the study.

The second recruitment method was using an invitation card in Thai as a multimedia approach from the researcher to distribute basic information about the study and invite patients and family caregivers to call the contact number if interested in participation. Direct in-person recruitment was the final recruitment method. These strategies hold promise to the researcher for the study of future recruitment efforts.

The recruitment process took place from December 2011 to April 2012. Recruitment was conducted on a daily basis from Monday to Friday each week so that the intervention was delivered Monday to Friday. Because the researcher was solely administering the study, the Monday-to-Friday schedules were reasonable for the five-month period.

**Randomization and Allocation to Group**

One week prior to the start of the data collection, the researcher asked the clinical nurse responsible for scheduling treatment appointments to provide a list of potential patients for future consecutive weeks. The eligible participants were selected from the listing of scheduled appointment. Each day of data collection, the researcher selected a sample by using a random sampling computer program. After completing all baseline assessments, however, the eligible,
consenting participants were randomly assigned to either the intervention group or the control group using simple randomization. The participants were placed in order of a table of random assignment using computerized sequence random numbers provided by a statistics professor at the University of Cincinnati. It is difficult for the researcher to be blind to the allocation of participants as the researcher recruited participants and completed the baseline and follow-up assessments. The researcher assessing outcomes was not blinded for pragmatic reasons only. The pilot study was partially blinded; however, the condition allocation was concealed from the patient until after the completion of the baseline assessments. Using consecutively numbered, sealed, opaque envelopes assembled by an individual not involved in this study, the researcher and the participant opened the sealed envelope to reveal the group allocation. To ensure the availability of an audit trail, the envelope number was recorded on an information sheet that includes the participant’s name, telephone number, group assignment, and trial enrollment date.
Figure 3-1. Flow of patient enrollment.
Intervention

Experimental intervention. The CSEP was developed to be consistent with the NCCN Clinical Practice Guidelines in Oncology on Cancer-Related Fatigue, the American College of Sports Medicine Roundtable on Exercise Guidelines for Cancer Survivors (ACSM) and this study’s literature review (Berger et al., 2010; McNeely & Courneya, 2010; Schmitz et al., 2010). In addition, the exercise intervention was designed to increase adherence and acceptability by incorporating important Thai cultural components and values related to family, spirituality, literacy, and economic issues.

The total length of the exercise intervention is a potential factor influencing its effectiveness. The ACSM recommends that to get adequate beneficial effects on cardiorespiratory fitness, the exercise intervention should last at least 12 weeks. The 12-minute walk test (12-MWT) was used to estimate exercise tolerance as an objective measure of exercise outcome in this present study. The exercise intervention was a 12-week home-based walking program to improve women’s exercise using the Compendium of Physical Activities (Ainsworth et al., 2000). Participants exercise for the duration of their adjuvant chemotherapy, beginning two or three days after starting each chemotherapy cycle. The intervention considered that progression should be slower and more gradual, to minimize declines in activity during certain treatment periods. That is, patients should meet frequency and duration goals before they increase intensity. Table 3-2 presents the structure of the exercise program.

The intervention was presented via an initial, 45-minute, training session with the researcher and an exercise kit. The kit contained written instructional materials, a pedometer (Yamax digiwalker SW-200®; Yamax, San Antonio, TX), and daily exercise logs. After randomization, each participant and their caregivers received in-person instructions on
continuous walking exercise focusing on an overall volume of weekly activity of 150 minutes and a gradual increase from low- to moderate-intensity exercise. The participants were instructed how to start exercising in each training session; how to monitor exercise intensity; how to warm up before and cool down after formal exercise; and how to wear a pedometer during walks for exercise and record in their daily diary logs the number of steps from the pedometer and perceived exertion rates. In addition, the exercise participants were given two booklets and a Video Compact Disc (VCD) provided by the health care team at the Lopburi Cancer Center. One booklet provides information about general issues about breast cancer. Another booklet addresses the concerns and self-care activities for patients receiving chemotherapy. The VCD provides self-care activities after breast cancer surgery.

Before initiating formal exercise training, the emphasis was to get individuals to participate in moderate-intensity physical activity. During the first four weeks of the intervention (initial stage called “get started and enhance daily activities”: week 1-4), in order to maintain their daily activities, participants were asked to choose walking involved in household activities that require amounts of energy at low-intensity level to a moderate-intensity level (<3-6 metabolic equivalents [METs]). Participants were asked to exercise each day for at least 20 minutes per session or the accumulation of 10-minute sessions to reach 20-30 minutes. The participants in the intervention group were given a definition of moderate-level activities and examples of activities. The nurse researcher provided sets of physical activities with detailed METs and description. These physical activities were selected from the Compendium of Physical Activities (Ainsworth et al., 2000) and modified for Thai household chores, occupations, and religious activities.
Participants in the exercise intervention group were taught to wear a pedometer during walks and record their steps and duration in minutes of activities at the end of each day. They were instructed to increase their total daily steps to total daily step counts that were by 5% over the average daily number of steps walked weekly during the 12-week intervention period. An example chart was provided to help them easily calculate their mean steps walked weekly and how many daily steps they could increase in consecutive weeks. The researcher invited a family member as a control person to help the participant to identify appropriate activities that are as safe as possible. The majority of family members who participated in the pilot study were their daughters (54.55%) and husbands (45.45%).

After four weeks (improvement stage: week 5-12), the program promoted a progressive aerobic exercise program to improve cardiorespiratory fitness. The nurse researcher reviewed the formal exercise session to build the confidence of Thai women with breast cancer in their ability to successfully start an exercise routine. The participants were asked to perform structured walking at least 20-30 minutes per session (not including 5 minutes of warm-up and 5 minutes of cool down) or the accumulation of 10-minute sessions to reach 20-30 minutes at least three to five days a week at a low- to moderate-intensity level as measured by the original Borg scale (score 12-14) or approximately 40-60% of age-adjusted maximal heart rate.

The Borg scale (Borg, 1998) is a method to assess exercise intensity by the rating of perceived exertion (RPE). RPE is a subjective measure and asks the exerciser to think about how hard they feel their body is working against a standardized scale. On the Borg Scale, there are numbers from 6 through 20. Each number corresponds to a certain level of intensity. Levels 6 to 11 are considered light intensity; moderate intensity is 12 to 14, and vigorous is 15 to 17. Maximum intensity is 18 to 20. RPE takes into account how hard the entire body is working.
This measurement is more than the exercisers’ legs getting tired or feet being sore. The measurement takes into account breathing rate, heart rate, muscle fatigue, and perspiration.

To take advantage of walking, the participants were instructed to walk trails in regional parks or temples near their houses, walk along the street to markets or malls. Their family caregivers were invited and encouraged to exercise with them. Each participant received a weekly phone call over 12 weeks from the researcher to monitor the exercise participation by asking how their walking has been progressing in the prior week and make adjustments to the walking prescription for the next week as needed, identify general malaise or symptoms relevant to exercise and health problems, reinforcement for their efforts, and solve any barriers to exercise.

Table 3-2

**Structure of the Exercise Program**

<table>
<thead>
<tr>
<th>Week</th>
<th>Type of training</th>
<th>Number of training sessions</th>
<th>Levels of intensity</th>
<th>Aim of the training</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-4</td>
<td>Get started</td>
<td>Aerobic training:</td>
<td>20 minutes/session/day Or 10 minutes/3 sessions/day</td>
<td>&lt;3-6 METs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lifestyle activities</td>
<td></td>
<td>1. become familiar with exercise program&lt;br&gt;2. overcome the fear of physical activity</td>
</tr>
<tr>
<td>5-12</td>
<td>Improvement</td>
<td>Aerobic training: Structured walking</td>
<td>20-30 minutes/session/day Or 10 minutes/3 sessions/day</td>
<td>Borg scale (score 12-14) Or 40-60% HR(_{max})</td>
</tr>
<tr>
<td></td>
<td>period</td>
<td></td>
<td></td>
<td>1. encourage patients to improve compliance to the exercise program&lt;br&gt;2. increase aerobic capacity and improve fitness level</td>
</tr>
</tbody>
</table>

**Control intervention.** The participants in the control group were encouraged to maintain their current levels of activity during the 12-week period, but no exercise prescription or formal programs were offered. The usual care participants were given two booklets and a VCD provided by the health care team at the Lopburi Cancer Center. One booklet provides
information about general issues about breast cancer. Another booklet addresses the concerns
and self-care activities for patients receiving chemotherapy. The VCD provides self-care
activities after breast cancer surgery. Participants were asked at the end of each day to record
general daily physical activities and duration in minutes of activity. They receive an equal
amount of time and attention from the researcher as the participants in the experimental group.
The weekly phone call was used to assess their levels of physical activity in the prior week. The
participants in the control group reporting unmanaged symptoms or other clinical problems were
referred to the health care team at the research site for proper treatment.

**Human Subject Concerns**

Prior to data collection, the Institution Review Boards of University of Cincinnati and
Lopburi Cancer Center under the jurisdiction of the Ministry of Public Health, Thailand
reviewed and approved the proposed study. Participants were recruited from the Lopburi Cancer
Center. Inform consent was obtained from women who were interested in participating in the
study (Appendix B).

Participants received a total of $20 cash for participating in the study. They received $5
cash for completing each of the assessments at baseline, 4 weeks, 7 weeks, and at the end of the
10-week program.

**Data Collection Instruments**

Two arms of measurement were used in this study: first, the evaluation of the CSEP on
perceptions of intervention feasibility; second, the evaluation of the CSEP’s effects on the levels
of fatigue as a primary outcome. In addition, sleep disturbance, mood disturbance, and
symptoms distress were assessed as secondary outcomes. Data were collected by the following
research instruments.
The Culturally Sensitive Exercise Program (CSEP). The Culturally Sensitive Exercise Program measured participants’ exercise levels and combined both objective methods (pedometers and 12-MWT) and subjective methods (self-reported data in daily exercise logs) to describe a total picture of the exercise program (Yap & Davis, 2007). With regard to the culturally sensitive intervention, exercise participants who completed the intervention at 12 weeks were asked questions regarding the culturally appropriate content of the overall exercise program (setting, booklet, preferences, and barriers). Exercise adherence was determined by weekly average daily steps walked and the percent of adherence weeks out of the total number of weeks during prescribed structured walking (8 weeks) in the exercise group.

12-Minute Walk Test (12-MWT). The 12-MWT has been used in exercise studies in breast cancer patients to measure patients’ physical fitness (Mock et al., 2005; Schwartz et al., 2001). The researcher assessed participants in both control and intervention groups at the cancer center by measuring the distance walked in 12 minutes (meters) at baseline and the post-test measure at week 10 to assess changes in physical function resulting from exercise.

Daily Exercise Logs. The daily exercise log was developed by the nurse researcher, primarily to measure the physical activity level for patients in both groups. The daily exercise logs differed by study groups. For the exercise group, the following information was reported in the log: performed physical activities each day (recorded in minutes), steps per day as measured by the pedometer, comments, and treatment-related symptoms. In weeks 5-12, the log included the duration (total minutes/time), frequency (times/week), and intensity (RPE) during each structured walking exercise session. Data in the daily exercise logs were reported in order to describe exercise adherence and exercise pattern in the exercise group. For the usual care group, the information recorded in the log included physical activities performed each day (recorded in
minutes), comments, and treatment-related symptoms. To reduce respondent burden, the participants in both groups recorded performed physical activities in the immediate three days prior to the next clinic appointment at week 4, 7, and 10.

The reported activities were calculated based on the MET level values (Ainsworth et al., 2000). The value of one MET was defined as an oxygen consumption rate of $3.5 \text{ mL} \times \text{kg}^{-1} \times \text{min}^{-1}$ in adults, and multiplying the number of METs for each physical activity by $3.5 \text{ mL} \times \text{kg}^{-1} \times \text{min}^{-1}$ and duration in minutes. This value was multiplied by the patient’s body weight in kilograms to give an estimation of the total daily oxygen consumption in $\text{mL} / \text{kg}^{-1} / \text{min}^{-1}$, and lastly multiplied by taking the oxygen energy equivalent rate to be $5 \text{ kcal/L}$ (every $1 \text{ L}$ oxygen burns $5 \text{ kcal}$) consumed. Thus, total physical activity energy expenditure level was computed by the formula: METs x $3.5 \text{ mL} \times \text{kg}^{-1} \times \text{min}^{-1}$ x time (in min) x weight (in kg) x 1 L/1000 mL x 5 kcal/L. These data were reported to compare exercise outcomes in the entire sample.

**Pedometer (Yamax digiwalker SW-200®).** The pedometer was used to measure the number of daily steps. The participants in the exercise intervention group wore the pedometer throughout the day during the study period and recorded daily steps in the daily exercise logs.

The instruments described below measured the CSEP’s effects on the primary and secondary outcomes. These instruments were obtained with permission from the researchers who developed scales in English and who translated the scales into Thai (Appendix C). These instruments were chosen because (i) they pose relatively no more subjective burden than others designed to measure the same concepts, (ii) their validity and reliability have been well-established in population of cancer patients, and (iii) they have a traditional Thai version.

**The Piper Fatigue Scale-Revised (PFS-R).** The PFS-R, developed in 1987 by Piper and revised in 1998, was used to measure the levels of fatigue. The PFS-R is a 22-item scale,
with the 0 to 10 numerical scaling for items consisting of four dimensions of fatigue: behavioral/severity (6 items), affective meaning (5 items), sensory (5 items), and cognitive/mood (6 items). The Cronbach's alphas for the four subscales were greater than .92, and the standardized alpha for the entire scale was .97 (Piper et al., 1998). The PFS-R includes four open-ended items in order to obtain qualitative data about the cause and relief of fatigue, the duration of fatigue, and other symptoms experienced. The instrument has been translated into Thai by Pritsanapanurungsie (2000). The scale was used to measure fatigue among Thai women with breast cancer receiving adjuvant chemotherapy by Hanprasitkam and colleagues (2007). The Cronbach’s alpha coefficient was .95.

The Modified General Sleep Disturbance Scale. The Modified General Sleep Disturbance Scale (MGSDS) was used to measure sleep disturbance. The original General Sleep Disturbance Scale (GSDS) was developed by Lee and DeJoseph (1992). The GSDS is a 21-item scale, 8-point Likert scale from 0 (never) to 7 (every day), which was developed to measure sleep disturbance in the past week. The GSDS was used by permission, translated into a Thai version, and verified by back-translation by Hanprasitkam and colleagues (2007). The GSDS was modified by deleting one item for appropriate use in Thai culture and used to measure sleep disturbance in 159 Thai women with breast cancer receiving adjuvant chemotherapy. The MGSDS is a 20-item scale with reported Cronbach’s alpha coefficient of .81. The professor who developed the scale gave permission and a suggestion to consider using the full version of the 21-item GSDS. After comparing each of the two versions, item # 18 (“use herbal product to help you get to sleep”) was added and translated into Thai to measure sleep disturbance in the present study.
The Profile of Mood States-Brief Form (POMS-BF). The POMS-BF was developed by McNair, Lorr, and Droppleman (1992). The POMS-BF is a 30-item self-report scale which is comprised of the six subscales (tension-anxiety, depression-dejection, anger-hostility, fatigue-inertia, confusion-bewilderment, and vigor-activity) rated on a 5-point scale that ranges from 0 (not at all) to 4 (extremely). After reverse scoring, the sum of the six subscales yields a total mood disturbance score. The POMS-BF has been translated into Thai by Petpichetchian (2001). The scale was used in 45 Thai women with breast cancer by Kritpracha (2004). The results showed Cronbach’s alphas ranging from .62 to .92 for each of the six subscales and .93 for the entire scale. Thus, the POM-BF was used to reduce respondent burden as well as because it is appropriate for the population being studied and has adequate reliability and validity.

The Memorial Symptom Assessment Scale (MSAS). Symptom distress was measured by the Memorial Symptom Assessment Scale (MSAS) (Portenoy et al., 1994). The MSAS consists of 32 items reflecting symptoms frequently associated with cancer in three subscales: (i) severity of the symptom, (ii) frequency with which it occurs, and (iii) distress it produces. The frequency and severity subscales were rated on a 4-point rating scale ranging from 1 (rarely or slight) to 4 (almost constantly or very severe). Symptom distress was rated on a 5-point scale ranging from 0 (a little bit) to 4 (very much). The items are scored by summing the items in each subscale (e.g., physical, psychological). The higher the score, the more severe, frequent, or distressing the symptoms are for patients. The reliability coefficients for the subscales were .83 to .92, indicating strong internal consistency. The MSAS has been translated into Thai by Suwisith and colleagues (2008), and was used to assess symptom experiences in 320 Thai women with breast cancer undergoing chemotherapy. The back-translated MSAS was reported
to have internal consistency of .96. The Pearson correlations for one-day test-retest were significant, ranging from .82 to .88 ($p < .05$) for the subscales.

**Demographic data forms.** The researcher developed a two-part demographic form to elicit personal data. In the first part, participants were asked for personal information including age, race, religious affiliation, marital status, education, employment status, income, family members, caregivers, and exercise status. The second part, the researcher collected information related to disease and treatment, including health and illness history, stage of breast cancer, types of surgical procedures, types of chemotherapy regimens, complete blood count results, height, and weight.

Data collection was carried out by verbal explanation to make sure that the research participants understood the questions and the measures taken to protect their rights and privacy. Table 3-3 summarizes the study instruments according to the timing of administration for both control and intervention groups.

Table 3-3

*Study Instruments and Timing of Administration*

<table>
<thead>
<tr>
<th>Study instrument</th>
<th>Baseline</th>
<th>Time 2 (week 4)</th>
<th>Time 3 (week 7)</th>
<th>Time 4 (week 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Demographic Data Forms</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12-Minute Walk Test (12-MWT)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Piper Fatigue Scale-Revised (PFS-R)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>The Modified General Sleep Disturbance Scale (MGSDS)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>The Profile of Mood States-Brief Form (POMS-BF)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>The Memorial Symptom Assessment Scale (MSAS)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
The instruments measuring four outcome variables were tested for reliability by the Cronbach’s alpha. Participants’ data from baseline and post-test (10 weeks after baseline) were used (Table 3-4).

Table 3-4

*Cronbach’s Alpha for the Study Instruments*

<table>
<thead>
<tr>
<th>Study instruments</th>
<th>Subscales/# of items</th>
<th>Cronbach’s alpha for the entire scale</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>At baseline (N = 23)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>At week 10 (N = 22)</td>
</tr>
<tr>
<td>The Piper Fatigue Scale-Revised (PFS-R)</td>
<td>4/22</td>
<td>.93</td>
</tr>
<tr>
<td></td>
<td></td>
<td>.98</td>
</tr>
<tr>
<td>The Modified General Sleep Disturbance Scale (MGSDS)</td>
<td>6/20</td>
<td>.52</td>
</tr>
<tr>
<td></td>
<td></td>
<td>.83</td>
</tr>
<tr>
<td>The Profile of Mood States-Brief Form (POMS-BF)</td>
<td>6/30</td>
<td>.89</td>
</tr>
<tr>
<td></td>
<td></td>
<td>.92</td>
</tr>
<tr>
<td>The Memorial Symptom Assessment Scale (MSAS)</td>
<td>3/32</td>
<td>.89</td>
</tr>
<tr>
<td></td>
<td></td>
<td>.94</td>
</tr>
</tbody>
</table>

**Data Management and Analyses**

**Data management.** Data cleaning and checking should begin during data collection to help correct systematic errors in collecting data, coding, or entry and assist in identifying the type, extent, and point where errors occurred (Roberts, Anthony, Madigan, & Chen, 1997). The researcher checked the data collection instruments at each measurement time point for completeness and accuracy. Data were coded and simultaneously entered after data collection into a personal computer using a protected password. Data were double-entered using the most recent version of the spreadsheet program Microsoft Excel by personnel who were blind to the subjects’ condition assignment. The data were double-checked for entry errors; errors were checked directly against the original data file and corrected.

**Data exploration and analyses.** For data analysis purposes, the data were imported into the statistical software IBM SPSS Statistics, version 20.0 for Windows. Initially, information
that was beyond the range of what was expected or logically inconsistent was identified by data cleaning strategies. Frequency was checked to determine whether the error was a coding error or an entry error. Mean and standard deviation was identified by errors in interval level data.

Missing data were examined by several approaches. Expectation maximization (EM) single imputation in SPSS missing value analysis was used to analyze the patterns of missing data and to impute missing value for two cases in the CSEP group. The EM results supported the hypothesis that the data were missing completely at random (MCAR). Data were analyzed on an “intention-to-treat” basis. Two data sets were created, one for the data set with missing values deleted and one for the data set with missing value imputed. Paired and independent t-tests were run to determine if there were significant mean differences for the within and between effects. The results from the two data analyses with and without the cases with missing data were not substantially different. Therefore, no imputations were necessary for the present pilot study analyses and there was no substantial difference between the models which included (intention-to-treat) and excluded two participants who withdrew from the study. Data analyses depended on the level of measurement of variables and the research questions. All statistical tests were performed at the one-tailed 5% level of significance, and 95% confidence intervals were computed.

**Univariate analysis.** Descriptive statistics were analyzed by using frequency, percentage, means, and standard deviation for participants’ characteristics in the two groups. Descriptive statistics (e.g., mean and standard deviation) were computed for all dependent variables at each of the four time points prior to modeling.

**Bivariate analysis.** Group differences and potential covariates were determined by t-tests for the continuous variables and chi-square tests for the categorical data. The sample
characteristics were assessed on whether the random assignment procedure was successful in creating comparable groups. A comparison of demographics was made between participants who dropped out to those who did not to determine if there was a different bias. Pearson correlation coefficients were computed between independent and dependent variables to explore the association between variables.

**Multivariate analysis.** All research questions were answered by using Generalized Estimating Equations (GEE) to examine the effects of the CSEP over time. Using GEE to analyze longitudinal data was first proposed by Liang and Zeger (1986). GEE models extend generalized linear models (GzLM) for the situation of correlated data. GzLM represent a class of models that are used to fit fixed effects regression models to normal and nonnormal data (McCullagh & Nelder, 1989). GzLM are fixed effects models which assume all observations are independent of each other; thus, GzLM are not generally appropriate for analysis of longitudinal data. Compared with GEE, none of the traditional statistical methods—repeated measures ANOVA, repeated measures multivariate ANOVA (MANOVA)—can handle the complexity of longitudinal data due to subjects with any missing data points and restrictive assumptions concerning data distribution (S. Liu, Dixon, Qiu, Tian, & McCorkle, 2009). Moreover, in longitudinal data analysis, there are two points that need attention: missing data and time intervals. GEE uses available data regardless of missing data. Within GEE, the actual time intervals (e.g., number of weeks) are added to the statistical model (S. Liu et al., 2009).
CHAPTER FOUR

RESULTS

This chapter contains the description of sample, group comparison of demographic variables and covariates, and data analysis organized by research questions. Additional analyses are also presented.

Demographic Characteristics of the Sample

A total of 23 female patients with early-stage breast cancer participated in this study. Eleven in the experimental group received the Culturally Sensitive Exercise Program (CSEP) and 12 in the usual care group (UC) did not. Two participants dropped out of the intervention group: one changed care provider to another hospital at week 7, and one stated that she had no time to continue exercising at week 10. Twenty-one participants completed the study at 12 weeks, nine in the intervention group and twelve in the control group.

The overall sample demographic characteristics and medical information are presented in Table 4-1 and Table 4-2, respectively. The CSEP group ranged in age from 31 to 59 years, with a mean age of 46.36 years old ($SD = 9.37$). The majority of participants in the CSEP group were married (63.6%), had less than 4 years of college (36.4%), and were employed (54.6%). The majority of them were diagnosed with breast cancer in Stage II (63.6%) or Stage III (27.3%) and had no comorbidities (63.6%).

Ages of the UC group ranged from 33 to 56 years, with a mean age of 47.17 years old ($SD = 6.87$). The majority of participants in the UC group were married (83.3%), finished elementary school (83.3%), and were not employed (41.7%). Most of them were diagnosed with breast cancer in Stage II (75%) or Stage III (25%) and reported no comorbidities (58.3%).
Study groups were checked for balance of baseline variables by \( t \) tests for continuous variables and chi-square tests for categorical variables. Compared across all previously listed characteristics, the CSEP group and the UC group were similar but significant differences were found on education (\( \chi^2 = 10.64, p = .007 \)) and monthly income (\( \chi^2 = 13.25, p = .005 \)). Potential covariates were assessed using either student’s \( t \)-tests for continuous variables or Pearson’s chi-square for categorical variables in order to examine their association with the grouping variables. Estimation used either exact methods or the bootstrap (Efron & Tibshirani, 1993). Alpha level for the multiple comparisons was set at .0025 using a Bonferroni correction. None of the potential covariates achieved statistical significance.

Table 4-1

Sample Demographic Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>CSEP group ((n = 11))</th>
<th>UC group ((n = 12))</th>
<th>Total ((N = 23))</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(M) (SD)</td>
<td>(M) (SD)</td>
<td>(M) (SD)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>46.36 (9.37)</td>
<td>47.17 (6.87)</td>
<td>46.78 (7.99)</td>
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<tr>
<td></td>
<td>((31-59))</td>
<td>((33-56))</td>
<td>((31-59))</td>
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<tr>
<td>Number of children</td>
<td>2.10 (1.04)</td>
<td>1.83 (0.94)</td>
<td>1.96 (0.98)</td>
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<tr>
<td></td>
<td>((1-4))</td>
<td>((0-3))</td>
<td>((0-4))</td>
</tr>
<tr>
<td>Number of family members</td>
<td>3.45 (1.21)</td>
<td>4.33 (1.23)</td>
<td>3.91 (1.28)</td>
</tr>
<tr>
<td></td>
<td>((2-6))</td>
<td>((2-6))</td>
<td>((2-6))</td>
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<tr>
<td>Race</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Thai</td>
<td>11 (100.00)</td>
<td>12 (100.00)</td>
<td>23 (100.00)</td>
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<tr>
<td>Religion</td>
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<td>Buddhism</td>
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<td>23 (100.00)</td>
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<td>Bachelor’s degree</td>
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<td>3 (13.00)</td>
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<td>Characteristics</td>
<td>CSEP group (n = 11)</td>
<td>UC group (n = 12)</td>
<td>Total (N = 23)</td>
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<tr>
<td>----------------------------------------</td>
<td>---------------------</td>
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<td>%</td>
<td>n</td>
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<td>7 days/week</td>
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<tr>
<td>Participate in a structured exercise</td>
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<tr>
<td>program</td>
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<td>4-6 days/week</td>
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Table 4-2

*Medical Information*

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<th>Total (N = 23)</th>
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<td></td>
<td>M</td>
<td>SD</td>
<td>M</td>
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<td>BMI (kg/m²)</td>
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<td>(17.85-29.49)</td>
<td>(19.90-28.38)</td>
<td>(17.85-29.49)</td>
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<td>Hemoglobin</td>
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<td>1.03</td>
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<td>(10.50-13.70)</td>
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<td>(10.10-14.00)</td>
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<td>Other</td>
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<td>9.10</td>
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<tr>
<td>Stage of breast cancer at present</td>
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<td>18.20</td>
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<td>FEC 100 + docetaxel</td>
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<tr>
<td>Course number of chemotherapy at baseline assessment</td>
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</tr>
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<td>1</td>
<td>7</td>
<td>63.60</td>
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<td>2</td>
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<td>3</td>
<td>3</td>
<td>27.30</td>
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<td>4</td>
<td>0</td>
<td>0.00</td>
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<td>Comorbidities</td>
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<tr>
<td>No</td>
<td>7</td>
<td>63.60</td>
<td>7</td>
</tr>
<tr>
<td>Yes</td>
<td>4</td>
<td>36.40</td>
<td>5</td>
</tr>
</tbody>
</table>

*Note.* BMI = body mass index; CMF = cyclophosphamide/methotrexate/fluorouracil; AC = doxorubicin (adriamycin)/cyclophosphamide; CAF = cyclophosphamide/doxorubicin/fluorouracil; FEC 100 = fluorouracil/epirubicin/cyclophosphamide; TAC = docetaxel/doxorubicin/cyclophosphamide; FEC 100 + docetaxel = fluorouracil/epirubicin/cyclophosphamide/docetaxel; AC + paclitaxel = doxorubicin (adriamycin)/cyclophosphamide/paclitaxel.
Evaluation of the Culturally Sensitive Exercise Program

The primary purpose of this study was to develop a clinically feasible, culturally sensitive exercise program. The intervention was evaluated in the CSEP group by examining two criteria: (1) culturally appropriate content of the overall exercise program, and (2) exercise adherence.

Culturally appropriate content. Information with regard to culturally appropriate content and format presented in the exercise booklet was evaluated by individual interviews from the nine participants who completed the intervention. The participants were asked open-ended questions about their opinions towards this booklet for readability, design and layout, and content. The participants were also asked whether the overall intervention delivery was appropriate. The researcher took only brief notes during the interview.

Linguistically appropriate material. The majority of participants estimated that the exercise booklet did not exceed a seventh-grade reading level. Some participants suggested that some English words (e.g., intensity, METs) were quite hard for the participants to understand. These words should be translated into plain Thai language. For example, a 40-year-old woman renamed “the Borg scale” as “a tired scale.” The participants appreciated the use of pictures and tables in the booklet and suggested that more pictures, such as images of household activities with levels of intensity, be added.

Content of the exercise booklet. General information on cancer-related fatigue is the first section to be evaluated. The CSEP participants expressed that a traditional booklet given by the cancer center did not describe any information about cancer-related fatigue, and thus the information on cancer-related fatigue was relatively new to them. The CSEP participants reported that having exercise information and fatigue management information was important.
particularly for providing a better understanding about fatigue itself and the importance of managing the condition. Participants interviewed said the following:

“They should have this book at hospitals. It will help cancer patients to fight the chemo’s side effects.” (A 44-year-old woman)

“It would be very useful. I’d never seen this kind of book before. Patients and their family would get some knowledge and should be aware of it.” (A 31-year-old woman)

“I know exercise will reduce fatigue, after you explained it and I read it in the provided booklet.” (A 31-year-old woman)

Second, the CSEP participants appreciated the information on how simple changes in lifestyle and exercise could help to manage fatigue and improve health. For example, a 31-year-old woman said that “Personally, I did not know how to start exercising. The booklet gives useful information and easy ways by selecting household activities for walking.”

A 54-year-old woman expressed feelings of struggling with chemotherapy. “After I got chemo for first time, I felt that I was going to die soon. I could not sleep and eat any food. Then, I felt tired and wanted only to sit or lie down. When I got encouragement from you (the nurse researcher), nurses, and my family (aunt), I have to be patient. If I wanted to survive, I need to be strong; I kept busy with activities such as cleaning house, cooking, or walking around my house. I go to the temple on Buddhist days, make merit with family and friends. I could survive and felt better.”

In addition, the information in this booklet was useful in assisting the participants to understand the benefits of exercising while actively receiving adjuvant chemotherapy. For example, a 58-year-old woman stated that “I rarely worked out because I generally believe that only eating foods and getting more sleep helped relieve tiredness. . . I should do exercising more
and help me feel better.” A 54-year-old woman also stated that “I was able to understand my fatigue and how to deal with it.”

The third section of this booklet is a description of performing structured walking. The CSEP participants revealed that it was helpful to review each step for continuing exercise. Particularly, the booklet’s specific examples on how to calculate steps helped participants to reach weekly goals. For example, a 58-year-old woman said that “It helped me when I forgot some...examples in the given booklet helped me.” A 54-year-old woman also appreciated that “The small machine (pedometer) is interesting. I have never seen it before. I liked it as well as it helped me simply know how many steps were taken.”

**Intervention delivery.** The participants (100%) strongly preferred home-based exercise. Walking was feasible for Thai women with breast cancer during active adjuvant chemotherapy. These participants also mentioned frequently that when they were sick, they stayed at home. This was more convenient. For example, a 54-year-old woman stated that “I liked the methods you gave me. My house is next to a community temple. I just walked about 20-30 minutes a day. It is not far from my house.” A 38-year-old woman also said, “Do you know? If you asked me to exercise here (the cancer center), I had to say no... I cannot do it. I live in a province 111 kilometers (69 miles) far from here.”

When asked about barriers to exercising, all participants (100%) reported that side effects arising from chemotherapy temporarily stopped them from exercising. More than half (55.56%) reported that medications that were prescribed to control the chemotherapy side effects (e.g., antiemetics, sleeping pills) interfered with their efforts to exercise, and some participants had to be hospitalized. Participants repeatedly stated that they followed directions for exercise by
walking in several short sessions throughout the day, particularly, for a few days after each chemotherapy cycle.

The participants explained that they mostly took part in the exercise program because the program lessened their suffering from receiving chemotherapy regimens. For example, a 38-year-old woman said that “One woman receiving chemotherapy told me that she was suffering. I have three children. They are still young. If I can do something that will help me get well soon, I will try to do it.” A frequent comment that characterized participants’ thoughts in Thai culture was “Cancer may be my bad karma for past acts. It is time for me to begin doing a good thing.” Similarly, a 40-year-old woman said that “I believe in Buddha’s teaching. I know everyone must die. . . I have two younger children. If I die, who will take care of them? My mother and husband always told me that it would not be long. Just keep busy with activities.”

Family members were invited to support these participants as part of the study. As a consequence, these participants frequently said that their family members were helpful and motivated them to keep moving. For example, a 58-year-old woman said that “My husband supports me. He had to get up early morning to drive me 3-4 hours to the cancer center. He feels tired but he does not complain (crying). He encouraged me to participate in the study. He wanted me to be strong and suffer less.” A 44-year-old woman also stated that “This is the first time I start exercising. My daughter and sisters reminded me to walk and told me that no one can help me but me.”

Approximately 12 telephone contacts were conducted with each of the nine participants. Almost all participants frequently noted that the telephone check-ups by the researcher via weekly telephone calls were helpful and kept them motivated. When participants encountered
troublesome side effects, the researcher helped to adjust the portions of exercise to their treatment. Some participants recommended the program to others.

**Exercise adherence.** Adherence to the CSEP was evaluated by weekly average of daily steps walked and the percent of adherence for each participant. Weekly exercise adherence is summarized in Table 4-3. There was 15.37% missing data in the daily pedometer steps. Excluding missing data, 11 patients assigned to the CSEP group reported increasing daily steps walked, with a mean increase of 5,920 steps ($SD = 1,523$) from baseline to post intervention. These 11 patients reported an average of 3.43 days ($SD = 0.97$) per week that they reached total daily step counts that were 5% over the average daily number of steps walked weekly.
Table 4-3

*Weekly Exercise Adherence in the CSEP Group*

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<th>Measurement</th>
<th>Baseline M±SD</th>
<th>Week 2 M±SD</th>
<th>Week 3 M±SD</th>
<th>Week 4 M±SD</th>
<th>Week 5 M±SD</th>
<th>Week 6 M±SD</th>
<th>Week 7 M±SD</th>
<th>Week 8 M±SD</th>
<th>Week 9 M±SD</th>
<th>Week 10 M±SD</th>
<th>Week 11 M±SD</th>
<th>Week 12 M±SD</th>
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<tbody>
<tr>
<td>Daily steps per week</td>
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<td>4,465.52 ±2,153.90</td>
<td>5,392.46 ±3,298.88</td>
<td>4,385.43 ±2,429.65</td>
<td>6,382.83 ±2,072.92</td>
<td>6,049.60 ±1,627.24</td>
<td>5,679.40 ±4,183.58</td>
<td>7,490.51 ±2,550.99</td>
<td>7,197.86 ±3,884.11</td>
<td>7,159.31 ±2,050.63</td>
<td>7,062.08 ±2,528.50</td>
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<td>Days per week (5% achieved)</td>
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<td>4.09 ±2.12</td>
<td>3.36 ±2.54</td>
<td>2.09 ±2.88</td>
<td>5.09 ±2.26</td>
<td>3.36 ±2.34</td>
<td>2.09 ±2.70</td>
<td>4.45 ±2.98</td>
<td>2.91 ±2.77</td>
<td>1.82 ±2.18</td>
<td>3.00 ±2.65</td>
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<td>- Frequency (days per week)</td>
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<td>-a</td>
<td>-a</td>
<td>3.73 ±2.57</td>
<td>3.82 ±2.93</td>
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<td>2.73 ±2.53</td>
<td>2.82 ±2.86</td>
<td>3.00 ±2.72</td>
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<td>- Duration (weekly walking minutes)</td>
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<td>-a</td>
<td>-a</td>
<td>-a</td>
<td>98.64 ±70.78</td>
<td>94.55 ±75.31</td>
<td>73.18 ±65.36</td>
<td>89.09 ±61.88</td>
<td>83.18 ±76.23</td>
<td>82.27 ±87.45</td>
<td>89.55 ±85.04</td>
<td>100.45 ±111.05</td>
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<tr>
<td>- Intensity (average Rating of perceived exertion (RPE))</td>
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<td>-a</td>
<td>-a</td>
<td>-a</td>
<td>11.84 ±0.94</td>
<td>11.91 ±1.19</td>
<td>10.77 ±3.71</td>
<td>11.98 ±0.62</td>
<td>11.51 ±1.04</td>
<td>11.79 ±1.08</td>
<td>11.66 ±1.09</td>
<td>11.72 ±1.10</td>
</tr>
</tbody>
</table>

*Note.*  
*a* During baseline to week 4, structured walking had not yet been implemented.
During week 5 to 12, the CSEP group was prescribed structured walking. The level of structured exercise was determined by frequency (numbers of days per week), duration (length of time spent in each session and weekly exercise minutes), and intensity (a rating of perceived exercise). As shown in Table 4-4, these 11 patients reported the average number of adherent days was 3.07 (SD = 2.43), and the average number adherent weeks 5.00 (SD = 3.38). The mean weekly exercise minutes were 88.86 (SD = 72.70), and the average duration of each exercise session was 28.53 minutes (SD = 4.59). The mean intensity of exercise was rated as 11.78 (SD = 0.94) on the Borg rating of perceived exertion level (RPE) scale from 6 to 20. The individual adherence rate was calculated as the percent of adherence weeks out of the total number of weeks for each participant and was 62.50% (SD = 42.20%).

Table 4-4

*Overall Structured Walking Adherence in the CSEP Group*

<table>
<thead>
<tr>
<th></th>
<th>M</th>
<th>SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of adherent days</td>
<td>3.07</td>
<td>2.43</td>
<td>0.25-7.00</td>
</tr>
<tr>
<td>Minutes per exercise session</td>
<td>28.53</td>
<td>4.59</td>
<td>19.08-33.50</td>
</tr>
<tr>
<td>Weekly exercise minutes</td>
<td>88.86</td>
<td>72.70</td>
<td>5-210</td>
</tr>
<tr>
<td>Rating of perceived exertion (RPE)</td>
<td>11.78</td>
<td>0.94</td>
<td>9.55-13.58</td>
</tr>
<tr>
<td>Number of adherent weeks</td>
<td>5.00</td>
<td>3.38</td>
<td>0-8</td>
</tr>
<tr>
<td>Individual adherence rate (%)</td>
<td>62.50</td>
<td>42.20</td>
<td>0-100</td>
</tr>
</tbody>
</table>

**Exercise pattern for the CSEP group.** Figure 4-1 demonstrates that the participants dropped their weekly average daily steps walked in the first week of each chemotherapy cycle received (week 4, 7, and 10), and then progressively climbed upward in the weeks remaining. Their weekly average daily steps remained above the average of 3,985 steps (SD = 1,907) at baseline. According to ACSM recommendations, only one participant met the following step index to classify her activity level as active based on steps per day (10,000-12,500 steps per day).
Comparison exercise variables for the entire sample. Data are summarized and listed in Table 4-5 and Table 4-6, respectively. Energy expenditure was calculated from data in three-day exercise daily logs during each treatment cycle at weeks 3, 6, and 9. Physical fitness was measured using the 12-MWT data at baseline and week 10.

Overall, there were no weight and BMI changes across the treatment in either groups. Participants in the CSEP group reported the average total energy expenditure at week 9 was higher than at week 3. A paired-sample $t$ test revealed no significant differences between week 3 and week 9 ($t(10) = -0.97, p = .35$).

Means and standard deviations for the 12-MWT are shown in Table 4-6. The 12-MWT at baseline was tested by an independent-sample $t$ test. There was no statistically significant difference between the groups ($t(21) = 0.05, p = .48$). As would be expected, an independent-samples $t$ test indicated that the 12-MWT was significantly different for participants who
completed the study in the CSEP group from baseline to week 10 \((M = 844.89, SD = 139.69)\)
than for those in the UC group \((M = 670.67, SD = 1194.42)\), \(t(19) = 2.28, p = .04\) (Table 4-6).

Table 4-5

*Exercise Outcomes of the Patients during the Study Period (N = 23)*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th>Baseline</th>
<th>Week 3</th>
<th>Week 6</th>
<th>Week 9</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>M</td>
<td>SD</td>
<td>M</td>
<td>SD</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>CSEP</td>
<td>55.05</td>
<td>6.04</td>
<td>54.64</td>
<td>6.15</td>
</tr>
<tr>
<td></td>
<td>UC</td>
<td>57.17</td>
<td>6.94</td>
<td>57.04</td>
<td>6.25</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>CSEP</td>
<td>22.62</td>
<td>3.18</td>
<td>22.45</td>
<td>3.16</td>
</tr>
<tr>
<td></td>
<td>UC</td>
<td>24.54</td>
<td>2.84</td>
<td>24.50</td>
<td>2.66</td>
</tr>
<tr>
<td>Energy expenditure (kcal/day)</td>
<td>CSEP</td>
<td>n/a</td>
<td>n/a</td>
<td>766.83</td>
<td>649.62</td>
</tr>
<tr>
<td></td>
<td>UC</td>
<td>n/a</td>
<td>n/a</td>
<td>847.00</td>
<td>589.95</td>
</tr>
</tbody>
</table>

*Note.* n/a = not applicable.

Table 4-6

*Change of 12-Minute Walk Test across Chemotherapy Treatment of the Entire Subject*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Time</th>
<th>CSEP group</th>
<th>UC group</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>M</td>
<td>SD</td>
<td>M</td>
</tr>
<tr>
<td>12-MWT (meters)</td>
<td>Baseline (N = 23)</td>
<td>597.45</td>
<td>216.62</td>
<td>593.75</td>
</tr>
<tr>
<td></td>
<td>Week 10 (N = 21)</td>
<td>844.89</td>
<td>139.69</td>
<td>670.67</td>
</tr>
</tbody>
</table>

*Note.* \(p < .05\), one-tailed; CI = confidence interval; LL = lower limit; UL = upper limit.
Results According to Research Questions

Descriptive Data of the Study Variables. Descriptive data for the study variables associated with each research question are presented first, and then the study groups are compared. Table 4-7 shows the means and standard deviations for the four outcome variables. Differences between groups on dependent variables at baseline were tested by independent sample t tests. There were no statistically significant differences between the groups on any of these variables, suggesting that the sample was drawn from similar populations of Thai women with breast cancer.

Table 4-7

<table>
<thead>
<tr>
<th>Group Difference in Outcome Variables at Baseline (N = 23)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
</tr>
<tr>
<td>---------------------------------------------------------</td>
</tr>
<tr>
<td>Fatigue (0-10)</td>
</tr>
<tr>
<td>Sleep disturbance (0-7)</td>
</tr>
<tr>
<td>Mood disturbance (0-4)</td>
</tr>
<tr>
<td>Symptom distress (0-4)</td>
</tr>
</tbody>
</table>

In addition, means and standard deviations of all dependent variables for the entire sample at each time point are presented in Table 4-8. The exercise intervention was a 12-week home-based walking program. Data are reported at week 10 because this present study was designed to capture the maximal effect of exercise intervention on fatigue at 48 hours after completion of each cycle of chemotherapy. The participants did not receive additional treatment at 12 weeks. Thus, not having treatment at 12 weeks becomes a confounding variable.
Table 4-8

*Time Course of Effects of the Culturally Sensitive Exercise Program on Subjects (N = 23)*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th>Baseline M</th>
<th>Baseline SD</th>
<th>Week 4 M</th>
<th>Week 4 SD</th>
<th>Week 7 M</th>
<th>Week 7 SD</th>
<th>Week 10 M</th>
<th>Week 10 SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue (0-10)</td>
<td>CSEP</td>
<td>4.56</td>
<td>1.82</td>
<td>4.93</td>
<td>1.51</td>
<td>4.15</td>
<td>2.79</td>
<td>3.62</td>
<td>2.07</td>
</tr>
<tr>
<td></td>
<td>UC</td>
<td>3.76</td>
<td>2.10</td>
<td>4.60</td>
<td>2.84</td>
<td>4.48</td>
<td>2.38</td>
<td>3.38</td>
<td>2.75</td>
</tr>
<tr>
<td>Sleep disturbance (0-7)</td>
<td>CSEP</td>
<td>3.45</td>
<td>1.14</td>
<td>3.60</td>
<td>1.43</td>
<td>4.00</td>
<td>1.04</td>
<td>3.87</td>
<td>1.61</td>
</tr>
<tr>
<td></td>
<td>UC</td>
<td>3.74</td>
<td>1.39</td>
<td>3.61</td>
<td>1.05</td>
<td>3.91</td>
<td>1.27</td>
<td>3.78</td>
<td>1.27</td>
</tr>
<tr>
<td>Mood disturbance (0-4)</td>
<td>CSEP</td>
<td>0.92</td>
<td>0.44</td>
<td>1.03</td>
<td>0.57</td>
<td>1.17</td>
<td>0.59</td>
<td>0.87</td>
<td>0.49</td>
</tr>
<tr>
<td></td>
<td>UC</td>
<td>1.03</td>
<td>0.68</td>
<td>0.98</td>
<td>0.54</td>
<td>1.11</td>
<td>0.64</td>
<td>1.04</td>
<td>0.68</td>
</tr>
<tr>
<td>Symptom distress (0-4)</td>
<td>CSEP</td>
<td>0.86</td>
<td>0.58</td>
<td>1.06</td>
<td>0.64</td>
<td>1.13</td>
<td>0.44</td>
<td>0.98</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td>UC</td>
<td>0.89</td>
<td>0.48</td>
<td>1.17</td>
<td>0.67</td>
<td>1.30</td>
<td>0.69</td>
<td>1.33</td>
<td>0.87</td>
</tr>
</tbody>
</table>

**Estimating Effects of the CSEP on Fatigue, Sleep Disturbance, Mood Disturbance, and Symptom Distress**

To answer the research questions, the GEE model was used to estimate the effects of the CSEP over time. GEE can appropriately assume population-averaged estimates or slopes based upon a quasi-likelihood model. With GEE modeling, missing data are assumed to be either missing completely at random (MCAR) or covariate-dependent missing at random (MAR). The quasi-likelihood information criterion (QIC) is used for model selection, and the corrected quasi-likelihood under independence model criterion (QICC) is used for variable selection.

GEE analysis indicated that in the full model, QIC and QICC were 133.62 and 133.46, respectively, for the present study. The QIC for this full model was compared to the QIC for an intercept-only GEE model (136.06). The QIC for the full model was smaller, indicating that this model is to be preferred over the intercept-only model. The QICC for the full model also yielded a small number; thus, all dependent variables fitted the model and were substantive in determining the effects of the intervention.
The results of GEE modeling are presented in Table 4-9. The results for the research question were reported one by one in detail, as follows.

Table 4-9

*Generalized Estimating Equations Analysis of Effects of the CSEP (N = 21)*

<table>
<thead>
<tr>
<th>Variable</th>
<th>β</th>
<th>Standard Error</th>
<th>Wald chi-square</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>.41</td>
<td>0.55</td>
<td>0.55</td>
<td>-0.68 - 1.49</td>
<td>.23</td>
</tr>
<tr>
<td>Fatigue</td>
<td>-0.00</td>
<td>0.00</td>
<td>1.09</td>
<td>-0.00 - 0.00</td>
<td>.15</td>
</tr>
<tr>
<td>Sleep disturbance</td>
<td>-0.00</td>
<td>0.01</td>
<td>0.15</td>
<td>-0.02 - 0.01</td>
<td>.35</td>
</tr>
<tr>
<td>Mood disturbance</td>
<td>0.03</td>
<td>0.01</td>
<td>3.28</td>
<td>-0.00 - 0.06</td>
<td>.04</td>
</tr>
<tr>
<td>Symptom distress</td>
<td>-0.00</td>
<td>0.01</td>
<td>0.06</td>
<td>-0.03 - 0.03</td>
<td>.40</td>
</tr>
</tbody>
</table>

*Note.* $p < .05$, one-tailed; CI = confidence interval; LL = lower limit; UL = upper limit.

*Research Question 1:* Are there slope differences in the levels of cancer-related fatigue between the group using the culturally sensitive exercise program (CSEP) as an intervention and the comparison group?

Follow-up data points for CRF were set at 48 hours following chemotherapy, which was the expected time of the highest level of fatigue, in order to capture the maximal effect of exercise intervention. The pattern of slope change for CRF was different between the exercise group and control group (Figure 4-2). At baseline, the mean CRF scores in the CSEP group indicated that they had more fatigue than the UC group; however, the slope of the line for the participants in the CSEP group showed improvement in CRF from baseline to post intervention (Figure 4-2). In contrast, the UC group reported lower CRF at baseline, and the slope remained stable over the two measurement points (week 4 and week 7), and then declined at the 10-week intervention. GEE analysis indicated that no significant slope differences were found between the two groups in fatigue over time ($β = -0.00, p = .15$).
Figure 4-2. Mean fatigue in the CSEP study group and control group at baseline, week 4, week 7, and week 10.

Research Question 2: Are there slope differences in the levels of sleep disturbance between the group using the CSEP as an intervention and the comparison group?

The pattern of slope change for sleep disturbance in the CSEP group was similar to the UC group (Figure 4-3). The mean sleep disturbance in the CSEP group rapidly accelerated over the 7-week intervention, whereas the slope of the mean sleep disturbance in the UC group slightly dropped at week 4 and then reversed and accelerated rapidly. However, the patterns of change for sleep disturbance between the two groups gradually slowed from week 7 to week 10, indicated by a decreasing slope for both groups. Overall, there was a tendency for participants in the CSEP group to have had more sleep disturbance than those in the UC group over the intervention period. GEE analysis indicated that no significant slope differences were found between the two groups in sleep disturbance over time ($\beta = -.00, p = .35$).
Research Question 3: Are there slope differences in the levels of mood disturbance between the group using the CSEP as an intervention and the comparison group?

The pattern of slope change for mood disturbance in the CSEP group gradually accelerated across the 7-week intervention, but not in the UC group (Figure 4-4). The mean mood disturbance in the UC group dropped slightly at week 4 and then slightly increased; however, it was not improved and reached the same level as the CSEP group over the intervention period. Participants in the CSEP group had less mood disturbance than those in the UC group at baseline and week 10. GEE analysis indicated that significant slope differences were found between the two groups in mood disturbance over time ($\beta = .03$, $p = .04$), indicating that mood disturbance decreased significantly for participants in the CSEP group.

Figure 4-3. Mean sleep disturbance in the CSEP study group and control group at baseline, week 4, week 7, and week 10.
Research Question 4: Are there slope differences in the levels of symptom distress between the group using the CSEP as an intervention and the comparison group?

The pattern of slope change was different between the CSEP and UC groups on symptom distress (Figure 4-5). Participants in the CSEP group indicated a tendency for symptom distress to gradually decline over time, but for participants in the UC group, symptom distress increased relative to baseline. GEE analysis indicated that no significant slope differences were found between the two groups in symptom distress over time ($\beta = -.00, p = .40$).
Figure 4-5. Mean symptom distress in the CSEP study group and control group at baseline, week 4, week 7, and week 10.

Effect Sizes Within and Between Groups on Fatigue, Sleep Disturbance, Mood Disturbance, and Symptom Distress

The GEE modeling revealed that only one variable (mood disturbance) was statistically significant. Effect size was calculated by using Cohen’s $d$, with 95% confidence intervals to examine the difference within and between the two groups. Cohen’s $d$ criteria for determining the levels of effect sizes in behavioral science was used in which values of less than 0.20 are small, those of 0.50 are medium, and those of 0.80 or greater are large.

Estimates of effect sizes were computed using Cohen’s $d$ for the outcome variables (Table 4-10). Lower scores on the scales and negative effect sizes indicate lower levels of fatigue, sleep disturbance, mood disturbance, and symptom distress.
The effect size index of fatigue in the CSEP group from baseline to post intervention (T₁ and T₄) is -0.48, 95% CI [-1.38, 0.41], which is close to a medium effect size.

Table 4-10
*Effect Size in Fatigue, Sleep Disturbance, Mood Disturbance, and Symptom Distress Over Time Between Groups*

<table>
<thead>
<tr>
<th>Variable</th>
<th>T₁ and T₂</th>
<th>T₁ and T₃</th>
<th>T₁ and T₄</th>
<th>T₂ and T₃</th>
<th>T₂ and T₄</th>
<th>T₃ and T₄</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CSEP</td>
<td>UC</td>
<td>CSEP</td>
<td>UC</td>
<td>CSEP</td>
<td>UC</td>
</tr>
<tr>
<td>Fatigue</td>
<td>-0.22</td>
<td>-0.34</td>
<td>-0.18</td>
<td>0.32</td>
<td>-0.48</td>
<td>-0.16</td>
</tr>
<tr>
<td>Sleep disturbance</td>
<td>0.12</td>
<td>-0.11</td>
<td>0.50</td>
<td>0.13</td>
<td>0.30</td>
<td>0.03</td>
</tr>
<tr>
<td>Mood disturbance</td>
<td>0.22</td>
<td>-0.08</td>
<td>0.48</td>
<td>0.12</td>
<td>-0.11</td>
<td>0.01</td>
</tr>
<tr>
<td>Symptom distress</td>
<td>0.33</td>
<td>0.48</td>
<td>0.52</td>
<td>0.69</td>
<td>0.24</td>
<td>0.63</td>
</tr>
</tbody>
</table>

*Note.* “-“value indicates improvement in scores; T₁ = baseline; T₂ = Week 4; T₃ = Week 7; T₄ = Week 10.

In addition, a repeated-measures interaction effect size estimate was used to calculate the effect sizes between the two groups over time and within conditions (Table 4-11). Compared to participants in the UC group, participants in the exercise condition (CSEP) demonstrated improvements in levels of fatigue, mood, and symptom distress with small to medium effect sizes (d = -0.27, -0.20, and -0.60 respectively).
Table 4-11

Interaction Effect Size Estimates in Fatigue, Sleep Disturbance, Mood Disturbance, and Symptom Distress Over Time and Within Conditions Between Groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>CSEP group</th>
<th>UC group</th>
<th>Cohen’s</th>
<th>95%CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Week 10</td>
<td>Baseline</td>
<td>Week 10</td>
</tr>
<tr>
<td></td>
<td>M</td>
<td>SD</td>
<td>M</td>
<td>SD</td>
</tr>
<tr>
<td>Fatigue</td>
<td>4.63</td>
<td>2.03</td>
<td>3.62</td>
<td>2.07</td>
</tr>
<tr>
<td>Sleep disturbance</td>
<td>3.53</td>
<td>1.16</td>
<td>4.01</td>
<td>1.64</td>
</tr>
<tr>
<td>Mood Disturbance</td>
<td>0.96</td>
<td>0.46</td>
<td>0.85</td>
<td>0.51</td>
</tr>
<tr>
<td>Symptom distress</td>
<td>0.93</td>
<td>0.60</td>
<td>1.00</td>
<td>0.40</td>
</tr>
</tbody>
</table>

Note. “-“value indicates improvement in scores; CI = confidence interval; LL = lower limit; UL = upper limit.

Summary of the Results

Based on the participants’ responses to the culturally sensitive exercise program, findings suggest that educational information in the booklet format is appropriate in the context of Thai culture. The use of the booklet has the potential to enhance the effectiveness of delivering information in the context of Thai culture. Additionally, the results of quantitative analyses demonstrated that the exercise program showed a trend toward improving most outcomes, but these changes did not reach statistical significance.
CHAPTER FIVE
DISCUSSION AND RECOMMENDATIONS

In this chapter, the findings of each outcome variable are discussed in relation to research questions and existing literature. Strengths and limitations of the study are identified. Implications for theory and clinical practice are suggested based on the findings. Recommendations for future research are also presented.

Evaluation of the Culturally Sensitive Exercise Program

Culturally appropriate content. Cultural sensitivity consists of two primary dimensions: surface structure and deep structure (Resnicow, Baranowski, Ahluwalia, & Braithwaite, 1999). Surface structure involves matching intervention materials and messages to characteristics of a target population. Deep structure refers to social and psychological factors rooted in experiences, beliefs, and values. Written instructions and materials were used to deliver home-based exercise interventions in cancer patients (Mock et al., 2005; Mustian et al., 2009; Wang et al., 2011). Written health materials provide complimentary information to improve knowledge and increase adherence to the behavior being promoted (Vallance, Courneya, Taylor, Plotnikoff, & Mackey, 2008). Based on the participants’ response in the exercise group to the exercise booklet, the booklet was designed to be read at fourth to sixth grade reading level. The use of literacy-level appropriateness was a component of culturally sensitive interventions that produced significant differences in behavioral outcomes among people with limited health literacy (Mier, Ory, & Medina, 2010). Readability is an essential component of health education materials for improving health outcomes in a low-literacy population. Low-literacy health education materials should be written at or below a sixth-grade
reading level (Vallance, Taylor, & Lavallee, 2008). Although, the booklet was given in Thai, terminology translated from English to Thai might still be difficult for Thai women due to the language barrier. The English terms may have been difficult to understand even though they were translated to Thai, as 100% of the participants reported Thai as the primary language. The use of plain language and judicious use of terminology enhance the readability of health material (Wilson, 2011). A systematic review also indicates that the use of pictures which is integrated with the text was helpful for adults with low-literacy (Houts, Doak, Doak, & Loscalzo, 2006).

All the participants agreed that the information in the booklet was formulated appropriately and written based on the context of their lifestyle. The exercise program developed in this study was feasible. The findings added more evidence that walking was the preferred exercise for Thai women being treated for early-stage breast cancer. The finding is consistent with earlier studies in Asian and Caucasian women (Dodd et al., 2010; Mock et al., 1997; Mock et al., 2005; Wang et al., 2011; Yang et al., 2010). This was supported by a national survey in the United States (Bernardo, Abt, Ren, & Bender, 2010), which reported that 59% of women performed walking during breast cancer treatment.

Moreover, this study also focused on cultural issues, such as beliefs, living patterns, and settings, by including household walking to encourage Thai midlife women with breast cancer move to a structured exercise program. In the present study, 78.26% of participants were midlife women. This finding may be supported by a qualitative online form study on Asian American midlife women’s attitudes toward physical activity in the United States that reported that Asian American women felt that physical activity was integrated into their daily lives with household chores (Im et al., 2012). Walking was one form of daily physical activity. The major difference
mentioned is that Thais or Asian Americans are more family-oriented and their main responsibility is taking care of the home.

In this study, women in the exercise group applied cultural-religious practices to help them fight the disease and to return to the normality of their pre-illness state. Similarly, the findings of a descriptive study by Lundberg and Rattanasuwan (2007) reported that practicing religion is a way to relieve fatigue for Thai cancer patients undergoing radiation therapy. This finding might be explained by the concept of using complementary alternative medicine (CAM). A qualitative study by Wanchai, Armer, and Stewart (2012) reported that mind/body medicine (e.g., meditation, prayer, practicing religion) is one of the most common types of CAM used by Thai women with breast cancer. This finding is also in line with a qualitative study in Thai women with breast cancer by Sirisupluxana, Sripichyakan, Wonghongkul, Sethabouppha, and Pierce (2009), which reported that the practice of religious activities was a critical approach in increasing Thai women’s mental powers, cheerfulness, and confidence to fight cancer and side effects from cancer treatment.

**Exercise adherence.** In the present study, adherence was estimated in two ways; pedometer information (which reflected activities of daily living including structured walking) and level of structured exercise (frequency, duration, and intensity) from exercise daily logs. Participants in the exercise group were required to wear the pedometer, and the weekly average of daily steps reported by the pedometer throughout the study period was 5,920 steps ($SD = 1,523$). Participants were motivated to remain physically active during treatment by increasing total daily step counts that were 5% over the average daily number of steps walked weekly. The mean number of days which they reached the goal was 3.43 days a week. Compared to expected values for steps per day in populations living with chronic illnesses and disability reviewed by
Tudor-Locke, Washington, and Hart (2009), the mean expected value for breast cancer patients undergoing treatment was 5,525 steps ($SD = 2,906$). The participants in this present study met the expected value but did not meet general public health exercise guidelines, which recommend a minimum of 10,000 steps per day. Only one participant met the recommended 10,000 steps per day. This finding of meeting the expected value is consistent with a RCT study by Swenson, Nissen, and Henly (2010), which reported that women with breast cancer aged 40-55 years who were receiving adjuvant chemotherapy received encouragement through motivation interviewing to walk 10,000 steps per day. The mean number of steps per day at 3 months was 8,730 steps ($SD = 2,209$). This finding may reflect that exercise programs aiming to prescribe 10,000 steps per day prove to be difficult and set an impractical goal for cancer patients during active cancer treatment.

In addition, another goal of the exercise program was to build the confidence of the participants to start an exercise routine. Participants in the exercise group reported that they exercised about 28.53 minutes per session ($SD = 4.59$), and 3.07 days a week ($SD = 2.43$). The mean intensity of exercise was 11.78 on the Borg scale ($SD = 0.94$). The total weekly exercise minutes was 88.86 minutes ($SD = 72.70$). This finding is somewhat similar to a randomized control trial (RCT) by Mock et al. (2005), which reported that the participants in the exercise program exercised 28.36 minutes per session ($SD = 9.04$), and 4.59 days a week ($SD = 1.16$). The mean minutes walked per week was 127.43 minutes ($SD = 44.04$). This finding is also in line with a recent RCT study by Chou, Dodd, and Paul (2012), which reported that the participants who were instructed to perform aerobic activity of the participant’s choice, such as walking or stationary bicycling, exercised 42.84 minutes per session ($SD = 18.89$), and 3.6 days a week ($SD = 4.28$). The mean intensity of exercise was 12.55 on the Borg scale ($SD = 3.31$).
This might reflect that Thai women with breast cancer undergoing active adjuvant chemotherapy can adopt exercise habits like women in other ethnic groups. This finding also provided important information on exercise habits that Thai women with breast cancer can start exercising at the beginning of chemotherapy and accomplish the minimum recommended level of exercise by first increasing frequency or duration, then later increasing intensity.

However, the adherence rate for the exercise group in the present study was 62.5%, relatively lower than adherence rates reported in previous studies of home-based exercise in breast cancer patients undergoing active treatment which ranged between 72% and 73% (Dodd et al., 2010; Mock et al., 2005). This finding might be explained in the Thai context as follows: although the Thai women with breast cancer in this study could remain physically active, exercise is challenging during active treatment. Thai women participants did not participate in a structured exercise program prior to commencing cancer treatment (81.8%). Moreover, a cross-sectional study by Piamjariyaku et al. (2010) found that Thai cancer patients reported more symptoms with greater severity during active cancer treatment. Severe medical illness or other treatment-related symptom may preclude exercising (Ingram et al., 2010; Mock et al., 2005; Swenson et al., 2010). The explanation was supported by a secondary analysis of data from an RCT of home-based walking intervention for patients undergoing active cancer treatment in the United States by Shang, Wenzel, Krumm, Griffith, and Stewart (2012), which reported that the variables that significantly predicted individual adherence rate in the hierarchical Poisson regression analysis were baseline physical fitness, exercise history, pretreatment fatigue level, lower mid-treatment mood disturbance, and being married.

Although the adherence rate in the present study was on the low end, participants in the exercise group showed significant improvement in physical fitness evaluated by the 12-MWT.
This finding is consistent with previous single studies (Campbell et al., 2005; Mock et al., 2005; Schwartz et al., 2001), and meta-analysis studies (C.-J. Kim et al., 2009; McNeely et al., 2006). This finding might reflect that the greater the level of physical activity the woman with breast cancer performed, the better the level of physical fitness.

**Estimating Effects of the CSEP on Fatigue, Sleep Disturbance, Mood Disturbance, and Symptom Distress**

*Research Question 1*: Are there slope differences in the levels of cancer-related fatigue between the group using the culturally sensitive exercise program (CSEP) as an intervention and the comparison group?

The mean fatigue scores indicated that participants in the exercise group (CSEP) had better improvement in fatigue than those in the usual care (UC) group at the expected time of the highest level of fatigue. Although change in fatigue favored the exercise group over time, GEE analysis revealed that it did not reach statistical significance ($\beta = -.00, p = .15$). Similar results were found in previous studies related to effects of a home-based walking program on levels of fatigue over time in women with breast cancer undergoing active adjuvant cancer treatment (Mock et al., 2005; Pinto et al., 2005; Schwartz et al., 2001; Wang et al., 2011). Recently, a six-week walking program RCT study by Wang et al. (2011) reported that Taiwanese women with breast cancer in the exercise group had less fatigue than those in the control group, but observed changes did not achieve statistical significance. In addition, a larger RCT study in the United States by Dodd et al. (2010) reported that women in the exercise group maintained a lower mean fatigue during cancer treatment, but there were no statistically significant between groups on fatigue.
Studies of exercise intervention being tested during the period of breast cancer treatment with chemotherapy have not yet yielded consistently positive outcomes across studies. However, medium effect sizes were detected in the exercise group for the levels of fatigue, whereas small effect sizes were presented in the control group at the same time points. It should be noted that in the present study, the majority of this study’s participants were diagnosed with breast cancer Stage II and were being treated with cyclophosphamide, doxorubicin, and fluorouracil (CAF). CAF is a standard treatment in current practice for Stage I or II breast cancer. Protocols containing doxorubicin were associated with the higher fatigue levels than those that did not contain doxorubicin (Berger & Walker, 2001). Changes in fatigue may be complicated by chemotherapy regimens. The effect of different chemotherapy regimens on fatigue is not yet clear and should be examined further. Regardless of the chemotherapy regimens, the findings of this present study support the observation that participants engaged in exercise interventions may not reduce fatigue, but fatigue did not increase at the expected time of highest fatigue in any of those in the exercise groups.

Research Question 2: Are there slope differences in the levels of sleep disturbance between the group using the CSEP as an intervention and the comparison group?

The mean sleep disturbance scores indicated that participants in the exercise group (CSEP) demonstrated a smaller improvement from baseline to post intervention. In contrast, the UC participants showed lower sleep disturbance than those in the exercise group. GEE analysis revealed no significant changes in sleep disturbance between the two groups ($\beta = -.00, p = .35$). The finding is somewhat consistent with a larger RCT study by Dodd et al. (2010), which reported that the trajectory of sleep disturbance was found in the exercise group but the linear change in sleep over time by groups did not show significant differences. This finding differed
from a RCT by Wang et al. (2011), which reported that the exercise group had significantly less sleep disturbance than those in the control group. A pilot RCT study also reported that older women with breast cancer receiving hormonal therapy in the exercise group experienced significantly reduced sleep disturbance (Payne et al., 2008). This might reflect that these findings are inconsistent in breast cancer population. More exercise interventional studies in women with breast cancer are needed to verify the result of the present study.

Additionally, this finding showed that Thai women with breast cancer in both groups experienced sleep disturbance across adjuvant chemotherapy cycles. Sleep disturbance scores did not change over time in any of the groups. Effect sizes also did not show improvements in sleep disturbance. Similarly, a cross-sectional study by Piamjariyaku et al. (2010) reported that the majority of Thai patients with cancer (> 50%) in all types of cancer treatment had difficulty sleeping. Praying and meditation were mentioned most often to help relieve this symptom. Health care providers should be aware of and be better prepared for how to optimize sleep quality when it affects fatigue (Berger & Mitchell, 2008). Therefore, this finding suggests that adding symptom-specific interventions may strengthen overall effects on fatigue and its related symptoms.

Research Question 3: Are there slope differences in the levels of mood disturbance between the group using the CSEP as an intervention and the comparison group?

The mean mood disturbance scores showed that the participants in the CSEP group had lower overall mood disturbance than the UC group at 10 weeks. Furthermore, GEE analysis revealed a statistically significant change in mood disturbance between the two groups (β = .03, p = .04). This finding is consistent with a RCT study by Yang, Tsai, Huang, and Lin (2010), which reported that women in the exercise group reported significantly lower mood disturbance
than those in the control group throughout the study period. This finding is also in line with a pilot RCT study by Chang et al. (2008), which reported that acute myelogenous leukemia (AML) patients in the exercise group had lower mood disturbance. This study also used as a measure the Profile of Mood States-Short Form, but only used the depression and anxiety subscales.

In addition, the findings of the present study might reflect that the designed exercise program did not include specific strategies for improving emotional adjustment. The change in mood disturbance scores in the exercise group may be the result of increased physical activity. Thai breast cancer women in the exercise group repeatedly mentioned that cancer may be their karma. Participation in the exercise program helped them have something to focus on and struggle through cancer treatment more easily. This might also be explained in the Thai context and supported by the study that Buddhists look at diseases as the result of karma and are under natural law (Paonil & Sringernyuang, 2005). Life tends to decay over time, and disease reminds us that this body is fragile. Buddhism principles helped the patients calmly accept and be able to live in harmony with nature and with less suffering (Paonil & Sringernyuang, 2005).

Research Question 4: Are there slope differences in the levels of symptom distress between the group using the CSEP as an intervention and the comparison group?

The mean symptom distress scores indicated that the participants in the CSEP group had lower symptom distress than those in the UC group over the 12-week intervention period. In addition, the mean symptom distress scores showed a tendency to increase for the UC group over time. GEE analysis revealed no statistically significant changes in symptom distress between the two groups ($\beta = -.00, p = .40$). This finding is somewhat consistent with a RCT study by Yang, Tsai, Huang, and Lin (2010), which reported that women with breast cancer in the exercise group had significantly lower symptom severity and interference from the symptoms during the 12-
week walking program than those in the control group. Similarly, a pilot RCT by Chang et al. (2008) reported that AML patients in the exercise group had lower symptom distress than the control group, but it did not achieve statistical significance. Effect sizes for symptom distress were detected in the exercise group at the same time points. The scores of symptom distress improved from baseline to post intervention. This might reflect that although the exercise program was designed to primarily decrease cancer-related fatigue, it also was effective in decreasing cancer patients’ distress from other treatment-related symptoms during their adjuvant chemotherapy. The findings of this present study suggest that home-based exercise interventions may be a promising intervention for reducing symptom distress. However, symptom distress and exercise efficacy were relatively less explored in the literature in breast cancer population. More studies regarding exercise interventions are needed to direct cancer-related fatigue management.

**Strengths and Limitations of the Study**

This study is the first experimental design with longitudinal follow-up conducted on Thai women diagnosed with early-stage breast cancer undergoing active adjuvant chemotherapy. This study used both objective and subjective measures and data analysis with robust statistical methods. This is also the first study in Thailand providing information regarding the difference in the pattern of change between women with breast cancer who exercise and those who do not. Moreover, the results of this pilot study provide preliminary support suggesting that the walking exercise program is safe and easy to implement in a busy chemotherapy oncology clinic. This exercise program was introduced in a chemotherapy oncology clinic and did not require specific exercise equipment or physical activity supervision by professionals. The intervention was delivered on the day before commencing each chemotherapy cycle while waiting for the doctor.
to come in. The relatively brief duration of face-to-face and weekly telephone contacts increases the likelihood that nursing staff could deliver the intervention after proper training.

This study was designed for Thai women with breast cancer that do not exercise regularly. Compared with participant characteristics in previous studies, the majority of Thai women in the present study were low-income with little health literacy. Thai women perceived the intervention to be feasible and were able to comply with exercise behaviors. Objective data also suggest that the intervention was feasible. The attrition for this study was relatively low (n = 2, 2.61%), compared with recent studies, which had a mean ranged between 5% and 8.30% (Dodd et al., 2010; Wang et al., 2011). The retention rate for this study was 91.30%, higher than the mean of 87.3% in a systematic review (Maddocks et al., 2009).

Significant increases were observed in self-reported moderate-intensity physical activity among participants. The participants in the exercise group reported a mean of 111.72 minutes per week of moderate-intensity physical activity. This is similar to an RCT study by Pinto, Frierson, Rabin, Trunzo, and Marcus (2005), which found that Caucasian breast cancer survivors had increased their activity by an average of 112 minutes per week. A significant increase was found for objective pedometer data. A noteworthy finding was that the exercise participants improved significantly over the control group on the 12-MWT at post intervention than the control group.

The overall findings of benefit from the exercise program must be interpreted cautiously because of some limitations. First, although a priori power analysis was used to suggest adequate sample size for the study, the pilot study provided valuable information on effect size to guide further the intervention protocol testing. Based on the average autocorrelation among the repeated observations (ρ = .63), the actual effect size (Cohen’s d = -0.27) obtained from the level
of fatigue change for the exercise intervention in the present study was found to be a sample of 50 participants. This supports that the small sample size of this pilot restricted statistical power and may explain why some of the observed changes did not achieve statistical significance.

Second, the pilot study was designed to measure the maximal effect of the CSEP on fatigue at 48 hours, which was the expected time of the highest level of fatigue. As a result, this study did not report data at 12 weeks because the participants did not receive additional treatment. Thus not having treatment becomes a confounding variable. Third, as breast cancer is the main focus of this study, these findings should not be generalized to the cancer patient population with other cancer sites or different types of cancer treatments. Finally, this study recruited participants from one cancer center, and these findings may be limited in generalization to a broader population of breast cancer patients undergoing active adjuvant chemotherapy in other parts of Thailand and other countries.

**Study Implications**

**Implications for nursing theory.** Results of this pilot study indicate that breast cancer patients experience fatigue and sleep disturbance, mood disturbance, and symptom distress simultaneously during active adjuvant chemotherapy. These findings are consistent with the Theory of Unpleasant Symptom (TOUS), which supposes that multiple symptoms can occur concurrently. All symptoms also vary in intensity, degree of associated distress, timing, and quality (Lenz et al., 1997). According to the TOUS, influential factors can produce variation in the symptom experience. In the theoretical framework for this study, the influential factors included physiological factors (i.e., age, stage of breast cancer, and treatment regimens); psychological factors (i.e., beliefs and anxiety); and situational factors (marital status, employment status, family income, educational level). Application of the TOUS with regard to
exercise-specific strategies is beneficial. The present study extends and complements previous investigations by appraising the influential factors as a direct effect on the CSEP. The CSEP may have mediating effect between factors and symptoms. Some of these variables (e.g., beliefs and anxiety) were not measured in this study, but could be incorporated in future research. These factors may influence the encouragement for exercise participation and the promotion of exercise adherence among women with breast cancer. The TOUS is a useful nursing model and should be refined and tested in further studies.

The TOUS is also useful in clarifying proposed relationships among the TOUS relevant variables. This present study did not aim to examine these relationships. Prior to GEE modeling, the researcher and statistics professor performed data exploration, and significant correlations were not found between fatigue and the influential factors at each time point. In contrast, at each time point, significant positive correlations were found between fatigue and sleep disturbance ($r = .43-.64$), mood disturbance ($r = .49-.68$), and symptom distress ($r = .43-.69$). These findings suggest that further development of exercise interventions should have a considerable impact on decreasing symptoms that cluster with fatigue. The small sample size of this present study is a limitation to precisely examine these correlations; thus, further development of this theoretical model is warranted.

**Implications for clinical practice.** Although several limitations need to be taken into consideration, several important clinical findings are worth noting. The self-monitored, home-based walking exercise program is culturally sensitive to Thai women with breast cancer during breast cancer adjuvant chemotherapy. Walking is an effective, low-cost, and safe intervention for women with breast cancer. The findings of this study suggest that the exercise program
decreases patients’ distress from fatigue and other concurrent symptoms in the exercise group across a treatment course, but this effect is not as strong as the impact on mood disturbance.

Results of this study also showed patterns of fatigue, sleep disturbance, mood disturbance, and symptom distress change between the two groups. It is important to be aware that women with breast cancer can experience these symptoms during adjuvant chemotherapy. Nurses need to assess fatigue and its treatment-related symptoms. Particularly, sleep disturbance should be assessed concurrently when patients with breast cancer report fatigue.

The increases in physical activity participation had a significant impact on physical fitness. However, the exercise logs demonstrated that the exercise time often dropped in the first week of each chemotherapy cycle; exercise adherence would be even more difficult for breast cancer patients on active cancer treatment. This finding suggests that nurses should introduce and encourage their cancer patients to participate in all kinds of physical activity in order to receive the potential benefit. There is a need to introduce the exercise concept as a part of cancer care in Thailand. Education for both patients and health care providers is important for their awareness to consider the need for inclusion of exercise programs in complementary cancer treatment.

**Recommendations for Future Research**

Given the findings and limitations of the pilot study, the following recommendations will improve studies, particularly in regard to the effects of home-based exercise interventions on fatigue and its related symptoms for women with breast cancer during adjuvant chemotherapy.

Special attention should be given to designing an exercise program for women with cancer and lack of exercise. Walking is the first preference to motivate exercise participation. Some participants in the exercise group did not increase the amount of exercise per week during
the rest of the eight-week intervention. In addition, there was no significant change in the average total energy expenditure. The absence of significant differences may account for a lack of difference in fatigue. Specific guidance on progression could potentially increase physical activity and exercise adherence. Increased adherence to exercise and physical activity may improve patient outcome or symptoms. Future research needs to emphasize the training progression to participants; what is expected in frequency, duration, and intensity with specific milestones.

Participants are less likely to drop out if they feel less burdened. With regard to the timing of data collection, there were four visits for this pilot study. All research visits were done at participants’ regular clinic visits. They did not make any extra visits to the clinic. Additional contacts, such as weekly telephone calls and individual meetings during the follow-up periods with participants, were appealing and allowed opportunities to retain participants. This could help to review exercise plans so they can be tailored to promote beneficial changes. The inclusion of family members was a strategy of this study. The family members stayed for each research visit and learned how to encourage the women to be more active. Future researchers may consider using the proposed strategies.

Although the results are promising, the sample size was relatively small. The small sample size precluded statistical significance. This was a primary study limitation which indicates a larger randomized control trial is needed to increase statistical power. In the present study, recruitment strategies were appropriate for getting more people. In planning future work, the sample criteria need to include women diagnosed with postoperative stage I-III breast cancer aged 18 to 65 years. Eligible women should be contacted earlier than in our timeline. A good
time for screening potentially eligible women expecting chemotherapy to obtain adequate numbers of participants should be during recovery from surgery.

Changes in outcome variables in the exercise group were unclear. Positive trends were observed showing decreases in fatigue and symptom distress. It is interesting to note that the changes in sleep disturbance and mood disturbance tended to continually increase from week 4 to week 7. Future research may add one more group so that the CSEP is strengthened by symptom-specific interventions to increase overall effects on fatigue to be compared and give more information to explain the changes. Conducting repeated measurements allows researchers to check whether the effects of the intervention can be maintained for a period of time. A follow-up measurement after the intervention completion at week 12 is recommended.

The control participants only reported the three-day exercise logs but did not wear pedometers. The absence of pedometer data in the control group may limit description of exercise pattern and comparison of exercise pattern for the entire sample over the duration of the study. Compared with exercise logs, pedometer data are more objective and should be used as a supplemental measure of exercise to capture exercise activity throughout the entire day. Likewise, measurement of exercise in unsupervised settings has been reported to be associated with self-reported bias. Further research should test validity by determining the strength of the relationship between exercise logs and pedometer data to minimize self-report bias.

Because this study was a quantitative study, cultural findings were limited and could not be detected by quantitative measures. Further research should employ qualitative techniques to provide important information for future development of culturally sensitive exercise programs. The exercise booklet is the first attempt developed for Thai women with breast cancer. Further evaluation of the exercise booklet in terms of effectiveness for behavior change is needed for it
to be a valuable resource that can be used by the growing population of Thai women with breast cancer.

**Summary**

This study was a pilot test, resulting in a small population of potential eligible patients. Several important clinical findings were obtained, but comparisons did not reach statistical significance. Replication of this study is needed to add support to the growing evidence that exercise reduces fatigue and concurrent symptoms of mood disturbance, sleep disturbance, and symptom distress, particularly for women with breast cancer. When interpreting the results and planning future research, some limitations need to be taken into consideration.
REFERENCES


*Oncology Nursing Forum, 36*(5), 563-570. doi: 10.1188/09.ONF.563-570


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Courneya, K. S., Segal, R. J., Mackey, J. R., Gelmon, K., Reid, R. D., Friedenreich, C. M., . . .


Research Committee. *Journal of the National Comprehensive Cancer Network, 8*(12), 1331-1339.


analysis. *Cancer Epidemiology Biomarkers & Prevention, 14*(7), 1588-1595. doi: 10.1158/1055-9965.epi-04-0703


Yang, C.-Y., Tsai, J.-C., Huang, Y.-C., & Lin, C.-C. (2010). Effects of a home-based walking program on perceived symptom and mood status in postoperative breast cancer women receiving adjuvant chemotherapy. *Journal of Advanced Nursing, 00*(0), 000-000. doi: 10.1111/j.1365-2648.2010.05492.x

APPENDIX A: Approval Letters

UNIVERSITY OF CINCINNATI

INSTITUTIONAL REVIEW BOARD PROTOCOL APPROVAL NOTIFICATION
FOR STUDIES GRANTED EXPELITED APPROVAL

PRINCIPAL INVESTIGATOR: Wipaphai Nataphong, MNS, RN

PROTOCOL: IRB 011-08-31-401 - Effects of a Culturally Sensitive Exercise Program on Fatigue, Sleep, Mood, and Symptom Distress among Thai Women with Breast Cancer Receiving Adjunct Chemotherapy: A Pilot Randomized Controlled Trial

- Includes informed consent: Yes
- Includes consent: Yes
- Informed consent requirement waived: No
- Survey materials constitute abbreviated consent: No
- Includes HIPAA Waiver: No

Sponsor: Principal Investigator
FWA #: 001031-52

The approval for this research activity expires on: November 22, 2011

The approval for this research activity expires on: November 22, 2012

2. The federal regulations at 45 CFR 46.110 which allow for the expedited review procedure, require that the IRB adopt a method for keeping all members advised of research proposals which have been approved under this procedure. The full Board will be notified of the expedited approval status of your study at its next convened meeting. You will be notified in writing in the event the Board disagrees with this expedited approval decision.

3. For adverse event reporting requirements, please refer to UC Policy H.02.

4. The period of approval of this research project is stated above. In order for a project to continue with IRB approval beyond the expiration date, a progress report form must be filed with the Institutional Review Board on at least an annual basis, and sometimes more frequently at the discretion of the Board.

5. There may be no change or addition to the project, or changes of the investigators involved, without prior approval of the IRB.

Chairperson (or Designee), Institutional Review Board

*The signed consent is stamped with the period of IRB approval. Please copy this IRB document and use for all subjects entered into the study.

Please note: This approval is through the U.C. IRB only. You must be responsible for reporting to other regulatory officials (e.g., VA, research and development, UC Health, University Hospital). Please check with your Institution and Department to ensure compliance with all other regulations.

University of Cincinnati Institutional Review Board Office
E1 Goodwin Dr., Suite 300, 2.5.3997, Cincinnati, Ohio, 45266-0969
Telephone: 513-558-2560, Fax: 513-558-2561

http://www.researchcompliance.uc.edu/
Ref. no. 3474
Date: September 9, 2011
Subject: Permission to collect data
To Dr. Adhikari, SLH:

Please refer to your letter dated on September 9, 2011. This letter will confirm that the Institutional Review Board of Luethai Cancer Center has reviewed and approved Ms. Wajjapha Atrakuprung’s doctoral student in the College of Nursing at the University of Cincinnati, for the doctoral dissertation entitled “Effects of a Culturally Sensitive Exercise Program on Fatigue, Sleep, Mood, and Symptom Distress among Thai Women with Breast Cancer Receiving Adjunctive Chemotherapy: A Pilot Randomized Controlled Trial.”

We believe that this project is significant and innovative because it will help improve our understanding of using exercise as a non-pharmacological intervention to relieve cancer or treatment symptoms in Thai women with breast cancer during adjunctive chemotherapy.

The Luethai Cancer Center (LCC), Thailand grants Ms. Atrakuprung permission to conduct her research at this site. LCC will assist her in the completion of her research while she is engaging in Thailand. Please place her on the list of oncologists and nursing staff who are willing to serve as clinical monitors and help her to introduce information about the study to potential participants.

Regard,

[Signature]

Dr. Chayapa Ram
Director
Luethai Cancer Center

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APPENDIX B: Informed consents

Adult Consent Form for Research
University of Cincinnati
Department: College of Nursing
Principal Investigator: Wipasiri Naraphong
Faculty Advisor: Adrianne J. Lane

Title of Study: Effects of a Culturally Sensitive Exercise Program on Fatigue, Sleep, Mood, and Symptom Distress among Thai Women with Breast Cancer Receiving Adjuvant Chemotherapy: A Pilot Randomized Controlled Trial

Introduction:
You are being asked to take part in a research study. Please read this paper carefully and ask questions about anything that you do not understand.

Who is doing this research study?
The person in charge of this research study is Wipasiri Naraphong of the University of Cincinnati (UC) College of Nursing. She is being guided in this research by Professor Adrianne J. Lane.

What is the purpose of this research study?
The purpose of this research study is to develop a 12-week culturally sensitive exercise program and then examine that the program’s effects on fatigue, sleep disturbance, mood disturbance, and symptom distress in a group of Thai women with breast cancer who are undergoing adjuvant chemotherapy.

Who will be in this research study?
About 40 women will take part in this study. You may be in this study if you:

a) Are diagnosed with postoperative stage I-III breast cancer
b) Are 18-60 years of age
c) Have no other concurrent cancer
d) Are scheduled to receive a minimum of 4 cycles of each chemotherapy protocol during the study period
e) Are able to speak, read and write in Thai and agree to sign consent to participate in the project
f) Can be contacted by phone.

What will you be asked to do in this research study, and how long will it take?
This study will take about 12 weeks overall and will take place at the outpatient chemotherapy clinic, Lopburi Cancer Center. You will be randomly assigned (like flipping a coin) to one of two groups. One group will do a home-based exercise program at least three times a week for twelve weeks. The other group will go about their usual activities for twelve weeks. Both groups are equally important for this study.
There are four visits for this research study. You will not need to make any extra visits to the clinic. All research visits will be done at your regular clinic visits. You will be asked to take part as follows;

- **First visit:** you will complete questionnaires asking about your demographic
information and your level of fatigue, sleep, mood, and symptom distress. You will also take a 12-minute walk test at the Lopburi Cancer Center. This test will assess your exercise capacity at the beginning of the study.

- If you are involved in the exercise program as part of this research study, you will receive the educational and exercise training sessions which will last for a total of 45 minutes. The total amount of time for the first visit will take about an hour and a half.
- If you are not involved in the exercise program, you will receive an exercise log and instructions to record physical activities during the three days prior to your next chemotherapy sessions. You have to bring these logs with you for three visits. The total amount of time for the first visit will take about an hour.
- Second visit: you will complete questionnaires about your level of fatigue, sleep, mood, and symptom distress. This will take about 20 minutes.
- If you are involved in the exercise program, you will receive the educational and exercise training sessions which will last for a total of 30 minutes. The total amount of time for the second visit will take about an hour.
- Third visit: you will complete questionnaires about your level of fatigue, sleep, mood, and symptom distress. The total amount of time for the third visit will take about 20 minutes.
- Fourth visit: you will complete questionnaires about your level of fatigue, sleep, mood, and symptom distress. The 12-minute walk test will be repeated to evaluate any changes in exercise capacity at the end of the study. The total amount of time for the fourth visit will take about 40 minutes.
- You will be phoned to ask fatigue questions between 48 and 72 hours after each of your chemotherapy cycles.
- You will be contacted through weekly phone calls to ask about activities you performed during the prior week or to monitor exercise participation depending on your assigned group.
- You are kindly asked not to share the information you are given during the study with any other patients in the cancer center.

Are there any risks to being in this research study?
There may be minimal risks from being in this research study. You may feel discomfort at times because of the exercise. This discomfort may include feeling out of breath, tired, heart pounding, shortness of breath, or dizziness. If you feel discomfort, it should be mild and temporary.

Are there any benefits from being in this research study?
You will probably not get any direct benefit because of being in this study. But, being in this study, you may receive an appropriate educational and exercise intervention that reduces fatigue, sleep disturbance, mood disturbance or cancer treatment side effects. The information learned from this study may benefit breast cancer patients in the future.
What will you get because of being in this research study?
You will be paid 100 Thai Baht cash each time you come for four study visits. The reason for payment is to thank you for being in the study.

Do you have choices about taking part in this research study?
If you do not want to take part in this research study, your treatment or the care given by your doctor will not be affected. No penalty or loss of benefits will be incurred.

How will your research information be kept confidential?
Information about you will be kept private by using a study ID number of your name on the questionnaires or research forms. The master lists of names, telephone numbers, and study ID numbers will be kept in a separate location from the research forms. Only the research team will have access to subject names.

Your information will be kept in a locked cabinet in the Thai research site while the study is ongoing and subsequently in the research center, College of Nursing at the University of Cincinnati for five years. Signed consent documents and master lists of participant names and ID numbers will not be stored in the same place as identifiable data. After that it will be destroyed by shredding paper research files when the study is complete. The data from this research study may be published, but you will not be identified by name.

Agents of the University of Cincinnati may inspect study records for audit or quality assurance purposes.

What are your legal rights in this research study?
Nothing in this consent form waives any legal rights you may have. This consent form also does not release the investigator, the institution, or its agents from liability for negligence.

What if you have questions about this research study?
In Thai language, if you have any questions or concerns about this research study, you should contact Wipatinee Narapittrakul at 081-866-2252 or email narapittrakul@nmuil.uc.edu. Or, in English, if needed, you may contact Professor Adrianne J. Lam, the Dissertation Chair at (1) 513-559-5211 or email adrianne.lam@uc.edu.

The UC Institutional Review Board reviews all research projects that involve human participants to ensure the rights and welfare of participants are protected.

If you have questions about your rights as a participant or complaints about the study, you may contact the UC IRB at (513) 558-5259. Or, you may call the UC Research Compliance Hotline at (800) 889-1947, or write to the IRB, 300 University Hall, MLL 0507, 31 Goodman Drive, Cincinnati, OH 45221-0507, or email the IRB office at irb@ucmail.uc.edu.
Do you HAVE to take part in this research study?

No one has to be in this research study. Refusing to take part will NOT cause any penalty or loss of benefits that you would otherwise have.

You may start the study, then change your mind and stop at any time. To stop being in the study, you should tell Wipasir Naraphong at 081 866 2329.

Agreement:

I have read this information and have received answers to any questions I asked. I give my consent to participate in this research study. I will receive a copy of this signed and dated consent form to keep.

Participant Name (please print) __________________________

Participant Signature ___________________________ Date ______

Signature of Person Obtaining Consent ___________________________ Date ______
From: Piper, Barbara [BPiper@SHC.org]
Sent: Thursday, June 16, 2011 10:54 AM
To: Naraphong, Wipasiri (naraphwi)
Subject: RE: To ask permissions for reprinting and using the Revised Piper Fatigue Scale

Dear Wipasiri,

Of course you have my permission to use the Piper Fatigue Scale-Revised (PFS-R) in your research, although permission from me is not really necessary as the scale is in the public domain having been published in its entirety in the 1998 May issue of the Oncology Nursing Forum. I am assuming that previously translated versions of the scale into the Thai language used the most recent version of the PFS-R since it was initially published. However, attached please find the current scale and its scoring instructions.

Good luck with your research and keep in touch. If I can help you further, please contact me.

BFP

Barbara F. Piper, DNSc, RN, AOCN, FAAN
Professor and Chair of Nursing Research
Scottsdale Healthcare/University of Arizona
Biobehavioral Health Science Division
10460 N. 92nd Street, Suite 206
Scottsdale, AZ 85258
Ph: 480-333-1243; Fax: 480-323-1739
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From: Lee, Kathryn (SON) [kathryn.lee@nursing.ucsf.edu]
Sent: Thursday, June 16, 2011 12:46 PM
To: Naraphong, Wipasiri (naraphwi)
Subject: RE: To ask permissions for reprinting and using the General Sleep Disturbance Scale

Dear Wipasiri — I am sorry your email went to my spam folder for some reason and I just talked with your professor to find your name and search my email. Your research sounds very interesting, and I wish you great success. Of course you have my permission to use the GSDS in your research project. Could you please send me a copy of the Thai version so that I can make sure it is the version that all Thai use? Do you have the scoring instructions? There are also some papers that use this instrument in cancer patients in the USA (see Miaskowski et al) if you want to compare your results, but they have been pleased with the GSDS psychometric properties.

Thank you!
Kathy Lee

Kathryn Lee, RN, PhD, FAAN, CBSM
Associate Dean for Research
Director, T32 Nurse Research Training in Symptom Management
UCSF School of Nursing
Box 0606 UCSF
Rm N411Y 2 Koret Way
San Francisco CA 94143-0606
(415) 476-4442
FAX (415) 753-2161

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RE: To consult for asking permissions
Loriann Tulik [loriann.tulik@MHS.com]
Sent: Wednesday, June 22, 2011 10:53 AM
To: Naraphong, Wipasiri (naraphwi)

Hi.

Thank you for your interest in our assessments. We do carry the POMS in Thai. I have included here a permissions and translations form for you to fill out and email back to permissions@mhs.com at your earliest convenience.

In doing so you will be required to complete section A, purchase the POMS Manual (if you haven't already done so), and provide payment with your completed application. Please note that because you are an international customer it will be necessary to add shipping and handling charges (for the Manual) to your order. Also, please indicate how many reproductions of the assessment you will require.

The cost is $1.50 per administration and there is a $50 administration fee. This does not include the cost of scoring.

If you have any questions please do not hesitate to contact me.

Regards,

Loriann Tulik
Client Services Specialist—Public Safety

www.mhs.com
SENT VIA ELECTRONIC MAIL

July 21, 2011

Attention: Wisnapi Naraphong

Re: Copyright Clearance Letter

Thank you for your interest in Multi-Health Systems Inc. ("MHS") and request for the POMS Brief (test). This letter provides Wisnapi Naraphong (the "Party") with permission to reproduce one copy of the POMS Brief (test) at no cost.

The Party will not be permitted to make additional reproductions of the POMS Brief (test) without first obtaining express written permission from MHS, which may be subject to additional costs. The Party agrees to return and/or destroy the POMS Brief (test) within thirty (30) days of receipt.

The Party shall not, directly or indirectly, disclose, divulge, reveal, report, publish, transfer or otherwise communicate, or use for its or its own benefit or the benefit of any other person, partnership, firm, corporation or other entity, or misuse in any way, any of the POMS Brief (test) components.

Please sign and return a copy of this letter acknowledging your understanding of our relations. If you have any questions or concerns regarding the foregoing, please feel free to contact me.

We accept the arrangements outlined above.

LICENSEE:

Wisnapi Naraphong

Authorized Signing Representative

Date

Sincerely,

MULTI-HEALTH SYSTEMS INC.

Per: Lorain Tulk

July 21, 2011

Date
Re: To ask permissions to reprinting and using the Memorial Symptom Assessment Scale
Russell Portenoy, MD [RPorteno@chpnet.org]
Sent: Monday, June 20, 2011 3:31 PM
To: Naraphong, Wipasri (naraphwi)
Cc: RPorteno@bethisraelny.org

Dear Dr. Naraphong

You are free to use the MSAS as you wish. Best of luck with your research.

R Portenoy MD
8 August, 2011

Subject: Permission to Use Research Instruments

Dear Mr. Wisesin Narophong,

Following your request to use Valeriana Harumakam's research tools, the Graduate School is pleased to inform you that permission is granted herewith.

Yours sincerely,

[Signature]

Associate Professor Dorasek Laeratanavalee, Dr.,ossal
Associate Dean The Graduate School